Dokumentvorlage, Version vom 21.02.2019

Dossier zur Nutzenbewertung gemäß § 35a SGB V

Avapritinib (AYVAKYT®)

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

Modul 4 A – Anhang 4G

Avapritinib (AYVAKYT®) ist als Monotherapie zur Behandlung erwachsener Patienten mit aggressiver systemischer Mastozytose (ASM), systemischer Mastozytose mit assoziierter hämatologischer Neoplasie (SM-AHN) oder Mastzellleukämie (MCL) nach zumindest einer systemischen Therapie indiziert.

Medizinischer Nutzen und medizinischer Zusatznutzen, Patientengruppen mit therapeutisch bedeutsamem Zusatznutzen

Stand: 01.04.2022

Anhang 4-G: Weitere Analysen und Kaplan-Meier-Plots zu den in Abschnitt 4.3.2.3 gezeigten Ergebnissen

Blueprint Medicines Corporation
Avapritinib Systemic Mastocytosis Integrated Summary of Efficacy
BLU-285 SM Germany HTA Analysis Cutoff date: 27may2020 (2101), 23jun2020 (2202)

Table 35.1.1.1 Analysis Populations
AdvSM Population with at least one prior antineoplastic therapy
Study 2101

	Starting Dose (QD)							
	30 mg n (%)	60 mg n (%)	100 mg n (%)	130 mg n (%)	200 mg n (%)	300 mg n (%)	<= 200 mg n (%)	All Doses n (%)
Safety Population	1 (100)	2 (100)	0	1 (100)	12 (100)	20 (100)	16 (100)	41 (100)
Subtype based on PI diagnosis[1]								
AdvSM	1 (100)	2 (100)	0	1 (100)	12 (100)	20 (100)	16 (100)	41 (100)
ASM	0	1 (50.0)	0	0	4 (33.3)	7 (35.0)	5 (31.3)	14 (34.1)
SM-AHN	1 (100)	0	0	1 (100)	4 (33.3)	10 (50.0)	6 (37.5)	19 (46.3)
MCL	0	1 (50.0)	0	0	4 (33.3)	3 (15.0)	5 (31.3)	8 (19.5)
Subtype based on RAC adjudication[2]								
AdvSM	1 (100)	2 (100)	0	1 (100)	12 (100)	20 (100)	16 (100)	41 (100)
ASM	0	1 (50.0)	0	0	1 (8.3)	4 (20.0)	2 (12.5)	7 (17.1)
SM-AHN	1 (100)	0	0	1 (100)	7 (58.3)	13 (65.0)	9 (56.3)	26 (63.4)
MCL	0	1 (50.0)	0	0	4 (33.3)	3 (15.0)	5 (31.3)	8 (19.5)
Response Assessment Committee Response-Evaluable (RAC-RE) Population [2]	1 (100)	1 (50.0)	0	1 (100)	9 (75.0)	16 (80.0)	12 (75.0)	32 (78.0)
AdvSM	1 (100)	1 (50.0)		1 (100)	9 (75.0)	16 (80.0)	12 (75.0)	32 (78.0)
ASM	0	0	0	0	0	2 (10.0)	0	2 (4.9)
SM-AHN	1 (100)	0	0	1 (100)	5 (41.7)	11 (55.0)	7 (43.8)	22 (53.7)
MCL	0	1 (50.0)	0	0	4 (33.3)	3 (15.0)	5 (31.3)	8 (19.5)
Pure Pathologic Response-Evaluable (PPRE) Population [2]	1 (100)	2 (100)	0	1 (100)	9 (75.0)	20 (100)	13 (81.3)	38 (92.7)
AdvSM	1 (100)	2 (100)		1 (100)	9 (75.0)	20 (100)	13 (81.3)	38 (92.7)
ASM	0	1 (50.0)	0	0	0	4 (20.0)	1 (6.3)	6 (14.6)
SM-AHN	1 (100)	0	0	1 (100)	5 (41.7)	13 (65.0)	7 (43.8)	24 (58.5)
MCL	0	1 (50.0)	0	0	4 (33.3)	3 (15.0)	5 (31.3)	8 (19.5)

Source: Listing 16.2.2
Notes: [1] The source of the sub-populations are from the CRF.
[2] The source of the sub-populations are from the RAC adjudicated diagnosis.

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Avapritinib Systemic Mastocytosis Integrated Summary of Efficacy
BLU-285 SM Germany HTA Analysis Cutoff date: 27may2020 (2101), 23jun2020 (2202)

Table 35.1.1.1 Analysis Populations
AdvSM Population with at least one prior antineoplastic therapy
Study 2101

	Starting Dose (QD)							
	30 mg n (%)	60 mg n (%)	100 mg n (%)	130 mg n (%)	200 mg n (%)	300 mg n (%)	<= 200 mg n (%)	All Doses n (%)
Dose Determining (DD) Population	1 (100)	2 (100)	0	1 (100)	2 (16.7)	3 (15.0)	6 (37.5)	13 (31.7)
No pre-existing severe thrombocytopenia Population[2]	1 (100)	2 (100)	0	1 (100)	11 (91.7)	20 (100)	15 (93.8)	38 (92.7)
AdvSM	1 (100)	2 (100)		1 (100)	11 (91.7)	20 (100)	15 (93.8)	38 (92.7)
ASM	0	1 (50.0)	0	0	1 (8.3)	4 (20.0)	2 (12.5)	7 (17.1)
SM-AHN	1 (100)	0	0	1 (100)	6 (50.0)	13 (65.0)	8 (50.0)	23 (56.1)
MCL	0	1 (50.0)	0	0	4 (33.3)	3 (15.0)	5 (31.3)	8 (19.5)

Source: Listing 16.2.2
Notes: [1] The source of the sub-populations are from the CRF.
[2] The source of the sub-populations are from the RAC adjudicated diagnosis.

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Avapritinib Systemic Mastocytosis Integrated Summary of Efficacy
BLU-285 SM Germany HTA Analysis Cutoff date: 27may2020 (2101), 23jun2020 (2202)

Table 35.1.1.1 Analysis Populations
AdvSM Population with at least one prior antineoplastic therapy
Study 2202

	Starting Dose (QD)							
	30 mg n (%)	60 mg n (%)	100 mg n (%)	130 mg n (%)	200 mg n (%)	300 mg n (%)	<= 200 mg n (%)	All Doses n (%)
Safety Population	0	0	2 (100)	0	40 (100)	0	42 (100)	42 (100)
Subtype based on PI diagnosis[1]								
AdvSM	0	0	2 (100)	0	40 (100)	0	42 (100)	42 (100)
ASM	0	0	2 (100)	0	6 (15.0)	0	8 (19.0)	8 (19.0)
SM-AHN	0	0	0	0	23 (57.5)	0	23 (54.8)	23 (54.8)
MCL	0	0	0	0	11 (27.5)	0	11 (26.2)	11 (26.2)
Subtype based on RAC adjudication[2]								
AdvSM	0	0	2 (100)	0	40 (100)	0	42 (100)	42 (100)
ASM	0	0	1 (50.0)	0	4 (10.0)	0	5 (11.9)	5 (11.9)
SM-AHN	0	0	1 (50.0)	0	27 (67.5)	0	28 (66.7)	28 (66.7)
MCL	0	0	0	0	9 (22.5)	0	9 (21.4)	9 (21.4)
Response Assessment Committee Response-Evaluable (RAC-RE) Population [2]	0	0	1 (50.0)	0	22 (55.0)	0	23 (54.8)	23 (54.8)
AdvSM			1 (50.0)		22 (55.0)		23 (54.8)	23 (54.8)
ASM	0	0	0	0	1 (2.5)	0	1 (2.4)	1 (2.4)
SM-AHN	0	0	1 (50.0)	0	17 (42.5)	0	18 (42.9)	18 (42.9)
MCL	0	0	0	0	4 (10.0)	0	4 (9.5)	4 (9.5)
Pure Pathologic Response-Evaluable (PPRE) Population [2]	0	0	1 (50.0)	0	25 (62.5)	0	26 (61.9)	26 (61.9)
AdvSM			1 (50.0)		25 (62.5)		26 (61.9)	26 (61.9)
ASM	0	0	0	0	2 (5.0)	0	2 (4.8)	2 (4.8)
SM-AHN	0	0	1 (50.0)	0	19 (47.5)	0	20 (47.6)	20 (47.6)
MCL	0	0	0	0	4 (10.0)	0	4 (9.5)	4 (9.5)

Source: Listing 16.2.2
Notes: [1] The source of the sub-populations are from the CRF.
[2] The source of the sub-populations are from the RAC adjudicated diagnosis.

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Avapritinib Systemic Mastocytosis Integrated Summary of Efficacy
BLU-285 SM Germany HTA Analysis Cutoff date: 27may2020 (2101), 23jun2020 (2202)

Table 35.1.1.1 Analysis Populations
AdvSM Population with at least one prior antineoplastic therapy
Study 2202

	Starting Dose (QD)							
	30 mg n (%)	60 mg n (%)	100 mg n (%)	130 mg n (%)	200 mg n (%)	300 mg n (%)	<= 200 mg n (%)	All Doses n (%)
Dose Determining (DD) Population	0	0	0	0	0	0	0	0
No pre-existing severe thrombocytopenia Population[2]	0	0	1 (50.0)	0	37 (92.5)	0	38 (90.5)	38 (90.5)
AdvSM			1 (50.0)		37 (92.5)		38 (90.5)	38 (90.5)
ASM	0	0	1 (50.0)	0	4 (10.0)	0	5 (11.9)	5 (11.9)
SM-AHN	0	0	0	0	25 (62.5)	0	25 (59.5)	25 (59.5)
MCL	0	0	0	0	8 (20.0)	0	8 (19.0)	8 (19.0)

Source: Listing 16.2.2
Notes: [1] The source of the sub-populations are from the CRF.
[2] The source of the sub-populations are from the RAC adjudicated diagnosis.

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Avapritinib Systemic Mastocytosis Integrated Summary of Efficacy
BLU-285 SM Germany HTA Analysis Cutoff date: 27may2020 (2101), 23jun2020 (2202)

Table 35.1.1.1 Analysis Populations
AdvSM Population with at least one prior antineoplastic therapy
Studies 2101 and 2202

	Starting Dose (QD)							
	30 mg n (%)	60 mg n (%)	100 mg n (%)	130 mg n (%)	200 mg n (%)	300 mg n (%)	<= 200 mg n (%)	All Doses n (%)
Safety Population	1 (100)	2 (100)	2 (100)	1 (100)	52 (100)	20 (100)	58 (100)	83 (100)
Subtype based on PI diagnosis[1]								
AdvSM	1 (100)	2 (100)	2 (100)	1 (100)	52 (100)	20 (100)	58 (100)	83 (100)
ASM	0	1 (50.0)	2 (100)	0	10 (19.2)	7 (35.0)	13 (22.4)	22 (26.5)
SM-AHN	1 (100)	0	0	1 (100)	27 (51.9)	10 (50.0)	29 (50.0)	42 (50.6)
MCL	0	1 (50.0)	0	0	15 (28.8)	3 (15.0)	16 (27.6)	19 (22.9)
Subtype based on RAC adjudication[2]								
AdvSM	1 (100)	2 (100)	2 (100)	1 (100)	52 (100)	20 (100)	58 (100)	83 (100)
ASM	0	1 (50.0)	1 (50.0)	0	5 (9.6)	4 (20.0)	7 (12.1)	12 (14.5)
SM-AHN	1 (100)	0	1 (50.0)	1 (100)	34 (65.4)	13 (65.0)	37 (63.8)	54 (65.1)
MCL	0	1 (50.0)	0	0	13 (25.0)	3 (15.0)	14 (24.1)	17 (20.5)
Response Assessment Committee Response-Evaluable (RAC-RE) Population [2]	1 (100)	1 (50.0)	1 (50.0)	1 (100)	31 (59.6)	16 (80.0)	35 (60.3)	55 (66.3)
AdvSM	1 (100)	1 (50.0)	1 (50.0)	1 (100)	31 (59.6)	16 (80.0)	35 (60.3)	55 (66.3)
ASM	0	0	0	0	1 (1.9)	2 (10.0)	1 (1.7)	3 (3.6)
SM-AHN	1 (100)	0	1 (50.0)	1 (100)	22 (42.3)	11 (55.0)	25 (43.1)	40 (48.2)
MCL	0	1 (50.0)	0	0	8 (15.4)	3 (15.0)	9 (15.5)	12 (14.5)
Pure Pathologic Response-Evaluable (PPRE) Population [2]	1 (100)	2 (100)	1 (50.0)	1 (100)	34 (65.4)	20 (100)	39 (67.2)	64 (77.1)
AdvSM	1 (100)	2 (100)	1 (50.0)	1 (100)	34 (65.4)	20 (100)	39 (67.2)	64 (77.1)
ASM	0	1 (50.0)	0	0	2 (3.8)	4 (20.0)	3 (5.2)	8 (9.6)
SM-AHN	1 (100)	0	1 (50.0)	1 (100)	24 (46.2)	13 (65.0)	27 (46.6)	44 (53.0)
MCL	0	1 (50.0)	0	0	8 (15.4)	3 (15.0)	9 (15.5)	12 (14.5)

Source: Listing 16.2.2
Notes: [1] The source of the sub-populations are from the CRF.
[2] The source of the sub-populations are from the RAC adjudicated diagnosis.

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BLU-285 SM Germany HTA Analysis Cutoff date: 27may2020 (2101), 23jun2020 (2202)

Table 35.1.1.1 Analysis Populations
AdvSM Population with at least one prior antineoplastic therapy
Studies 2101 and 2202

	Starting Dose (QD)							
	30 mg n (%)	60 mg n (%)	100 mg n (%)	130 mg n (%)	200 mg n (%)	300 mg n (%)	<= 200 mg n (%)	All Doses n (%)
Dose Determining (DD) Population	1 (100)	2 (100)	0	1 (100)	2 (3.8)	3 (15.0)	6 (10.3)	13 (15.7)
No pre-existing severe thrombocytopenia Population[2]	1 (100)	2 (100)	1 (50.0)	1 (100)	48 (92.3)	20 (100)	53 (91.4)	76 (91.6)
AdvSM	1 (100)	2 (100)	1 (50.0)	1 (100)	48 (92.3)	20 (100)	53 (91.4)	76 (91.6)
ASM	0	1 (50.0)	1 (50.0)	0	5 (9.6)	4 (20.0)	7 (12.1)	12 (14.5)
SM-AHN	1 (100)	0	0	1 (100)	31 (59.6)	13 (65.0)	33 (56.9)	48 (57.8)
MCL	0	1 (50.0)	0	0	12 (23.1)	3 (15.0)	13 (22.4)	16 (19.3)

Source: Listing 16.2.2
Notes: [1] The source of the sub-populations are from the CRF.
[2] The source of the sub-populations are from the RAC adjudicated diagnosis.

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Table 35.3.1.2
Summary of Patient Disposition
AdvSM Population & Prior Neoplastic Therapy = Yes

	BLU-285-2101		
Patient Disposition	200 mg (N=12) n (%)	<=200 mg (N=16) n (%)	All Doses (N=41) n (%)
Patients Continuing Treatment	8 (66.7)	12 (75.0)	23 (56.1)
Patients Discontinued Treatment	4 (33.3)	4 (25.0)	18 (43.9)
Reason for Discontinuation of Treatment			
Disease Progression	2 (16.7)	2 (12.5)	7 (17.1)
Clinical Progression	0	0	0
Adverse Event	0	0	7 (17.1)
Adverse Event Related to Study Drug	0	0	4 (9.8)
Adverse Event of special interest	0	0	3 (7.3)
COGNITIVE EFFECTS	0	0	2 (4.9)
INTRACRANIAL BLEEDING	0	0	1 (2.4)
Death	0	0	0
Lost to Follow-up	0	0	0
Protocol Deviation	0	0	0
Withdrew Consent	2 (16.7)	2 (12.5)	3 (7.3)
Pregnancy	0	0	0
Investigator’s Decision	0	0	1 (2.4)
Administrative/Other	0	0	0
Sponsor Decision	0	0	0

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note: Percentages are based on the number of patients in the Safety Population in each column.

Source (Date): Program: t-35-3-1-2-ds.sas Date: 16:43/17SEP2021

Table 35.3.1.2
Summary of Patient Disposition
AdvSM Population & Prior Neoplastic Therapy = Yes

	BLU-285-2101		
Patient Disposition	200 mg (N=12) n (%)	<=200 mg (N=16) n (%)	All Doses (N=41) n (%)
Patients Continuing Study	9 (75.0)	13 (81.3)	26 (63.4)
Patients Discontinued Study	3 (25.0)	3 (18.8)	15 (36.6)
Reason for Discontinuation of Study			
Disease Progression	0	0	0
Adverse Event	0	0	2 (4.9)
Adverse Event Related to Study Drug	0	0	2 (4.9)
Death	3 (25.0)	3 (18.8)	7 (17.1)
Lost to Follow-up	0	0	0
Protocol Deviation	0	0	0
Withdrew Consent	0	0	4 (9.8)
Pregnancy	0	0	0
Investigator’s Decision	0	0	0
Administrative/Other	0	0	0
Sponsor Decision	0	0	0
Initiation of New Antineoplastic Therapy	0	0	2 (4.9)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note: Percentages are based on the number of patients in the Safety Population in each column.

Source (Date): Program: t-35-3-1-2-ds.sas Date: 16:43/17SEP2021

Table 35.3.1.2
Summary of Patient Disposition
AdvSM Population & Prior Neoplastic Therapy = Yes

	BLU-285-2202		
Patient Disposition	200 mg (N=40) n (%)	<=200 mg (N=42) n (%)	All Doses (N=42) n (%)
Patients Continuing Treatment	31 (77.5)	33 (78.6)	33 (78.6)
Patients Discontinued Treatment	9 (22.5)	9 (21.4)	9 (21.4)
Reason for Discontinuation of Treatment			
Disease Progression	2 (5.0)	2 (4.8)	2 (4.8)
Clinical Progression	0	0	0
Adverse Event	5 (12.5)	5 (11.9)	5 (11.9)
Adverse Event Related to Study Drug	2 (5.0)	2 (4.8)	2 (4.8)
Adverse Event of special interest	1 (2.5)	1 (2.4)	1 (2.4)
COGNITIVE EFFECTS	0	0	0
INTRACRANIAL BLEEDING	1 (2.5)	1 (2.4)	1 (2.4)
Death	0	0	0
Lost to Follow-up	0	0	0
Protocol Deviation	0	0	0
Withdrew Consent	1 (2.5)	1 (2.4)	1 (2.4)
Pregnancy	0	0	0
Investigator’s Decision	0	0	0
Administrative/Other	1 (2.5)	1 (2.4)	1 (2.4)
Sponsor Decision	0	0	0

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note: Percentages are based on the number of patients in the Safety Population in each column.

Source (Date): Program: t-35-3-1-2-ds.sas Date: 16:43/17SEP2021

Table 35.3.1.2
Summary of Patient Disposition
AdvSM Population & Prior Neoplastic Therapy = Yes

	BLU-285-2202		
Patient Disposition	200 mg (N=40) n (%)	<=200 mg (N=42) n (%)	All Doses (N=42) n (%)
Patients Continuing Study	33 (82.5)	35 (83.3)	35 (83.3)
Patients Discontinued Study	7 (17.5)	7 (16.7)	7 (16.7)
Reason for Discontinuation of Study			
Disease Progression	0	0	0
Adverse Event	0	0	0
Adverse Event Related to Study Drug	0	0	0
Death	4 (10.0)	4 (9.5)	4 (9.5)
Lost to Follow-up	0	0	0
Protocol Deviation	0	0	0
Withdrew Consent	1 (2.5)	1 (2.4)	1 (2.4)
Pregnancy	0	0	0
Investigator’s Decision	0	0	0
Administrative/Other	1 (2.5)	1 (2.4)	1 (2.4)
Sponsor Decision	1 (2.5)	1 (2.4)	1 (2.4)
Initiation of New Antineoplastic Therapy	0	0	0

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note: Percentages are based on the number of patients in the Safety Population in each column.

Source (Date): Program: t-35-3-1-2-ds.sas Date: 16:43/17SEP2021

Table 35.3.1.2
Summary of Patient Disposition
AdvSM Population & Prior Neoplastic Therapy = Yes

	BLU-285-2101 + BLU-285-2202		
Patient Disposition	200 mg (N=52) n (%)	<=200 mg (N=58) n (%)	All Doses (N=83) n (%)
Patients Continuing Treatment	39 (75.0)	45 (77.6)	56 (67.5)
Patients Discontinued Treatment	13 (25.0)	13 (22.4)	27 (32.5)
Reason for Discontinuation of Treatment			
Disease Progression	4 (7.7)	4 (6.9)	9 (10.8)
Clinical Progression	0	0	0
Adverse Event	5 (9.6)	5 (8.6)	12 (14.5)
Adverse Event Related to Study Drug	2 (3.8)	2 (3.4)	6 (7.2)
Adverse Event of special interest	1 (1.9)	1 (1.7)	4 (4.8)
COGNITIVE EFFECTS	0	0	2 (2.4)
INTRACRANIAL BLEEDING	1 (1.9)	1 (1.7)	2 (2.4)
Death	0	0	0
Lost to Follow-up	0	0	0
Protocol Deviation	0	0	0
Withdrew Consent	3 (5.8)	3 (5.2)	4 (4.8)
Pregnancy	0	0	0
Investigator’s Decision	0	0	1 (1.2)
Administrative/Other	1 (1.9)	1 (1.7)	1 (1.2)
Sponsor Decision	0	0	0

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note: Percentages are based on the number of patients in the Safety Population in each column.

Source (Date): Program: t-35-3-1-2-ds.sas Date: 16:43/17SEP2021

Table 35.3.1.2
Summary of Patient Disposition
AdvSM Population & Prior Neoplastic Therapy = Yes

	BLU-285-2101 + BLU-285-2202		
Patient Disposition	200 mg (N=52) n (%)	<=200 mg (N=58) n (%)	All Doses (N=83) n (%)
Patients Continuing Study	42 (80.8)	48 (82.8)	61 (73.5)
Patients Discontinued Study	10 (19.2)	10 (17.2)	22 (26.5)
Reason for Discontinuation of Study			
Disease Progression	0	0	0
Adverse Event	0	0	2 (2.4)
Adverse Event Related to Study Drug	0	0	2 (2.4)
Death	7 (13.5)	7 (12.1)	11 (13.3)
Lost to Follow-up	0	0	0
Protocol Deviation	0	0	0
Withdrew Consent	1 (1.9)	1 (1.7)	5 (6.0)
Pregnancy	0	0	0
Investigator's Decision	0	0	0
Administrative/Other	1 (1.9)	1 (1.7)	1 (1.2)
Sponsor Decision	1 (1.9)	1 (1.7)	1 (1.2)
Initiation of New Antineoplastic Therapy	0	0	2 (2.4)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note: Percentages are based on the number of patients in the Safety Population in each column.

Source (Date): Program: t-35-3-1-2-ds.sas Date: 16:43/17SEP2021

Blueprint Medicines Corporation
Avapritinib Systemic Mastocytosis Integrated Summary of Efficacy
BLU-285 SM Germany HTA Analysis Cutoff date: 27may2020 (2101), 23jun2020 (2202)

Table 35.1.3.1 Number of Patients by Region by Country by Site
AdvSM Population with at least one prior antineoplastic therapy
Study 2101

	Starting Dose (QD)				
	<200 mg (N=4) n (%)	200 mg (N=12) n (%)	300 mg (N=20) n (%)	<=200 mg (N=16) n (%)	All Doses (N=41) n (%)
United States	4 (100)	11 (91.7)	19 (95.0)	15 (93.8)	39 (95.1)
Site 2001	1 (25.0)	0	1 (5.0)	1 (6.3)	2 (4.9)
Site 2002	0	2 (16.7)	6 (30.0)	2 (12.5)	9 (22.0)
Site 2003	0	0	3 (15.0)	0	4 (9.8)
Site 2004	2 (50.0)	4 (33.3)	1 (5.0)	6 (37.5)	7 (17.1)
Site 2005	0	1 (8.3)	2 (10.0)	1 (6.3)	4 (9.8)
Site 2006	1 (25.0)	1 (8.3)	4 (20.0)	2 (12.5)	8 (19.5)
Site 2008	0	1 (8.3)	2 (10.0)	1 (6.3)	3 (7.3)
Site 2011	0	2 (16.7)	0	2 (12.5)	2 (4.9)
UK	0	1 (8.3)	1 (5.0)	1 (6.3)	2 (4.9)
Site 1101	0	0	1 (5.0)	0	1 (2.4)
Site 1102	0	1 (8.3)	0	1 (6.3)	1 (2.4)

Source: Listing 16.2.1

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Avapritinib Systemic Mastocytosis Integrated Summary of Efficacy
BLU-285 SM Germany HTA Analysis
Cutoff date: 27may2020 (2101), 23jun2020 (2202)

Table 35.1.3.1 Number of Patients by Region by Country by Site
AdvSM Population with at least one prior antineoplastic therapy
Study 2202

	Starting Dose (QD) 200 mg (N=40) n (%)	All Doses (N=42) n (%)
North America	19 (47.5)	19 (45.2)
United States	18 (45.0)	18 (42.9)
Site 20-01	1 (2.5)	1 (2.4)
Site 20-02	6 (15.0)	6 (14.3)
Site 20-03	2 (5.0)	2 (4.8)
Site 20-05	1 (2.5)	1 (2.4)
Site 20-06	6 (15.0)	6 (14.3)
Site 20-07	1 (2.5)	1 (2.4)
Site 20-10	1 (2.5)	1 (2.4)
Canada	1 (2.5)	1 (2.4)
Site 10-01	1 (2.5)	1 (2.4)

Source: Listing 16.2.1

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Blueprint Medicines Corporation
Avapritinib Systemic Mastocytosis Integrated Summary of Efficacy
BLU-285 SM Germany HTA Analysis Cutoff date: 27may2020 (2101), 23jun2020 (2202)

Table 35.1.3.1 Number of Patients by Region by Country by Site
AdvSM Population with at least one prior antineoplastic therapy
Study 2202

	Starting Dose (QD) 200 mg (N=40) n (%)	All Doses (N=42) n (%)
Europe	21 (52.5)	23 (54.8)
Germany	11 (27.5)	13 (31.0)
Site 43-01	6 (15.0)	8 (19.0)
Site 43-03	3 (7.5)	3 (7.1)
Site 43-04	2 (5.0)	2 (4.8)
Spain	3 (7.5)	3 (7.1)
Site 47-01	3 (7.5)	3 (7.1)
France	2 (5.0)	2 (4.8)
Site 42-01	2 (5.0)	2 (4.8)
Italy	1 (2.5)	1 (2.4)
Site 45-03	1 (2.5)	1 (2.4)
Netherlands	1 (2.5)	1 (2.4)
Site 44-01	1 (2.5)	1 (2.4)
Norway	1 (2.5)	1 (2.4)
Site 49-01	1 (2.5)	1 (2.4)
Poland	1 (2.5)	1 (2.4)
Site 52-01	1 (2.5)	1 (2.4)
UK	1 (2.5)	1 (2.4)
Site 11-01	1 (2.5)	1 (2.4)

Source: Listing 16.2.1

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Blueprint Medicines Corporation
Avapritinib Systemic Mastocytosis Integrated Summary of Efficacy
BLU-285 SM Germany HTA Analysis Cutoff date: 27may2020 (2101), 23jun2020 (2202)

Table 35.1.3.1 Number of Patients by Region by Country by Site
AdvSM Population with at least one prior antineoplastic therapy
Studies 2101 and 2202

	Starting Dose (QD)				
	<200 mg (N=6) n (%)	200 mg (N=52) n (%)	300 mg (N=20) n (%)	<=200 mg (N=58) n (%)	All Doses (N=83) n (%)
North America	4 (66.7)	30 (57.7)	19 (95.0)	34 (58.6)	58 (69.9)
United States	4 (66.7)	29 (55.8)	19 (95.0)	33 (56.9)	57 (68.7)
Site 20-01	0	1 (1.9)	0	1 (1.7)	1 (1.2)
Site 20-02	0	6 (11.5)	0	6 (10.3)	6 (7.2)
Site 20-03	0	2 (3.8)	0	2 (3.4)	2 (2.4)
Site 20-05	0	1 (1.9)	0	1 (1.7)	1 (1.2)
Site 20-06	0	6 (11.5)	0	6 (10.3)	6 (7.2)
Site 20-07	0	1 (1.9)	0	1 (1.7)	1 (1.2)
Site 20-10	0	1 (1.9)	0	1 (1.7)	1 (1.2)
Site 2001	1 (16.7)	0	1 (5.0)	1 (1.7)	2 (2.4)
Site 2002	0	2 (3.8)	6 (30.0)	2 (3.4)	9 (10.8)
Site 2003	0	0	3 (15.0)	0	4 (4.8)
Site 2004	2 (33.3)	4 (7.7)	1 (5.0)	6 (10.3)	7 (8.4)
Site 2005	0	1 (1.9)	2 (10.0)	1 (1.7)	4 (4.8)
Site 2006	1 (16.7)	1 (1.9)	4 (20.0)	2 (3.4)	8 (9.6)
Site 2008	0	1 (1.9)	2 (10.0)	1 (1.7)	3 (3.6)
Site 2011	0	2 (3.8)	0	2 (3.4)	2 (2.4)
Canada	0	1 (1.9)	0	1 (1.7)	1 (1.2)
Site 10-01	0	1 (1.9)	0	1 (1.7)	1 (1.2)

Source: Listing 16.2.1

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Blueprint Medicines Corporation
Avapritinib Systemic Mastocytosis Integrated Summary of Efficacy
BLU-285 SM Germany HTA Analysis
Cutoff date: 27may2020 (2101), 23jun2020 (2202)

Table 35.1.3.1 Number of Patients by Region by Country by Site
AdvSM Population with at least one prior antineoplastic therapy
Studies 2101 and 2202

	Starting Dose (QD)				
	<200 mg (N=6) n (%)	200 mg (N=52) n (%)	300 mg (N=20) n (%)	<=200 mg (N=58) n (%)	All Doses (N=83) n (%)
Europe	2 (33.3)	22 (42.3)	1 (5.0)	24 (41.4)	25 (30.1)
Germany	2 (33.3)	11 (21.2)	0	13 (22.4)	13 (15.7)
Site 43-01	2 (33.3)	6 (11.5)	0	8 (13.8)	8 (9.6)
Site 43-03	0	3 (5.8)	0	3 (5.2)	3 (3.6)
Site 43-04	0	2 (3.8)	0	2 (3.4)	2 (2.4)
Spain	0	3 (5.8)	0	3 (5.2)	3 (3.6)
Site 47-01	0	3 (5.8)	0	3 (5.2)	3 (3.6)
UK	0	2 (3.8)	1 (5.0)	2 (3.4)	3 (3.6)
Site 11-01	0	1 (1.9)	0	1 (1.7)	1 (1.2)
Site 1101	0	0	1 (5.0)	0	1 (1.2)
Site 1102	0	1 (1.9)	0	1 (1.7)	1 (1.2)
France	0	2 (3.8)	0	2 (3.4)	2 (2.4)
Site 42-01	0	2 (3.8)	0	2 (3.4)	2 (2.4)
Italy	0	1 (1.9)	0	1 (1.7)	1 (1.2)
Site 45-03	0	1 (1.9)	0	1 (1.7)	1 (1.2)
Netherlands	0	1 (1.9)	0	1 (1.7)	1 (1.2)
Site 44-01	0	1 (1.9)	0	1 (1.7)	1 (1.2)
Norway	0	1 (1.9)	0	1 (1.7)	1 (1.2)
Site 49-01	0	1 (1.9)	0	1 (1.7)	1 (1.2)
Poland	0	1 (1.9)	0	1 (1.7)	1 (1.2)
Site 52-01	0	1 (1.9)	0	1 (1.7)	1 (1.2)

Source: Listing 16.2.1

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Table 35.3.1.3
Summary of Demographics and Baseline Disease Characteristics
AdvSM Population & Prior Neoplastic Therapy = Yes

	BLU-285-2101		
Variable	200 mg (N=12) n (%)	<=200 mg (N=16) n (%)	All Doses (N=41) n (%)
Age (years)			
n	12	16	41
Mean (StdDev)	63.1 (13.26)	63.2 (12.15)	63.1 (11.72)
Median	63.5	62.5	64.0
Min, Max	42, 82	42, 82	34, 83
Age Group (n, (%))			
<65 years	7 (58.3)	10 (62.5)	21 (51.2)
>=65 years	5 (41.7)	6 (37.5)	20 (48.8)
Sex, n (%)			
Female	5 (41.7)	8 (50.0)	20 (48.8)
Male	7 (58.3)	8 (50.0)	21 (51.2)
Race, n (%)			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Black or African American	0	0	1 (2.4)
Native Hawaiian or Other Pacific Islander	0	0	0
White	12 (100.0)	15 (93.8)	38 (92.7)
Other	0	0	0
Unknown	0	1 (6.3)	2 (4.9)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note: Percentages are based on the number of patients in the Safety Population in each column.

Source (Date): Program: t-35-3-1-3-dm.sas Date: 16:43/17SEP2021

Table 35.3.1.3
Summary of Demographics and Baseline Disease Characteristics
AdvSM Population & Prior Neoplastic Therapy = Yes

	BLU-285-2101		
Variable	200 mg (N=12) n (%)	<=200 mg (N=16) n (%)	All Doses (N=41) n (%)
Ethnicity, n (%)			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	12 (100.0)	16 (100.0)	41 (100.0)
Unknown	0	0	0
Not Reported	0	0	0
Region, n (%)			
Asia	0	0	0
Europe or Australia	1 (8.3)	1 (6.3)	2 (4.9)
North America	11 (91.7)	15 (93.8)	39 (95.1)
Height (cm)			
n	11	15	38
Mean (Stddev)	168.85 (8.487)	168.16 (7.825)	168.23 (9.522)
Median	165.10	165.10	168.05
Min, Max	160.0, 182.9	160.0, 182.9	151.3, 192.8
Weight (kg)			
n	12	16	41
Mean (StdDev)	83.48 (14.424)	79.83 (16.416)	75.00 (17.706)
Median	80.15	76.45	73.80
Min, Max	65.5, 105.5	51.5, 105.5	42.5, 105.5

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note: Percentages are based on the number of patients in the Safety Population in each column.

Source (Date): Program: t-35-3-1-3-dm.sas Date: 16:43/17SEP2021

Table 35.3.1.3
Summary of Demographics and Baseline Disease Characteristics
AdvSM Population & Prior Neoplastic Therapy = Yes

Variable	BLU-285-2101 200 mg (N=12) n (%)	BLU-285-2101 <=200 mg (N=16) n (%)	BLU-285-2101 All Doses (N=41) n (%)
BMI (kg/m^2)			
n	11	15	38
Mean (StdDev)	30.04 (6.831)	28.64 (6.824)	26.24 (5.761)
Median	27.15	27.15	25.27
Min, Max	22.5, 41.2	19.5, 41.2	17.5, 41.2
BMI (kg/m^2), n (%)			
<25	3 (25.0)	5 (31.3)	18 (43.9)
>=25-<30	4 (33.3)	5 (31.3)	11 (26.8)
>=30	4 (33.3)	5 (31.3)	9 (22.0)
ECOG Performance Status, n (%)			
0	3 (25.0)	3 (18.8)	7 (17.1)
1	5 (41.7)	8 (50.0)	21 (51.2)
2	3 (25.0)	4 (25.0)	9 (22.0)
3	1 (8.3)	1 (6.3)	4 (9.8)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note: Percentages are based on the number of patients in the Safety Population in each column.

Source (Date): Program: t-35-3-1-3-dm.sas Date: 16:43/17SEP2021

Table 35.3.1.3
Summary of Demographics and Baseline Disease Characteristics
AdvSM Population & Prior Neoplastic Therapy = Yes

Variable	BLU-285-2101 200 mg (N=12) n (%)	BLU-285-2101 <=200 mg (N=16) n (%)	BLU-285-2101 All Doses (N=41) n (%)
Central Diagnosis, n (%)			
ASM	1 (8.3)	2 (12.5)	7 (17.1)
SM-AHN	7 (58.3)	9 (56.3)	26 (63.4)
MCL	4 (33.3)	5 (31.3)	8 (19.5)
ISM	0	0	0
SSM	0	0	0
Other	0	0	0
Nadir Platelet Count in Screening (n, (%))			
<50,000/µL	1 (8.3)	1 (6.3)	3 (7.3)
>=50,000/µL	11 (91.7)	15 (93.8)	38 (92.7)
Prior midostaurin, n (%)			
Yes	10 (83.3)	12 (75.0)	23 (56.1)
No	2 (16.7)	4 (25.0)	18 (43.9)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note: Percentages are based on the number of patients in the Safety Population in each column.

Source (Date): Program: t-35-3-1-3-dm.sas Date: 16:43/17SEP2021

Table 35.3.1.3
Summary of Demographics and Baseline Disease Characteristics
AdvSM Population & Prior Neoplastic Therapy = Yes

Variable	BLU-285-2202 200 mg (N=40) n (%)	BLU-285-2202 <=200 mg (N=42) n (%)	BLU-285-2202 All Doses (N=42) n (%)
Age (years)			
n	40	42	42
Mean (StdDev)	66.5 (12.34)	66.4 (12.10)	66.4 (12.10)
Median	69.0	69.0	69.0
Min, Max	31, 86	31, 86	31, 86
Age Group (n, (%))			
<65 years	14 (35.0)	15 (35.7)	15 (35.7)
>=65 years	26 (65.0)	27 (64.3)	27 (64.3)
Sex, n (%)			
Female	13 (32.5)	14 (33.3)	14 (33.3)
Male	27 (67.5)	28 (66.7)	28 (66.7)
Race, n (%)			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Black or African American	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
White	33 (82.5)	35 (83.3)	35 (83.3)
Other	6 (15.0)	6 (14.3)	6 (14.3)
Unknown	1 (2.5)	1 (2.4)	1 (2.4)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note: Percentages are based on the number of patients in the Safety Population in each column.

Source (Date): Program: t-35-3-1-3-dm.sas Date: 16:43/17SEP2021

Table 35.3.1.3
Summary of Demographics and Baseline Disease Characteristics
AdvSM Population & Prior Neoplastic Therapy = Yes

Variable	BLU-285-2202 200 mg (N=40) n (%)	BLU-285-2202 <=200 mg (N=42) n (%)	BLU-285-2202 All Doses (N=42) n (%)
Ethnicity, n (%)			
Hispanic or Latino	2 (5.0)	2 (4.8)	2 (4.8)
Not Hispanic or Latino	33 (82.5)	35 (83.3)	35 (83.3)
Unknown	0	0	0
Not Reported	5 (12.5)	5 (11.9)	5 (11.9)
Region, n (%)			
Asia	0	0	0
Europe or Australia	21 (52.5)	23 (54.8)	23 (54.8)
North America	19 (47.5)	19 (45.2)	19 (45.2)
Height (cm)			
n	37	39	39
Mean (Stddev)	172.49 (9.392)	172.80 (9.745)	172.80 (9.745)
Median	172.00	172.00	172.00
Min, Max	154.0, 188.0	154.0, 192.0	154.0, 192.0
Weight (kg)			
n	40	42	42
Mean (StdDev)	72.03 (15.151)	71.97 (14.865)	71.97 (14.865)
Median	68.95	68.95	68.95
Min, Max	44.0, 106.0	44.0, 106.0	44.0, 106.0

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note: Percentages are based on the number of patients in the Safety Population in each column.

Source (Date): Program: t-35-3-1-3-dm.sas Date: 16:43/17SEP2021

Table 35.3.1.3
Summary of Demographics and Baseline Disease Characteristics
AdvSM Population & Prior Neoplastic Therapy = Yes

Variable	BLU-285-2202 200 mg (N=40) n (%)	BLU-285-2202 <=200 mg (N=42) n (%)	BLU-285-2202 All Doses (N=42) n (%)
BMI (kg/m^2)			
n	37	39	39
Mean (StdDev)	24.06 (4.205)	23.96 (4.120)	23.96 (4.120)
Median	23.61	23.36	23.36
Min, Max	17.6, 34.8	17.6, 34.8	17.6, 34.8
BMI (kg/m^2), n (%)			
<25	22 (55.0)	24 (57.1)	24 (57.1)
>=25-<30	12 (30.0)	12 (28.6)	12 (28.6)
>=30	3 (7.5)	3 (7.1)	3 (7.1)
ECOG Performance Status, n (%)			
0	7 (17.5)	7 (16.7)	7 (16.7)
1	20 (50.0)	21 (50.0)	21 (50.0)
2	9 (22.5)	10 (23.8)	10 (23.8)
3	4 (10.0)	4 (9.5)	4 (9.5)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note: Percentages are based on the number of patients in the Safety Population in each column.

Source (Date): Program: t-35-3-1-3-dm.sas Date: 16:43/17SEP2021

Table 35.3.1.3
Summary of Demographics and Baseline Disease Characteristics
AdvSM Population & Prior Neoplastic Therapy = Yes

	BLU-285-2202		
Variable	200 mg (N=40) n (%)	<=200 mg (N=42) n (%)	All Doses (N=42) n (%)
Central Diagnosis, n (%)			
ASM	4 (10.0)	5 (11.9)	5 (11.9)
SM-AHN	27 (67.5)	28 (66.7)	28 (66.7)
MCL	9 (22.5)	9 (21.4)	9 (21.4)
ISM	0	0	0
SSM	0	0	0
Other	0	0	0
Nadir Platelet Count in Screening (n, (%))			
<50,000/µL	3 (7.5)	4 (9.5)	4 (9.5)
>=50,000/µL	37 (92.5)	38 (90.5)	38 (90.5)
Prior midostaurin, n (%)			
Yes	32 (80.0)	34 (81.0)	34 (81.0)
No	8 (20.0)	8 (19.0)	8 (19.0)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note: Percentages are based on the number of patients in the Safety Population in each column.

Source (Date): Program: t-35-3-1-3-dm.sas Date: 16:43/17SEP2021

Table 35.3.1.3
Summary of Demographics and Baseline Disease Characteristics
AdvSM Population & Prior Neoplastic Therapy = Yes

Variable	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	BLU-285-2101 + BLU-285-2202 <=200 mg (N=58) n (%)	BLU-285-2101 + BLU-285-2202 All Doses (N=83) n (%)
Age (years)			
n	52	58	83
Mean (StdDev)	65.7 (12.51)	65.5 (12.10)	64.7 (11.96)
Median	68.5	68.0	67.0
Min, Max	31, 86	31, 86	31, 86
Age Group (n, (%))			
<65 years	21 (40.4)	25 (43.1)	36 (43.4)
>=65 years	31 (59.6)	33 (56.9)	47 (56.6)
Sex, n (%)			
Female	18 (34.6)	22 (37.9)	34 (41.0)
Male	34 (65.4)	36 (62.1)	49 (59.0)
Race, n (%)			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Black or African American	0	0	1 (1.2)
Native Hawaiian or Other Pacific Islander	0	0	0
White	45 (86.5)	50 (86.2)	73 (88.0)
Other	6 (11.5)	6 (10.3)	6 (7.2)
Unknown	1 (1.9)	2 (3.4)	3 (3.6)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note: Percentages are based on the number of patients in the Safety Population in each column.

Source (Date): Program: t-35-3-1-3-dm.sas Date: 16:43/17SEP2021

Table 35.3.1.3
Summary of Demographics and Baseline Disease Characteristics
AdvSM Population & Prior Neoplastic Therapy = Yes

Variable	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	BLU-285-2101 + BLU-285-2202 <=200 mg (N=58) n (%)	BLU-285-2101 + BLU-285-2202 All Doses (N=83) n (%)
Ethnicity, n (%)			
Hispanic or Latino	2 (3.8)	2 (3.4)	2 (2.4)
Not Hispanic or Latino	45 (86.5)	51 (87.9)	76 (91.6)
Unknown	0	0	0
Not Reported	5 (9.6)	5 (8.6)	5 (6.0)
Region, n (%)			
Asia	0	0	0
Europe or Australia	22 (42.3)	24 (41.4)	25 (30.1)
North America	30 (57.7)	34 (58.6)	58 (69.9)
Height (cm)			
n	48	54	77
Mean (Stddev)	171.65 (9.235)	171.51 (9.415)	170.54 (9.844)
Median	171.10	170.10	170.00
Min, Max	154.0, 188.0	154.0, 192.0	151.3, 192.8
Weight (kg)			
n	52	58	83
Mean (StdDev)	74.67 (15.625)	74.14 (15.569)	73.47 (16.301)
Median	71.65	71.65	71.00
Min, Max	44.0, 106.0	44.0, 106.0	42.5, 106.0

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note: Percentages are based on the number of patients in the Safety Population in each column.

Source (Date): Program: t-35-3-1-3-dm.sas Date: 16:43/17SEP2021

Table 35.3.1.3
Summary of Demographics and Baseline Disease Characteristics
AdvSM Population & Prior Neoplastic Therapy = Yes

Variable	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	BLU-285-2101 + BLU-285-2202 <=200 mg (N=58) n (%)	BLU-285-2101 + BLU-285-2202 All Doses (N=83) n (%)
BMI (kg/m^2)			
n	48	54	77
Mean (StdDev)	25.43 (5.471)	25.26 (5.379)	25.09 (5.095)
Median	24.51	24.22	24.62
Min, Max	17.6, 41.2	17.6, 41.2	17.5, 41.2
BMI (kg/m^2), n (%)			
<25	25 (48.1)	29 (50.0)	42 (50.6)
>=25-<30	16 (30.8)	17 (29.3)	23 (27.7)
>=30	7 (13.5)	8 (13.8)	12 (14.5)
ECOG Performance Status, n (%)			
0	10 (19.2)	10 (17.2)	14 (16.9)
1	25 (48.1)	29 (50.0)	42 (50.6)
2	12 (23.1)	14 (24.1)	19 (22.9)
3	5 (9.6)	5 (8.6)	8 (9.6)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note: Percentages are based on the number of patients in the Safety Population in each column.

Source (Date): Program: t-35-3-1-3-dm.sas Date: 16:43/17SEP2021

Table 35.3.1.3
Summary of Demographics and Baseline Disease Characteristics
AdvSM Population & Prior Neoplastic Therapy = Yes

Variable	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	BLU-285-2101 + BLU-285-2202 <=200 mg (N=58) n (%)	BLU-285-2101 + BLU-285-2202 All Doses (N=83) n (%)
Central Diagnosis, n (%)			
ASM	5 (9.6)	7 (12.1)	12 (14.5)
SM-AHN	34 (65.4)	37 (63.8)	54 (65.1)
MCL	13 (25.0)	14 (24.1)	17 (20.5)
ISM	0	0	0
SSM	0	0	0
Other	0	0	0
Nadir Platelet Count in Screening (n, (%))			
<50,000/µL	4 (7.7)	5 (8.6)	7 (8.4)
>=50,000/µL	48 (92.3)	53 (91.4)	76 (91.6)
Prior midostaurin, n (%)			
Yes	42 (80.8)	46 (79.3)	57 (68.7)
No	10 (19.2)	12 (20.7)	26 (31.3)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note: Percentages are based on the number of patients in the Safety Population in each column.

Source (Date): Program: t-35-3-1-3-dm.sas Date: 16:43/17SEP2021

Table 14.1.4.1.2b
Demographics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=3)	200 mg (N=9)	300 mg (N=16)	200+300 mg (N=25)	All Doses (N=32)
Age (years)					
n	3	9	16	25	32
Mean (StdDev)	66.7 (8.96)	62.8 (12.01)	61.8 (13.91)	62.2 (13.01)	63.1 (11.98)
Median	62.0	63.0	66.0	64.0	63.5
Min, Max	61, 77	46, 82	34, 83	34, 83	34, 83
Age Group (years) (n (%))					
<65	2 (66.7)	6 (66.7)	7 (43.8)	13 (52.0)	17 (53.1)
≥65	1 (33.3)	3 (33.3)	9 (56.3)	12 (48.0)	15 (46.9)
Sex (n (%))					
Female	2 (66.7)	3 (33.3)	11 (68.8)	14 (56.0)	16 (50.0)
Male	1 (33.3)	6 (66.7)	5 (31.3)	11 (44.0)	16 (50.0)
Ethnicity (n (%))					
Hispanic or Latino	0	0	0	0	0
Not Hispanic or Latino	3 (100)	9 (100)	16 (100)	25 (100)	32 (100)
Not Reported	0	0	0	0	0
Unknown	0	0	0	0	0

Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-demo-rac-tpy.sas Date: 19:07/02NOV2020

Table 14.1.4.1.2b
Demographics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=3)	200 mg (N=9)	300 mg (N=16)	200+300 mg (N=25)	All Doses (N=32)
Race (n (%))					
American Indian or Alaska Native	0	0	0	0	0
Asian	0	0	0	0	0
Black or African American	0	0	1 (6.3)	1 (4.0)	1 (3.1)
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
White	3 (100)	9 (100)	14 (87.5)	23 (92.0)	30 (93.8)
Unknown	0	0	1 (6.3)	1 (4.0)	1 (3.1)
Other	0	0	0	0	0
Height (cm)					
n	3	9	15	24	31
Mean (StdDev)	168.37 (5.701)	170.59 (8.425)	166.28 (12.019)	167.90 (10.824)	168.79 (9.905)
Median	168.50	167.00	164.90	166.05	168.50
Min, Max	162.6, 174.0	160.0, 182.9	151.3, 192.8	151.3, 192.8	151.3, 192.8
Weight (kg)					
n	3	9	16	25	32
Mean (StdDev)	67.73 (23.435)	82.76 (14.219)	67.46 (18.154)	72.97 (18.152)	74.10 (17.879)
Median	57.10	79.10	62.50	70.20	73.05
Min, Max	51.5, 94.6	65.5, 104.7	42.5, 99.9	42.5, 104.7	42.5, 104.7

Table 14.1.4.1.2b
Demographics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=3)	200 mg (N=9)	300 mg (N=16)	200+300 mg (N=25)	All Doses (N=32)
BMI (kg/m^2)					
n	3	9	15	24	31
Mean (StdDev)	23.61 (6.619)	28.70 (6.373)	23.62 (4.176)	25.52 (5.573)	25.69 (5.368)
Median	20.11	27.07	24.05	24.64	24.99
Min, Max	19.5, 31.2	22.5, 39.8	17.5, 31.4	17.5, 39.8	17.5, 39.8

Table 14.1.4.1.2b
Demographics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=4)	300 mg (N=11)	200+300 mg (N=15)	All Doses (N=21)
Age (years)					
n	5	4	11	15	21
Mean (StdDev)	68.4 (15.08)	65.0 (2.71)	64.1 (9.93)	64.3 (8.50)	65.2 (9.97)
Median	75.0	64.0	68.0	68.0	68.0
Min, Max	45, 82	63, 69	42, 72	42, 72	42, 82
Age Group (years) (n (%))					
<65	2 (40.0)	3 (75.0)	3 (27.3)	6 (40.0)	9 (42.9)
≥65	3 (60.0)	1 (25.0)	8 (72.7)	9 (60.0)	12 (57.1)
Sex (n (%))					
Female	1 (20.0)	2 (50.0)	4 (36.4)	6 (40.0)	7 (33.3)
Male	4 (80.0)	2 (50.0)	7 (63.6)	9 (60.0)	14 (66.7)
Ethnicity (n (%))					
Hispanic or Latino	0	0	0	0	0
Not Hispanic or Latino	5 (100)	4 (100)	11 (100)	15 (100)	20 (95.2)
Not Reported	0	0	0	0	0
Unknown	0	0	0	0	1 (4.8)

Table 14.1.4.1.2b
Demographics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=4)	300 mg (N=11)	200+300 mg (N=15)	All Doses (N=21)
Race (n (%))					
American Indian or Alaska Native	0	0	0	0	0
Asian	0	0	2 (18.2)	2 (13.3)	2 (9.5)
Black or African American	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
White	4 (80.0)	4 (100)	9 (81.8)	13 (86.7)	17 (81.0)
Unknown	1 (20.0)	0	0	0	2 (9.5)
Other	0	0	0	0	0
Height (cm)					
n	5	4	9	13	19
Mean (StdDev)	177.10 (5.539)	176.50 (4.373)	170.76 (7.346)	172.52 (6.955)	174.01 (6.641)
Median	177.50	177.75	170.00	175.00	177.50
Min, Max	169.0, 183.5	170.2, 180.3	161.1, 181.0	161.1, 181.0	161.1, 183.5
Weight (kg)					
n	5	4	11	15	21
Mean (StdDev)	83.48 (16.329)	81.55 (9.111)	80.07 (11.801)	80.47 (10.850)	82.22 (12.585)
Median	90.00	83.05	85.70	85.70	86.00
Min, Max	63.5, 98.6	69.5, 90.6	55.9, 95.6	55.9, 95.6	55.9, 102.2

Table 14.1.4.1.2b
Demographics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=4)	300 mg (N=11)	200+300 mg (N=15)	All Doses (N=21)
BMI (kg/m^2)					
n	5	4	9	13	19
Mean (StdDev)	26.47 (4.128)	26.25 (3.620)	27.30 (4.695)	26.98 (4.269)	27.12 (4.193)
Median	26.73	26.70	28.34	28.34	28.34
Min, Max	22.2, 31.3	21.9, 29.7	19.3, 32.7	19.3, 32.7	19.3, 32.7

Table 14.1.4.1.2b
Demographics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)	
	200 mg (N=22)	All Doses (N=23)
Age (years)		
n	22	23
Mean (StdDev)	66.1 (11.31)	65.8 (11.15)
Median	68.5	68.0
Min, Max	37, 80	37, 80
Age Group (years) (n (%))		
<65	7 (31.8)	8 (34.8)
≥65	15 (68.2)	15 (65.2)
Sex (n (%))		
Female	7 (31.8)	8 (34.8)
Male	15 (68.2)	15 (65.2)
Ethnicity (n (%))		
Hispanic or Latino	1 (4.5)	1 (4.3)
Not Hispanic or Latino	21 (95.5)	22 (95.7)
Not Reported	0	0
Unknown	0	0

Table 14.1.4.1.2b
Demographics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)	
	200 mg (N=22)	All Doses (N=23)
Race (n (%))		
American Indian or Alaska Native	0	0
Asian	0	0
Black or African American	0	0
Native Hawaiian or Other Pacific Islander	0	0
White	22 (100)	23 (100)
Unknown	0	0
Other	0	0
Height (cm)		
n	20	21
Mean (StdDev)	174.54 (8.474)	174.08 (8.518)
Median	174.00	173.00
Min, Max	160.0, 188.0	160.0, 188.0
Weight (kg)		
n	22	23
Mean (StdDev)	73.31 (14.871)	72.89 (14.669)
Median	67.65	64.30
Min, Max	48.2, 103.1	48.2, 103.1

Table 14.1.4.1.2b
Demographics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)	
	200 mg (N=22)	All Doses (N=23)
BMI (kg/m^2)		
n	20	21
Mean (StdDev)	24.04 (3.965)	24.01 (3.867)
Median	22.89	22.97
Min, Max	18.2, 30.8	18.2, 30.8

Table 14.1.4.1.2b
Demographics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)	
	200 mg (N=9)	All Doses (N=9)
Age (years)		
n	9	9
Mean (StdDev)	67.3 (9.04)	67.3 (9.04)
Median	68.0	68.0
Min, Max	54, 85	54, 85
Age Group (years) (n (%))		
<65	4 (44.4)	4 (44.4)
≥65	5 (55.6)	5 (55.6)
Sex (n (%))		
Female	6 (66.7)	6 (66.7)
Male	3 (33.3)	3 (33.3)
Ethnicity (n (%))		
Hispanic or Latino	0	0
Not Hispanic or Latino	9 (100)	9 (100)
Not Reported	0	0
Unknown	0	0

Table 14.1.4.1.2b
Demographics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)	
	200 mg (N=9)	All Doses (N=9)
Race (n (%))		
American Indian or Alaska Native	0	0
Asian	0	0
Black or African American	0	0
Native Hawaiian or Other Pacific Islander	0	0
White	9 (100)	9 (100)
Unknown	0	0
Other	0	0
Height (cm)		
n	9	9
Mean (StdDev)	166.72 (8.596)	166.72 (8.596)
Median	167.60	167.60
Min, Max	155.0, 177.0	155.0, 177.0
Weight (kg)		
n	9	9
Mean (StdDev)	74.78 (11.258)	74.78 (11.258)
Median	71.00	71.00
Min, Max	62.4, 94.3	62.4, 94.3

Table 14.1.4.1.2b
Demographics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)	
	200 mg (N=9)	All Doses (N=9)
BMI (kg/m^2)		
n	9	9
Mean (StdDev)	26.83 (2.836)	26.83 (2.836)
Median	26.04	26.04
Min, Max	23.7, 31.4	23.7, 31.4

Table 14.1.4.1.2b
Demographics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=4)	200 mg (N=31)	300 mg (N=16)	200+300 mg (N=47)	All Doses (N=55)
Age (years)					
n	4	31	16	47	55
Mean (StdDev)	64.8 (8.26)	65.1 (11.42)	61.8 (13.91)	64.0 (12.27)	64.2 (11.61)
Median	61.5	68.0	66.0	67.0	66.0
Min, Max	59, 77	37, 82	34, 83	34, 83	34, 83
Age Group (years) (n (%))					
<65	3 (75.0)	13 (41.9)	7 (43.8)	20 (42.6)	25 (45.5)
≥65	1 (25.0)	18 (58.1)	9 (56.3)	27 (57.4)	30 (54.5)
Sex (n (%))					
Female	3 (75.0)	10 (32.3)	11 (68.8)	21 (44.7)	24 (43.6)
Male	1 (25.0)	21 (67.7)	5 (31.3)	26 (55.3)	31 (56.4)
Ethnicity (n (%))					
Hispanic or Latino	0	1 (3.2)	0	1 (2.1)	1 (1.8)
Not Hispanic or Latino	4 (100)	30 (96.8)	16 (100)	46 (97.9)	54 (98.2)
Not Reported	0	0	0	0	0
Unknown	0	0	0	0	0

Table 14.1.4.1.2b
Demographics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=4)	200 mg (N=31)	300 mg (N=16)	200+300 mg (N=47)	All Doses (N=55)
Race (n (%))					
American Indian or Alaska Native	0	0	0	0	0
Asian	0	0	0	0	0
Black or African American	0	0	1 (6.3)	1 (2.1)	1 (1.8)
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
White	4 (100)	31 (100)	14 (87.5)	45 (95.7)	53 (96.4)
Unknown	0	0	1 (6.3)	1 (2.1)	1 (1.8)
Other	0	0	0	0	0
Height (cm)					
n	4	29	15	44	52
Mean (StdDev)	167.53 (4.950)	173.31 (8.513)	166.28 (12.019)	170.92 (10.276)	170.93 (9.646)
Median	166.75	173.00	164.90	170.10	170.10
Min, Max	162.6, 174.0	160.0, 188.0	151.3, 192.8	151.3, 192.8	151.3, 192.8
Weight (kg)					
n	4	31	16	47	55
Mean (StdDev)	66.70 (19.246)	76.05 (15.090)	67.46 (18.154)	73.13 (16.520)	73.59 (16.478)
Median	60.35	73.80	62.50	70.20	71.00
Min, Max	51.5, 94.6	48.2, 104.7	42.5, 99.9	42.5, 104.7	42.5, 104.7

Table 14.1.4.1.2b
Demographics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=4)	200 mg (N=31)	300 mg (N=16)	200+300 mg (N=47)	All Doses (N=55)
BMI (kg/m^2)					
n	4	29	15	44	52
Mean (StdDev)	23.55 (5.406)	25.49 (5.204)	23.62 (4.176)	24.85 (4.911)	25.01 (4.848)
Median	21.74	24.65	24.05	24.33	24.62
Min, Max	19.5, 31.2	18.2, 39.8	17.5, 31.4	17.5, 39.8	17.5, 39.8

Table 14.1.4.1.2b
Demographics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=13)	300 mg (N=11)	200+300 mg (N=24)	All Doses (N=30)
Age (years)					
n	5	13	11	24	30
Mean (StdDev)	68.4 (15.08)	66.6 (7.59)	64.1 (9.93)	65.5 (8.64)	65.9 (9.59)
Median	75.0	64.0	68.0	68.0	68.0
Min, Max	45, 82	54, 85	42, 72	42, 85	42, 85
Age Group (years) (n (%))					
<65	2 (40.0)	7 (53.8)	3 (27.3)	10 (41.7)	13 (43.3)
≥65	3 (60.0)	6 (46.2)	8 (72.7)	14 (58.3)	17 (56.7)
Sex (n (%))					
Female	1 (20.0)	8 (61.5)	4 (36.4)	12 (50.0)	13 (43.3)
Male	4 (80.0)	5 (38.5)	7 (63.6)	12 (50.0)	17 (56.7)
Ethnicity (n (%))					
Hispanic or Latino	0	0	0	0	0
Not Hispanic or Latino	5 (100)	13 (100)	11 (100)	24 (100)	29 (96.7)
Not Reported	0	0	0	0	0
Unknown	0	0	0	0	1 (3.3)

Table 14.1.4.1.2b
Demographics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=13)	300 mg (N=11)	200+300 mg (N=24)	All Doses (N=30)
Race (n (%))					
American Indian or Alaska Native	0	0	0	0	0
Asian	0	0	2 (18.2)	2 (8.3)	2 (6.7)
Black or African American	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
White	4 (80.0)	13 (100)	9 (81.8)	22 (91.7)	26 (86.7)
Unknown	1 (20.0)	0	0	0	2 (6.7)
Other	0	0	0	0	0
Height (cm)					
n	5	13	9	22	28
Mean (StdDev)	177.10 (5.539)	169.73 (8.724)	170.76 (7.346)	170.15 (8.020)	171.66 (7.956)
Median	177.50	173.00	170.00	171.60	174.10
Min, Max	169.0, 183.5	155.0, 180.3	161.1, 181.0	155.0, 181.0	155.0, 183.5
Weight (kg)					
n	5	13	11	24	30
Mean (StdDev)	83.48 (16.329)	76.86 (10.763)	80.07 (11.801)	78.33 (11.120)	79.99 (12.499)
Median	90.00	75.90	85.70	80.45	82.15
Min, Max	63.5, 98.6	62.4, 94.3	55.9, 95.6	55.9, 95.6	55.9, 102.2

Table 14.1.4.1.2b
Demographics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=13)	300 mg (N=11)	200+300 mg (N=24)	All Doses (N=30)
BMI (kg/m^2)					
n	5	13	9	22	28
Mean (StdDev)	26.47 (4.128)	26.66 (2.952)	27.30 (4.695)	26.92 (3.672)	27.03 (3.758)
Median	26.73	26.04	28.34	27.20	27.24
Min, Max	22.2, 31.3	21.9, 31.4	19.3, 32.7	19.3, 32.7	19.3, 32.7

Table 14.1.4.2b
Baseline Characteristics by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=4)	200 mg (N=12)	300 mg (N=20)	200+300 mg (N=32)	All Doses (N=41)
Major and Minor WHO Diagnosis Criteria for SM by PI					
Major					
Multifocal dense infiltrations of MC	4 (100)	10 (83.3)	13 (65.0)	23 (71.9)	30 (73.2)
Minor					
>25% MC atypical/spindle shaped in biopsy or immature/atypical in aspirate	1 (25.0)	6 (50.0)	6 (30.0)	12 (37.5)	13 (31.7)
expression of CD markers CD2 and/or CD25	2 (50.0)	10 (83.3)	14 (70.0)	24 (75.0)	30 (73.2)
KIT mutation at codon 816	4 (100)	11 (91.7)	15 (75.0)	26 (81.3)	35 (85.4)
Baseline serum tryptase >20ng/mL	2 (50.0)	9 (75.0)	13 (65.0)	22 (68.8)	27 (65.9)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-bl-advsm-tpy.sas Date: 19:08/02NOV2020

Table 14.1.4.2b
Baseline Characteristics by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=4)	200 mg (N=12)	300 mg (N=20)	200+300 mg (N=32)	All Doses (N=41)
WHO diagnosis criteria for AdvSM subclassification by PI					
MCL only [1]	0	0	0	0	0
C-findings 1 [2]	1 (25.0)	8 (66.7)	9 (45.0)	17 (53.1)	21 (51.2)
C-findings 2 [3]	1 (25.0)	0	3 (15.0)	3 (9.4)	6 (14.6)
C-findings 3 [4]	2 (50.0)	2 (16.7)	6 (30.0)	8 (25.0)	12 (29.3)
C-findings 4 [5]	1 (25.0)	1 (8.3)	4 (20.0)	5 (15.6)	7 (17.1)
C-findings 5 [6]	0	1 (8.3)	2 (10.0)	3 (9.4)	4 (9.8)
Extracutaneous organ involvement					
Yes	1 (25.0)	2 (16.7)	9 (45.0)	11 (34.4)	13 (31.7)
No	3 (75.0)	10 (83.3)	11 (55.0)	21 (65.6)	28 (68.3)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
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Table 14.1.4.2b
Baseline Characteristics by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=4)	200 mg (N=12)	300 mg (N=20)	200+300 mg (N=32)	All Doses (N=41)
Mutation Status (n (%))					
KIT Mutation (CRF)					
Wild Type (No)	0	2 (16.7)	4 (20.0)	6 (18.8)	6 (14.6)
Yes	4 (100)	10 (83.3)	16 (80.0)	26 (81.3)	35 (85.4)
Source Sample Type					
BM	1 (25.0)	10 (83.3)	13 (65.0)	23 (71.9)	28 (68.3)
Blood	2 (50.0)	0	3 (15.0)	3 (9.4)	6 (14.6)
BM, Blood	1 (25.0)	0	0	0	1 (2.4)
Other	0	0	0	0	0
Exon 17 Mutation					
D816V	4 (100)	10 (83.3)	15 (75.0)	25 (78.1)	34 (82.9)
D816Y	0	0	1 (5.0)	1 (3.1)	1 (2.4)
Other	0	0	0	0	0

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
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Table 14.1.4.2b
Baseline Characteristics by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=4)	200 mg (N=12)	300 mg (N=20)	200+300 mg (N=32)	All Doses (N=41)
Non-KIT Mutation (CRF)					
No	3 (75.0)	5 (41.7)	7 (35.0)	12 (37.5)	18 (43.9)
Yes	1 (25.0)	7 (58.3)	13 (65.0)	20 (62.5)	23 (56.1)
Source Sample Type					
BM	1 (25.0)	7 (58.3)	7 (35.0)	14 (43.8)	17 (41.5)
Blood	0	0	4 (20.0)	4 (12.5)	4 (9.8)
Other	0	0	0	0	0
Missing	0	0	2 (10.0)	2 (6.3)	2 (4.9)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-bl-advsm-tpy.sas Date: 19:08/02NOV2020

Table 14.1.4.2b
Baseline Characteristics by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=4)	200 mg (N=12)	300 mg (N=20)	200+300 mg (N=32)	All Doses (N=41)
ASXL1	0	2 (16.7)	3 (15.0)	5 (15.6)	5 (12.2)
CBL	0	1 (8.3)	2 (10.0)	3 (9.4)	3 (7.3)
DNMT3A	1 (25.0)	2 (16.7)	2 (10.0)	4 (12.5)	5 (12.2)
EZH2	0	1 (8.3)	2 (10.0)	3 (9.4)	3 (7.3)
JAK2	0	1 (8.3)	1 (5.0)	2 (6.3)	3 (7.3)
KRAS	0	0	0	0	0
NRAS	0	0	1 (5.0)	1 (3.1)	1 (2.4)
RUNX1	0	3 (25.0)	1 (5.0)	4 (12.5)	5 (12.2)
SF3B1	0	0	2 (10.0)	2 (6.3)	2 (4.9)
SRSF2	0	3 (25.0)	2 (10.0)	5 (15.6)	6 (14.6)
NOTCH1	0	1 (8.3)	0	1 (3.1)	1 (2.4)
SMC1A	0	1 (8.3)	0	1 (3.1)	1 (2.4)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-bl-advsm-tpy.sas Date: 19:08/02NOV2020

Table 14.1.4.2b
Baseline Characteristics by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=4)	200 mg (N=12)	300 mg (N=20)	200+300 mg (N=32)	All Doses (N=41)
ECOG Performance Status (n (%))					
0	0	3 (25.0)	4 (20.0)	7 (21.9)	7 (17.1)
1	3 (75.0)	5 (41.7)	8 (40.0)	13 (40.6)	21 (51.2)
2	1 (25.0)	3 (25.0)	5 (25.0)	8 (25.0)	9 (22.0)
3	0	1 (8.3)	3 (15.0)	4 (12.5)	4 (9.8)
Corticosteroid Therapy Use for SM (n (%))					
Yes	1 (25.0)	5 (41.7)	7 (35.0)	12 (37.5)	14 (34.1)
No	3 (75.0)	7 (58.3)	13 (65.0)	20 (62.5)	27 (65.9)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-bl-advsm-tpy.sas Date: 19:08/02NOV2020

Table 14.1.4.2b
Baseline Characteristics by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=8)	300 mg (N=14)	200+300 mg (N=22)	All Doses (N=28)
Major and Minor WHO Diagnosis Criteria for SM by PI					
Major					
Multifocal dense infiltrations of MC	3 (60.0)	6 (75.0)	9 (64.3)	15 (68.2)	19 (67.9)
Minor					
>25% MC atypical/spindle shaped in biopsy or immature/atypical in aspirate	1 (20.0)	5 (62.5)	4 (28.6)	9 (40.9)	10 (35.7)
expression of CD markers CD2 and/or CD25	4 (80.0)	8 (100)	10 (71.4)	18 (81.8)	23 (82.1)
KIT mutation at codon 816	4 (80.0)	8 (100)	12 (85.7)	20 (90.9)	25 (89.3)
Baseline serum tryptase >20ng/mL	4 (80.0)	7 (87.5)	11 (78.6)	18 (81.8)	22 (78.6)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 $x10^9$/L or HGB <10g/dL or PLT count <$100x10^9$/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <$100x10^9$/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-bl-advsm-tpy.sas Date: 19:08/02NOV2020

Table 14.1.4.2b
Baseline Characteristics by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=8)	300 mg (N=14)	200+300 mg (N=22)	All Doses (N=28)
WHO diagnosis criteria for AdvSM subclassification by PI					
MCL only [1]	0	0	0	0	0
C-findings 1 [2]	5 (100)	4 (50.0)	12 (85.7)	16 (72.7)	21 (75.0)
C-findings 2 [3]	2 (40.0)	2 (25.0)	9 (64.3)	11 (50.0)	13 (46.4)
C-findings 3 [4]	3 (60.0)	2 (25.0)	8 (57.1)	10 (45.5)	13 (46.4)
C-findings 4 [5]	4 (80.0)	3 (37.5)	7 (50.0)	10 (45.5)	14 (50.0)
C-findings 5 [6]	0	2 (25.0)	0	2 (9.1)	2 (7.1)
Extracutaneous organ involvement					
Yes	3 (60.0)	7 (87.5)	6 (42.9)	13 (59.1)	16 (57.1)
No	2 (40.0)	1 (12.5)	8 (57.1)	9 (40.9)	12 (42.9)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-bl-advsm-tpy.sas Date: 19:08/02NOV2020

Table 14.1.4.2b
Baseline Characteristics by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=8)	300 mg (N=14)	200+300 mg (N=22)	All Doses (N=28)
Mutation Status (n (%))					
KIT Mutation (CRF)					
Wild Type (No)	1 (20.0)	0	1 (7.1)	1 (4.5)	2 (7.1)
Yes	4 (80.0)	8 (100)	13 (92.9)	21 (95.5)	26 (92.9)
Source Sample Type					
BM	4 (80.0)	7 (87.5)	9 (64.3)	16 (72.7)	21 (75.0)
Blood	0	1 (12.5)	3 (21.4)	4 (18.2)	4 (14.3)
BM, Blood	0	0	0	0	0
Other	0	0	1 (7.1)	1 (4.5)	1 (3.6)
Exon 17 Mutation					
D816V	4 (80.0)	8 (100)	13 (92.9)	21 (95.5)	26 (92.9)
D816Y	0	0	0	0	0
Other	0	0	0	0	0

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-bl-advsm-tpy.sas Date: 19:08/02NOV2020

Table 14.1.4.2b
Baseline Characteristics by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=8)	300 mg (N=14)	200+300 mg (N=22)	All Doses (N=28)
Non-KIT Mutation (CRF)					
No	4 (80.0)	7 (87.5)	8 (57.1)	15 (68.2)	20 (71.4)
Yes	1 (20.0)	1 (12.5)	6 (42.9)	7 (31.8)	8 (28.6)
Source Sample Type					
BM	1 (20.0)	1 (12.5)	3 (21.4)	4 (18.2)	5 (17.9)
Blood	0	0	3 (21.4)	3 (13.6)	3 (10.7)
Other	0	0	0	0	0

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-bl-advsm-tpy.sas Date: 19:08/02NOV2020

Table 14.1.4.2b
Baseline Characteristics by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=8)	300 mg (N=14)	200+300 mg (N=22)	All Doses (N=28)
ASXL1	0	1 (12.5)	2 (14.3)	3 (13.6)	3 (10.7)
CBL	0	0	1 (7.1)	1 (4.5)	1 (3.6)
DNMT3A	0	0	1 (7.1)	1 (4.5)	1 (3.6)
EZH2	0	0	0	0	0
JAK2	0	0	0	0	0
KRAS	0	0	0	0	0
NRAS	0	0	0	0	0
RUNX1	0	0	1 (7.1)	1 (4.5)	1 (3.6)
SF3B1	0	0	0	0	0
SRSF2	1 (20.0)	0	3 (21.4)	3 (13.6)	4 (14.3)
NOTCH1	0	0	0	0	0
SMC1A	0	0	0	0	0

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-bl-advsm-tpy.sas Date: 19:08/02NOV2020

Table 14.1.4.2b
Baseline Characteristics by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=8)	300 mg (N=14)	200+300 mg (N=22)	All Doses (N=28)
ECOG Performance Status (n (%))					
0	1 (20.0)	2 (25.0)	3 (21.4)	5 (22.7)	7 (25.0)
1	4 (80.0)	3 (37.5)	6 (42.9)	9 (40.9)	13 (46.4)
2	0	2 (25.0)	3 (21.4)	5 (22.7)	5 (17.9)
3	0	1 (12.5)	2 (14.3)	3 (13.6)	3 (10.7)
Corticosteroid Therapy Use for SM (n (%))					
Yes	4 (80.0)	3 (37.5)	4 (28.6)	7 (31.8)	12 (42.9)
No	1 (20.0)	5 (62.5)	10 (71.4)	15 (68.2)	16 (57.1)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-bl-advsm-tpy.sas Date: 19:08/02NOV2020

Table 14.1.4.2b
Baseline Characteristics by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)	
	200 mg (N=40)	All Doses (N=42)
Major and Minor WHO Diagnosis Criteria for SM by PI		
Major		
Multifocal dense infiltrations of MC	33 (82.5)	35 (83.3)
Minor		
>25% MC atypical/spindle shaped in biopsy or immature/atypical in aspirate	30 (75.0)	32 (76.2)
expression of CD markers CD2 and/or CD25	35 (87.5)	37 (88.1)
KIT mutation at codon 816	39 (97.5)	41 (97.6)
Baseline serum tryptase >20ng/mL	37 (92.5)	39 (92.9)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-bl-advsm-tpy.sas Date: 19:08/02NOV2020

Table 14.1.4.2b
Baseline Characteristics by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)	
	200 mg (N=40)	All Doses (N=42)
WHO diagnosis criteria for AdvSM subclassification by PI		
MCL only [1]	3 (7.5)	3 (7.1)
C-findings 1 [2]	25 (62.5)	26 (61.9)
C-findings 2 [3]	10 (25.0)	12 (28.6)
C-findings 3 [4]	11 (27.5)	12 (28.6)
C-findings 4 [5]	5 (12.5)	6 (14.3)
C-findings 5 [6]	1 (2.5)	1 (2.4)
Extracutaneous organ involvement		
Yes	29 (72.5)	31 (73.8)
No	11 (27.5)	11 (26.2)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
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Table 14.1.4.2b
Baseline Characteristics by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)	
	200 mg (N=40)	All Doses (N=42)
Mutation Status (n (%))		
KIT Mutation (CRF)		
Wild Type (No)	1 (2.5)	1 (2.4)
Yes	38 (95.0)	40 (95.2)
Source Sample Type		
BM	19 (47.5)	20 (47.6)
Blood	0	0
BM, Blood	0	0
Other	0	0
Exon 17 Mutation		
D816V	38 (95.0)	40 (95.2)
D816Y	0	0
Other	0	0

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
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Table 14.1.4.2b
Baseline Characteristics by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)	
	200 mg (N=40)	All Doses (N=42)
Non-KIT Mutation (CRF)		
No	8 (20.0)	9 (21.4)
Yes	11 (27.5)	11 (26.2)
Source Sample Type		
BM	11 (27.5)	11 (26.2)
Blood	0	0
Other	0	0

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
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Table 14.1.4.2b
Baseline Characteristics by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)	
	200 mg (N=40)	All Doses (N=42)
ASXL1	3 (7.5)	3 (7.1)
CBL	3 (7.5)	3 (7.1)
DNMT3A	1 (2.5)	1 (2.4)
EZH2	0	0
JAK2	1 (2.5)	1 (2.4)
KRAS	0	0
NRAS	1 (2.5)	1 (2.4)
RUNX1	2 (5.0)	2 (4.8)
SF3B1	2 (5.0)	2 (4.8)
SRSF2	4 (10.0)	4 (9.5)
TET2	5 (12.5)	5 (11.9)
U2AF1	0	0
NOTCH1	0	0
SMC1A	0	0

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
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Table 14.1.4.2b
Baseline Characteristics by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)	
	200 mg (N=40)	All Doses (N=42)
ECOG Performance Status (n (%))		
0	7 (17.5)	7 (16.7)
1	20 (50.0)	21 (50.0)
2	9 (22.5)	10 (23.8)
3	4 (10.0)	4 (9.5)
Corticosteroid Therapy Use for SM (n (%))		
Yes	18 (45.0)	20 (47.6)
No	22 (55.0)	22 (52.4)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
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Table 14.1.4.2b
Baseline Characteristics by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)	
	200 mg (N=20)	All Doses (N=20)
Major and Minor WHO Diagnosis Criteria for SM by PI		
Major		
Multifocal dense infiltrations of MC	15 (75.0)	15 (75.0)
Minor		
>25% MC atypical/spindle shaped in biopsy or immature/atypical in aspirate	15 (75.0)	15 (75.0)
expression of CD markers CD2 and/or CD25	16 (80.0)	16 (80.0)
KIT mutation at codon 816	16 (80.0)	16 (80.0)
Baseline serum tryptase >20ng/mL	18 (90.0)	18 (90.0)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-bl-advsm-tpy.sas Date: 19:08/02NOV2020

Table 14.1.4.2b
Baseline Characteristics by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)	
	200 mg (N=20)	All Doses (N=20)
WHO diagnosis criteria for AdvSM subclassification by PI		
MCL only [1]	1 (5.0)	1 (5.0)
C-findings 1 [2]	7 (35.0)	7 (35.0)
C-findings 2 [3]	2 (10.0)	2 (10.0)
C-findings 3 [4]	4 (20.0)	4 (20.0)
C-findings 4 [5]	3 (15.0)	3 (15.0)
C-findings 5 [6]	1 (5.0)	1 (5.0)
Extracutaneous organ involvement		
Yes	10 (50.0)	10 (50.0)
No	10 (50.0)	10 (50.0)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
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Table 14.1.4.2b
Baseline Characteristics by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)	
	200 mg (N=20)	All Doses (N=20)
Mutation Status (n (%))		
KIT Mutation (CRF)		
Wild Type (No)	0	0
Yes	18 (90.0)	18 (90.0)
Source Sample Type		
BM	9 (45.0)	9 (45.0)
Blood	0	0
BM, Blood	0	0
Other	0	0
Exon 17 Mutation		
D816V	18 (90.0)	18 (90.0)
D816Y	0	0
Other	0	0

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
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Table 14.1.4.2b
Baseline Characteristics by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)	
	200 mg (N=20)	All Doses (N=20)
Non-KIT Mutation (CRF)		
No	4 (20.0)	4 (20.0)
Yes	8 (40.0)	8 (40.0)
Source Sample Type		
BM	5 (25.0)	5 (25.0)
Blood	3 (15.0)	3 (15.0)
Other	0	0

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
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Table 14.1.4.2b
Baseline Characteristics by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)	
	200 mg (N=20)	All Doses (N=20)
ASXL1	2 (10.0)	2 (10.0)
CBL	1 (5.0)	1 (5.0)
DNMT3A	0	0
EZH2	0	0
JAK2	1 (5.0)	1 (5.0)
KRAS	1 (5.0)	1 (5.0)
NRAS	1 (5.0)	1 (5.0)
RUNX1	2 (10.0)	2 (10.0)
SF3B1	0	0
SRSF2	5 (25.0)	5 (25.0)
TET2	7 (35.0)	7 (35.0)
U2AF1	0	0
NOTCH1	0	0
SMC1A	0	0

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-bl-advsm-tpy.sas Date: 19:08/02NOV2020

Table 14.1.4.2b
Baseline Characteristics by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)	
	200 mg (N=20)	All Doses (N=20)
ECOG Performance Status (n (%))		
0	3 (15.0)	3 (15.0)
1	12 (60.0)	12 (60.0)
2	4 (20.0)	4 (20.0)
3	1 (5.0)	1 (5.0)
Corticosteroid Therapy Use for SM (n (%))		
Yes	3 (15.0)	3 (15.0)
No	17 (85.0)	17 (85.0)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
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Table 14.1.4.2b
Baseline Characteristics by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=6)	200 mg (N=52)	300 mg (N=20)	200+300 mg (N=72)	All Doses (N=83)
Major and Minor WHO Diagnosis Criteria for SM by PI					
Major					
Multifocal dense infiltrations of MC	6 (100)	43 (82.7)	13 (65.0)	56 (77.8)	65 (78.3)
Minor					
>25% MC atypical/spindle shaped in biopsy or immature/atypical in aspirate	3 (50.0)	36 (69.2)	6 (30.0)	42 (58.3)	45 (54.2)
expression of CD markers CD2 and/or CD25	4 (66.7)	45 (86.5)	14 (70.0)	59 (81.9)	67 (80.7)
KIT mutation at codon 816	6 (100)	50 (96.2)	15 (75.0)	65 (90.3)	76 (91.6)
Baseline serum tryptase >20ng/mL	4 (66.7)	46 (88.5)	13 (65.0)	59 (81.9)	66 (79.5)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-bl-advsm-tpy.sas Date: 19:08/02NOV2020

Table 14.1.4.2b
Baseline Characteristics by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=6)	200 mg (N=52)	300 mg (N=20)	200+300 mg (N=72)	All Doses (N=83)
WHO diagnosis criteria for AdvSM subclassification by PI					
MCL only [1]	0	3 (5.8)	0	3 (4.2)	3 (3.6)
C-findings 1 [2]	2 (33.3)	33 (63.5)	9 (45.0)	42 (58.3)	47 (56.6)
C-findings 2 [3]	3 (50.0)	10 (19.2)	3 (15.0)	13 (18.1)	18 (21.7)
C-findings 3 [4]	3 (50.0)	13 (25.0)	6 (30.0)	19 (26.4)	24 (28.9)
C-findings 4 [5]	2 (33.3)	6 (11.5)	4 (20.0)	10 (13.9)	13 (15.7)
C-findings 5 [6]	0	2 (3.8)	2 (10.0)	4 (5.6)	5 (6.0)
Extracutaneous organ involvement					
Yes	3 (50.0)	31 (59.6)	9 (45.0)	40 (55.6)	44 (53.0)
No	3 (50.0)	21 (40.4)	11 (55.0)	32 (44.4)	39 (47.0)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-bl-advsm-tpy.sas Date: 19:08/02NOV2020

Table 14.1.4.2b
Baseline Characteristics by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=6)	200 mg (N=52)	300 mg (N=20)	200+300 mg (N=72)	All Doses (N=83)
Mutation Status (n (%))					
KIT Mutation (CRF)					
Wild Type (No)	0	3 (5.8)	4 (20.0)	7 (9.7)	7 (8.4)
Yes	6 (100)	48 (92.3)	16 (80.0)	64 (88.9)	75 (90.4)
Source Sample Type					
BM	2 (33.3)	29 (55.8)	13 (65.0)	42 (58.3)	48 (57.8)
Blood	2 (33.3)	0	3 (15.0)	3 (4.2)	6 (7.2)
BM, Blood	1 (16.7)	0	0	0	1 (1.2)
Other	0	0	0	0	0
Exon 17 Mutation					
D816V	6 (100)	48 (92.3)	15 (75.0)	63 (87.5)	74 (89.2)
D816Y	0	0	1 (5.0)	1 (1.4)	1 (1.2)
Other	0	0	0	0	0

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-bl-advsm-tpy.sas Date: 19:08/02NOV2020

Table 14.1.4.2b
Baseline Characteristics by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=6)	200 mg (N=52)	300 mg (N=20)	200+300 mg (N=72)	All Doses (N=83)
Non-KIT Mutation (CRF)					
No	4 (66.7)	13 (25.0)	7 (35.0)	20 (27.8)	27 (32.5)
Yes	1 (16.7)	18 (34.6)	13 (65.0)	31 (43.1)	34 (41.0)
Source Sample Type					
BM	1 (16.7)	18 (34.6)	7 (35.0)	25 (34.7)	28 (33.7)
Blood	0	0	4 (20.0)	4 (5.6)	4 (4.8)
Other	0	0	0	0	0
Missing	0	0	2 (10.0)	2 (2.8)	2 (2.4)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
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Table 14.1.4.2b
Baseline Characteristics by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=6)	200 mg (N=52)	300 mg (N=20)	200+300 mg (N=72)	All Doses (N=83)
ASXL1	0	5 (9.6)	3 (15.0)	8 (11.1)	8 (9.6)
CBL	0	4 (7.7)	2 (10.0)	6 (8.3)	6 (7.2)
DNMT3A	1 (16.7)	3 (5.8)	2 (10.0)	5 (6.9)	6 (7.2)
EZH2	0	1 (1.9)	2 (10.0)	3 (4.2)	3 (3.6)
JAK2	0	2 (3.8)	1 (5.0)	3 (4.2)	4 (4.8)
KRAS	0	0	0	0	0
NRAS	0	1 (1.9)	1 (5.0)	2 (2.8)	2 (2.4)
RUNX1	0	5 (9.6)	1 (5.0)	6 (8.3)	7 (8.4)
SF3B1	0	2 (3.8)	2 (10.0)	4 (5.6)	4 (4.8)
SRSF2	0	7 (13.5)	2 (10.0)	9 (12.5)	10 (12.0)
TET2	0	5 (9.6)	0	5 (6.9)	5 (6.0)
U2AF1	0	0	0	0	0
NOTCH1	0	1 (1.9)	0	1 (1.4)	1 (1.2)
SMC1A	0	1 (1.9)	0	1 (1.4)	1 (1.2)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-bl-advsm-tpy.sas Date: 19:08/02NOV2020

Table 14.1.4.2b
Baseline Characteristics by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=6)	200 mg (N=52)	300 mg (N=20)	200+300 mg (N=72)	All Doses (N=83)
ECOG Performance Status (n (%))					
0	0	10 (19.2)	4 (20.0)	14 (19.4)	14 (16.9)
1	4 (66.7)	25 (48.1)	8 (40.0)	33 (45.8)	42 (50.6)
2	2 (33.3)	12 (23.1)	5 (25.0)	17 (23.6)	19 (22.9)
3	0	5 (9.6)	3 (15.0)	8 (11.1)	8 (9.6)
Corticosteroid Therapy Use for SM (n (%))					
Yes	3 (50.0)	23 (44.2)	7 (35.0)	30 (41.7)	34 (41.0)
No	3 (50.0)	29 (55.8)	13 (65.0)	42 (58.3)	49 (59.0)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 $x10^9$/L or HGB <10g/dL or PLT count <$100x10^9$/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <$100x10^9$/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-bl-advsm-tpy.sas Date: 19:08/02NOV2020

Table 14.1.4.2b
Baseline Characteristics by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=28)	300 mg (N=14)	200+300 mg (N=42)	All Doses (N=48)
Major and Minor WHO Diagnosis Criteria for SM by PI					
Major					
Multifocal dense infiltrations of MC	3 (60.0)	21 (75.0)	9 (64.3)	30 (71.4)	34 (70.8)
Minor					
>25% MC atypical/spindle shaped in biopsy or immature/atypical in aspirate	1 (20.0)	20 (71.4)	4 (28.6)	24 (57.1)	25 (52.1)
expression of CD markers CD2 and/or CD25	4 (80.0)	24 (85.7)	10 (71.4)	34 (81.0)	39 (81.3)
KIT mutation at codon 816	4 (80.0)	24 (85.7)	12 (85.7)	36 (85.7)	41 (85.4)
Baseline serum tryptase >20ng/mL	4 (80.0)	25 (89.3)	11 (78.6)	36 (85.7)	40 (83.3)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-bl-advsm-tpy.sas Date: 19:08/02NOV2020

Table 14.1.4.2b
Baseline Characteristics by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=28)	300 mg (N=14)	200+300 mg (N=42)	All Doses (N=48)
WHO diagnosis criteria for AdvSM subclassification by PI					
MCL only [1]	0	1 (3.6)	0	1 (2.4)	1 (2.1)
C-findings 1 [2]	5 (100)	11 (39.3)	12 (85.7)	23 (54.8)	28 (58.3)
C-findings 2 [3]	2 (40.0)	4 (14.3)	9 (64.3)	13 (31.0)	15 (31.3)
C-findings 3 [4]	3 (60.0)	6 (21.4)	8 (57.1)	14 (33.3)	17 (35.4)
C-findings 4 [5]	4 (80.0)	6 (21.4)	7 (50.0)	13 (31.0)	17 (35.4)
C-findings 5 [6]	0	3 (10.7)	0	3 (7.1)	3 (6.3)
Extracutaneous organ involvement					
Yes	3 (60.0)	17 (60.7)	6 (42.9)	23 (54.8)	26 (54.2)
No	2 (40.0)	11 (39.3)	8 (57.1)	19 (45.2)	22 (45.8)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-bl-advsm-tpy.sas Date: 19:08/02NOV2020

Table 14.1.4.2b
Baseline Characteristics by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=28)	300 mg (N=14)	200+300 mg (N=42)	All Doses (N=48)
Mutation Status (n (%))					
KIT Mutation (CRF)					
Wild Type (No)	1 (20.0)	0	1 (7.1)	1 (2.4)	2 (4.2)
Yes	4 (80.0)	26 (92.9)	13 (92.9)	39 (92.9)	44 (91.7)
Source Sample Type					
BM	4 (80.0)	16 (57.1)	9 (64.3)	25 (59.5)	30 (62.5)
Blood	0	1 (3.6)	3 (21.4)	4 (9.5)	4 (8.3)
BM, Blood	0	0	0	0	0
Other	0	0	1 (7.1)	1 (2.4)	1 (2.1)
Exon 17 Mutation					
D816V	4 (80.0)	26 (92.9)	13 (92.9)	39 (92.9)	44 (91.7)
D816Y	0	0	0	0	0
Other	0	0	0	0	0

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-bl-advsm-tpy.sas Date: 19:08/02NOV2020

Table 14.1.4.2b
Baseline Characteristics by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=28)	300 mg (N=14)	200+300 mg (N=42)	All Doses (N=48)
Non-KIT Mutation (CRF)					
No	4 (80.0)	11 (39.3)	8 (57.1)	19 (45.2)	24 (50.0)
Yes	1 (20.0)	9 (32.1)	6 (42.9)	15 (35.7)	16 (33.3)
Source Sample Type					
BM	1 (20.0)	6 (21.4)	3 (21.4)	9 (21.4)	10 (20.8)
Blood	0	3 (10.7)	3 (21.4)	6 (14.3)	6 (12.5)
Other	0	0	0	0	0

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-bl-advsm-tpy.sas Date: 19:08/02NOV2020

Table 14.1.4.2b
Baseline Characteristics by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=28)	300 mg (N=14)	200+300 mg (N=42)	All Doses (N=48)
ASXL1	0	3 (10.7)	2 (14.3)	5 (11.9)	5 (10.4)
CBL	0	1 (3.6)	1 (7.1)	2 (4.8)	2 (4.2)
DNMT3A	0	0	1 (7.1)	1 (2.4)	1 (2.1)
EZH2	0	0	0	0	0
JAK2	0	1 (3.6)	0	1 (2.4)	1 (2.1)
KRAS	0	1 (3.6)	0	1 (2.4)	1 (2.1)
NRAS	0	1 (3.6)	0	1 (2.4)	1 (2.1)
RUNX1	0	2 (7.1)	1 (7.1)	3 (7.1)	3 (6.3)
SF3B1	0	0	0	0	0
SRSF2	1 (20.0)	5 (17.9)	3 (21.4)	8 (19.0)	9 (18.8)
TET2	0	7 (25.0)	0	7 (16.7)	7 (14.6)
U2AF1	0	0	0	0	0
NOTCH1	0	0	0	0	0
SMC1A	0	0	0	0	0

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-bl-advsm-tpy.sas Date: 19:08/02NOV2020

Table 14.1.4.2b
Baseline Characteristics by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=28)	300 mg (N=14)	200+300 mg (N=42)	All Doses (N=48)
ECOG Performance Status (n (%))					
0	1 (20.0)	5 (17.9)	3 (21.4)	8 (19.0)	10 (20.8)
1	4 (80.0)	15 (53.6)	6 (42.9)	21 (50.0)	25 (52.1)
2	0	6 (21.4)	3 (21.4)	9 (21.4)	9 (18.8)
3	0	2 (7.1)	2 (14.3)	4 (9.5)	4 (8.3)
Corticosteroid Therapy Use for SM (n (%))					
Yes	4 (80.0)	6 (21.4)	4 (28.6)	10 (23.8)	15 (31.3)
No	1 (20.0)	22 (78.6)	10 (71.4)	32 (76.2)	33 (68.8)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
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Table 14.1.4.2.2b
Baseline Characteristics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=3)	200 mg (N=9)	300 mg (N=16)	200+300 mg (N=25)	All Doses (N=32)
Major and Minor WHO Diagnosis Criteria for SM by PI					
Major					
Multifocal dense infiltrations of MC	3 (100)	7 (77.8)	9 (56.3)	16 (64.0)	22 (68.8)
Minor					
>25% MC atypical/spindle shaped in biopsy or immature/atypical in aspirate	1 (33.3)	4 (44.4)	5 (31.3)	9 (36.0)	10 (31.3)
expression of CD markers CD2 and/or CD25	2 (66.7)	7 (77.8)	11 (68.8)	18 (72.0)	23 (71.9)
KIT mutation at codon 816	3 (100)	9 (100)	14 (87.5)	23 (92.0)	30 (93.8)
Baseline serum tryptase >20ng/mL	1 (33.3)	7 (77.8)	13 (81.3)	20 (80.0)	24 (75.0)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-bl-rac-tpy.sas Date: 19:09/02NOV2020

Table 14.1.4.2.2b
Baseline Characteristics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=3)	200 mg (N=9)	300 mg (N=16)	200+300 mg (N=25)	All Doses (N=32)
WHO diagnosis criteria for AdvSM subclassification by PI					
MCL only [1]	0	0	0	0	0
C-findings 1 [2]	1 (33.3)	6 (66.7)	9 (56.3)	15 (60.0)	19 (59.4)
C-findings 2 [3]	1 (33.3)	0	3 (18.8)	3 (12.0)	6 (18.8)
C-findings 3 [4]	1 (33.3)	1 (11.1)	5 (31.3)	6 (24.0)	9 (28.1)
C-findings 4 [5]	1 (33.3)	1 (11.1)	3 (18.8)	4 (16.0)	6 (18.8)
C-findings 5 [6]	0	0	0	0	0
Extracutaneous organ involvement					
Yes	1 (33.3)	1 (11.1)	8 (50.0)	9 (36.0)	11 (34.4)
No	2 (66.7)	8 (88.9)	8 (50.0)	16 (64.0)	21 (65.6)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 $x10^9$/L or HGB <10g/dL or PLT count <$100x10^9$/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <$100x10^9$/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-bl-rac-tpy.sas Date: 19:09/02NOV2020

Table 14.1.4.2.2b
Baseline Characteristics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=3)	200 mg (N=9)	300 mg (N=16)	200+300 mg (N=25)	All Doses (N=32)
Mutation Status (n (%))					
KIT Mutation (CRF)					
Wild Type (No)	0	1 (11.1)	2 (12.5)	3 (12.0)	3 (9.4)
Yes	3 (100)	8 (88.9)	14 (87.5)	22 (88.0)	29 (90.6)
Source Sample Type					
BM	1 (33.3)	8 (88.9)	12 (75.0)	20 (80.0)	24 (75.0)
Blood	1 (33.3)	0	2 (12.5)	2 (8.0)	4 (12.5)
BM, Blood	1 (33.3)	0	0	0	1 (3.1)
Other	0	0	0	0	0
Exon 17 Mutation					
D816V	3 (100)	8 (88.9)	13 (81.3)	21 (84.0)	28 (87.5)
D816Y	0	0	1 (6.3)	1 (4.0)	1 (3.1)
Other	0	0	0	0	0

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-bl-rac-tpy.sas Date: 19:09/02NOV2020

Table 14.1.4.2.2b
Baseline Characteristics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=3)	200 mg (N=9)	300 mg (N=16)	200+300 mg (N=25)	All Doses (N=32)
Non-KIT Mutation (CRF)					
No	2 (66.7)	4 (44.4)	4 (25.0)	8 (32.0)	12 (37.5)
Yes	1 (33.3)	5 (55.6)	12 (75.0)	17 (68.0)	20 (62.5)
Source Sample Type					
BM	1 (33.3)	5 (55.6)	7 (43.8)	12 (48.0)	15 (46.9)
Blood	0	0	3 (18.8)	3 (12.0)	3 (9.4)
Other	0	0	0	0	0
Missing	0	0	2 (12.5)	2 (8.0)	2 (6.3)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
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Table 14.1.4.2.2b
Baseline Characteristics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=3)	200 mg (N=9)	300 mg (N=16)	200+300 mg (N=25)	All Doses (N=32)
ASXL1	0	1 (11.1)	3 (18.8)	4 (16.0)	4 (12.5)
CBL	0	1 (11.1)	2 (12.5)	3 (12.0)	3 (9.4)
DNMT3A	1 (33.3)	2 (22.2)	2 (12.5)	4 (16.0)	5 (15.6)
EZH2	0	0	2 (12.5)	2 (8.0)	2 (6.3)
JAK2	0	1 (11.1)	1 (6.3)	2 (8.0)	3 (9.4)
KRAS	0	0	0	0	0
NRAS	0	0	1 (6.3)	1 (4.0)	1 (3.1)
RUNX1	0	2 (22.2)	1 (6.3)	3 (12.0)	4 (12.5)
SF3B1	0	0	2 (12.5)	2 (8.0)	2 (6.3)
SRSF2	0	2 (22.2)	2 (12.5)	4 (16.0)	5 (15.6)
NOTCH1	0	1 (11.1)	0	1 (4.0)	1 (3.1)
SMC1A	0	1 (11.1)	0	1 (4.0)	1 (3.1)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-bl-rac-tpy.sas Date: 19:09/02NOV2020

Table 14.1.4.2.2b
Baseline Characteristics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=3)	200 mg (N=9)	300 mg (N=16)	200+300 mg (N=25)	All Doses (N=32)
ECOG Performance Status (n (%))					
0	0	2 (22.2)	3 (18.8)	5 (20.0)	5 (15.6)
1	2 (66.7)	4 (44.4)	7 (43.8)	11 (44.0)	17 (53.1)
2	1 (33.3)	3 (33.3)	3 (18.8)	6 (24.0)	7 (21.9)
3	0	0	3 (18.8)	3 (12.0)	3 (9.4)
Corticosteroid Therapy Use for SM (n (%))					
Yes	1 (33.3)	4 (44.4)	6 (37.5)	10 (40.0)	12 (37.5)
No	2 (66.7)	5 (55.6)	10 (62.5)	15 (60.0)	20 (62.5)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 $x10^9$/L or HGB <10g/dL or PLT count <$100x10^9$/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <$100x10^9$/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-bl-rac-tpy.sas Date: 19:09/02NOV2020

Table 14.1.4.2.2b
Baseline Characteristics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=4)	300 mg (N=11)	200+300 mg (N=15)	All Doses (N=21)
Major and Minor WHO Diagnosis Criteria for SM by PI					
Major					
Multifocal dense infiltrations of MC	3 (60.0)	2 (50.0)	7 (63.6)	9 (60.0)	13 (61.9)
Minor					
>25% MC atypical/spindle shaped in biopsy or immature/atypical in aspirate	1 (20.0)	2 (50.0)	4 (36.4)	6 (40.0)	7 (33.3)
expression of CD markers CD2 and/or CD25	4 (80.0)	4 (100)	9 (81.8)	13 (86.7)	18 (85.7)
KIT mutation at codon 816	4 (80.0)	4 (100)	9 (81.8)	13 (86.7)	18 (85.7)
Baseline serum tryptase >20ng/mL	4 (80.0)	3 (75.0)	10 (90.9)	13 (86.7)	17 (81.0)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-bl-rac-tpy.sas Date: 19:09/02NOV2020

Table 14.1.4.2.2b
Baseline Characteristics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=4)	300 mg (N=11)	200+300 mg (N=15)	All Doses (N=21)
WHO diagnosis criteria for AdvSM subclassification by PI					
MCL only [1]	0	0	0	0	0
C-findings 1 [2]	5 (100)	3 (75.0)	10 (90.9)	13 (86.7)	18 (85.7)
C-findings 2 [3]	2 (40.0)	1 (25.0)	9 (81.8)	10 (66.7)	12 (57.1)
C-findings 3 [4]	3 (60.0)	1 (25.0)	8 (72.7)	9 (60.0)	12 (57.1)
C-findings 4 [5]	4 (80.0)	1 (25.0)	5 (45.5)	6 (40.0)	10 (47.6)
C-findings 5 [6]	0	2 (50.0)	0	2 (13.3)	2 (9.5)
Extracutaneous organ involvement					
Yes	3 (60.0)	4 (100)	5 (45.5)	9 (60.0)	12 (57.1)
No	2 (40.0)	0	6 (54.5)	6 (40.0)	9 (42.9)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 $x10^9$/L or HGB <10g/dL or PLT count <$100x10^9$/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <$100x10^9$/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-bl-rac-tpy.sas Date: 19:09/02NOV2020

Table 14.1.4.2.2b
Baseline Characteristics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=4)	300 mg (N=11)	200+300 mg (N=15)	All Doses (N=21)
Mutation Status (n (%))					
KIT Mutation (CRF)					
Wild Type (No)	1 (20.0)	0	1 (9.1)	1 (6.7)	2 (9.5)
Yes	4 (80.0)	4 (100)	10 (90.9)	14 (93.3)	19 (90.5)
Source Sample Type					
BM	4 (80.0)	3 (75.0)	7 (63.6)	10 (66.7)	15 (71.4)
Blood	0	1 (25.0)	2 (18.2)	3 (20.0)	3 (14.3)
BM, Blood	0	0	0	0	0
Other	0	0	1 (9.1)	1 (6.7)	1 (4.8)
Exon 17 Mutation					
D816V	4 (80.0)	4 (100)	10 (90.9)	14 (93.3)	19 (90.5)
D816Y	0	0	0	0	0
Other	0	0	0	0	0

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-bl-rac-tpy.sas Date: 19:09/02NOV2020

Table 14.1.4.2.2b
Baseline Characteristics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=4)	300 mg (N=11)	200+300 mg (N=15)	All Doses (N=21)
Non-KIT Mutation (CRF)					
No	4 (80.0)	3 (75.0)	5 (45.5)	8 (53.3)	13 (61.9)
Yes	1 (20.0)	1 (25.0)	6 (54.5)	7 (46.7)	8 (38.1)
Source Sample Type					
BM	1 (20.0)	1 (25.0)	3 (27.3)	4 (26.7)	5 (23.8)
Blood	0	0	3 (27.3)	3 (20.0)	3 (14.3)
Other	0	0	0	0	0

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-bl-rac-tpy.sas Date: 19:09/02NOV2020

Table 14.1.4.2.2b
Baseline Characteristics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=4)	300 mg (N=11)	200+300 mg (N=15)	All Doses (N=21)
ASXL1	0	1 (25.0)	2 (18.2)	3 (20.0)	3 (14.3)
CBL	0	0	1 (9.1)	1 (6.7)	1 (4.8)
DNMT3A	0	0	1 (9.1)	1 (6.7)	1 (4.8)
EZH2	0	0	0	0	0
JAK2	0	0	0	0	0
KRAS	0	0	0	0	0
NRAS	0	0	0	0	0
RUNX1	0	0	1 (9.1)	1 (6.7)	1 (4.8)
SF3B1	0	0	0	0	0
SRSF2	1 (20.0)	0	3 (27.3)	3 (20.0)	4 (19.0)
NOTCH1	0	0	0	0	0
SMC1A	0	0	0	0	0

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 $x10^9$/L or HGB <10g/dL or PLT count <$100x10^9$/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <$100x10^9$/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-bl-rac-tpy.sas Date: 19:09/02NOV2020

Table 14.1.4.2.2b
Baseline Characteristics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=4)	300 mg (N=11)	200+300 mg (N=15)	All Doses (N=21)
ECOG Performance Status (n (%))					
0	1 (20.0)	2 (50.0)	2 (18.2)	4 (26.7)	6 (28.6)
1	4 (80.0)	0	4 (36.4)	4 (26.7)	8 (38.1)
2	0	2 (50.0)	3 (27.3)	5 (33.3)	5 (23.8)
3	0	0	2 (18.2)	2 (13.3)	2 (9.5)
Corticosteroid Therapy Use for SM (n (%))					
Yes	4 (80.0)	2 (50.0)	3 (27.3)	5 (33.3)	10 (47.6)
No	1 (20.0)	2 (50.0)	8 (72.7)	10 (66.7)	11 (52.4)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-bl-rac-tpy.sas Date: 19:09/02NOV2020

Table 14.1.4.2.2b
Baseline Characteristics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)	
	200 mg (N=22)	All Doses (N=23)
Major and Minor WHO Diagnosis Criteria for SM by PI		
Major		
Multifocal dense infiltrations of MC	16 (72.7)	17 (73.9)
Minor		
>25% MC atypical/spindle shaped in biopsy or immature/atypical in aspirate	13 (59.1)	14 (60.9)
expression of CD markers CD2 and/or CD25	19 (86.4)	20 (87.0)
KIT mutation at codon 816	21 (95.5)	22 (95.7)
Baseline serum tryptase >20ng/mL	21 (95.5)	22 (95.7)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-bl-rac-tpy.sas Date: 19:09/02NOV2020

Table 14.1.4.2.2b
Baseline Characteristics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)	
	200 mg (N=22)	All Doses (N=23)
WHO diagnosis criteria for AdvSM subclassification by PI		
MCL only [1]	0	0
C-findings 1 [2]	17 (77.3)	18 (78.3)
C-findings 2 [3]	7 (31.8)	8 (34.8)
C-findings 3 [4]	6 (27.3)	7 (30.4)
C-findings 4 [5]	4 (18.2)	5 (21.7)
C-findings 5 [6]	0	0
Extracutaneous organ involvement		
Yes	15 (68.2)	16 (69.6)
No	7 (31.8)	7 (30.4)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-bl-rac-tpy.sas Date: 19:09/02NOV2020

Table 14.1.4.2.2b
Baseline Characteristics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)	
	200 mg (N=22)	All Doses (N=23)
Mutation Status (n (%))		
KIT Mutation (CRF)		
Wild Type (No)	1 (4.5)	1 (4.3)
Yes	20 (90.9)	21 (91.3)
Source Sample Type		
BM	13 (59.1)	14 (60.9)
Blood	0	0
BM, Blood	0	0
Other	0	0
Exon 17 Mutation		
D816V	20 (90.9)	21 (91.3)
D816Y	0	0
Other	0	0

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-bl-rac-tpy.sas Date: 19:09/02NOV2020

Table 14.1.4.2.2b
Baseline Characteristics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)	
	200 mg (N=22)	All Doses (N=23)
Non-KIT Mutation (CRF)		
No	3 (13.6)	3 (13.0)
Yes	8 (36.4)	8 (34.8)
Source Sample Type		
BM	8 (36.4)	8 (34.8)
Blood	0	0
Other	0	0

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-bl-rac-tpy.sas Date: 19:09/02NOV2020

Table 14.1.4.2.2b
Baseline Characteristics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)	
	200 mg (N=22)	All Doses (N=23)
ASXL1	2 (9.1)	2 (8.7)
CBL	2 (9.1)	2 (8.7)
DNMT3A	0	0
EZH2	0	0
JAK2	1 (4.5)	1 (4.3)
KRAS	0	0
NRAS	1 (4.5)	1 (4.3)
RUNX1	1 (4.5)	1 (4.3)
SF3B1	2 (9.1)	2 (8.7)
SRSF2	2 (9.1)	2 (8.7)
TET2	4 (18.2)	4 (17.4)
U2AF1	0	0
NOTCH1	0	0
SMC1A	0	0

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
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Table 14.1.4.2.2b
Baseline Characteristics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)	
	200 mg (N=22)	All Doses (N=23)
ECOG Performance Status (n (%))		
0	4 (18.2)	4 (17.4)
1	10 (45.5)	10 (43.5)
2	4 (18.2)	5 (21.7)
3	4 (18.2)	4 (17.4)
Corticosteroid Therapy Use for SM (n (%))		
Yes	7 (31.8)	8 (34.8)
No	15 (68.2)	15 (65.2)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
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Table 14.1.4.2.2b
Baseline Characteristics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)	
	200 mg (N=9)	All Doses (N=9)
Major and Minor WHO Diagnosis Criteria for SM by PI		
Major		
Multifocal dense infiltrations of MC	6 (66.7)	6 (66.7)
Minor		
>25% MC atypical/spindle shaped in biopsy or immature/atypical in aspirate	5 (55.6)	5 (55.6)
expression of CD markers CD2 and/or CD25	7 (77.8)	7 (77.8)
KIT mutation at codon 816	7 (77.8)	7 (77.8)
Baseline serum tryptase >20ng/mL	8 (88.9)	8 (88.9)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
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Table 14.1.4.2.2b
Baseline Characteristics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)	
	200 mg (N=9)	All Doses (N=9)
WHO diagnosis criteria for AdvSM subclassification by PI		
MCL only [1]	0	0
C-findings 1 [2]	6 (66.7)	6 (66.7)
C-findings 2 [3]	1 (11.1)	1 (11.1)
C-findings 3 [4]	3 (33.3)	3 (33.3)
C-findings 4 [5]	0	0
C-findings 5 [6]	0	0
Extracutaneous organ involvement		
Yes	4 (44.4)	4 (44.4)
No	5 (55.6)	5 (55.6)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
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Table 14.1.4.2.2b
Baseline Characteristics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)	
	200 mg (N=9)	All Doses (N=9)
Mutation Status (n (%))		
KIT Mutation (CRF)		
Wild Type (No)	0	0
Yes	7 (77.8)	7 (77.8)
Source Sample Type		
BM	3 (33.3)	3 (33.3)
Blood	0	0
BM, Blood	0	0
Other	0	0
Exon 17 Mutation		
D816V	7 (77.8)	7 (77.8)
D816Y	0	0
Other	0	0

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
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Table 14.1.4.2.2b
Baseline Characteristics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)	
	200 mg (N=9)	All Doses (N=9)
Non-KIT Mutation (CRF)		
No	0	0
Yes	5 (55.6)	5 (55.6)
Source Sample Type		
BM	3 (33.3)	3 (33.3)
Blood	2 (22.2)	2 (22.2)
Other	0	0

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
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Table 14.1.4.2.2b
Baseline Characteristics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)	
	200 mg (N=9)	All Doses (N=9)
ASXL1	1 (11.1)	1 (11.1)
CBL	1 (11.1)	1 (11.1)
DNMT3A	0	0
EZH2	0	0
JAK2	0	0
KRAS	1 (11.1)	1 (11.1)
NRAS	0	0
RUNX1	2 (22.2)	2 (22.2)
SF3B1	0	0
SRSF2	4 (44.4)	4 (44.4)
TET2	4 (44.4)	4 (44.4)
U2AF1	0	0
NOTCH1	0	0
SMC1A	0	0

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
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Table 14.1.4.2.2b
Baseline Characteristics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)	
	200 mg (N=9)	All Doses (N=9)
ECOG Performance Status (n (%))		
0	2 (22.2)	2 (22.2)
1	5 (55.6)	5 (55.6)
2	2 (22.2)	2 (22.2)
3	0	0
Corticosteroid Therapy Use for SM (n (%))		
Yes	2 (22.2)	2 (22.2)
No	7 (77.8)	7 (77.8)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
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Table 14.1.4.2.2b
Baseline Characteristics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=4)	200 mg (N=31)	300 mg (N=16)	200+300 mg (N=47)	All Doses (N=55)
Major and Minor WHO Diagnosis Criteria for SM by PI					
Major					
Multifocal dense infiltrations of MC	4 (100)	23 (74.2)	9 (56.3)	32 (68.1)	39 (70.9)
Minor					
>25% MC atypical/spindle shaped in biopsy or immature/atypical in aspirate	2 (50.0)	17 (54.8)	5 (31.3)	22 (46.8)	24 (43.6)
expression of CD markers CD2 and/or CD25	3 (75.0)	26 (83.9)	11 (68.8)	37 (78.7)	43 (78.2)
KIT mutation at codon 816	4 (100)	30 (96.8)	14 (87.5)	44 (93.6)	52 (94.5)
Baseline serum tryptase >20ng/mL	2 (50.0)	28 (90.3)	13 (81.3)	41 (87.2)	46 (83.6)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
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Table 14.1.4.2.2b
Baseline Characteristics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=4)	200 mg (N=31)	300 mg (N=16)	200+300 mg (N=47)	All Doses (N=55)
WHO diagnosis criteria for AdvSM subclassification by PI					
MCL only [1]	0	0	0	0	0
C-findings 1 [2]	2 (50.0)	23 (74.2)	9 (56.3)	32 (68.1)	37 (67.3)
C-findings 2 [3]	2 (50.0)	7 (22.6)	3 (18.8)	10 (21.3)	14 (25.5)
C-findings 3 [4]	2 (50.0)	7 (22.6)	5 (31.3)	12 (25.5)	16 (29.1)
C-findings 4 [5]	2 (50.0)	5 (16.1)	3 (18.8)	8 (17.0)	11 (20.0)
C-findings 5 [6]	0	0	0	0	0
Extracutaneous organ involvement					
Yes	2 (50.0)	16 (51.6)	8 (50.0)	24 (51.1)	27 (49.1)
No	2 (50.0)	15 (48.4)	8 (50.0)	23 (48.9)	28 (50.9)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 $x10^9$/L or HGB <10g/dL or PLT count <$100x10^9$/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <$100x10^9$/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
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Table 14.1.4.2.2b
Baseline Characteristics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=4)	200 mg (N=31)	300 mg (N=16)	200+300 mg (N=47)	All Doses (N=55)
Mutation Status (n (%))					
KIT Mutation (CRF)					
Wild Type (No)	0	2 (6.5)	2 (12.5)	4 (8.5)	4 (7.3)
Yes	4 (100)	28 (90.3)	14 (87.5)	42 (89.4)	50 (90.9)
Source Sample Type					
BM	2 (50.0)	21 (67.7)	12 (75.0)	33 (70.2)	38 (69.1)
Blood	1 (25.0)	0	2 (12.5)	2 (4.3)	4 (7.3)
BM, Blood	1 (25.0)	0	0	0	1 (1.8)
Other	0	0	0	0	0
Exon 17 Mutation					
D816V	4 (100)	28 (90.3)	13 (81.3)	41 (87.2)	49 (89.1)
D816Y	0	0	1 (6.3)	1 (2.1)	1 (1.8)
Other	0	0	0	0	0

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
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Table 14.1.4.2.2b
Baseline Characteristics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=4)	200 mg (N=31)	300 mg (N=16)	200+300 mg (N=47)	All Doses (N=55)
Non-KIT Mutation (CRF)					
No	2 (50.0)	7 (22.6)	4 (25.0)	11 (23.4)	15 (27.3)
Yes	1 (25.0)	13 (41.9)	12 (75.0)	25 (53.2)	28 (50.9)
Source Sample Type					
BM	1 (25.0)	13 (41.9)	7 (43.8)	20 (42.6)	23 (41.8)
Blood	0	0	3 (18.8)	3 (6.4)	3 (5.5)
Other	0	0	0	0	0
Missing	0	0	2 (12.5)	2 (4.3)	2 (3.6)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
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Table 14.1.4.2.2b
Baseline Characteristics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=4)	200 mg (N=31)	300 mg (N=16)	200+300 mg (N=47)	All Doses (N=55)
ASXL1	0	3 (9.7)	3 (18.8)	6 (12.8)	6 (10.9)
CBL	0	3 (9.7)	2 (12.5)	5 (10.6)	5 (9.1)
DNMT3A	1 (25.0)	2 (6.5)	2 (12.5)	4 (8.5)	5 (9.1)
EZH2	0	0	2 (12.5)	2 (4.3)	2 (3.6)
JAK2	0	2 (6.5)	1 (6.3)	3 (6.4)	4 (7.3)
KRAS	0	0	0	0	0
NRAS	0	1 (3.2)	1 (6.3)	2 (4.3)	2 (3.6)
RUNX1	0	3 (9.7)	1 (6.3)	4 (8.5)	5 (9.1)
SF3B1	0	2 (6.5)	2 (12.5)	4 (8.5)	4 (7.3)
SRSF2	0	4 (12.9)	2 (12.5)	6 (12.8)	7 (12.7)
TET2	0	4 (12.9)	0	4 (8.5)	4 (7.3)
U2AF1	0	0	0	0	0
NOTCH1	0	1 (3.2)	0	1 (2.1)	1 (1.8)
SMC1A	0	1 (3.2)	0	1 (2.1)	1 (1.8)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
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Table 14.1.4.2.2b
Baseline Characteristics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=4)	200 mg (N=31)	300 mg (N=16)	200+300 mg (N=47)	All Doses (N=55)
ECOG Performance Status (n (%))					
0	0	6 (19.4)	3 (18.8)	9 (19.1)	9 (16.4)
1	2 (50.0)	14 (45.2)	7 (43.8)	21 (44.7)	27 (49.1)
2	2 (50.0)	7 (22.6)	3 (18.8)	10 (21.3)	12 (21.8)
3	0	4 (12.9)	3 (18.8)	7 (14.9)	7 (12.7)
Corticosteroid Therapy Use for SM (n (%))					
Yes	2 (50.0)	11 (35.5)	6 (37.5)	17 (36.2)	20 (36.4)
No	2 (50.0)	20 (64.5)	10 (62.5)	30 (63.8)	35 (63.6)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
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Table 14.1.4.2.2b
Baseline Characteristics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=13)	300 mg (N=11)	200+300 mg (N=24)	All Doses (N=30)
Major and Minor WHO Diagnosis Criteria for SM by PI					
Major					
Multifocal dense infiltrations of MC	3 (60.0)	8 (61.5)	7 (63.6)	15 (62.5)	19 (63.3)
Minor					
>25% MC atypical/spindle shaped in biopsy or immature/atypical in aspirate	1 (20.0)	7 (53.8)	4 (36.4)	11 (45.8)	12 (40.0)
expression of CD markers CD2 and/or CD25	4 (80.0)	11 (84.6)	9 (81.8)	20 (83.3)	25 (83.3)
KIT mutation at codon 816	4 (80.0)	11 (84.6)	9 (81.8)	20 (83.3)	25 (83.3)
Baseline serum tryptase >20ng/mL	4 (80.0)	11 (84.6)	10 (90.9)	21 (87.5)	25 (83.3)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
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Table 14.1.4.2.2b
Baseline Characteristics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=13)	300 mg (N=11)	200+300 mg (N=24)	All Doses (N=30)
WHO diagnosis criteria for AdvSM subclassification by PI					
MCL only [1]	0	0	0	0	0
C-findings 1 [2]	5 (100)	9 (69.2)	10 (90.9)	19 (79.2)	24 (80.0)
C-findings 2 [3]	2 (40.0)	2 (15.4)	9 (81.8)	11 (45.8)	13 (43.3)
C-findings 3 [4]	3 (60.0)	4 (30.8)	8 (72.7)	12 (50.0)	15 (50.0)
C-findings 4 [5]	4 (80.0)	1 (7.7)	5 (45.5)	6 (25.0)	10 (33.3)
C-findings 5 [6]	0	2 (15.4)	0	2 (8.3)	2 (6.7)
Extracutaneous organ involvement					
Yes	3 (60.0)	8 (61.5)	5 (45.5)	13 (54.2)	16 (53.3)
No	2 (40.0)	5 (38.5)	6 (54.5)	11 (45.8)	14 (46.7)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
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Table 14.1.4.2.2b
Baseline Characteristics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=13)	300 mg (N=11)	200+300 mg (N=24)	All Doses (N=30)
Mutation Status (n (%))					
KIT Mutation (CRF)					
Wild Type (No)	1 (20.0)	0	1 (9.1)	1 (4.2)	2 (6.7)
Yes	4 (80.0)	11 (84.6)	10 (90.9)	21 (87.5)	26 (86.7)
Source Sample Type					
BM	4 (80.0)	6 (46.2)	7 (63.6)	13 (54.2)	18 (60.0)
Blood	0	1 (7.7)	2 (18.2)	3 (12.5)	3 (10.0)
BM, Blood	0	0	0	0	0
Other	0	0	1 (9.1)	1 (4.2)	1 (3.3)
Exon 17 Mutation					
D816V	4 (80.0)	11 (84.6)	10 (90.9)	21 (87.5)	26 (86.7)
D816Y	0	0	0	0	0
Other	0	0	0	0	0

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
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Table 14.1.4.2.2b
Baseline Characteristics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=13)	300 mg (N=11)	200+300 mg (N=24)	All Doses (N=30)
Non-KIT Mutation (CRF)					
No	4 (80.0)	3 (23.1)	5 (45.5)	8 (33.3)	13 (43.3)
Yes	1 (20.0)	6 (46.2)	6 (54.5)	12 (50.0)	13 (43.3)
Source Sample Type					
BM	1 (20.0)	4 (30.8)	3 (27.3)	7 (29.2)	8 (26.7)
Blood	0	2 (15.4)	3 (27.3)	5 (20.8)	5 (16.7)
Other	0	0	0	0	0

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-bl-rac-tpy.sas Date: 19:09/02NOV2020

Table 14.1.4.2.2b
Baseline Characteristics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=13)	300 mg (N=11)	200+300 mg (N=24)	All Doses (N=30)
ASXL1	0	2 (15.4)	2 (18.2)	4 (16.7)	4 (13.3)
CBL	0	1 (7.7)	1 (9.1)	2 (8.3)	2 (6.7)
DNMT3A	0	0	1 (9.1)	1 (4.2)	1 (3.3)
EZH2	0	0	0	0	0
JAK2	0	0	0	0	0
KRAS	0	1 (7.7)	0	1 (4.2)	1 (3.3)
NRAS	0	0	0	0	0
RUNX1	0	2 (15.4)	1 (9.1)	3 (12.5)	3 (10.0)
SF3B1	0	0	0	0	0
SRSF2	1 (20.0)	4 (30.8)	3 (27.3)	7 (29.2)	8 (26.7)
TET2	0	4 (30.8)	0	4 (16.7)	4 (13.3)
U2AF1	0	0	0	0	0
NOTCH1	0	0	0	0	0
SMC1A	0	0	0	0	0

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
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Table 14.1.4.2.2b
Baseline Characteristics by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=13)	300 mg (N=11)	200+300 mg (N=24)	All Doses (N=30)
ECOG Performance Status (n (%))					
0	1 (20.0)	4 (30.8)	2 (18.2)	6 (25.0)	8 (26.7)
1	4 (80.0)	5 (38.5)	4 (36.4)	9 (37.5)	13 (43.3)
2	0	4 (30.8)	3 (27.3)	7 (29.2)	7 (23.3)
3	0	0	2 (18.2)	2 (8.3)	2 (6.7)
Corticosteroid Therapy Use for SM (n (%))					
Yes	4 (80.0)	4 (30.8)	3 (27.3)	7 (29.2)	12 (40.0)
No	1 (20.0)	9 (69.2)	8 (72.7)	17 (70.8)	18 (60.0)

Notes: Abbreviations: MC = Mast Cells, BM = Bone Marrow, BMB = Bone Marrow Biopsy, CD = Cluster Designation, ANC = Absolute Neutrophil Count, HGB = Hemoglobin, PLT = Platelet
[1] Diagnosis of MCL without C-Finding
[2] Cytopenia(s), including ANC <1.0 x10^9/L or HGB <10g/dL or PLT count <100x10^9/L
[3] Hepatomegaly with impaired liver function, ie, elevated transaminases and/or bilirubin levels and/or hypoalbuminemia (with or without ascites or portal hypertension)
[4] Palpable splenomegaly with hypersplenism (eg, as documented by thrombocytopenia; ie, PLT <100x10^9/L)
[5] Malabsorption with hypoalbuminemia and/or significant weight loss defined as >10 % weight loss over the last 6 months
[6] Skeletal involvement with large osteolytic lesions with pathologic fractures
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=4)	200 mg (N=12)	300 mg (N=20)	200+300 mg (N=32)	All Doses (N=41)
Mutation Status (n (%))					
KIT Exon 17 Mutation by Central Assay					
Positive	4 (100)	10 (83.3)	17 (85.0)	27 (84.4)	36 (87.8)
Negative	0	2 (16.7)	3 (15.0)	5 (15.6)	5 (12.2)
SRSF2/ASXL1/RUNX1 Mutation (S/A/R) by Central Assay					
Positive	2 (50.0)	5 (41.7)	6 (30.0)	11 (34.4)	16 (39.0)
Negative	2 (50.0)	7 (58.3)	14 (70.0)	21 (65.6)	25 (61.0)
Number of Co-Mutations by Central Assay					
0	0	1 (8.3)	2 (10.0)	3 (9.4)	4 (9.8)
1	1 (25.0)	2 (16.7)	3 (15.0)	5 (15.6)	6 (14.6)
2-3	1 (25.0)	3 (25.0)	9 (45.0)	12 (37.5)	14 (34.1)
4-5	0	4 (33.3)	5 (25.0)	9 (28.1)	12 (29.3)
>=6	2 (50.0)	2 (16.7)	1 (5.0)	3 (9.4)	5 (12.2)
n	4	12	20	32	41
Mean (StdDev)	4.8 (3.50)	3.3 (2.02)	2.9 (1.74)	3.1 (1.83)	3.2 (2.02)
Median	4.5	3.5	3.0	3.0	3.0
Min, Max	1, 9	0, 6	0, 6	0, 6	0, 9

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=4)	200 mg (N=12)	300 mg (N=20)	200+300 mg (N=32)	All Doses (N=41)
Spleen Volume (mL) by Central Radiologic Review					
n	3	12	18	30	38
Mean (StdDev)	784.34 (507.986)	844.46 (306.077)	1114.05 (609.591)	1006.21 (520.975)	972.06 (527.077)
Median	580.85	829.70	1092.31	958.12	862.44
Min, Max	409.6, 1362.5	298.5, 1245.1	257.8, 2262.7	257.8, 2262.7	163.4, 2262.7
Spleen Palpation (n (%))					
Not Palpable	3 (75.0)	7 (63.6)	8 (42.1)	15 (50.0)	21 (53.8)
Palpable <5cm	0	0	1 (5.3)	1 (3.3)	1 (2.6)
Palpable =5cm	0	0	2 (10.5)	2 (6.7)	2 (5.1)
Palpable >5cm	1 (25.0)	4 (36.4)	8 (42.1)	12 (40.0)	15 (38.5)
Missing	0	1	1	2	2
n	4	11	19	30	39
Mean (StdDev)	2.0 (4.00)	2.5 (3.62)	5.2 (5.82)	4.3 (5.22)	4.0 (5.18)
Median	0.0	0.0	5.0	1.0	0.0
Min, Max	0, 8	0, 9	0, 18	0, 18	0, 18

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=4)	200 mg (N=12)	300 mg (N=20)	200+300 mg (N=32)	All Doses (N=41)
Liver Volume (mL) by Central Radiologic Review					
n	4	12	20	32	41
Mean (StdDev)	2111.27 (464.682)	2497.29 (576.794)	2242.82 (550.463)	2338.24 (565.185)	2326.77 (591.032)
Median	2277.33	2337.74	2070.22	2219.34	2285.21
Min, Max	1435.8, 2454.6	1764.2, 3603.1	1436.4, 3624.1	1436.4, 3624.1	1019.9, 3624.1
Liver Palpation (n (%))					
Not Palpable	3 (75.0)	6 (60.0)	11 (57.9)	17 (58.6)	23 (60.5)
Palpable	1 (25.0)	4 (40.0)	8 (42.1)	12 (41.4)	15 (39.5)
Missing	0	2	1	3	3
ALB (g/L)					
n	4	12	20	32	41
Mean (StdDev)	39.3 (7.14)	40.3 (4.90)	37.6 (5.99)	38.6 (5.67)	38.8 (5.93)
Median	41.5	41.5	40.0	40.5	41.0
Min, Max	29, 45	29, 46	23, 45	23, 46	23, 47
CTCAE Grade (n (%))					
0	3 (75.0)	10 (83.3)	16 (80.0)	26 (81.3)	33 (80.5)
1	0	1 (8.3)	1 (5.0)	2 (6.3)	2 (4.9)
2	1 (25.0)	1 (8.3)	3 (15.0)	4 (12.5)	6 (14.6)
3	0	0	0	0	0
4	0	0	0	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=4)	200 mg (N=12)	300 mg (N=20)	200+300 mg (N=32)	All Doses (N=41)
ANC (x 10^9/L)					
n	4	12	20	32	41
Mean (StdDev)	4.678 (1.083)	6.416 (5.038)	9.383 (8.008)	8.270 (7.102)	7.812 (7.016)
Median	4.905	4.490	6.560	6.160	5.210
Min, Max	3.20, 5.70	0.88, 15.65	1.20, 27.08	0.88, 27.08	0.88, 27.08
CTCAE Grade (n (%))					
0	4 (100)	11 (91.7)	19 (95.0)	30 (93.8)	38 (92.7)
1	0	0	0	0	0
2	0	0	1 (5.0)	1 (3.1)	2 (4.9)
3	0	1 (8.3)	0	1 (3.1)	1 (2.4)
4	0	0	0	0	0
HGB (g/L)					
n	4	12	20	32	41
Mean (StdDev)	119.3 (10.08)	109.2 (14.33)	109.4 (23.13)	109.3 (20.02)	110.2 (18.85)
Median	118.5	111.5	115.5	115.5	115.0
Min, Max	109, 131	87, 132	80, 169	80, 169	80, 169
CTCAE Grade (n (%))					
0	2 (50.0)	1 (8.3)	2 (10.0)	3 (9.4)	6 (14.6)
1	2 (50.0)	8 (66.7)	10 (50.0)	18 (56.3)	22 (53.7)
2	0	3 (25.0)	8 (40.0)	11 (34.4)	13 (31.7)
3	0	0	0	0	0
4	0	0	0	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-assess-advsm-tpy.sDate: 19:15/02NOV2020

Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=4)	200 mg (N=12)	300 mg (N=20)	200+300 mg (N=32)	All Doses (N=41)
PLT (x 10^9/L)					
n	4	12	20	32	41
Mean (StdDev)	271.3 (161.21)	121.8 (70.63)	224.9 (158.33)	186.2 (140.39)	193.1 (139.32)
Median	276.5	107.5	201.0	136.5	152.0
Min, Max	109, 423	40, 291	55, 602	40, 602	40, 602
CTCAE Grade (n (%))					
0	3 (75.0)	4 (33.3)	11 (55.0)	15 (46.9)	21 (51.2)
1	1 (25.0)	4 (33.3)	4 (20.0)	8 (25.0)	9 (22.0)
2	0	3 (25.0)	5 (25.0)	8 (25.0)	8 (19.5)
3	0	1 (8.3)	0	1 (3.1)	3 (7.3)
4	0	0	0	0	0
Monocytes (x 10^9/L)					
n	4	12	20	32	41
Mean (StdDev)	0.898 (0.688)	1.078 (0.780)	2.420 (2.967)	1.917 (2.459)	1.756 (2.262)
Median	0.645	1.100	1.150	1.150	1.000
Min, Max	0.40, 1.90	0.20, 2.50	0.06, 9.08	0.06, 9.08	0.06, 9.08

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=4)	200 mg (N=12)	300 mg (N=20)	200+300 mg (N=32)	All Doses (N=41)
Direct Bilirubin (umol/L)					
n	3	12	20	32	40
Mean (StdDev)	2.850 (0.987)	3.801 (2.948)	3.536 (2.292)	3.635 (2.514)	3.806 (2.546)
Median	3.420	3.420	2.868	3.412	3.420
Min, Max	1.71, 3.42	0.66, 11.97	0.00, 6.84	0.00, 11.97	0.00, 11.97
CTCAE Grade (n (%))					
0	3 (100)	9 (75.0)	18 (90.0)	27 (84.4)	33 (82.5)
1	0	2 (16.7)	2 (10.0)	4 (12.5)	5 (12.5)
2	0	1 (8.3)	0	1 (3.1)	2 (5.0)
3	0	0	0	0	0
4	0	0	0	0	0
ALT (U/L)					
n	4	12	20	32	41
Mean (StdDev)	14.5 (3.11)	17.4 (9.73)	19.2 (11.06)	18.5 (10.45)	19.3 (10.16)
Median	15.5	13.0	17.0	15.5	16.0
Min, Max	10, 17	7, 36	5, 44	5, 44	5, 44
CTCAE Grade (n (%))					
0	4 (100)	11 (91.7)	20 (100)	31 (96.9)	40 (97.6)
1	0	1 (8.3)	0	1 (3.1)	1 (2.4)
2	0	0	0	0	0
3	0	0	0	0	0
4	0	0	0	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=4)	200 mg (N=12)	300 mg (N=20)	200+300 mg (N=32)	All Doses (N=41)
AST (U/L)					
n	4	12	20	32	41
Mean (StdDev)	14.3 (4.11)	14.7 (7.95)	16.8 (10.87)	16.0 (9.79)	16.6 (9.54)
Median	15.0	11.0	13.0	13.0	13.0
Min, Max	9, 18	7, 33	5, 54	5, 54	5, 54
CTCAE Grade (n (%))					
0	4 (100)	11 (91.7)	19 (95.0)	30 (93.8)	39 (95.1)
1	0	1 (8.3)	1 (5.0)	2 (6.3)	2 (4.9)
2	0	0	0	0	0
3	0	0	0	0	0
4	0	0	0	0	0
ALP (U/L)					
n	4	12	20	32	41
Mean (StdDev)	174.0 (130.60)	170.0 (122.25)	233.7 (364.81)	209.8 (296.40)	195.2 (266.61)
Median	136.5	117.0	142.5	135.5	133.0
Min, Max	67, 356	27, 370	59, 1747	27, 1747	27, 1747
CTCAE Grade (n (%))					
0	2 (50.0)	7 (58.3)	7 (35.0)	14 (43.8)	19 (46.3)
1	1 (25.0)	2 (16.7)	11 (55.0)	13 (40.6)	16 (39.0)
2	1 (25.0)	3 (25.0)	1 (5.0)	4 (12.5)	5 (12.2)
3	0	0	1 (5.0)	1 (3.1)	1 (2.4)
4	0	0	0	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=4)	200 mg (N=12)	300 mg (N=20)	200+300 mg (N=32)	All Doses (N=41)
Serum Tryptase (ng/mL) from Central Assay					
n	4	12	20	32	41
Mean (StdDev)	437.35 (656.349)	317.21 (266.253)	312.75 (189.257)	314.42 (217.055)	301.25 (275.734)
Median	141.25	196.60	313.80	263.15	214.90
Min, Max	52.6, 1414.3	19.9, 723.2	21.2, 760.1	19.9, 760.1	19.9, 1414.3
<11.4 ng/mL	0	0	0	0	0
>=11.4 and <20 ng/mL	0	1 (8.3)	0	1 (3.1)	1 (2.4)
>=20 and <40 ng/mL	0	0	1 (5.0)	1 (3.1)	3 (7.3)
>=40 and <200 ng/mL	2 (50.0)	5 (41.7)	5 (25.0)	10 (31.3)	15 (36.6)
>=200 ng/mL	2 (50.0)	6 (50.0)	14 (70.0)	20 (62.5)	22 (53.7)
BM MC (%) by Central Pathology Review					
n	4	10	17	27	36
Mean (StdDev)	21.3 (11.81)	44.0 (28.46)	52.4 (29.64)	49.3 (28.95)	44.7 (29.35)
Median	25.0	40.0	50.0	50.0	40.0
Min, Max	5, 30	10, 80	10, 95	10, 95	5, 95
KIT D816V MAF (%) from Blood					
n	3	12	20	32	40
Mean (StdDev)	17.487 (24.953)	15.223 (17.651)	22.192 (22.961)	19.578 (21.105)	18.668 (20.167)
Median	3.110	7.045	15.655	11.525	11.525
Min, Max	3.05, 46.30	0.00, 44.30	0.00, 80.10	0.00, 80.10	0.00, 80.10
<0.17%	0	4 (33.3)	6 (30.0)	10 (31.3)	10 (25.0)
>=0.17% and <1%	0	0	0	0	1 (2.5)
>=1%	3 (100)	8 (66.7)	14 (70.0)	22 (68.8)	29 (72.5)

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=4)	200 mg (N=12)	300 mg (N=20)	200+300 mg (N=32)	All Doses (N=41)
SM Related Organ Damages					
Ascites and Pleural Effusions					
Ascites					
No	3 (75.0)	8 (66.7)	13 (65.0)	21 (65.6)	27 (65.9)
Grade 1	0	1 (8.3)	2 (10.0)	3 (9.4)	4 (9.8)
Grade 2	0	2 (16.7)	3 (15.0)	5 (15.6)	5 (12.2)
Grade 3	1 (25.0)	1 (8.3)	2 (10.0)	3 (9.4)	5 (12.2)
Pleural Effusions					
No	4 (100)	11 (91.7)	17 (85.0)	28 (87.5)	36 (87.8)
Grade 1	0	0	3 (15.0)	3 (9.4)	4 (9.8)
Grade 2	0	1 (8.3)	0	1 (3.1)	1 (2.4)
Grade 3	0	0	0	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=4)	200 mg (N=12)	300 mg (N=20)	200+300 mg (N=32)	All Doses (N=41)
SM Related Organ Damages Continued					
Liver Function Abnormalities					
Other Cause for Abnormal Liver Function not Related to SM					
Yes	0	0	2 (10.0)	2 (6.3)	3 (7.3)
No	4 (100)	11 (91.7)	18 (90.0)	29 (90.6)	37 (90.2)
Unknown	0	1 (8.3)	0	1 (3.1)	1 (2.4)
Clinical-relevant Portal Hypertension					
Yes	0	0	2 (10.0)	2 (6.3)	3 (7.3)
No	4 (100)	12 (100)	18 (90.0)	30 (93.8)	38 (92.7)
Unknown	0	0	0	0	0
Biopsy-proven Liver MC Infiltration					
Yes	2 (50.0)	0	4 (20.0)	4 (12.5)	7 (17.1)
No	2 (50.0)	12 (100)	15 (75.0)	27 (84.4)	33 (80.5)
Unknown	0	0	1 (5.0)	1 (3.1)	1 (2.4)

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=8)	300 mg (N=14)	200+300 mg (N=22)	All Doses (N=28)
Mutation Status (n (%))					
KIT Exon 17 Mutation by Central Assay					
Positive	5 (100)	8 (100)	14 (100)	22 (100)	28 (100)
Negative	0	0	0	0	0
SRSF2/ASXL1/RUNX1 Mutation (S/A/R) by Central Assay					
Positive	3 (60.0)	5 (62.5)	12 (85.7)	17 (77.3)	20 (71.4)
Negative	2 (40.0)	3 (37.5)	2 (14.3)	5 (22.7)	8 (28.6)
Number of Co-Mutations by Central Assay					
0	0	1 (12.5)	0	1 (4.5)	1 (3.6)
1	0	1 (12.5)	0	1 (4.5)	2 (7.1)
2-3	2 (40.0)	2 (25.0)	7 (50.0)	9 (40.9)	11 (39.3)
4-5	3 (60.0)	3 (37.5)	5 (35.7)	8 (36.4)	11 (39.3)
>=6	0	1 (12.5)	2 (14.3)	3 (13.6)	3 (10.7)
n	5	8	14	22	28
Mean (StdDev)	4.2 (1.10)	4.1 (3.64)	3.5 (1.65)	3.7 (2.49)	3.7 (2.31)
Median	5.0	3.5	3.5	3.5	3.5
Min, Max	3, 5	0, 12	2, 7	0, 12	0, 12

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=8)	300 mg (N=14)	200+300 mg (N=22)	All Doses (N=28)
Spleen Volume (mL) by Central Radiologic Review					
n	5	8	14	22	28
Mean (StdDev)	1228.63 (359.433)	1009.83 (587.937)	1220.33 (631.325)	1143.79 (610.491)	1136.39 (570.141)
Median	1190.55	738.31	1236.43	1056.60	1056.60
Min, Max	819.0, 1626.6	523.5, 1951.7	148.7, 2300.1	148.7, 2300.1	148.7, 2300.1
Spleen Palpation (n (%))					
Not Palpable	0	5 (62.5)	2 (14.3)	7 (31.8)	7 (25.0)
Palpable <5cm	2 (40.0)	1 (12.5)	4 (28.6)	5 (22.7)	8 (28.6)
Palpable =5cm	2 (40.0)	0	1 (7.1)	1 (4.5)	3 (10.7)
Palpable >5cm	1 (20.0)	2 (25.0)	7 (50.0)	9 (40.9)	10 (35.7)
n	5	8	14	22	28
Mean (StdDev)	4.4 (1.34)	3.6 (6.41)	7.7 (7.09)	6.2 (6.98)	5.8 (6.24)
Median	5.0	0.0	7.5	2.5	3.0
Min, Max	3, 6	0, 17	0, 24	0, 24	0, 24

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=8)	300 mg (N=14)	200+300 mg (N=22)	All Doses (N=28)
Liver Volume (mL) by Central Radiologic Review					
n	5	8	14	22	28
Mean (StdDev)	2397.90 (379.747)	2589.79 (488.322)	2411.31 (644.787)	2476.22 (587.007)	2483.07 (550.513)
Median	2395.62	2373.87	2564.47	2517.51	2513.59
Min, Max	1898.2, 2924.0	2095.2, 3226.0	1013.4, 3520.9	1013.4, 3520.9	1013.4, 3520.9
Liver Palpation (n (%))					
Not Palpable	3 (60.0)	5 (62.5)	6 (42.9)	11 (50.0)	15 (53.6)
Palpable	2 (40.0)	3 (37.5)	8 (57.1)	11 (50.0)	13 (46.4)
ALB (g/L)					
n	5	8	14	22	28
Mean (StdDev)	37.8 (4.09)	36.6 (5.42)	37.3 (6.21)	37.0 (5.81)	37.5 (5.57)
Median	40.0	34.5	37.5	36.0	37.5
Min, Max	32, 41	31, 45	28, 47	28, 47	28, 47
CTCAE Grade (n (%))					
0	3 (60.0)	3 (37.5)	9 (64.3)	12 (54.5)	16 (57.1)
1	2 (40.0)	5 (62.5)	3 (21.4)	8 (36.4)	10 (35.7)
2	0	0	2 (14.3)	2 (9.1)	2 (7.1)
3	0	0	0	0	0
4	0	0	0	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=8)	300 mg (N=14)	200+300 mg (N=22)	All Doses (N=28)
ANC (x 10^9/L)					
n	5	8	14	22	28
Mean (StdDev)	8.852 (7.887)	7.893 (6.887)	6.181 (5.108)	6.803 (5.716)	7.087 (5.960)
Median	5.800	5.670	4.050	4.050	4.300
Min, Max	1.48, 20.20	0.82, 20.40	0.60, 16.94	0.60, 20.40	0.60, 20.40
CTCAE Grade (n (%))					
0	4 (80.0)	7 (87.5)	11 (78.6)	18 (81.8)	23 (82.1)
1	0	0	0	0	0
2	1 (20.0)	0	2 (14.3)	2 (9.1)	3 (10.7)
3	0	1 (12.5)	1 (7.1)	2 (9.1)	2 (7.1)
4	0	0	0	0	0
HGB (g/L)					
n	5	8	14	22	28
Mean (StdDev)	109.2 (17.05)	112.9 (15.54)	104.1 (12.96)	107.3 (14.26)	109.8 (18.10)
Median	108.0	113.0	105.5	107.0	107.5
Min, Max	83, 128	91, 135	84, 129	84, 135	83, 167
CTCAE Grade (n (%))					
0	0	2 (25.0)	2 (14.3)	4 (18.2)	5 (17.9)
1	4 (80.0)	4 (50.0)	8 (57.1)	12 (54.5)	16 (57.1)
2	1 (20.0)	2 (25.0)	4 (28.6)	6 (27.3)	7 (25.0)
3	0	0	0	0	0
4	0	0	0	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=8)	300 mg (N=14)	200+300 mg (N=22)	All Doses (N=28)
PLT (x 10^9/L)					
n	5	8	14	22	28
Mean (StdDev)	110.8 (74.48)	197.1 (172.77)	102.4 (78.25)	136.8 (126.16)	132.9 (115.44)
Median	82.0	150.5	72.0	103.0	97.0
Min, Max	62, 243	58, 606	32, 306	32, 606	32, 606
CTCAE Grade (n (%))					
0	1 (20.0)	4 (50.0)	3 (21.4)	7 (31.8)	9 (32.1)
1	3 (60.0)	3 (37.5)	3 (21.4)	6 (27.3)	9 (32.1)
2	1 (20.0)	1 (12.5)	4 (28.6)	5 (22.7)	6 (21.4)
3	0	0	4 (28.6)	4 (18.2)	4 (14.3)
4	0	0	0	0	0
Monocytes (x 10^9/L)					
n	5	8	14	22	28
Mean (StdDev)	2.832 (2.493)	2.601 (1.628)	2.166 (2.558)	2.325 (2.232)	2.350 (2.228)
Median	1.910	2.420	1.670	2.215	2.020
Min, Max	0.50, 7.00	0.12, 4.50	0.10, 9.86	0.10, 9.86	0.10, 9.86

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=8)	300 mg (N=14)	200+300 mg (N=22)	All Doses (N=28)
Direct Bilirubin (umol/L)					
n	5	8	14	22	27
Mean (StdDev)	4.650 (3.117)	5.125 (4.403)	6.594 (8.420)	6.060 (7.132)	5.799 (6.549)
Median	4.200	4.874	5.065	5.065	5.000
Min, Max	0.66, 8.55	0.32, 13.85	0.91, 35.00	0.32, 35.00	0.32, 35.00
CTCAE Grade (n (%))					
0	2 (40.0)	3 (37.5)	9 (64.3)	12 (54.5)	14 (51.9)
1	2 (40.0)	1 (12.5)	4 (28.6)	5 (22.7)	7 (25.9)
2	1 (20.0)	3 (37.5)	0	3 (13.6)	4 (14.8)
3	0	1 (12.5)	1 (7.1)	2 (9.1)	2 (7.4)
4	0	0	0	0	0
ALT (U/L)					
n	5	8	14	22	28
Mean (StdDev)	17.4 (6.66)	22.9 (15.59)	30.4 (19.76)	27.7 (18.34)	26.2 (16.99)
Median	18.0	19.5	25.0	22.0	22.0
Min, Max	9, 26	5, 54	3, 78	3, 78	3, 78
CTCAE Grade (n (%))					
0	5 (100)	7 (87.5)	12 (85.7)	19 (86.4)	25 (89.3)
1	0	1 (12.5)	2 (14.3)	3 (13.6)	3 (10.7)
2	0	0	0	0	0
3	0	0	0	0	0
4	0	0	0	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=8)	300 mg (N=14)	200+300 mg (N=22)	All Doses (N=28)
AST (U/L)					
n	5	8	14	22	28
Mean (StdDev)	16.6 (5.77)	16.1 (7.32)	22.0 (9.88)	19.9 (9.31)	19.2 (8.60)
Median	14.0	18.5	21.5	20.5	20.0
Min, Max	11, 25	5, 25	5, 44	5, 44	5, 44
CTCAE Grade (n (%))					
0	5 (100)	8 (100)	12 (85.7)	20 (90.9)	26 (92.9)
1	0	0	2 (14.3)	2 (9.1)	2 (7.1)
2	0	0	0	0	0
3	0	0	0	0	0
4	0	0	0	0	0
ALP (U/L)					
n	5	8	14	22	28
Mean (StdDev)	280.8 (93.64)	332.1 (258.06)	401.8 (309.19)	376.5 (287.32)	348.9 (263.86)
Median	327.0	252.5	330.5	277.0	277.0
Min, Max	139, 364	68, 811	70, 1073	68, 1073	68, 1073
CTCAE Grade (n (%))					
0	0	1 (12.5)	4 (28.6)	5 (22.7)	6 (21.4)
1	2 (40.0)	5 (62.5)	2 (14.3)	7 (31.8)	9 (32.1)
2	3 (60.0)	1 (12.5)	5 (35.7)	6 (27.3)	9 (32.1)
3	0	1 (12.5)	3 (21.4)	4 (18.2)	4 (14.3)
4	0	0	0	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=8)	300 mg (N=14)	200+300 mg (N=22)	All Doses (N=28)
Serum Tryptase (ng/mL) from Central Assay					
n	5	8	14	22	28
Mean (StdDev)	340.38 (263.975)	243.50 (192.973)	195.89 (202.878)	213.20 (196.066)	234.10 (207.027)
Median	182.40	177.95	144.85	144.85	159.15
Min, Max	102.4, 684.8	74.8, 629.4	12.4, 765.3	12.4, 765.3	12.4, 765.3
<11.4 ng/mL	0	0	0	0	0
>=11.4 and <20 ng/mL	0	0	1 (7.1)	1 (4.5)	1 (3.6)
>=20 and <40 ng/mL	0	0	1 (7.1)	1 (4.5)	1 (3.6)
>=40 and <200 ng/mL	3 (60.0)	4 (50.0)	9 (64.3)	13 (59.1)	17 (60.7)
>=200 ng/mL	2 (40.0)	4 (50.0)	3 (21.4)	7 (31.8)	9 (32.1)
BM MC (%) by Central Pathology Review					
n	5	8	14	22	28
Mean (StdDev)	45.0 (18.71)	46.3 (29.25)	39.6 (23.73)	42.0 (25.39)	43.9 (24.58)
Median	50.0	45.0	35.0	35.0	40.0
Min, Max	15, 60	10, 80	5, 80	5, 80	5, 80
KIT D816V MAF (%) from Blood					
n	5	8	14	22	27
Mean (StdDev)	9.954 (13.735)	19.371 (12.321)	22.448 (16.528)	21.329 (14.900)	19.223 (15.120)
Median	4.430	19.050	21.100	20.000	17.700
Min, Max	0.56, 33.70	4.32, 41.70	0.03, 45.30	0.03, 45.30	0.03, 45.30
<0.17%	0	0	1 (7.1)	1 (4.5)	1 (3.7)
>=0.17% and <1%	1 (20.0)	0	1 (7.1)	1 (4.5)	2 (7.4)
>=1%	4 (80.0)	8 (100)	12 (85.7)	20 (90.9)	24 (88.9)

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=8)	300 mg (N=14)	200+300 mg (N=22)	All Doses (N=28)
SM Related Organ Damages					
Ascites and Pleural Effusions					
Ascites					
No	3 (60.0)	7 (87.5)	11 (78.6)	18 (81.8)	22 (78.6)
Grade 1	0	0	2 (14.3)	2 (9.1)	2 (7.1)
Grade 2	2 (40.0)	1 (12.5)	1 (7.1)	2 (9.1)	4 (14.3)
Grade 3	0	0	0	0	0
Pleural Effusions					
No	4 (80.0)	7 (87.5)	12 (85.7)	19 (86.4)	24 (85.7)
Grade 1	0	0	2 (14.3)	2 (9.1)	2 (7.1)
Grade 2	1 (20.0)	0	0	0	1 (3.6)
Grade 3	0	1 (12.5)	0	1 (4.5)	1 (3.6)

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=8)	300 mg (N=14)	200+300 mg (N=22)	All Doses (N=28)
SM Related Organ Damages Continued					
Liver Function Abnormalities					
Other Cause for Abnormal Liver Function not Related to SM					
Yes	0	0	0	0	0
No	5 (100)	8 (100)	14 (100)	22 (100)	28 (100)
Unknown	0	0	0	0	0
Clinical-relevant Portal Hypertension					
Yes	0	0	0	0	0
No	5 (100)	8 (100)	13 (92.9)	21 (95.5)	27 (96.4)
Unknown	0	0	1 (7.1)	1 (4.5)	1 (3.6)
Biopsy-proven Liver MC Infiltration					
Yes	0	1 (12.5)	2 (14.3)	3 (13.6)	3 (10.7)
No	5 (100)	7 (87.5)	10 (71.4)	17 (77.3)	23 (82.1)
Unknown	0	0	2 (14.3)	2 (9.1)	2 (7.1)

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)	
	200 mg (N=40)	All Doses (N=42)
Mutation Status (n (%))		
KIT Exon 17 Mutation by Central Assay		
Positive	38 (95.0)	40 (95.2)
Negative	2 (5.0)	2 (4.8)
SRSF2/ASXL1/RUNX1 Mutation (S/A/R) by Central Assay		
Positive	15 (37.5)	15 (35.7)
Negative	25 (62.5)	27 (64.3)
Number of Co-Mutations by Central Assay		
0	4 (10.0)	4 (9.5)
1	4 (10.0)	4 (9.5)
2-3	13 (32.5)	14 (33.3)
4-5	13 (32.5)	14 (33.3)
>=6	6 (15.0)	6 (14.3)
n	40	42
Mean (StdDev)	3.7 (3.41)	3.6 (3.34)
Median	3.0	3.0
Min, Max	0, 21	0, 21

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)	
	200 mg (N=40)	All Doses (N=42)
Spleen Volume (mL) by Central Radiologic Review		
n	40	42
Mean (StdDev)	1011.65 (537.971)	992.04 (546.109)
Median	766.96	766.96
Min, Max	367.4, 2600.8	44.2, 2600.8
Spleen Palpation (n (%))		
Not Palpable	18 (46.2)	19 (46.3)
Palpable <5cm	7 (17.9)	8 (19.5)
Palpable =5cm	1 (2.6)	1 (2.4)
Palpable >5cm	13 (33.3)	13 (31.7)
Missing	1	1
n	39	41
Mean (StdDev)	3.5 (4.13)	3.4 (4.07)
Median	3.0	1.5
Min, Max	0, 13	0, 13

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)	
	200 mg (N=40)	All Doses (N=42)
Liver Volume (mL) by Central Radiologic Review		
n	40	42
Mean (StdDev)	2523.95 (545.168)	2536.90 (546.893)
Median	2462.19	2462.19
Min, Max	1660.5, 4020.8	1660.5, 4020.8
Liver Palpation (n (%))		
Not Palpable	17 (43.6)	18 (43.9)
Palpable	22 (56.4)	23 (56.1)
Missing	1	1
ALB (g/L)		
n	39	41
Mean (StdDev)	37.4 (5.65)	36.4 (7.16)
Median	37.0	37.0
Min, Max	23, 49	13, 49
CTCAE Grade (n (%))		
0	29 (74.4)	29 (70.7)
1	7 (17.9)	7 (17.1)
2	3 (7.7)	4 (9.8)
3	0	1 (2.4)
4	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)	
	200 mg (N=40)	All Doses (N=42)
ANC (x 10^9/L)		
n	39	41
Mean (StdDev)	8.180 (8.324)	8.122 (8.118)
Median	6.110	6.300
Min, Max	1.20, 43.80	1.20, 43.80
CTCAE Grade (n (%))		
0	35 (89.7)	37 (90.2)
1	2 (5.1)	2 (4.9)
2	2 (5.1)	2 (4.9)
3	0	0
4	0	0
HGB (g/L)		
n	40	42
Mean (StdDev)	104.8 (19.14)	104.6 (19.35)
Median	104.5	104.5
Min, Max	65, 159	65, 159
CTCAE Grade (n (%))		
0	6 (15.0)	6 (14.3)
1	16 (40.0)	17 (40.5)
2	15 (37.5)	15 (35.7)
3	3 (7.5)	4 (9.5)
4	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)	
	200 mg (N=40)	All Doses (N=42)
PLT (x 10^9/L)		
n	40	42
Mean (StdDev)	169.1 (101.19)	172.5 (110.42)
Median	163.0	163.0
Min, Max	28, 456	28, 456
CTCAE Grade (n (%))		
0	23 (57.5)	24 (57.1)
1	8 (20.0)	8 (19.0)
2	6 (15.0)	6 (14.3)
3	3 (7.5)	4 (9.5)
4	0	0
Monocytes (x 10^9/L)		
n	39	41
Mean (StdDev)	1.270 (1.267)	1.261 (1.237)
Median	0.870	0.870
Min, Max	0.13, 5.14	0.13, 5.14

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)	
	200 mg (N=40)	All Doses (N=42)
Direct Bilirubin (umol/L)		
n	31	31
Mean (StdDev)	5.309 (2.697)	5.309 (2.697)
Median	5.000	5.000
Min, Max	0.00, 10.78	0.00, 10.78
CTCAE Grade (n (%))		
0	21 (67.7)	21 (67.7)
1	6 (19.4)	6 (19.4)
2	3 (9.7)	3 (9.7)
3	1 (3.2)	1 (3.2)
4	0	0
ALT (U/L)		
n	40	42
Mean (StdDev)	21.6 (16.25)	21.6 (16.01)
Median	15.0	15.0
Min, Max	5, 75	5, 75
CTCAE Grade (n (%))		
0	38 (95.0)	40 (95.2)
1	2 (5.0)	2 (4.8)
2	0	0
3	0	0
4	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)	
	200 mg (N=40)	All Doses (N=42)
AST (U/L)		
n	40	42
Mean (StdDev)	15.8 (10.27)	16.0 (10.21)
Median	11.0	11.5
Min, Max	5, 57	5, 57
CTCAE Grade (n (%))		
0	39 (97.5)	41 (97.6)
1	1 (2.5)	1 (2.4)
2	0	0
3	0	0
4	0	0
ALP (U/L)		
n	40	42
Mean (StdDev)	229.7 (196.76)	234.8 (194.95)
Median	179.5	182.5
Min, Max	61, 1150	61, 1150
CTCAE Grade (n (%))		
0	13 (32.5)	13 (31.0)
1	17 (42.5)	18 (42.9)
2	8 (20.0)	9 (21.4)
3	2 (5.0)	2 (4.8)
4	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)	
	200 mg (N=40)	All Doses (N=42)
Serum Tryptase (ng/mL) from Central Assay		
n	40	42
Mean (StdDev)	370.69 (299.896)	394.59 (350.808)
Median	314.00	314.00
Min, Max	23.8, 1600.0	23.8, 1600.0
<11.4 ng/mL	0	0
>=11.4 and <20 ng/mL	0	0
>=20 and <40 ng/mL	2 (5.0)	2 (4.8)
>=40 and <200 ng/mL	11 (27.5)	12 (28.6)
>=200 ng/mL	27 (67.5)	28 (66.7)
BM MC (%) by Central Pathology Review		
n	40	42
Mean (StdDev)	52.8 (28.12)	51.9 (27.72)
Median	60.0	55.0
Min, Max	1, 95	1, 95
KIT D816V MAF (%) from Blood		
n	39	41
Mean (StdDev)	22.747 (17.239)	22.638 (17.219)
Median	25.140	25.140
Min, Max	0.00, 47.45	0.00, 47.45
<0.17%	3 (7.7)	3 (7.3)
>=0.17% and <1%	2 (5.1)	2 (4.9)
>=1%	34 (87.2)	36 (87.8)

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)	
	200 mg (N=40)	All Doses (N=42)
SM Related Organ Damages		
Ascites and Pleural Effusions		
Ascites		
No	28 (73.7)	28 (73.7)
Grade 1	0	0
Grade 2	8 (21.1)	8 (21.1)
Grade 3	2 (5.3)	2 (5.3)
Missing	2	4
Pleural Effusions		
No	31 (81.6)	31 (79.5)
Grade 1	2 (5.3)	2 (5.1)
Grade 2	5 (13.2)	6 (15.4)
Grade 3	0	0
Missing	2	3

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)	
	200 mg (N=40)	All Doses (N=42)
SM Related Organ Damages Continued		
Liver Function Abnormalities		
Other Cause for Abnormal Liver Function not Related to SM		
Yes	5 (45.5)	5 (45.5)
No	6 (54.5)	6 (54.5)
Missing	29	31
Clinical-relevant Portal Hypertension		
Yes	3 (27.3)	3 (27.3)
No	8 (72.7)	8 (72.7)
Missing	29	31
Biopsy-proven Liver MC Infiltration		
Yes	3 (27.3)	4 (33.3)
No	8 (72.7)	8 (66.7)
Missing	29	30

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)	
	200 mg (N=20)	All Doses (N=20)
Mutation Status (n (%))		
KIT Exon 17 Mutation by Central Assay		
Positive	19 (95.0)	19 (95.0)
Negative	1 (5.0)	1 (5.0)
SRSF2/ASXL1/RUNX1 Mutation (S/A/R) by Central Assay		
Positive	11 (55.0)	11 (55.0)
Negative	9 (45.0)	9 (45.0)
Number of Co-Mutations by Central Assay		
0	0	0
1	1 (5.0)	1 (5.0)
2-3	4 (20.0)	4 (20.0)
4-5	10 (50.0)	10 (50.0)
>=6	5 (25.0)	5 (25.0)
n	20	20
Mean (StdDev)	4.4 (1.73)	4.4 (1.73)
Median	4.0	4.0
Min, Max	1, 8	1, 8

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)	
	200 mg (N=20)	All Doses (N=20)
Spleen Volume (mL) by Central Radiologic Review		
n	20	20
Mean (StdDev)	711.12 (387.734)	711.12 (387.734)
Median	616.75	616.75
Min, Max	149.8, 1522.4	149.8, 1522.4
Spleen Palpation (n (%))		
Not Palpable	11 (57.9)	11 (57.9)
Palpable <5cm	1 (5.3)	1 (5.3)
Palpable =5cm	1 (5.3)	1 (5.3)
Palpable >5cm	6 (31.6)	6 (31.6)
Missing	1	1
n	19	19
Mean (StdDev)	2.9 (3.76)	2.9 (3.76)
Median	0.0	0.0
Min, Max	0, 10	0, 10

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)	
	200 mg (N=20)	All Doses (N=20)
Liver Volume (mL) by Central Radiologic Review		
n	20	20
Mean (StdDev)	2005.41 (459.900)	2005.41 (459.900)
Median	1960.02	1960.02
Min, Max	1334.5, 3342.6	1334.5, 3342.6
Liver Palpation (n (%))		
Not Palpable	10 (52.6)	10 (52.6)
Palpable	9 (47.4)	9 (47.4)
Missing	1	1
ALB (g/L)		
n	20	20
Mean (StdDev)	39.6 (6.14)	39.6 (6.14)
Median	39.5	39.5
Min, Max	27, 50	27, 50
CTCAE Grade (n (%))		
0	15 (75.0)	15 (75.0)
1	3 (15.0)	3 (15.0)
2	2 (10.0)	2 (10.0)
3	0	0
4	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)	
	200 mg (N=20)	All Doses (N=20)
ANC (x 10^9/L)		
n	20	20
Mean (StdDev)	6.070 (6.676)	6.070 (6.676)
Median	3.675	3.675
Min, Max	0.49, 26.60	0.49, 26.60
CTCAE Grade (n (%))		
0	16 (80.0)	16 (80.0)
1	1 (5.0)	1 (5.0)
2	1 (5.0)	1 (5.0)
3	1 (5.0)	1 (5.0)
4	1 (5.0)	1 (5.0)
HGB (g/L)		
n	20	20
Mean (StdDev)	111.9 (17.34)	111.9 (17.34)
Median	114.0	114.0
Min, Max	78, 137	78, 137
CTCAE Grade (n (%))		
0	9 (45.0)	9 (45.0)
1	6 (30.0)	6 (30.0)
2	4 (20.0)	4 (20.0)
3	1 (5.0)	1 (5.0)
4	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)	
	200 mg (N=20)	All Doses (N=20)
PLT (x 10^9/L)		
n	20	20
Mean (StdDev)	191.0 (80.03)	191.0 (80.03)
Median	173.5	173.5
Min, Max	57, 360	57, 360
CTCAE Grade (n (%))		
0	14 (70.0)	14 (70.0)
1	4 (20.0)	4 (20.0)
2	2 (10.0)	2 (10.0)
3	0	0
4	0	0
Monocytes (x 10^9/L)		
n	20	20
Mean (StdDev)	1.680 (1.827)	1.680 (1.827)
Median	0.930	0.930
Min, Max	0.20, 6.90	0.20, 6.90

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)	
	200 mg (N=20)	All Doses (N=20)
Direct Bilirubin (umol/L)		
n	20	20
Mean (StdDev)	5.692 (4.255)	5.692 (4.255)
Median	5.066	5.066
Min, Max	1.71, 20.53	1.71, 20.53
CTCAE Grade (n (%))		
0	13 (65.0)	13 (65.0)
1	4 (20.0)	4 (20.0)
2	2 (10.0)	2 (10.0)
3	1 (5.0)	1 (5.0)
4	0	0
ALT (U/L)		
n	20	20
Mean (StdDev)	19.2 (15.01)	19.2 (15.01)
Median	14.0	14.0
Min, Max	6, 69	6, 69
CTCAE Grade (n (%))		
0	18 (90.0)	18 (90.0)
1	2 (10.0)	2 (10.0)
2	0	0
3	0	0
4	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)	
	200 mg (N=20)	All Doses (N=20)
AST (U/L)		
n	20	20
Mean (StdDev)	19.1 (11.93)	19.1 (11.93)
Median	15.5	15.5
Min, Max	8, 57	8, 57
CTCAE Grade (n (%))		
0	19 (95.0)	19 (95.0)
1	1 (5.0)	1 (5.0)
2	0	0
3	0	0
4	0	0
ALP (U/L)		
n	20	20
Mean (StdDev)	361.1 (313.98)	361.1 (313.98)
Median	244.5	244.5
Min, Max	68, 1101	68, 1101
CTCAE Grade (n (%))		
0	5 (25.0)	5 (25.0)
1	7 (35.0)	7 (35.0)
2	4 (20.0)	4 (20.0)
3	4 (20.0)	4 (20.0)
4	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)	
	200 mg (N=20)	All Doses (N=20)
Serum Tryptase (ng/mL) from Central Assay		
n	20	20
Mean (StdDev)	253.00 (258.029)	253.00 (258.029)
Median	165.50	165.50
Min, Max	37.3, 1208.0	37.3, 1208.0
<11.4 ng/mL	0	0
>=11.4 and <20 ng/mL	0	0
>=20 and <40 ng/mL	1 (5.0)	1 (5.0)
>=40 and <200 ng/mL	11 (55.0)	11 (55.0)
>=200 ng/mL	8 (40.0)	8 (40.0)
BM MC (%) by Central Pathology Review		
n	20	20
Mean (StdDev)	38.2 (23.62)	38.2 (23.62)
Median	30.0	30.0
Min, Max	3, 80	3, 80
KIT D816V MAF (%) from Blood		
n	20	20
Mean (StdDev)	14.411 (14.548)	14.411 (14.548)
Median	9.690	9.690
Min, Max	0.01, 45.25	0.01, 45.25
<0.17%	3 (15.0)	3 (15.0)
>=0.17% and <1%	1 (5.0)	1 (5.0)
>=1%	16 (80.0)	16 (80.0)

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)	
	200 mg (N=20)	All Doses (N=20)
SM Related Organ Damages		
Ascites and Pleural Effusions		
Ascites		
No	16 (80.0)	16 (80.0)
Grade 1	0	0
Grade 2	3 (15.0)	3 (15.0)
Grade 3	1 (5.0)	1 (5.0)
Pleural Effusions		
No	16 (80.0)	16 (80.0)
Grade 1	0	0
Grade 2	3 (15.0)	3 (15.0)
Grade 3	1 (5.0)	1 (5.0)

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)	
	200 mg (N=20)	All Doses (N=20)
SM Related Organ Damages Continued		
Liver Function Abnormalities		
Other Cause for Abnormal Liver Function not Related to SM		
Yes	1 (10.0)	1 (10.0)
No	9 (90.0)	9 (90.0)
Missing	10	10
Clinical-relevant Portal Hypertension		
Yes	1 (10.0)	1 (10.0)
No	9 (90.0)	9 (90.0)
Missing	10	10
Biopsy-proven Liver MC Infiltration		
Yes	1 (10.0)	1 (10.0)
No	9 (90.0)	9 (90.0)
Missing	10	10

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=6)	200 mg (N=52)	300 mg (N=20)	200+300 mg (N=72)	All Doses (N=83)
Mutation Status (n (%))					
KIT Exon 17 Mutation by Central Assay					
Positive	6 (100)	48 (92.3)	17 (85.0)	65 (90.3)	76 (91.6)
Negative	0	4 (7.7)	3 (15.0)	7 (9.7)	7 (8.4)
SRSF2/ASXL1/RUNX1 Mutation (S/A/R) by Central Assay					
Positive	2 (33.3)	20 (38.5)	6 (30.0)	26 (36.1)	31 (37.3)
Negative	4 (66.7)	32 (61.5)	14 (70.0)	46 (63.9)	52 (62.7)
Number of Co-Mutations by Central Assay					
0	0	5 (9.6)	2 (10.0)	7 (9.7)	8 (9.6)
1	1 (16.7)	6 (11.5)	3 (15.0)	9 (12.5)	10 (12.0)
2-3	2 (33.3)	16 (30.8)	9 (45.0)	25 (34.7)	28 (33.7)
4-5	1 (16.7)	17 (32.7)	5 (25.0)	22 (30.6)	26 (31.3)
>=6	2 (33.3)	8 (15.4)	1 (5.0)	9 (12.5)	11 (13.3)
n	6	52	20	72	83
Mean (StdDev)	4.3 (2.94)	3.6 (3.13)	2.9 (1.74)	3.4 (2.82)	3.4 (2.76)
Median	4.0	3.0	3.0	3.0	3.0
Min, Max	1, 9	0, 21	0, 6	0, 21	0, 21

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=6)	200 mg (N=52)	300 mg (N=20)	200+300 mg (N=72)	All Doses (N=83)
Spleen Volume (mL) by Central Radiologic Review					
n	5	52	18	70	80
Mean (StdDev)	710.52 (541.851)	973.07 (496.569)	1114.05 (609.591)	1009.32 (526.936)	982.55 (533.849)
Median	580.85	795.96	1092.31	862.44	829.70
Min, Max	44.2, 1362.5	298.5, 2600.8	257.8, 2262.7	257.8, 2600.8	44.2, 2600.8
Spleen Palpation (n (%))					
Not Palpable	4 (66.7)	25 (50.0)	8 (42.1)	33 (47.8)	40 (50.0)
Palpable <5cm	1 (16.7)	7 (14.0)	1 (5.3)	8 (11.6)	9 (11.3)
Palpable =5cm	0	1 (2.0)	2 (10.5)	3 (4.3)	3 (3.8)
Palpable >5cm	1 (16.7)	17 (34.0)	8 (42.1)	25 (36.2)	28 (35.0)
Missing	0	2	1	3	3
n	6	50	19	69	80
Mean (StdDev)	1.6 (3.20)	3.3 (4.00)	5.2 (5.82)	3.8 (4.61)	3.7 (4.63)
Median	0.0	0.5	5.0	2.0	0.5
Min, Max	0, 8	0, 13	0, 18	0, 18	0, 18

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=6)	200 mg (N=52)	300 mg (N=20)	200+300 mg (N=72)	All Doses (N=83)
Liver Volume (mL) by Central Radiologic Review					
n	6	52	20	72	83
Mean (StdDev)	2339.52 (600.607)	2517.79 (546.957)	2242.82 (550.463)	2441.41 (557.998)	2433.10 (575.428)
Median	2327.23	2442.97	2070.22	2355.69	2361.64
Min, Max	1435.8, 3311.1	1660.5, 4020.8	1436.4, 3624.1	1436.4, 4020.8	1019.9, 4020.8
Liver Palpation (n (%))					
Not Palpable	4 (66.7)	23 (46.9)	11 (57.9)	34 (50.0)	41 (51.9)
Palpable	2 (33.3)	26 (53.1)	8 (42.1)	34 (50.0)	38 (48.1)
Missing	0	3	1	4	4
ALB (g/L)					
n	6	51	20	71	82
Mean (StdDev)	31.8 (13.12)	38.1 (5.57)	37.6 (5.99)	37.9 (5.65)	37.6 (6.65)
Median	34.5	38.0	40.0	38.0	38.0
Min, Max	13, 45	23, 49	23, 45	23, 49	13, 49
CTCAE Grade (n (%))					
0	3 (50.0)	39 (76.5)	16 (80.0)	55 (77.5)	62 (75.6)
1	0	8 (15.7)	1 (5.0)	9 (12.7)	9 (11.0)
2	2 (33.3)	4 (7.8)	3 (15.0)	7 (9.9)	10 (12.2)
3	1 (16.7)	0	0	0	1 (1.2)
4	0	0	0	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=6)	200 mg (N=52)	300 mg (N=20)	200+300 mg (N=72)	All Doses (N=83)
ANC (x 10^9/L)					
n	6	51	20	71	82
Mean (StdDev)	5.450 (1.476)	7.765 (7.669)	9.383 (8.008)	8.221 (7.743)	7.967 (7.542)
Median	5.455	6.110	6.560	6.110	5.700
Min, Max	3.20, 7.32	0.88, 43.80	1.20, 27.08	0.88, 43.80	0.88, 43.80
CTCAE Grade (n (%))					
0	6 (100)	46 (90.2)	19 (95.0)	65 (91.5)	75 (91.5)
1	0	2 (3.9)	0	2 (2.8)	2 (2.4)
2	0	2 (3.9)	1 (5.0)	3 (4.2)	4 (4.9)
3	0	1 (2.0)	0	1 (1.4)	1 (1.2)
4	0	0	0	0	0
HGB (g/L)					
n	6	52	20	72	83
Mean (StdDev)	112.7 (19.17)	105.8 (18.11)	109.4 (23.13)	106.8 (19.52)	107.4 (19.20)
Median	117.5	107.0	115.5	109.5	110.0
Min, Max	77, 131	65, 159	80, 169	65, 169	65, 169
CTCAE Grade (n (%))					
0	2 (33.3)	7 (13.5)	2 (10.0)	9 (12.5)	12 (14.5)
1	3 (50.0)	24 (46.2)	10 (50.0)	34 (47.2)	39 (47.0)
2	0	18 (34.6)	8 (40.0)	26 (36.1)	28 (33.7)
3	1 (16.7)	3 (5.8)	0	3 (4.2)	4 (4.8)
4	0	0	0	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=6)	200 mg (N=52)	300 mg (N=20)	200+300 mg (N=72)	All Doses (N=83)
PLT (x 10^9/L)					
n	6	52	20	72	83
Mean (StdDev)	261.2 (184.35)	158.2 (96.50)	224.9 (158.33)	176.7 (119.59)	182.7 (125.19)
Median	276.5	147.0	201.0	150.0	157.0
Min, Max	28, 454	28, 456	55, 602	28, 602	28, 602
CTCAE Grade (n (%))					
0	4 (66.7)	27 (51.9)	11 (55.0)	38 (52.8)	45 (54.2)
1	1 (16.7)	12 (23.1)	4 (20.0)	16 (22.2)	17 (20.5)
2	0	9 (17.3)	5 (25.0)	14 (19.4)	14 (16.9)
3	1 (16.7)	4 (7.7)	0	4 (5.6)	7 (8.4)
4	0	0	0	0	0
Monocytes (x 10^9/L)					
n	6	51	20	71	82
Mean (StdDev)	0.960 (0.567)	1.225 (1.166)	2.420 (2.967)	1.562 (1.911)	1.509 (1.829)
Median	0.805	0.950	1.150	1.000	0.930
Min, Max	0.40, 1.90	0.13, 5.14	0.06, 9.08	0.06, 9.08	0.06, 9.08

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=6)	200 mg (N=52)	300 mg (N=20)	200+300 mg (N=72)	All Doses (N=83)
Direct Bilirubin (umol/L)					
n	3	43	20	63	71
Mean (StdDev)	2.850 (0.987)	4.889 (2.818)	3.536 (2.292)	4.459 (2.719)	4.462 (2.701)
Median	3.420	4.275	2.868	3.421	3.421
Min, Max	1.71, 3.42	0.00, 11.97	0.00, 6.84	0.00, 11.97	0.00, 11.97
CTCAE Grade (n (%))					
0	3 (100)	30 (69.8)	18 (90.0)	48 (76.2)	54 (76.1)
1	0	8 (18.6)	2 (10.0)	10 (15.9)	11 (15.5)
2	0	4 (9.3)	0	4 (6.3)	5 (7.0)
3	0	1 (2.3)	0	1 (1.6)	1 (1.4)
4	0	0	0	0	0
ALT (U/L)					
n	6	52	20	72	83
Mean (StdDev)	17.0 (7.80)	20.6 (15.02)	19.2 (11.06)	20.2 (13.97)	20.5 (13.41)
Median	15.5	15.0	17.0	15.0	16.0
Min, Max	10, 32	5, 75	5, 44	5, 75	5, 75
CTCAE Grade (n (%))					
0	6 (100)	49 (94.2)	20 (100)	69 (95.8)	80 (96.4)
1	0	3 (5.8)	0	3 (4.2)	3 (3.6)
2	0	0	0	0	0
3	0	0	0	0	0
4	0	0	0	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=6)	200 mg (N=52)	300 mg (N=20)	200+300 mg (N=72)	All Doses (N=83)
AST (U/L)					
n	6	52	20	72	83
Mean (StdDev)	16.2 (6.68)	15.5 (9.72)	16.8 (10.87)	15.9 (9.99)	16.3 (9.83)
Median	15.0	11.0	13.0	13.0	13.0
Min, Max	9, 28	5, 57	5, 54	5, 57	5, 57
CTCAE Grade (n (%))					
0	6 (100)	50 (96.2)	19 (95.0)	69 (95.8)	80 (96.4)
1	0	2 (3.8)	1 (5.0)	3 (4.2)	3 (3.6)
2	0	0	0	0	0
3	0	0	0	0	0
4	0	0	0	0	0
ALP (U/L)					
n	6	52	20	72	83
Mean (StdDev)	228.5 (150.36)	215.9 (182.95)	233.7 (364.81)	220.8 (244.38)	215.3 (232.53)
Median	201.5	166.5	142.5	149.0	148.0
Min, Max	67, 452	27, 1150	59, 1747	27, 1747	27, 1747
CTCAE Grade (n (%))					
0	2 (33.3)	20 (38.5)	7 (35.0)	27 (37.5)	32 (38.6)
1	2 (33.3)	19 (36.5)	11 (55.0)	30 (41.7)	34 (41.0)
2	2 (33.3)	11 (21.2)	1 (5.0)	12 (16.7)	14 (16.9)
3	0	2 (3.8)	1 (5.0)	3 (4.2)	3 (3.6)
4	0	0	0	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=6)	200 mg (N=52)	300 mg (N=20)	200+300 mg (N=72)	All Doses (N=83)
Serum Tryptase (ng/mL) from Central Assay					
n	6	52	20	72	83
Mean (StdDev)	582.40 (721.577)	358.35 (290.833)	312.75 (189.257)	345.68 (266.018)	348.48 (317.529)
Median	185.80	312.00	313.80	312.00	270.00
Min, Max	52.6, 1600.0	19.9, 1600.0	21.2, 760.1	19.9, 1600.0	19.9, 1600.0
<11.4 ng/mL	0	0	0	0	0
>=11.4 and <20 ng/mL	0	1 (1.9)	0	1 (1.4)	1 (1.2)
>=20 and <40 ng/mL	0	2 (3.8)	1 (5.0)	3 (4.2)	5 (6.0)
>=40 and <200 ng/mL	3 (50.0)	16 (30.8)	5 (25.0)	21 (29.2)	27 (32.5)
>=200 ng/mL	3 (50.0)	33 (63.5)	14 (70.0)	47 (65.3)	50 (60.2)
BM MC (%) by Central Pathology Review					
n	6	50	17	67	78
Mean (StdDev)	25.8 (12.01)	51.0 (28.12)	52.4 (29.64)	51.4 (28.29)	48.6 (28.52)
Median	30.0	55.0	50.0	50.0	50.0
Min, Max	5, 40	1, 95	10, 95	1, 95	1, 95
KIT D816V MAF (%) from Blood					
n	5	51	20	71	81
Mean (StdDev)	18.698 (21.294)	20.977 (17.458)	22.192 (22.961)	21.319 (19.003)	20.678 (18.722)
Median	3.820	19.430	15.655	19.200	18.420
Min, Max	3.05, 46.30	0.00, 47.45	0.00, 80.10	0.00, 80.10	0.00, 80.10
<0.17%	0	7 (13.7)	6 (30.0)	13 (18.3)	13 (16.0)
>=0.17% and <1%	0	2 (3.9)	0	2 (2.8)	3 (3.7)
>=1%	5 (100)	42 (82.4)	14 (70.0)	56 (78.9)	65 (80.2)

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=6)	200 mg (N=52)	300 mg (N=20)	200+300 mg (N=72)	All Doses (N=83)
SM Related Organ Damages					
Ascites and Pleural Effusions					
Ascites					
No	3 (75.0)	36 (72.0)	13 (65.0)	49 (70.0)	55 (69.6)
Grade 1	0	1 (2.0)	2 (10.0)	3 (4.3)	4 (5.1)
Grade 2	0	10 (20.0)	3 (15.0)	13 (18.6)	13 (16.5)
Grade 3	1 (25.0)	3 (6.0)	2 (10.0)	5 (7.1)	7 (8.9)
Missing	2	2	0	2	4
Pleural Effusions					
No	4 (80.0)	42 (84.0)	17 (85.0)	59 (84.3)	67 (83.8)
Grade 1	0	2 (4.0)	3 (15.0)	5 (7.1)	6 (7.5)
Grade 2	1 (20.0)	6 (12.0)	0	6 (8.6)	7 (8.8)
Grade 3	0	0	0	0	0
Missing	1	2	0	2	3

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=6)	200 mg (N=52)	300 mg (N=20)	200+300 mg (N=72)	All Doses (N=83)
SM Related Organ Damages Continued					
Liver Function Abnormalities					
Other Cause for Abnormal Liver Function not Related to SM					
Yes	0	5 (21.7)	2 (10.0)	7 (16.3)	8 (15.4)
No	4 (100)	17 (73.9)	18 (90.0)	35 (81.4)	43 (82.7)
Unknown	0	1 (4.3)	0	1 (2.3)	1 (1.9)
Missing	2	29	0	29	31
Clinical-relevant Portal Hypertension					
Yes	0	3 (13.0)	2 (10.0)	5 (11.6)	6 (11.5)
No	4 (100)	20 (87.0)	18 (90.0)	38 (88.4)	46 (88.5)
Unknown	0	0	0	0	0
Missing	2	29	0	29	31
Biopsy-proven Liver MC Infiltration					
Yes	3 (60.0)	3 (13.0)	4 (20.0)	7 (16.3)	11 (20.8)
No	2 (40.0)	20 (87.0)	15 (75.0)	35 (81.4)	41 (77.4)
Unknown	0	0	1 (5.0)	1 (2.3)	1 (1.9)
Missing	1	29	0	29	30

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=28)	300 mg (N=14)	200+300 mg (N=42)	All Doses (N=48)
Mutation Status (n (%))					
KIT Exon 17 Mutation by Central Assay					
Positive	5 (100)	27 (96.4)	14 (100)	41 (97.6)	47 (97.9)
Negative	0	1 (3.6)	0	1 (2.4)	1 (2.1)
SRSF2/ASXL1/RUNX1 Mutation (S/A/R) by Central Assay					
Positive	3 (60.0)	16 (57.1)	12 (85.7)	28 (66.7)	31 (64.6)
Negative	2 (40.0)	12 (42.9)	2 (14.3)	14 (33.3)	17 (35.4)
Number of Co-Mutations by Central Assay					
0	0	1 (3.6)	0	1 (2.4)	1 (2.1)
1	0	2 (7.1)	0	2 (4.8)	3 (6.3)
2-3	2 (40.0)	6 (21.4)	7 (50.0)	13 (31.0)	15 (31.3)
4-5	3 (60.0)	13 (46.4)	5 (35.7)	18 (42.9)	21 (43.8)
>=6	0	6 (21.4)	2 (14.3)	8 (19.0)	8 (16.7)
n	5	28	14	42	48
Mean (StdDev)	4.2 (1.10)	4.3 (2.35)	3.5 (1.65)	4.0 (2.16)	4.0 (2.09)
Median	5.0	4.0	3.5	4.0	4.0
Min, Max	3, 5	0, 12	2, 7	0, 12	0, 12

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=28)	300 mg (N=14)	200+300 mg (N=42)	All Doses (N=48)
Spleen Volume (mL) by Central Radiologic Review					
n	5	28	14	42	48
Mean (StdDev)	1228.63 (359.433)	796.46 (462.921)	1220.33 (631.325)	937.75 (555.335)	959.19 (540.744)
Median	1190.55	669.74	1236.43	759.06	799.25
Min, Max	819.0, 1626.6	149.8, 1951.7	148.7, 2300.1	148.7, 2300.1	148.7, 2300.1
Spleen Palpation (n (%))					
Not Palpable	0	16 (59.3)	2 (14.3)	18 (43.9)	18 (38.3)
Palpable <5cm	2 (40.0)	2 (7.4)	4 (28.6)	6 (14.6)	9 (19.1)
Palpable =5cm	2 (40.0)	1 (3.7)	1 (7.1)	2 (4.9)	4 (8.5)
Palpable >5cm	1 (20.0)	8 (29.6)	7 (50.0)	15 (36.6)	16 (34.0)
Missing	0	1	0	1	1
n	5	27	14	41	47
Mean (StdDev)	4.4 (1.34)	3.1 (4.58)	7.7 (7.09)	4.7 (5.89)	4.6 (5.51)
Median	5.0	0.0	7.5	2.0	3.0
Min, Max	3, 6	0, 17	0, 24	0, 24	0, 24

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=28)	300 mg (N=14)	200+300 mg (N=42)	All Doses (N=48)
Liver Volume (mL) by Central Radiologic Review					
n	5	28	14	42	48
Mean (StdDev)	2397.90 (379.747)	2172.38 (531.918)	2411.31 (644.787)	2252.02 (575.451)	2284.04 (562.351)
Median	2395.62	2066.05	2564.47	2162.22	2221.64
Min, Max	1898.2, 2924.0	1334.5, 3342.6	1013.4, 3520.9	1013.4, 3520.9	1013.4, 3520.9
Liver Palpation (n (%))					
Not Palpable	3 (60.0)	15 (55.6)	6 (42.9)	21 (51.2)	25 (53.2)
Palpable	2 (40.0)	12 (44.4)	8 (57.1)	20 (48.8)	22 (46.8)
Missing	0	1	0	1	1
ALB (g/L)					
n	5	28	14	42	48
Mean (StdDev)	37.8 (4.09)	38.8 (6.00)	37.3 (6.21)	38.3 (6.04)	38.4 (5.85)
Median	40.0	39.0	37.5	38.5	39.0
Min, Max	32, 41	27, 50	28, 47	27, 50	27, 50
CTCAE Grade (n (%))					
0	3 (60.0)	18 (64.3)	9 (64.3)	27 (64.3)	31 (64.6)
1	2 (40.0)	8 (28.6)	3 (21.4)	11 (26.2)	13 (27.1)
2	0	2 (7.1)	2 (14.3)	4 (9.5)	4 (8.3)
3	0	0	0	0	0
4	0	0	0	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=28)	300 mg (N=14)	200+300 mg (N=42)	All Doses (N=48)
ANC (x 10^9/L)					
n	5	28	14	42	48
Mean (StdDev)	8.852 (7.887)	6.590 (6.660)	6.181 (5.108)	6.454 (6.126)	6.663 (6.219)
Median	5.800	4.045	4.050	4.045	4.095
Min, Max	1.48, 20.20	0.49, 26.60	0.60, 16.94	0.49, 26.60	0.49, 26.60
CTCAE Grade (n (%))					
0	4 (80.0)	23 (82.1)	11 (78.6)	34 (81.0)	39 (81.3)
1	0	1 (3.6)	0	1 (2.4)	1 (2.1)
2	1 (20.0)	1 (3.6)	2 (14.3)	3 (7.1)	4 (8.3)
3	0	2 (7.1)	1 (7.1)	3 (7.1)	3 (6.3)
4	0	1 (3.6)	0	1 (2.4)	1 (2.1)
HGB (g/L)					
n	5	28	14	42	48
Mean (StdDev)	109.2 (17.05)	112.2 (16.57)	104.1 (12.96)	109.5 (15.78)	110.6 (17.63)
Median	108.0	114.0	105.5	109.0	109.0
Min, Max	83, 128	78, 137	84, 129	78, 137	78, 167
CTCAE Grade (n (%))					
0	0	11 (39.3)	2 (14.3)	13 (31.0)	14 (29.2)
1	4 (80.0)	10 (35.7)	8 (57.1)	18 (42.9)	22 (45.8)
2	1 (20.0)	6 (21.4)	4 (28.6)	10 (23.8)	11 (22.9)
3	0	1 (3.6)	0	1 (2.4)	1 (2.1)
4	0	0	0	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=28)	300 mg (N=14)	200+300 mg (N=42)	All Doses (N=48)
PLT (x 10^9/L)					
n	5	28	14	42	48
Mean (StdDev)	110.8 (74.48)	192.7 (110.69)	102.4 (78.25)	162.6 (108.95)	157.1 (105.27)
Median	82.0	173.5	72.0	151.0	142.5
Min, Max	62, 243	57, 606	32, 306	32, 606	32, 606
CTCAE Grade (n (%))					
0	1 (20.0)	18 (64.3)	3 (21.4)	21 (50.0)	23 (47.9)
1	3 (60.0)	7 (25.0)	3 (21.4)	10 (23.8)	13 (27.1)
2	1 (20.0)	3 (10.7)	4 (28.6)	7 (16.7)	8 (16.7)
3	0	0	4 (28.6)	4 (9.5)	4 (8.3)
4	0	0	0	0	0
Monocytes (x 10^9/L)					
n	5	28	14	42	48
Mean (StdDev)	2.832 (2.493)	1.943 (1.794)	2.166 (2.558)	2.018 (2.051)	2.071 (2.077)
Median	1.910	1.200	1.670	1.255	1.305
Min, Max	0.50, 7.00	0.12, 6.90	0.10, 9.86	0.10, 9.86	0.10, 9.86

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=28)	300 mg (N=14)	200+300 mg (N=42)	All Doses (N=48)
Direct Bilirubin (umol/L)					
n	5	28	14	42	47
Mean (StdDev)	4.650 (3.117)	5.530 (4.223)	6.594 (8.420)	5.885 (5.872)	5.753 (5.633)
Median	4.200	5.066	5.065	5.065	5.000
Min, Max	0.66, 8.55	0.32, 20.53	0.91, 35.00	0.32, 35.00	0.32, 35.00
CTCAE Grade (n (%))					
0	2 (40.0)	16 (57.1)	9 (64.3)	25 (59.5)	27 (57.4)
1	2 (40.0)	5 (17.9)	4 (28.6)	9 (21.4)	11 (23.4)
2	1 (20.0)	5 (17.9)	0	5 (11.9)	6 (12.8)
3	0	2 (7.1)	1 (7.1)	3 (7.1)	3 (6.4)
4	0	0	0	0	0
ALT (U/L)					
n	5	28	14	42	48
Mean (StdDev)	17.4 (6.66)	20.3 (14.98)	30.4 (19.76)	23.7 (17.18)	23.3 (16.40)
Median	18.0	15.0	25.0	19.5	19.5
Min, Max	9, 26	5, 69	3, 78	3, 78	3, 78
CTCAE Grade (n (%))					
0	5 (100)	25 (89.3)	12 (85.7)	37 (88.1)	43 (89.6)
1	0	3 (10.7)	2 (14.3)	5 (11.9)	5 (10.4)
2	0	0	0	0	0
3	0	0	0	0	0
4	0	0	0	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=28)	300 mg (N=14)	200+300 mg (N=42)	All Doses (N=48)
AST (U/L)					
n	5	28	14	42	48
Mean (StdDev)	16.6 (5.77)	18.2 (10.77)	22.0 (9.88)	19.5 (10.51)	19.2 (10.00)
Median	14.0	16.5	21.5	17.0	17.0
Min, Max	11, 25	5, 57	5, 44	5, 57	5, 57
CTCAE Grade (n (%))					
0	5 (100)	27 (96.4)	12 (85.7)	39 (92.9)	45 (93.8)
1	0	1 (3.6)	2 (14.3)	3 (7.1)	3 (6.3)
2	0	0	0	0	0
3	0	0	0	0	0
4	0	0	0	0	0
ALP (U/L)					
n	5	28	14	42	48
Mean (StdDev)	280.8 (93.64)	352.8 (294.65)	401.8 (309.19)	369.1 (296.70)	354.0 (282.64)
Median	327.0	252.5	330.5	277.0	277.0
Min, Max	139, 364	68, 1101	70, 1073	68, 1101	68, 1101
CTCAE Grade (n (%))					
0	0	6 (21.4)	4 (28.6)	10 (23.8)	11 (22.9)
1	2 (40.0)	12 (42.9)	2 (14.3)	14 (33.3)	16 (33.3)
2	3 (60.0)	5 (17.9)	5 (35.7)	10 (23.8)	13 (27.1)
3	0	5 (17.9)	3 (21.4)	8 (19.0)	8 (16.7)
4	0	0	0	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=28)	300 mg (N=14)	200+300 mg (N=42)	All Doses (N=48)
Serum Tryptase (ng/mL) from Central Assay					
n	5	28	14	42	48
Mean (StdDev)	340.38 (263.975)	250.29 (237.751)	195.89 (202.878)	232.15 (225.717)	241.98 (227.212)
Median	182.40	165.50	144.85	152.00	161.25
Min, Max	102.4, 684.8	37.3, 1208.0	12.4, 765.3	12.4, 1208.0	12.4, 1208.0
<11.4 ng/mL	0	0	0	0	0
>=11.4 and <20 ng/mL	0	0	1 (7.1)	1 (2.4)	1 (2.1)
>=20 and <40 ng/mL	0	1 (3.6)	1 (7.1)	2 (4.8)	2 (4.2)
>=40 and <200 ng/mL	3 (60.0)	15 (53.6)	9 (64.3)	24 (57.1)	28 (58.3)
>=200 ng/mL	2 (40.0)	12 (42.9)	3 (21.4)	15 (35.7)	17 (35.4)
BM MC (%) by Central Pathology Review					
n	5	28	14	42	48
Mean (StdDev)	45.0 (18.71)	40.5 (25.07)	39.6 (23.73)	40.2 (24.34)	41.5 (24.10)
Median	50.0	30.0	35.0	30.0	40.0
Min, Max	15, 60	3, 80	5, 80	3, 80	3, 80
KIT D816V MAF (%) from Blood					
n	5	28	14	42	47
Mean (StdDev)	9.954 (13.735)	15.828 (13.910)	22.448 (16.528)	18.035 (14.967)	17.175 (14.914)
Median	4.430	13.270	21.100	16.560	14.950
Min, Max	0.56, 33.70	0.01, 45.25	0.03, 45.30	0.01, 45.30	0.01, 45.30
<0.17%	0	3 (10.7)	1 (7.1)	4 (9.5)	4 (8.5)
>=0.17% and <1%	1 (20.0)	1 (3.6)	1 (7.1)	2 (4.8)	3 (6.4)
>=1%	4 (80.0)	24 (85.7)	12 (85.7)	36 (85.7)	40 (85.1)

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=28)	300 mg (N=14)	200+300 mg (N=42)	All Doses (N=48)
SM Related Organ Damages					
Ascites and Pleural Effusions					
Ascites					
No	3 (60.0)	23 (82.1)	11 (78.6)	34 (81.0)	38 (79.2)
Grade 1	0	0	2 (14.3)	2 (4.8)	2 (4.2)
Grade 2	2 (40.0)	4 (14.3)	1 (7.1)	5 (11.9)	7 (14.6)
Grade 3	0	1 (3.6)	0	1 (2.4)	1 (2.1)
Pleural Effusions					
No	4 (80.0)	23 (82.1)	12 (85.7)	35 (83.3)	40 (83.3)
Grade 1	0	0	2 (14.3)	2 (4.8)	2 (4.2)
Grade 2	1 (20.0)	3 (10.7)	0	3 (7.1)	4 (8.3)
Grade 3	0	2 (7.1)	0	2 (4.8)	2 (4.2)

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3b
Baseline Disease Assessments by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=28)	300 mg (N=14)	200+300 mg (N=42)	All Doses (N=48)
SM Related Organ Damages Continued					
Liver Function Abnormalities					
Other Cause for Abnormal Liver Function not Related to SM					
Yes	0	1 (5.6)	0	1 (3.1)	1 (2.6)
No	5 (100)	17 (94.4)	14 (100)	31 (96.9)	37 (97.4)
Unknown	0	0	0	0	0
Missing	0	10	0	10	10
Clinical-relevant Portal Hypertension					
Yes	0	1 (5.6)	0	1 (3.1)	1 (2.6)
No	5 (100)	17 (94.4)	13 (92.9)	30 (93.8)	36 (94.7)
Unknown	0	0	1 (7.1)	1 (3.1)	1 (2.6)
Missing	0	10	0	10	10
Biopsy-proven Liver MC Infiltration					
Yes	0	2 (11.1)	2 (14.3)	4 (12.5)	4 (10.5)
No	5 (100)	16 (88.9)	10 (71.4)	26 (81.3)	32 (84.2)
Unknown	0	0	2 (14.3)	2 (6.3)	2 (5.3)
Missing	0	10	0	10	10

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=3)	200 mg (N=9)	300 mg (N=16)	200+300 mg (N=25)	All Doses (N=32)
Mutation Status (n (%))					
KIT Exon 17 Mutation by Central Assay					
Positive	3 (100)	8 (88.9)	15 (93.8)	23 (92.0)	30 (93.8)
Negative	0	1 (11.1)	1 (6.3)	2 (8.0)	2 (6.3)
SRSF2/ASXL1/RUNX1 Mutation (S/A/R) by Central Assay					
Positive	1 (33.3)	3 (33.3)	5 (31.3)	8 (32.0)	12 (37.5)
Negative	2 (66.7)	6 (66.7)	11 (68.8)	17 (68.0)	20 (62.5)
Number of Co-Mutations by Central Assay					
0	0	1 (11.1)	2 (12.5)	3 (12.0)	3 (9.4)
1	1 (33.3)	2 (22.2)	3 (18.8)	5 (20.0)	6 (18.8)
2-3	1 (33.3)	2 (22.2)	5 (31.3)	7 (28.0)	9 (28.1)
4-5	0	3 (33.3)	5 (31.3)	8 (32.0)	11 (34.4)
>=6	1 (33.3)	1 (11.1)	1 (6.3)	2 (8.0)	3 (9.4)
n	3	9	16	25	32
Mean (StdDev)	3.3 (2.52)	3.0 (2.12)	2.9 (1.96)	2.9 (1.98)	3.1 (1.88)
Median	3.0	3.0	3.0	3.0	3.0
Min, Max	1, 6	0, 6	0, 6	0, 6	0, 6

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=3)	200 mg (N=9)	300 mg (N=16)	200+300 mg (N=25)	All Doses (N=32)
Spleen Volume (mL) by Central Radiologic Review					
n	3	9	15	24	31
Mean (StdDev)	784.34 (507.986)	833.77 (307.253)	1156.25 (611.011)	1035.32 (534.339)	1014.08 (526.855)
Median	580.85	810.35	1120.69	1052.17	1040.40
Min, Max	409.6, 1362.5	298.5, 1240.3	257.8, 2262.7	257.8, 2262.7	257.8, 2262.7
Spleen Palpation (n (%))					
Not Palpable	2 (66.7)	6 (75.0)	5 (31.3)	11 (45.8)	15 (48.4)
Palpable <5cm	0	0	1 (6.3)	1 (4.2)	1 (3.2)
Palpable =5cm	0	0	2 (12.5)	2 (8.3)	2 (6.5)
Palpable >5cm	1 (33.3)	2 (25.0)	8 (50.0)	10 (41.7)	13 (41.9)
Missing	0	1	0	1	1
n	3	8	16	24	31
Mean (StdDev)	2.7 (4.62)	1.9 (3.56)	6.2 (5.85)	4.8 (5.52)	4.7 (5.47)
Median	0.0	0.0	5.5	3.5	2.0
Min, Max	0, 8	0, 9	0, 18	0, 18	0, 18

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=3)	200 mg (N=9)	300 mg (N=16)	200+300 mg (N=25)	All Doses (N=32)
Liver Volume (mL) by Central Radiologic Review					
n	3	9	16	25	32
Mean (StdDev)	2023.85 (527.301)	2474.41 (503.310)	2316.96 (591.508)	2373.64 (555.937)	2391.30 (559.243)
Median	2181.15	2390.27	2318.58	2349.73	2370.00
Min, Max	1435.8, 2454.6	1764.2, 3437.5	1436.4, 3624.1	1436.4, 3624.1	1435.8, 3624.1
Liver Palpation (n (%))					
Not Palpable	3 (100)	5 (62.5)	8 (50.0)	13 (54.2)	18 (58.1)
Palpable	0	3 (37.5)	8 (50.0)	11 (45.8)	13 (41.9)
Missing	0	1	0	1	1
ALB (g/L)					
n	3	9	16	25	32
Mean (StdDev)	38.0 (8.19)	40.7 (3.64)	37.1 (6.54)	38.4 (5.85)	38.3 (6.06)
Median	40.0	41.0	40.5	41.0	40.5
Min, Max	29, 45	36, 46	23, 45	23, 46	23, 46
CTCAE Grade (n (%))					
0	2 (66.7)	8 (88.9)	12 (75.0)	20 (80.0)	25 (78.1)
1	0	1 (11.1)	1 (6.3)	2 (8.0)	2 (6.3)
2	1 (33.3)	0	3 (18.8)	3 (12.0)	5 (15.6)
3	0	0	0	0	0
4	0	0	0	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=3)	200 mg (N=9)	300 mg (N=16)	200+300 mg (N=25)	All Doses (N=32)
ANC (x 10^9/L)					
n	3	9	16	25	32
Mean (StdDev)	5.170 (0.551)	6.260 (4.513)	10.284 (8.697)	8.836 (7.613)	8.410 (7.557)
Median	5.210	6.280	7.245	7.080	5.475
Min, Max	4.60, 5.70	0.88, 12.52	1.20, 27.08	0.88, 27.08	0.88, 27.08
CTCAE Grade (n (%))					
0	3 (100)	8 (88.9)	15 (93.8)	23 (92.0)	29 (90.6)
1	0	0	0	0	0
2	0	0	1 (6.3)	1 (4.0)	2 (6.3)
3	0	1 (11.1)	0	1 (4.0)	1 (3.1)
4	0	0	0	0	0
HGB (g/L)					
n	3	9	16	25	32
Mean (StdDev)	121.3 (11.24)	111.7 (14.20)	104.8 (23.52)	107.2 (20.60)	108.1 (19.39)
Median	124.0	117.0	101.5	109.0	109.0
Min, Max	109, 131	91, 132	80, 169	80, 169	80, 169
CTCAE Grade (n (%))					
0	2 (66.7)	1 (11.1)	2 (12.5)	3 (12.0)	5 (15.6)
1	1 (33.3)	6 (66.7)	6 (37.5)	12 (48.0)	15 (46.9)
2	0	2 (22.2)	8 (50.0)	10 (40.0)	12 (37.5)
3	0	0	0	0	0
4	0	0	0	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=3)	200 mg (N=9)	300 mg (N=16)	200+300 mg (N=25)	All Doses (N=32)
PLT (x 10^9/L)					
n	3	9	16	25	32
Mean (StdDev)	220.7 (153.73)	126.3 (79.96)	203.4 (139.99)	175.6 (125.72)	177.4 (125.33)
Median	157.0	123.0	167.5	134.0	136.5
Min, Max	109, 396	40, 291	55, 504	40, 504	40, 504
CTCAE Grade (n (%))					
0	2 (66.7)	3 (33.3)	8 (50.0)	11 (44.0)	15 (46.9)
1	1 (33.3)	2 (22.2)	3 (18.8)	5 (20.0)	6 (18.8)
2	0	3 (33.3)	5 (31.3)	8 (32.0)	8 (25.0)
3	0	1 (11.1)	0	1 (4.0)	3 (9.4)
4	0	0	0	0	0
Monocytes (x 10^9/L)					
n	3	9	16	25	32
Mean (StdDev)	1.030 (0.778)	1.088 (0.848)	2.808 (3.211)	2.188 (2.719)	2.011 (2.497)
Median	0.790	1.000	1.640	1.200	1.005
Min, Max	0.40, 1.90	0.20, 2.50	0.06, 9.08	0.06, 9.08	0.06, 9.08

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=3)	200 mg (N=9)	300 mg (N=16)	200+300 mg (N=25)	All Doses (N=32)
Direct Bilirubin (umol/L)					
n	2	9	16	25	31
Mean (StdDev)	3.420 (0.000)	3.928 (3.339)	3.885 (2.420)	3.901 (2.716)	4.194 (2.707)
Median	3.420	3.420	3.210	3.420	3.420
Min, Max	3.42, 3.42	0.66, 11.97	0.00, 6.84	0.00, 11.97	0.00, 11.97
CTCAE Grade (n (%))					
0	2 (100)	6 (66.7)	14 (87.5)	20 (80.0)	24 (77.4)
1	0	2 (22.2)	2 (12.5)	4 (16.0)	5 (16.1)
2	0	1 (11.1)	0	1 (4.0)	2 (6.5)
3	0	0	0	0	0
4	0	0	0	0	0
ALT (U/L)					
n	3	9	16	25	32
Mean (StdDev)	13.7 (3.21)	16.9 (8.55)	19.4 (12.18)	18.5 (10.89)	19.1 (10.46)
Median	15.0	13.0	16.5	15.0	15.5
Min, Max	10, 16	7, 32	5, 44	5, 44	5, 44
CTCAE Grade (n (%))					
0	3 (100)	9 (100)	16 (100)	25 (100)	32 (100)
1	0	0	0	0	0
2	0	0	0	0	0
3	0	0	0	0	0
4	0	0	0	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=3)	200 mg (N=9)	300 mg (N=16)	200+300 mg (N=25)	All Doses (N=32)
AST (U/L)					
n	3	9	16	25	32
Mean (StdDev)	13.0 (4.00)	14.3 (8.37)	16.4 (11.85)	15.7 (10.59)	16.1 (10.20)
Median	13.0	10.0	13.0	12.0	13.0
Min, Max	9, 17	7, 33	5, 54	5, 54	5, 54
CTCAE Grade (n (%))					
0	3 (100)	8 (88.9)	15 (93.8)	23 (92.0)	30 (93.8)
1	0	1 (11.1)	1 (6.3)	2 (8.0)	2 (6.3)
2	0	0	0	0	0
3	0	0	0	0	0
4	0	0	0	0	0
ALP (U/L)					
n	3	9	16	25	32
Mean (StdDev)	172.0 (159.88)	166.8 (126.26)	264.6 (404.02)	229.4 (331.10)	212.1 (297.57)
Median	93.0	120.0	152.0	147.0	139.5
Min, Max	67, 356	27, 370	59, 1747	27, 1747	27, 1747
CTCAE Grade (n (%))					
0	2 (66.7)	5 (55.6)	5 (31.3)	10 (40.0)	14 (43.8)
1	0	2 (22.2)	9 (56.3)	11 (44.0)	13 (40.6)
2	1 (33.3)	2 (22.2)	1 (6.3)	3 (12.0)	4 (12.5)
3	0	0	1 (6.3)	1 (4.0)	1 (3.1)
4	0	0	0	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=3)	200 mg (N=9)	300 mg (N=16)	200+300 mg (N=25)	All Doses (N=32)
Serum Tryptase (ng/mL) from Central Assay					
n	3	9	16	25	32
Mean (StdDev)	111.70 (99.520)	347.23 (275.717)	341.62 (195.027)	343.64 (221.630)	294.85 (218.927)
Median	55.90	255.80	377.95	367.40	226.85
Min, Max	52.6, 226.6	40.7, 723.2	21.2, 760.1	21.2, 760.1	21.2, 760.1
<11.4 ng/mL	0	0	0	0	0
>=11.4 and <20 ng/mL	0	0	0	0	0
>=20 and <40 ng/mL	0	0	1 (6.3)	1 (4.0)	2 (6.3)
>=40 and <200 ng/mL	2 (66.7)	4 (44.4)	3 (18.8)	7 (28.0)	12 (37.5)
>=200 ng/mL	1 (33.3)	5 (55.6)	12 (75.0)	17 (68.0)	18 (56.3)
BM MC (%) by Central Pathology Review					
n	3	8	13	21	28
Mean (StdDev)	18.3 (12.58)	47.5 (29.28)	64.6 (21.74)	58.1 (25.62)	52.1 (28.36)
Median	20.0	45.0	70.0	60.0	55.0
Min, Max	5, 30	10, 80	30, 95	10, 95	5, 95
KIT D816V MAF (%) from Blood					
n	2	9	16	25	31
Mean (StdDev)	24.675 (30.582)	16.264 (17.737)	25.181 (23.365)	21.971 (21.567)	21.450 (20.562)
Median	24.675	7.370	20.400	12.900	14.500
Min, Max	3.05, 46.30	0.00, 44.30	0.00, 80.10	0.00, 80.10	0.00, 80.10
<0.17%	0	2 (22.2)	4 (25.0)	6 (24.0)	6 (19.4)
>=0.17% and <1%	0	0	0	0	1 (3.2)
>=1%	2 (100)	7 (77.8)	12 (75.0)	19 (76.0)	24 (77.4)

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=3)	200 mg (N=9)	300 mg (N=16)	200+300 mg (N=25)	All Doses (N=32)
SM Related Organ Damages					
Ascites and Pleural Effusions					
Ascites					
No	2 (66.7)	6 (66.7)	10 (62.5)	16 (64.0)	20 (62.5)
Grade 1	0	1 (11.1)	2 (12.5)	3 (12.0)	4 (12.5)
Grade 2	0	1 (11.1)	2 (12.5)	3 (12.0)	3 (9.4)
Grade 3	1 (33.3)	1 (11.1)	2 (12.5)	3 (12.0)	5 (15.6)
Pleural Effusions					
No	3 (100)	8 (88.9)	13 (81.3)	21 (84.0)	27 (84.4)
Grade 1	0	0	3 (18.8)	3 (12.0)	4 (12.5)
Grade 2	0	1 (11.1)	0	1 (4.0)	1 (3.1)
Grade 3	0	0	0	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=3)	200 mg (N=9)	300 mg (N=16)	200+300 mg (N=25)	All Doses (N=32)
SM Related Organ Damages Continued					
Liver Function Abnormalities					
Other Cause for Abnormal Liver Function not Related to SM					
Yes	0	0	2 (12.5)	2 (8.0)	3 (9.4)
No	3 (100)	8 (88.9)	14 (87.5)	22 (88.0)	28 (87.5)
Unknown	0	1 (11.1)	0	1 (4.0)	1 (3.1)
Clinical-relevant Portal Hypertension					
Yes	0	0	2 (12.5)	2 (8.0)	3 (9.4)
No	3 (100)	9 (100)	14 (87.5)	23 (92.0)	29 (90.6)
Unknown	0	0	0	0	0
Biopsy-proven Liver MC Infiltration					
Yes	1 (33.3)	0	4 (25.0)	4 (16.0)	6 (18.8)
No	2 (66.7)	9 (100)	11 (68.8)	20 (80.0)	25 (78.1)
Unknown	0	0	1 (6.3)	1 (4.0)	1 (3.1)

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=4)	300 mg (N=11)	200+300 mg (N=15)	All Doses (N=21)
Mutation Status (n (%))					
KIT Exon 17 Mutation by Central Assay					
Positive	5 (100)	4 (100)	11 (100)	15 (100)	21 (100)
Negative	0	0	0	0	0
SRSF2/ASXL1/RUNX1 Mutation (S/A/R) by Central Assay					
Positive	3 (60.0)	2 (50.0)	10 (90.9)	12 (80.0)	15 (71.4)
Negative	2 (40.0)	2 (50.0)	1 (9.1)	3 (20.0)	6 (28.6)
Number of Co-Mutations by Central Assay					
0	0	1 (25.0)	0	1 (6.7)	1 (4.8)
1	0	1 (25.0)	0	1 (6.7)	2 (9.5)
2-3	2 (40.0)	1 (25.0)	5 (45.5)	6 (40.0)	8 (38.1)
4-5	3 (60.0)	1 (25.0)	4 (36.4)	5 (33.3)	8 (38.1)
>=6	0	0	2 (18.2)	2 (13.3)	2 (9.5)
n	5	4	11	15	21
Mean (StdDev)	4.2 (1.10)	2.3 (2.22)	3.6 (1.69)	3.3 (1.87)	3.4 (1.77)
Median	5.0	2.0	4.0	3.0	3.0
Min, Max	3, 5	0, 5	2, 7	0, 7	0, 7

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=4)	300 mg (N=11)	200+300 mg (N=15)	All Doses (N=21)
Spleen Volume (mL) by Central Radiologic Review					
n	5	4	11	15	21
Mean (StdDev)	1228.63 (359.433)	1249.64 (781.938)	1429.98 (525.371)	1381.89 (578.781)	1303.99 (545.560)
Median	1190.55	1261.68	1438.50	1438.50	1264.60
Min, Max	819.0, 1626.6	523.5, 1951.7	591.3, 2300.1	523.5, 2300.1	512.4, 2300.1
Spleen Palpation (n (%))					
Not Palpable	0	2 (50.0)	1 (9.1)	3 (20.0)	3 (14.3)
Palpable <5cm	2 (40.0)	0	2 (18.2)	2 (13.3)	5 (23.8)
Palpable =5cm	2 (40.0)	0	1 (9.1)	1 (6.7)	3 (14.3)
Palpable >5cm	1 (20.0)	2 (50.0)	7 (63.6)	9 (60.0)	10 (47.6)
n	5	4	11	15	21
Mean (StdDev)	4.4 (1.34)	6.8 (8.30)	9.6 (6.81)	8.8 (7.04)	7.5 (6.31)
Median	5.0	5.0	11.0	10.0	5.0
Min, Max	3, 6	0, 17	0, 24	0, 24	0, 24

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=4)	300 mg (N=11)	200+300 mg (N=15)	All Doses (N=21)
Liver Volume (mL) by Central Radiologic Review					
n	5	4	11	15	21
Mean (StdDev)	2397.90 (379.747)	2735.38 (507.415)	2618.81 (415.301)	2649.90 (425.694)	2609.41 (422.188)
Median	2395.62	2726.35	2576.97	2576.97	2551.96
Min, Max	1898.2, 2924.0	2262.8, 3226.0	2069.2, 3520.9	2069.2, 3520.9	1898.2, 3520.9
Liver Palpation (n (%))					
Not Palpable	3 (60.0)	3 (75.0)	4 (36.4)	7 (46.7)	11 (52.4)
Palpable	2 (40.0)	1 (25.0)	7 (63.6)	8 (53.3)	10 (47.6)
ALB (g/L)					
n	5	4	11	15	21
Mean (StdDev)	37.8 (4.09)	36.3 (5.32)	36.1 (6.01)	36.1 (5.64)	37.0 (5.44)
Median	40.0	34.5	37.0	35.0	37.0
Min, Max	32, 41	32, 44	28, 47	28, 47	28, 47
CTCAE Grade (n (%))					
0	3 (60.0)	1 (25.0)	6 (54.5)	7 (46.7)	11 (52.4)
1	2 (40.0)	3 (75.0)	3 (27.3)	6 (40.0)	8 (38.1)
2	0	0	2 (18.2)	2 (13.3)	2 (9.5)
3	0	0	0	0	0
4	0	0	0	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=4)	300 mg (N=11)	200+300 mg (N=15)	All Doses (N=21)
ANC (x 10^9/L)					
n	5	4	11	15	21
Mean (StdDev)	8.852 (7.887)	7.100 (6.674)	7.147 (5.368)	7.135 (5.489)	7.418 (5.876)
Median	5.800	6.090	5.460	5.460	5.460
Min, Max	1.48, 20.20	0.82, 15.40	0.60, 16.94	0.60, 16.94	0.60, 20.20
CTCAE Grade (n (%))					
0	4 (80.0)	3 (75.0)	9 (81.8)	12 (80.0)	17 (81.0)
1	0	0	0	0	0
2	1 (20.0)	0	1 (9.1)	1 (6.7)	2 (9.5)
3	0	1 (25.0)	1 (9.1)	2 (13.3)	2 (9.5)
4	0	0	0	0	0
HGB (g/L)					
n	5	4	11	15	21
Mean (StdDev)	109.2 (17.05)	110.8 (16.66)	103.0 (10.95)	105.1 (12.56)	109.0 (18.66)
Median	108.0	111.0	104.0	105.0	107.0
Min, Max	83, 128	91, 130	84, 118	84, 130	83, 167
CTCAE Grade (n (%))					
0	0	2 (50.0)	1 (9.1)	3 (20.0)	4 (19.0)
1	4 (80.0)	1 (25.0)	7 (63.6)	8 (53.3)	12 (57.1)
2	1 (20.0)	1 (25.0)	3 (27.3)	4 (26.7)	5 (23.8)
3	0	0	0	0	0
4	0	0	0	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=4)	300 mg (N=11)	200+300 mg (N=15)	All Doses (N=21)
PLT (x 10^9/L)					
n	5	4	11	15	21
Mean (StdDev)	110.8 (74.48)	223.3 (256.65)	73.9 (39.14)	113.7 (141.00)	115.1 (122.97)
Median	82.0	114.5	70.0	72.0	81.0
Min, Max	62, 243	58, 606	32, 151	32, 606	32, 606
CTCAE Grade (n (%))					
0	1 (20.0)	1 (25.0)	1 (9.1)	2 (13.3)	4 (19.0)
1	3 (60.0)	2 (50.0)	2 (18.2)	4 (26.7)	7 (33.3)
2	1 (20.0)	1 (25.0)	4 (36.4)	5 (33.3)	6 (28.6)
3	0	0	4 (36.4)	4 (26.7)	4 (19.0)
4	0	0	0	0	0
Monocytes (x 10^9/L)					
n	5	4	11	15	21
Mean (StdDev)	2.832 (2.493)	1.665 (1.089)	2.483 (2.779)	2.265 (2.431)	2.316 (2.369)
Median	1.910	2.000	2.130	2.130	1.910
Min, Max	0.50, 7.00	0.12, 2.54	0.20, 9.86	0.12, 9.86	0.12, 9.86

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=4)	300 mg (N=11)	200+300 mg (N=15)	All Doses (N=21)
Direct Bilirubin (umol/L)					
n	5	4	11	15	20
Mean (StdDev)	4.650 (3.117)	6.453 (5.410)	7.673 (9.260)	7.347 (8.236)	6.673 (7.311)
Median	4.200	5.125	5.130	5.130	5.130
Min, Max	0.66, 8.55	1.71, 13.85	0.91, 35.00	0.91, 35.00	0.66, 35.00
CTCAE Grade (n (%))					
0	2 (40.0)	1 (25.0)	7 (63.6)	8 (53.3)	10 (50.0)
1	2 (40.0)	1 (25.0)	3 (27.3)	4 (26.7)	6 (30.0)
2	1 (20.0)	1 (25.0)	0	1 (6.7)	2 (10.0)
3	0	1 (25.0)	1 (9.1)	2 (13.3)	2 (10.0)
4	0	0	0	0	0
ALT (U/L)					
n	5	4	11	15	21
Mean (StdDev)	17.4 (6.66)	19.5 (12.71)	32.6 (21.69)	29.1 (20.17)	26.7 (18.03)
Median	18.0	18.5	25.0	25.0	22.0
Min, Max	9, 26	5, 36	3, 78	3, 78	3, 78
CTCAE Grade (n (%))					
0	5 (100)	4 (100)	9 (81.8)	13 (86.7)	19 (90.5)
1	0	0	2 (18.2)	2 (13.3)	2 (9.5)
2	0	0	0	0	0
3	0	0	0	0	0
4	0	0	0	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=4)	300 mg (N=11)	200+300 mg (N=15)	All Doses (N=21)
AST (U/L)					
n	5	4	11	15	21
Mean (StdDev)	16.6 (5.77)	15.5 (7.14)	22.5 (10.69)	20.6 (10.13)	19.5 (9.04)
Median	14.0	18.5	21.0	20.0	20.0
Min, Max	11, 25	5, 20	5, 44	5, 44	5, 44
CTCAE Grade (n (%))					
0	5 (100)	4 (100)	9 (81.8)	13 (86.7)	19 (90.5)
1	0	0	2 (18.2)	2 (13.3)	2 (9.5)
2	0	0	0	0	0
3	0	0	0	0	0
4	0	0	0	0	0
ALP (U/L)					
n	5	4	11	15	21
Mean (StdDev)	280.8 (93.64)	446.0 (340.97)	488.5 (292.73)	477.1 (294.10)	411.6 (274.28)
Median	327.0	452.5	493.0	493.0	341.0
Min, Max	139, 364	68, 811	99, 1073	68, 1073	68, 1073
CTCAE Grade (n (%))					
0	0	1 (25.0)	1 (9.1)	2 (13.3)	3 (14.3)
1	2 (40.0)	1 (25.0)	2 (18.2)	3 (20.0)	5 (23.8)
2	3 (60.0)	1 (25.0)	5 (45.5)	6 (40.0)	9 (42.9)
3	0	1 (25.0)	3 (27.3)	4 (26.7)	4 (19.0)
4	0	0	0	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=4)	300 mg (N=11)	200+300 mg (N=15)	All Doses (N=21)
Serum Tryptase (ng/mL) from Central Assay					
n	5	4	11	15	21
Mean (StdDev)	340.38 (263.975)	354.10 (222.960)	235.90 (211.836)	267.42 (213.619)	279.80 (218.174)
Median	182.40	330.40	155.80	173.30	173.30
Min, Max	102.4, 684.8	126.2, 629.4	48.2, 765.3	48.2, 765.3	48.2, 765.3
<11.4 ng/mL	0	0	0	0	0
>=11.4 and <20 ng/mL	0	0	0	0	0
>=20 and <40 ng/mL	0	0	0	0	0
>=40 and <200 ng/mL	3 (60.0)	1 (25.0)	8 (72.7)	9 (60.0)	13 (61.9)
>=200 ng/mL	2 (40.0)	3 (75.0)	3 (27.3)	6 (40.0)	8 (38.1)
BM MC (%) by Central Pathology Review					
n	5	4	11	15	21
Mean (StdDev)	45.0 (18.71)	65.0 (23.80)	41.8 (24.42)	48.0 (25.69)	48.8 (24.18)
Median	50.0	75.0	30.0	40.0	50.0
Min, Max	15, 60	30, 80	10, 80	10, 80	10, 80
KIT D816V MAF (%) from Blood					
n	5	4	11	15	20
Mean (StdDev)	9.954 (13.735)	24.063 (14.308)	24.525 (15.367)	24.401 (14.580)	20.790 (15.413)
Median	4.430	23.050	22.600	22.600	18.650
Min, Max	0.56, 33.70	8.45, 41.70	0.03, 45.30	0.03, 45.30	0.03, 45.30
<0.17%	0	0	1 (9.1)	1 (6.7)	1 (5.0)
>=0.17% and <1%	1 (20.0)	0	0	0	1 (5.0)
>=1%	4 (80.0)	4 (100)	10 (90.9)	14 (93.3)	18 (90.0)

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=4)	300 mg (N=11)	200+300 mg (N=15)	All Doses (N=21)
SM Related Organ Damages					
Ascites and Pleural Effusions					
Ascites					
No	3 (60.0)	4 (100)	8 (72.7)	12 (80.0)	16 (76.2)
Grade 1	0	0	2 (18.2)	2 (13.3)	2 (9.5)
Grade 2	2 (40.0)	0	1 (9.1)	1 (6.7)	3 (14.3)
Grade 3	0	0	0	0	0
Pleural Effusions					
No	4 (80.0)	3 (75.0)	9 (81.8)	12 (80.0)	17 (81.0)
Grade 1	0	0	2 (18.2)	2 (13.3)	2 (9.5)
Grade 2	1 (20.0)	0	0	0	1 (4.8)
Grade 3	0	1 (25.0)	0	1 (6.7)	1 (4.8)

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=4)	300 mg (N=11)	200+300 mg (N=15)	All Doses (N=21)
SM Related Organ Damages Continued					
Liver Function Abnormalities					
Other Cause for Abnormal Liver Function not Related to SM					
Yes	0	0	0	0	0
No	5 (100)	4 (100)	11 (100)	15 (100)	21 (100)
Unknown	0	0	0	0	0
Clinical-relevant Portal Hypertension					
Yes	0	0	0	0	0
No	5 (100)	4 (100)	10 (90.9)	14 (93.3)	20 (95.2)
Unknown	0	0	1 (9.1)	1 (6.7)	1 (4.8)
Biopsy-proven Liver MC Infiltration					
Yes	0	1 (25.0)	2 (18.2)	3 (20.0)	3 (14.3)
No	5 (100)	3 (75.0)	7 (63.6)	10 (66.7)	16 (76.2)
Unknown	0	0	2 (18.2)	2 (13.3)	2 (9.5)

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)	
	200 mg (N=22)	All Doses (N=23)
Mutation Status (n (%))		
KIT Exon 17 Mutation by Central Assay		
Positive	20 (90.9)	21 (91.3)
Negative	2 (9.1)	2 (8.7)
SRSF2/ASXL1/RUNX1 Mutation (S/A/R) by Central Assay		
Positive	10 (45.5)	10 (43.5)
Negative	12 (54.5)	13 (56.5)
Number of Co-Mutations by Central Assay		
0	1 (4.5)	1 (4.3)
1	0	0
2-3	8 (36.4)	9 (39.1)
4-5	9 (40.9)	9 (39.1)
>=6	4 (18.2)	4 (17.4)
n	22	23
Mean (StdDev)	3.8 (1.88)	3.7 (1.87)
Median	4.0	4.0
Min, Max	0, 7	0, 7

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)	
	200 mg (N=22)	All Doses (N=23)
Spleen Volume (mL) by Central Radiologic Review		
n	22	23
Mean (StdDev)	991.73 (524.505)	998.85 (513.581)
Median	766.96	781.57
Min, Max	367.4, 2270.0	367.4, 2270.0
Spleen Palpation (n (%))		
Not Palpable	10 (45.5)	10 (43.5)
Palpable <5cm	4 (18.2)	5 (21.7)
Palpable =5cm	0	0
Palpable >5cm	8 (36.4)	8 (34.8)
n	22	23
Mean (StdDev)	4.0 (4.62)	3.8 (4.54)
Median	3.0	3.0
Min, Max	0, 13	0, 13

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)	
	200 mg (N=22)	All Doses (N=23)
Liver Volume (mL) by Central Radiologic Review		
n	22	23
Mean (StdDev)	2538.34 (478.619)	2571.94 (494.600)
Median	2506.97	2516.74
Min, Max	1707.4, 3361.1	1707.4, 3361.1
Liver Palpation (n (%))		
Not Palpable	9 (40.9)	9 (39.1)
Palpable	13 (59.1)	14 (60.9)
ALB (g/L)		
n	22	23
Mean (StdDev)	36.4 (6.23)	35.4 (7.84)
Median	37.0	37.0
Min, Max	23, 49	13, 49
CTCAE Grade (n (%))		
0	16 (72.7)	16 (69.6)
1	3 (13.6)	3 (13.0)
2	3 (13.6)	3 (13.0)
3	0	1 (4.3)
4	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)	
	200 mg (N=22)	All Doses (N=23)
ANC (x 10^9/L)		
n	21	22
Mean (StdDev)	7.130 (6.552)	7.139 (6.394)
Median	5.560	5.930
Min, Max	1.20, 31.52	1.20, 31.52
CTCAE Grade (n (%))		
0	18 (85.7)	19 (86.4)
1	1 (4.8)	1 (4.5)
2	2 (9.5)	2 (9.1)
3	0	0
4	0	0
HGB (g/L)		
n	22	23
Mean (StdDev)	100.1 (16.40)	99.1 (16.73)
Median	99.0	96.0
Min, Max	68, 129	68, 129
CTCAE Grade (n (%))		
0	2 (9.1)	2 (8.7)
1	9 (40.9)	9 (39.1)
2	9 (40.9)	9 (39.1)
3	2 (9.1)	3 (13.0)
4	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)	
	200 mg (N=22)	All Doses (N=23)
PLT (x 10^9/L)		
n	22	23
Mean (StdDev)	138.8 (92.87)	134.0 (93.63)
Median	119.0	92.0
Min, Max	28, 324	28, 324
CTCAE Grade (n (%))		
0	10 (45.5)	10 (43.5)
1	6 (27.3)	6 (26.1)
2	3 (13.6)	3 (13.0)
3	3 (13.6)	4 (17.4)
4	0	0
Monocytes (x 10^9/L)		
n	21	22
Mean (StdDev)	1.579 (1.533)	1.569 (1.497)
Median	1.000	1.120
Min, Max	0.22, 5.14	0.22, 5.14

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)	
	200 mg (N=22)	All Doses (N=23)
Direct Bilirubin (umol/L)		
n	18	18
Mean (StdDev)	5.743 (2.651)	5.743 (2.651)
Median	4.866	4.866
Min, Max	3.40, 10.26	3.40, 10.26
CTCAE Grade (n (%))		
0	11 (61.1)	11 (61.1)
1	5 (27.8)	5 (27.8)
2	2 (11.1)	2 (11.1)
3	0	0
4	0	0
ALT (U/L)		
n	22	23
Mean (StdDev)	19.2 (13.05)	18.9 (12.84)
Median	15.0	15.0
Min, Max	5, 53	5, 53
CTCAE Grade (n (%))		
0	22 (100)	23 (100)
1	0	0
2	0	0
3	0	0
4	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)	
	200 mg (N=22)	All Doses (N=23)
AST (U/L)		
n	22	23
Mean (StdDev)	13.7 (7.55)	13.7 (7.38)
Median	11.0	11.0
Min, Max	6, 35	6, 35
CTCAE Grade (n (%))		
0	22 (100)	23 (100)
1	0	0
2	0	0
3	0	0
4	0	0
ALP (U/L)		
n	22	23
Mean (StdDev)	217.9 (142.63)	228.1 (147.66)
Median	186.7	196.4
Min, Max	61, 625	61, 625
CTCAE Grade (n (%))		
0	7 (31.8)	7 (30.4)
1	8 (36.4)	8 (34.8)
2	6 (27.3)	7 (30.4)
3	1 (4.5)	1 (4.3)
4	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)	
	200 mg (N=22)	All Doses (N=23)
Serum Tryptase (ng/mL) from Central Assay		
n	22	23
Mean (StdDev)	440.62 (338.680)	491.03 (409.795)
Median	348.00	362.00
Min, Max	23.8, 1600.0	23.8, 1600.0
<11.4 ng/mL	0	0
>=11.4 and <20 ng/mL	0	0
>=20 and <40 ng/mL	1 (4.5)	1 (4.3)
>=40 and <200 ng/mL	4 (18.2)	4 (17.4)
>=200 ng/mL	17 (77.3)	18 (78.3)
BM MC (%) by Central Pathology Review		
n	22	23
Mean (StdDev)	55.9 (28.56)	55.2 (28.10)
Median	65.0	60.0
Min, Max	10, 95	10, 95
KIT D816V MAF (%) from Blood		
n	22	23
Mean (StdDev)	22.644 (17.886)	23.277 (17.737)
Median	25.650	26.160
Min, Max	0.00, 45.25	0.00, 45.25
<0.17%	3 (13.6)	3 (13.0)
>=0.17% and <1%	1 (4.5)	1 (4.3)
>=1%	18 (81.8)	19 (82.6)

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)	
	200 mg (N=22)	All Doses (N=23)
SM Related Organ Damages		
Ascites and Pleural Effusions		
Ascites		
No	13 (65.0)	13 (65.0)
Grade 1	0	0
Grade 2	6 (30.0)	6 (30.0)
Grade 3	1 (5.0)	1 (5.0)
Missing	2	3
Pleural Effusions		
No	15 (75.0)	15 (75.0)
Grade 1	2 (10.0)	2 (10.0)
Grade 2	3 (15.0)	3 (15.0)
Grade 3	0	0
Missing	2	3

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)	
	200 mg (N=22)	All Doses (N=23)
SM Related Organ Damages Continued		
Liver Function Abnormalities		
Other Cause for Abnormal Liver Function not Related to SM		
Yes	5 (83.3)	5 (83.3)
No	1 (16.7)	1 (16.7)
Missing	16	17
Clinical-relevant Portal Hypertension		
Yes	2 (28.6)	2 (28.6)
No	5 (71.4)	5 (71.4)
Missing	15	16
Biopsy-proven Liver MC Infiltration		
Yes	1 (16.7)	2 (28.6)
No	5 (83.3)	5 (71.4)
Missing	16	16

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)	
	200 mg (N=9)	All Doses (N=9)
Mutation Status (n (%))		
KIT Exon 17 Mutation by Central Assay		
Positive	9 (100)	9 (100)
Negative	0	0
SRSF2/ASXL1/RUNX1 Mutation (S/A/R) by Central Assay		
Positive	7 (77.8)	7 (77.8)
Negative	2 (22.2)	2 (22.2)
Number of Co-Mutations by Central Assay		
0	0	0
1	0	0
2-3	2 (22.2)	2 (22.2)
4-5	4 (44.4)	4 (44.4)
>=6	3 (33.3)	3 (33.3)
n	9	9
Mean (StdDev)	4.7 (1.80)	4.7 (1.80)
Median	4.0	4.0
Min, Max	2, 8	2, 8

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-assess-rac-tpy.sasDate: 19:23/02NOV2020

Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)	
	200 mg (N=9)	All Doses (N=9)
Spleen Volume (mL) by Central Radiologic Review		
n	9	9
Mean (StdDev)	838.38 (408.727)	838.38 (408.727)
Median	962.55	962.55
Min, Max	149.8, 1396.3	149.8, 1396.3
Spleen Palpation (n (%))		
Not Palpable	3 (33.3)	3 (33.3)
Palpable <5cm	0	0
Palpable =5cm	1 (11.1)	1 (11.1)
Palpable >5cm	5 (55.6)	5 (55.6)
n	9	9
Mean (StdDev)	4.7 (3.77)	4.7 (3.77)
Median	6.0	6.0
Min, Max	0, 10	0, 10

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)	
	200 mg (N=9)	All Doses (N=9)
Liver Volume (mL) by Central Radiologic Review		
n	9	9
Mean (StdDev)	1992.98 (338.395)	1992.98 (338.395)
Median	1983.15	1983.15
Min, Max	1334.5, 2571.5	1334.5, 2571.5
Liver Palpation (n (%))		
Not Palpable	7 (77.8)	7 (77.8)
Palpable	2 (22.2)	2 (22.2)
ALB (g/L)		
n	9	9
Mean (StdDev)	41.5 (6.07)	41.5 (6.07)
Median	40.0	40.0
Min, Max	32, 50	32, 50
CTCAE Grade (n (%))		
0	8 (88.9)	8 (88.9)
1	1 (11.1)	1 (11.1)
2	0	0
3	0	0
4	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)	
	200 mg (N=9)	All Doses (N=9)
ANC (x 10^9/L)		
n	9	9
Mean (StdDev)	3.211 (3.245)	3.211 (3.245)
Median	2.200	2.200
Min, Max	0.49, 11.19	0.49, 11.19
CTCAE Grade (n (%))		
0	5 (55.6)	5 (55.6)
1	1 (11.1)	1 (11.1)
2	1 (11.1)	1 (11.1)
3	1 (11.1)	1 (11.1)
4	1 (11.1)	1 (11.1)
HGB (g/L)		
n	9	9
Mean (StdDev)	108.4 (18.25)	108.4 (18.25)
Median	111.0	111.0
Min, Max	85, 133	85, 133
CTCAE Grade (n (%))		
0	4 (44.4)	4 (44.4)
1	1 (11.1)	1 (11.1)
2	4 (44.4)	4 (44.4)
3	0	0
4	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)	
	200 mg (N=9)	All Doses (N=9)
PLT (x 10^9/L)		
n	9	9
Mean (StdDev)	177.2 (76.00)	177.2 (76.00)
Median	153.0	153.0
Min, Max	72, 316	72, 316
CTCAE Grade (n (%))		
0	5 (55.6)	5 (55.6)
1	3 (33.3)	3 (33.3)
2	1 (11.1)	1 (11.1)
3	0	0
4	0	0
Monocytes (x 10^9/L)		
n	9	9
Mean (StdDev)	1.902 (1.735)	1.902 (1.735)
Median	1.100	1.100
Min, Max	0.25, 5.69	0.25, 5.69

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)	
	200 mg (N=9)	All Doses (N=9)
Direct Bilirubin (umol/L)		
n	9	9
Mean (StdDev)	5.862 (5.642)	5.862 (5.642)
Median	4.000	4.000
Min, Max	1.71, 20.53	1.71, 20.53
CTCAE Grade (n (%))		
0	7 (77.8)	7 (77.8)
1	1 (11.1)	1 (11.1)
2	1 (11.1)	1 (11.1)
3	0	0
4	0	0
ALT (U/L)		
n	9	9
Mean (StdDev)	15.7 (11.83)	15.7 (11.83)
Median	13.0	13.0
Min, Max	6, 45	6, 45
CTCAE Grade (n (%))		
0	8 (88.9)	8 (88.9)
1	1 (11.1)	1 (11.1)
2	0	0
3	0	0
4	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)	
	200 mg (N=9)	All Doses (N=9)
AST (U/L)		
n	9	9
Mean (StdDev)	15.7 (8.97)	15.7 (8.97)
Median	14.0	14.0
Min, Max	8, 38	8, 38
CTCAE Grade (n (%))		
0	9 (100)	9 (100)
1	0	0
2	0	0
3	0	0
4	0	0
ALP (U/L)		
n	9	9
Mean (StdDev)	427.7 (277.56)	427.7 (277.56)
Median	399.0	399.0
Min, Max	89, 903	89, 903
CTCAE Grade (n (%))		
0	1 (11.1)	1 (11.1)
1	3 (33.3)	3 (33.3)
2	3 (33.3)	3 (33.3)
3	2 (22.2)	2 (22.2)
4	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)	
	200 mg (N=9)	All Doses (N=9)
Serum Tryptase (ng/mL) from Central Assay		
n	9	9
Mean (StdDev)	143.52 (84.993)	143.52 (84.993)
Median	132.00	132.00
Min, Max	37.3, 316.0	37.3, 316.0
<11.4 ng/mL	0	0
>=11.4 and <20 ng/mL	0	0
>=20 and <40 ng/mL	1 (11.1)	1 (11.1)
>=40 and <200 ng/mL	6 (66.7)	6 (66.7)
>=200 ng/mL	2 (22.2)	2 (22.2)
BM MC (%) by Central Pathology Review		
n	9	9
Mean (StdDev)	39.4 (24.42)	39.4 (24.42)
Median	30.0	30.0
Min, Max	10, 80	10, 80
KIT D816V MAF (%) from Blood		
n	9	9
Mean (StdDev)	10.333 (9.919)	10.333 (9.919)
Median	7.790	7.790
Min, Max	0.02, 26.10	0.02, 26.10
<0.17%	2 (22.2)	2 (22.2)
>=0.17% and <1%	0	0
>=1%	7 (77.8)	7 (77.8)

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)	
	200 mg (N=9)	All Doses (N=9)
SM Related Organ Damages		
Ascites and Pleural Effusions		
Ascites		
No	7 (77.8)	7 (77.8)
Grade 1	0	0
Grade 2	1 (11.1)	1 (11.1)
Grade 3	1 (11.1)	1 (11.1)
Pleural Effusions		
No	7 (77.8)	7 (77.8)
Grade 1	0	0
Grade 2	1 (11.1)	1 (11.1)
Grade 3	1 (11.1)	1 (11.1)

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)	
	200 mg (N=9)	All Doses (N=9)
SM Related Organ Damages Continued		
Liver Function Abnormalities		
Other Cause for Abnormal Liver Function not Related to SM		
Yes	1 (20.0)	1 (20.0)
No	4 (80.0)	4 (80.0)
Missing	4	4
Clinical-relevant Portal Hypertension		
Yes	0	0
No	5 (100)	5 (100)
Missing	4	4
Biopsy-proven Liver MC Infiltration		
Yes	0	0
No	5 (100)	5 (100)
Missing	4	4

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=4)	200 mg (N=31)	300 mg (N=16)	200+300 mg (N=47)	All Doses (N=55)
Mutation Status (n (%))					
KIT Exon 17 Mutation by Central Assay					
Positive	4 (100)	28 (90.3)	15 (93.8)	43 (91.5)	51 (92.7)
Negative	0	3 (9.7)	1 (6.3)	4 (8.5)	4 (7.3)
SRSF2/ASXL1/RUNX1 Mutation (S/A/R) by Central Assay					
Positive	1 (25.0)	13 (41.9)	5 (31.3)	18 (38.3)	22 (40.0)
Negative	3 (75.0)	18 (58.1)	11 (68.8)	29 (61.7)	33 (60.0)
Number of Co-Mutations by Central Assay					
0	0	2 (6.5)	2 (12.5)	4 (8.5)	4 (7.3)
1	1 (25.0)	2 (6.5)	3 (18.8)	5 (10.6)	6 (10.9)
2-3	2 (50.0)	10 (32.3)	5 (31.3)	15 (31.9)	18 (32.7)
4-5	0	12 (38.7)	5 (31.3)	17 (36.2)	20 (36.4)
>=6	1 (25.0)	5 (16.1)	1 (6.3)	6 (12.8)	7 (12.7)
n	4	31	16	47	55
Mean (StdDev)	3.0 (2.16)	3.5 (1.95)	2.9 (1.96)	3.3 (1.96)	3.3 (1.89)
Median	2.5	4.0	3.0	3.0	3.0
Min, Max	1, 6	0, 7	0, 6	0, 7	0, 7

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=4)	200 mg (N=31)	300 mg (N=16)	200+300 mg (N=47)	All Doses (N=55)
Spleen Volume (mL) by Central Radiologic Review					
n	4	31	15	46	54
Mean (StdDev)	877.11 (454.376)	945.87 (472.293)	1156.25 (611.011)	1014.48 (524.212)	1007.59 (516.395)
Median	868.13	781.57	1120.69	933.74	933.74
Min, Max	409.6, 1362.5	298.5, 2270.0	257.8, 2262.7	257.8, 2270.0	257.8, 2270.0
Spleen Palpation (n (%))					
Not Palpable	2 (50.0)	16 (53.3)	5 (31.3)	21 (45.7)	25 (46.3)
Palpable <5cm	1 (25.0)	4 (13.3)	1 (6.3)	5 (10.9)	6 (11.1)
Palpable =5cm	0	0	2 (12.5)	2 (4.3)	2 (3.7)
Palpable >5cm	1 (25.0)	10 (33.3)	8 (50.0)	18 (39.1)	21 (38.9)
Missing	0	1	0	1	1
n	4	30	16	46	54
Mean (StdDev)	2.4 (3.82)	3.4 (4.40)	6.2 (5.85)	4.4 (5.07)	4.3 (5.07)
Median	0.8	0.0	5.5	3.0	2.5
Min, Max	0, 8	0, 13	0, 18	0, 18	0, 18

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=4)	200 mg (N=31)	300 mg (N=16)	200+300 mg (N=47)	All Doses (N=55)
Liver Volume (mL) by Central Radiologic Review					
n	4	31	16	47	55
Mean (StdDev)	2345.67 (774.362)	2519.78 (478.305)	2316.96 (591.508)	2450.73 (522.237)	2466.84 (535.998)
Median	2317.88	2497.20	2318.58	2423.43	2424.89
Min, Max	1435.8, 3311.1	1707.4, 3437.5	1436.4, 3624.1	1436.4, 3624.1	1435.8, 3624.1
Liver Palpation (n (%))					
Not Palpable	3 (75.0)	14 (46.7)	8 (50.0)	22 (47.8)	27 (50.0)
Palpable	1 (25.0)	16 (53.3)	8 (50.0)	24 (52.2)	27 (50.0)
Missing	0	1	0	1	1
ALB (g/L)					
n	4	31	16	47	55
Mean (StdDev)	31.7 (14.31)	37.6 (5.88)	37.1 (6.54)	37.5 (6.05)	37.1 (6.95)
Median	34.5	38.0	40.5	38.0	38.0
Min, Max	13, 45	23, 49	23, 45	23, 49	13, 49
CTCAE Grade (n (%))					
0	2 (50.0)	24 (77.4)	12 (75.0)	36 (76.6)	41 (74.5)
1	0	4 (12.9)	1 (6.3)	5 (10.6)	5 (9.1)
2	1 (25.0)	3 (9.7)	3 (18.8)	6 (12.8)	8 (14.5)
3	1 (25.0)	0	0	0	1 (1.8)
4	0	0	0	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=4)	200 mg (N=31)	300 mg (N=16)	200+300 mg (N=47)	All Doses (N=55)
ANC (x 10^9/L)					
n	4	30	16	46	54
Mean (StdDev)	5.708 (1.165)	6.869 (5.949)	10.284 (8.697)	8.057 (7.122)	7.892 (7.071)
Median	5.455	5.920	7.245	6.290	5.630
Min, Max	4.60, 7.32	0.88, 31.52	1.20, 27.08	0.88, 31.52	0.88, 31.52
CTCAE Grade (n (%))					
0	4 (100)	26 (86.7)	15 (93.8)	41 (89.1)	48 (88.9)
1	0	1 (3.3)	0	1 (2.2)	1 (1.9)
2	0	2 (6.7)	1 (6.3)	3 (6.5)	4 (7.4)
3	0	1 (3.3)	0	1 (2.2)	1 (1.9)
4	0	0	0	0	0
HGB (g/L)					
n	4	31	16	47	55
Mean (StdDev)	110.3 (23.99)	103.4 (16.45)	104.8 (23.52)	103.9 (18.90)	104.3 (18.72)
Median	116.5	102.0	101.5	102.0	103.0
Min, Max	77, 131	68, 132	80, 169	68, 169	68, 169
CTCAE Grade (n (%))					
0	2 (50.0)	3 (9.7)	2 (12.5)	5 (10.6)	7 (12.7)
1	1 (25.0)	15 (48.4)	6 (37.5)	21 (44.7)	24 (43.6)
2	0	11 (35.5)	8 (50.0)	19 (40.4)	21 (38.2)
3	1 (25.0)	2 (6.5)	0	2 (4.3)	3 (5.5)
4	0	0	0	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=4)	200 mg (N=31)	300 mg (N=16)	200+300 mg (N=47)	All Doses (N=55)
PLT (x 10^9/L)					
n	4	31	16	47	55
Mean (StdDev)	172.5 (158.22)	135.2 (88.18)	203.4 (139.99)	158.4 (111.93)	159.2 (114.26)
Median	133.0	123.0	167.5	134.0	134.0
Min, Max	28, 396	28, 324	55, 504	28, 504	28, 504
CTCAE Grade (n (%))					
0	2 (50.0)	13 (41.9)	8 (50.0)	21 (44.7)	25 (45.5)
1	1 (25.0)	8 (25.8)	3 (18.8)	11 (23.4)	12 (21.8)
2	0	6 (19.4)	5 (31.3)	11 (23.4)	11 (20.0)
3	1 (25.0)	4 (12.9)	0	4 (8.5)	7 (12.7)
4	0	0	0	0	0
Monocytes (x 10^9/L)					
n	4	30	16	46	54
Mean (StdDev)	1.110 (0.655)	1.432 (1.368)	2.808 (3.211)	1.910 (2.255)	1.831 (2.141)
Median	1.070	1.000	1.640	1.100	1.005
Min, Max	0.40, 1.90	0.20, 5.14	0.06, 9.08	0.06, 9.08	0.06, 9.08

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=4)	200 mg (N=31)	300 mg (N=16)	200+300 mg (N=47)	All Doses (N=55)
Direct Bilirubin (umol/L)					
n	2	27	16	43	49
Mean (StdDev)	3.420 (0.000)	5.138 (2.964)	3.885 (2.420)	4.672 (2.812)	4.763 (2.764)
Median	3.420	4.275	3.210	4.000	4.000
Min, Max	3.42, 3.42	0.66, 11.97	0.00, 6.84	0.00, 11.97	0.00, 11.97
CTCAE Grade (n (%))					
0	2 (100)	17 (63.0)	14 (87.5)	31 (72.1)	35 (71.4)
1	0	7 (25.9)	2 (12.5)	9 (20.9)	10 (20.4)
2	0	3 (11.1)	0	3 (7.0)	4 (8.2)
3	0	0	0	0	0
4	0	0	0	0	0
ALT (U/L)					
n	4	31	16	47	55
Mean (StdDev)	13.3 (2.75)	18.5 (11.83)	19.4 (12.18)	18.9 (11.83)	19.0 (11.40)
Median	13.5	15.0	16.5	15.0	15.0
Min, Max	10, 16	5, 53	5, 44	5, 53	5, 53
CTCAE Grade (n (%))					
0	4 (100)	31 (100)	16 (100)	47 (100)	55 (100)
1	0	0	0	0	0
2	0	0	0	0	0
3	0	0	0	0	0
4	0	0	0	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=4)	200 mg (N=31)	300 mg (N=16)	200+300 mg (N=47)	All Doses (N=55)
AST (U/L)					
n	4	31	16	47	55
Mean (StdDev)	12.8 (3.30)	13.9 (7.66)	16.4 (11.85)	14.8 (9.24)	15.1 (9.13)
Median	12.5	11.0	13.0	11.0	12.0
Min, Max	9, 17	6, 35	5, 54	5, 54	5, 54
CTCAE Grade (n (%))					
0	4 (100)	30 (96.8)	15 (93.8)	45 (95.7)	53 (96.4)
1	0	1 (3.2)	1 (6.3)	2 (4.3)	2 (3.6)
2	0	0	0	0	0
3	0	0	0	0	0
4	0	0	0	0	0
ALP (U/L)					
n	4	31	16	47	55
Mean (StdDev)	242.0 (191.42)	203.0 (138.01)	264.6 (404.02)	224.0 (257.91)	218.8 (244.50)
Median	224.5	177.0	152.0	157.0	156.0
Min, Max	67, 452	27, 625	59, 1747	27, 1747	27, 1747
CTCAE Grade (n (%))					
0	2 (50.0)	12 (38.7)	5 (31.3)	17 (36.2)	21 (38.2)
1	0	10 (32.3)	9 (56.3)	19 (40.4)	21 (38.2)
2	2 (50.0)	8 (25.8)	1 (6.3)	9 (19.1)	11 (20.0)
3	0	1 (3.2)	1 (6.3)	2 (4.3)	2 (3.6)
4	0	0	0	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=4)	200 mg (N=31)	300 mg (N=16)	200+300 mg (N=47)	All Doses (N=55)
Serum Tryptase (ng/mL) from Central Assay					
n	4	31	16	47	55
Mean (StdDev)	483.78 (748.573)	413.51 (320.033)	341.62 (195.027)	389.03 (283.523)	376.89 (324.759)
Median	141.25	334.00	377.95	362.00	316.00
Min, Max	52.6, 1600.0	23.8, 1600.0	21.2, 760.1	21.2, 1600.0	21.2, 1600.0
<11.4 ng/mL	0	0	0	0	0
>=11.4 and <20 ng/mL	0	0	0	0	0
>=20 and <40 ng/mL	0	1 (3.2)	1 (6.3)	2 (4.3)	3 (5.5)
>=40 and <200 ng/mL	2 (50.0)	8 (25.8)	3 (18.8)	11 (23.4)	16 (29.1)
>=200 ng/mL	2 (50.0)	22 (71.0)	12 (75.0)	34 (72.3)	36 (65.5)
BM MC (%) by Central Pathology Review					
n	4	30	13	43	51
Mean (StdDev)	23.8 (14.93)	53.7 (28.49)	64.6 (21.74)	57.0 (26.86)	53.5 (28.01)
Median	25.0	60.0	70.0	60.0	60.0
Min, Max	5, 40	10, 95	30, 95	10, 95	5, 95
KIT D816V MAF (%) from Blood					
n	3	31	16	47	54
Mean (StdDev)	28.853 (22.804)	20.792 (17.790)	25.181 (23.365)	22.286 (19.719)	22.228 (19.255)
Median	37.210	13.350	20.400	19.200	20.400
Min, Max	3.05, 46.30	0.00, 45.25	0.00, 80.10	0.00, 80.10	0.00, 80.10
<0.17%	0	5 (16.1)	4 (25.0)	9 (19.1)	9 (16.7)
>=0.17% and <1%	0	1 (3.2)	0	1 (2.1)	2 (3.7)
>=1%	3 (100)	25 (80.6)	12 (75.0)	37 (78.7)	43 (79.6)

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=4)	200 mg (N=31)	300 mg (N=16)	200+300 mg (N=47)	All Doses (N=55)
SM Related Organ Damages					
Ascites and Pleural Effusions					
Ascites					
No	2 (66.7)	19 (65.5)	10 (62.5)	29 (64.4)	33 (63.5)
Grade 1	0	1 (3.4)	2 (12.5)	3 (6.7)	4 (7.7)
Grade 2	0	7 (24.1)	2 (12.5)	9 (20.0)	9 (17.3)
Grade 3	1 (33.3)	2 (6.9)	2 (12.5)	4 (8.9)	6 (11.5)
Missing	1	2	0	2	3
Pleural Effusions					
No	3 (100)	23 (79.3)	13 (81.3)	36 (80.0)	42 (80.8)
Grade 1	0	2 (6.9)	3 (18.8)	5 (11.1)	6 (11.5)
Grade 2	0	4 (13.8)	0	4 (8.9)	4 (7.7)
Grade 3	0	0	0	0	0
Missing	1	2	0	2	3

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = Yes

	Starting Dose (QD)				
	<200 mg (N=4)	200 mg (N=31)	300 mg (N=16)	200+300 mg (N=47)	All Doses (N=55)
SM Related Organ Damages Continued					
Liver Function Abnormalities					
Other Cause for Abnormal Liver Function not Related to SM					
Yes	0	5 (33.3)	2 (12.5)	7 (22.6)	8 (21.1)
No	3 (100)	9 (60.0)	14 (87.5)	23 (74.2)	29 (76.3)
Unknown	0	1 (6.7)	0	1 (3.2)	1 (2.6)
Missing	1	16	0	16	17
Clinical-relevant Portal Hypertension					
Yes	0	2 (12.5)	2 (12.5)	4 (12.5)	5 (12.8)
No	3 (100)	14 (87.5)	14 (87.5)	28 (87.5)	34 (87.2)
Unknown	0	0	0	0	0
Missing	1	15	0	15	16
Biopsy-proven Liver MC Infiltration					
Yes	2 (50.0)	1 (6.7)	4 (25.0)	5 (16.1)	8 (20.5)
No	2 (50.0)	14 (93.3)	11 (68.8)	25 (80.6)	30 (76.9)
Unknown	0	0	1 (6.3)	1 (3.2)	1 (2.6)
Missing	0	16	0	16	16

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=13)	300 mg (N=11)	200+300 mg (N=24)	All Doses (N=30)
Mutation Status (n (%))					
KIT Exon 17 Mutation by Central Assay					
Positive	5 (100)	13 (100)	11 (100)	24 (100)	30 (100)
Negative	0	0	0	0	0
SRSF2/ASXL1/RUNX1 Mutation (S/A/R) by Central Assay					
Positive	3 (60.0)	9 (69.2)	10 (90.9)	19 (79.2)	22 (73.3)
Negative	2 (40.0)	4 (30.8)	1 (9.1)	5 (20.8)	8 (26.7)
Number of Co-Mutations by Central Assay					
0	0	1 (7.7)	0	1 (4.2)	1 (3.3)
1	0	1 (7.7)	0	1 (4.2)	2 (6.7)
2-3	2 (40.0)	3 (23.1)	5 (45.5)	8 (33.3)	10 (33.3)
4-5	3 (60.0)	5 (38.5)	4 (36.4)	9 (37.5)	12 (40.0)
>=6	0	3 (23.1)	2 (18.2)	5 (20.8)	5 (16.7)
n	5	13	11	24	30
Mean (StdDev)	4.2 (1.10)	3.9 (2.18)	3.6 (1.69)	3.8 (1.93)	3.8 (1.85)
Median	5.0	4.0	4.0	4.0	4.0
Min, Max	3, 5	0, 8	2, 7	0, 8	0, 8

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=13)	300 mg (N=11)	200+300 mg (N=24)	All Doses (N=30)
Spleen Volume (mL) by Central Radiologic Review					
n	5	13	11	24	30
Mean (StdDev)	1228.63 (359.433)	964.92 (550.690)	1429.98 (525.371)	1178.07 (578.150)	1164.31 (546.303)
Median	1190.55	962.55	1438.50	1122.65	1122.65
Min, Max	819.0, 1626.6	149.8, 1951.7	591.3, 2300.1	149.8, 2300.1	149.8, 2300.1
Spleen Palpation (n (%))					
Not Palpable	0	5 (38.5)	1 (9.1)	6 (25.0)	6 (20.0)
Palpable <5cm	2 (40.0)	0	2 (18.2)	2 (8.3)	5 (16.7)
Palpable =5cm	2 (40.0)	1 (7.7)	1 (9.1)	2 (8.3)	4 (13.3)
Palpable >5cm	1 (20.0)	7 (53.8)	7 (63.6)	14 (58.3)	15 (50.0)
n	5	13	11	24	30
Mean (StdDev)	4.4 (1.34)	5.3 (5.27)	9.6 (6.81)	7.3 (6.28)	6.7 (5.76)
Median	5.0	6.0	11.0	6.5	5.5
Min, Max	3, 6	0, 17	0, 24	0, 24	0, 24

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=13)	300 mg (N=11)	200+300 mg (N=24)	All Doses (N=30)
Liver Volume (mL) by Central Radiologic Review					
n	5	13	11	24	30
Mean (StdDev)	2397.90 (379.747)	2221.41 (517.591)	2618.81 (415.301)	2403.55 (505.643)	2424.48 (486.893)
Median	2395.62	2206.57	2576.97	2311.92	2364.72
Min, Max	1898.2, 2924.0	1334.5, 3226.0	2069.2, 3520.9	1334.5, 3520.9	1334.5, 3520.9
Liver Palpation (n (%))					
Not Palpable	3 (60.0)	10 (76.9)	4 (36.4)	14 (58.3)	18 (60.0)
Palpable	2 (40.0)	3 (23.1)	7 (63.6)	10 (41.7)	12 (40.0)
ALB (g/L)					
n	5	13	11	24	30
Mean (StdDev)	37.8 (4.09)	39.9 (6.15)	36.1 (6.01)	38.1 (6.26)	38.3 (5.91)
Median	40.0	38.0	37.0	38.0	38.0
Min, Max	32, 41	32, 50	28, 47	28, 50	28, 50
CTCAE Grade (n (%))					
0	3 (60.0)	9 (69.2)	6 (54.5)	15 (62.5)	19 (63.3)
1	2 (40.0)	4 (30.8)	3 (27.3)	7 (29.2)	9 (30.0)
2	0	0	2 (18.2)	2 (8.3)	2 (6.7)
3	0	0	0	0	0
4	0	0	0	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=13)	300 mg (N=11)	200+300 mg (N=24)	All Doses (N=30)
ANC (x 10^9/L)					
n	5	13	11	24	30
Mean (StdDev)	8.852 (7.887)	4.408 (4.653)	7.147 (5.368)	5.663 (5.076)	6.156 (5.529)
Median	5.800	2.680	5.460	3.615	4.050
Min, Max	1.48, 20.20	0.49, 15.40	0.60, 16.94	0.49, 16.94	0.49, 20.20
CTCAE Grade (n (%))					
0	4 (80.0)	8 (61.5)	9 (81.8)	17 (70.8)	22 (73.3)
1	0	1 (7.7)	0	1 (4.2)	1 (3.3)
2	1 (20.0)	1 (7.7)	1 (9.1)	2 (8.3)	3 (10.0)
3	0	2 (15.4)	1 (9.1)	3 (12.5)	3 (10.0)
4	0	1 (7.7)	0	1 (4.2)	1 (3.3)
HGB (g/L)					
n	5	13	11	24	30
Mean (StdDev)	109.2 (17.05)	109.2 (17.11)	103.0 (10.95)	106.3 (14.65)	108.8 (18.22)
Median	108.0	111.0	104.0	106.0	107.0
Min, Max	83, 128	85, 133	84, 118	84, 133	83, 167
CTCAE Grade (n (%))					
0	0	6 (46.2)	1 (9.1)	7 (29.2)	8 (26.7)
1	4 (80.0)	2 (15.4)	7 (63.6)	9 (37.5)	13 (43.3)
2	1 (20.0)	5 (38.5)	3 (27.3)	8 (33.3)	9 (30.0)
3	0	0	0	0	0
4	0	0	0	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=13)	300 mg (N=11)	200+300 mg (N=24)	All Doses (N=30)
PLT (x 10^9/L)					
n	5	13	11	24	30
Mean (StdDev)	110.8 (74.48)	191.4 (144.24)	73.9 (39.14)	137.5 (122.87)	133.7 (113.40)
Median	82.0	134.0	70.0	114.5	103.0
Min, Max	62, 243	58, 606	32, 151	32, 606	32, 606
CTCAE Grade (n (%))					
0	1 (20.0)	6 (46.2)	1 (9.1)	7 (29.2)	9 (30.0)
1	3 (60.0)	5 (38.5)	2 (18.2)	7 (29.2)	10 (33.3)
2	1 (20.0)	2 (15.4)	4 (36.4)	6 (25.0)	7 (23.3)
3	0	0	4 (36.4)	4 (16.7)	4 (13.3)
4	0	0	0	0	0
Monocytes (x 10^9/L)					
n	5	13	11	24	30
Mean (StdDev)	2.832 (2.493)	1.829 (1.522)	2.483 (2.779)	2.129 (2.163)	2.192 (2.177)
Median	1.910	1.600	2.130	1.650	1.725
Min, Max	0.50, 7.00	0.12, 5.69	0.20, 9.86	0.12, 9.86	0.12, 9.86

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
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Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=13)	300 mg (N=11)	200+300 mg (N=24)	All Doses (N=30)
Direct Bilirubin (umol/L)					
n	5	13	11	24	29
Mean (StdDev)	4.650 (3.117)	6.044 (5.350)	7.673 (9.260)	6.790 (7.273)	6.421 (6.747)
Median	4.200	4.000	5.130	5.130	5.130
Min, Max	0.66, 8.55	1.71, 20.53	0.91, 35.00	0.91, 35.00	0.66, 35.00
CTCAE Grade (n (%))					
0	2 (40.0)	8 (61.5)	7 (63.6)	15 (62.5)	17 (58.6)
1	2 (40.0)	2 (15.4)	3 (27.3)	5 (20.8)	7 (24.1)
2	1 (20.0)	2 (15.4)	0	2 (8.3)	3 (10.3)
3	0	1 (7.7)	1 (9.1)	2 (8.3)	2 (6.9)
4	0	0	0	0	0
ALT (U/L)					
n	5	13	11	24	30
Mean (StdDev)	17.4 (6.66)	16.8 (11.71)	32.6 (21.69)	24.1 (18.46)	23.4 (17.01)
Median	18.0	13.0	25.0	20.0	20.0
Min, Max	9, 26	5, 45	3, 78	3, 78	3, 78
CTCAE Grade (n (%))					
0	5 (100)	12 (92.3)	9 (81.8)	21 (87.5)	27 (90.0)
1	0	1 (7.7)	2 (18.2)	3 (12.5)	3 (10.0)
2	0	0	0	0	0
3	0	0	0	0	0
4	0	0	0	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-assess-rac-tpy.sasDate: 19:23/02NOV2020

Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=13)	300 mg (N=11)	200+300 mg (N=24)	All Doses (N=30)
AST (U/L)					
n	5	13	11	24	30
Mean (StdDev)	16.6 (5.77)	15.6 (8.15)	22.5 (10.69)	18.8 (9.82)	18.4 (9.04)
Median	14.0	15.0	21.0	17.0	17.0
Min, Max	11, 25	5, 38	5, 44	5, 44	5, 44
CTCAE Grade (n (%))					
0	5 (100)	13 (100)	9 (81.8)	22 (91.7)	28 (93.3)
1	0	0	2 (18.2)	2 (8.3)	2 (6.7)
2	0	0	0	0	0
3	0	0	0	0	0
4	0	0	0	0	0
ALP (U/L)					
n	5	13	11	24	30
Mean (StdDev)	280.8 (93.64)	433.3 (283.73)	488.5 (292.73)	458.6 (282.92)	416.4 (270.54)
Median	327.0	399.0	493.0	430.5	349.0
Min, Max	139, 364	68, 903	99, 1073	68, 1073	68, 1073
CTCAE Grade (n (%))					
0	0	2 (15.4)	1 (9.1)	3 (12.5)	4 (13.3)
1	2 (40.0)	4 (30.8)	2 (18.2)	6 (25.0)	8 (26.7)
2	3 (60.0)	4 (30.8)	5 (45.5)	9 (37.5)	12 (40.0)
3	0	3 (23.1)	3 (27.3)	6 (25.0)	6 (20.0)
4	0	0	0	0	0

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-assess-rac-tpy.sasDate: 19:23/02NOV2020

Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=13)	300 mg (N=11)	200+300 mg (N=24)	All Doses (N=30)
Serum Tryptase (ng/mL) from Central Assay					
n	5	13	11	24	30
Mean (StdDev)	340.38 (263.975)	208.32 (165.761)	235.90 (211.836)	220.96 (184.509)	238.91 (197.116)
Median	182.40	137.00	155.80	152.00	166.10
Min, Max	102.4, 684.8	37.3, 629.4	48.2, 765.3	37.3, 765.3	37.3, 765.3
<11.4 ng/mL	0	0	0	0	0
>=11.4 and <20 ng/mL	0	0	0	0	0
>=20 and <40 ng/mL	0	1 (7.7)	0	1 (4.2)	1 (3.3)
>=40 and <200 ng/mL	3 (60.0)	7 (53.8)	8 (72.7)	15 (62.5)	19 (63.3)
>=200 ng/mL	2 (40.0)	5 (38.5)	3 (27.3)	8 (33.3)	10 (33.3)
BM MC (%) by Central Pathology Review					
n	5	13	11	24	30
Mean (StdDev)	45.0 (18.71)	47.3 (26.27)	41.8 (24.42)	44.8 (25.04)	46.0 (24.23)
Median	50.0	40.0	30.0	35.0	40.0
Min, Max	15, 60	10, 80	10, 80	10, 80	10, 80
KIT D816V MAF (%) from Blood					
n	5	13	11	24	29
Mean (StdDev)	9.954 (13.735)	14.558 (12.659)	24.525 (15.367)	19.126 (14.561)	17.544 (14.613)
Median	4.430	11.590	22.600	17.200	16.420
Min, Max	0.56, 33.70	0.02, 41.70	0.03, 45.30	0.02, 45.30	0.02, 45.30
<0.17%	0	2 (15.4)	1 (9.1)	3 (12.5)	3 (10.3)
>=0.17% and <1%	1 (20.0)	0	0	0	1 (3.4)
>=1%	4 (80.0)	11 (84.6)	10 (90.9)	21 (87.5)	25 (86.2)

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-assess-rac-tpy.sasDate: 19:23/02NOV2020

Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=13)	300 mg (N=11)	200+300 mg (N=24)	All Doses (N=30)
SM Related Organ Damages					
Ascites and Pleural Effusions					
Ascites					
No	3 (60.0)	11 (84.6)	8 (72.7)	19 (79.2)	23 (76.7)
Grade 1	0	0	2 (18.2)	2 (8.3)	2 (6.7)
Grade 2	2 (40.0)	1 (7.7)	1 (9.1)	2 (8.3)	4 (13.3)
Grade 3	0	1 (7.7)	0	1 (4.2)	1 (3.3)
Pleural Effusions					
No	4 (80.0)	10 (76.9)	9 (81.8)	19 (79.2)	24 (80.0)
Grade 1	0	0	2 (18.2)	2 (8.3)	2 (6.7)
Grade 2	1 (20.0)	1 (7.7)	0	1 (4.2)	2 (6.7)
Grade 3	0	2 (15.4)	0	2 (8.3)	2 (6.7)

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-assess-rac-tpy.sasDate: 19:23/02NOV2020

Table 14.1.4.3.2b
Baseline Disease Assessments by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Prior Antineoplastic Therapy = No

	Starting Dose (QD)				
	<200 mg (N=5)	200 mg (N=13)	300 mg (N=11)	200+300 mg (N=24)	All Doses (N=30)
SM Related Organ Damages Continued					
Liver Function Abnormalities					
Other Cause for Abnormal Liver Function not Related to SM					
Yes	0	1 (11.1)	0	1 (5.0)	1 (3.8)
No	5 (100)	8 (88.9)	11 (100)	19 (95.0)	25 (96.2)
Unknown	0	0	0	0	0
Missing	0	4	0	4	4
Clinical-relevant Portal Hypertension					
Yes	0	0	0	0	0
No	5 (100)	9 (100)	10 (90.9)	19 (95.0)	25 (96.2)
Unknown	0	0	1 (9.1)	1 (5.0)	1 (3.8)
Missing	0	4	0	4	4
Biopsy-proven Liver MC Infiltration					
Yes	0	1 (11.1)	2 (18.2)	3 (15.0)	3 (11.5)
No	5 (100)	8 (88.9)	7 (63.6)	15 (75.0)	21 (80.8)
Unknown	0	0	2 (18.2)	2 (10.0)	2 (7.7)
Missing	0	4	0	4	4

Notes: Abbreviations: ALB = Albumin, ANC = Absolute neutrophil count, HGB = Hemoglobin, PLT = Platelet, ALT = Alanine aminotransferase, ALT = Alanine amionotransferase, AST = Aspartate aminotransferase , ALP = Alkaline phosphatase, RBC = red blood cell, BM = Bone Marrow, MC = Mast Cells, BMB = Bone Marrow Biopsy, MAF = Mutant allele fraction
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-assess-rac-tpy.sasDate: 19:23/02NOV2020

Blueprint Medicines Corporation
Avapritinib Integrated Summary of Safety
Data Cutoff Dates: 2101 – 27MAY2020; 2202 – 23JUN2020

Table 35.3.2.1
Summary of Study Treatment
AdvSM Population & Prior Neoplastic Therapy = Yes

Variable	BLU-285-2101 200 mg (N=12) n (%)	BLU-285-2101 <=200 mg (N=16) n (%)	BLU-285-2101 All Doses (N=41) n (%)
Duration of Treatment (Weeks)			
n	12	16	41
Mean (StdDev)	52.05 (46.430)	89.91 (78.834)	87.67 (61.394)
Median	40.07	58.29	70.14
Min, Max	7.3, 179.3	7.3, 220.0	7.3, 220.0
Treatment Interval (Weeks), n (%)			
<=4 Weeks	0	0	0
>4 to <=8 Weeks	1 (8.3)	1 (6.3)	1 (2.4)
>8 to <=12 Weeks	0	0	0
>12 to <=16 Weeks	1 (8.3)	1 (6.3)	2 (4.9)
>16 to <=20 Weeks	1 (8.3)	1 (6.3)	2 (4.9)
>20 to <=24 Weeks	1 (8.3)	1 (6.3)	2 (4.9)
>24 to <=28 Weeks	0	0	0
>28 to <=32 Weeks	0	0	1 (2.4)
>32 to <=36 Weeks	1 (8.3)	1 (6.3)	4 (9.8)
>36 to <=40 Weeks	1 (8.3)	1 (6.3)	1 (2.4)
>40 to <=44 Weeks	1 (8.3)	1 (6.3)	1 (2.4)
>44 to <=48 Weeks	0	0	1 (2.4)
>48 to <=52 Weeks	1 (8.3)	1 (6.3)	1 (2.4)
>52 to <=56 Weeks	0	0	0
>56 Weeks	4 (33.3)	8 (50.0)	25 (61.0)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis

Source (Date): Program: t-35-3-2-1-st.sas Date: 17:10/17SEP2021

Table 35.3.2.1
Summary of Study Treatment
AdvSM Population & Prior Neoplastic Therapy = Yes

Variable	BLU-285-2101 200 mg (N=12) n (%)	BLU-285-2101 <=200 mg (N=16) n (%)	BLU-285-2101 All Doses (N=41) n (%)
Cumulative Dose (mg)			
n	12	16	41
Mean (StdDev)	65064.58 (71931.729)	86274.69 (73993.528)	99046.83 (70890.192)
Median	33350.00	76000.00	97800.00
Min, Max	6500.0, 250000.0	6500.0, 250000.0	6500.0, 256900.0
Average Daily Dose (mg)			
n	12	16	41
Mean (StdDev)	168.20 (58.902)	153.05 (58.196)	180.19 (61.340)
Median	188.19	153.32	191.18
Min, Max	63.0, 281.7	63.0, 281.7	63.0, 316.7
Dose Intensity (mg/day)			
n	12	16	41
Mean (StdDev)	156.32 (64.136)	143.52 (60.292)	168.52 (61.470)
Median	167.75	132.01	181.94
Min, Max	50.4, 278.6	50.4, 278.6	50.4, 316.7

Abbreviations: AdvSM = Advanced Systemic Mastocytosis

Source (Date): Program: t-35-3-2-1-st.sas Date: 17:10/17SEP2021

Table 35.3.2.1
Summary of Study Treatment
AdvSM Population & Prior Neoplastic Therapy = Yes

Variable	BLU-285-2101 200 mg (N=12) n (%)	BLU-285-2101 <=200 mg (N=16) n (%)	BLU-285-2101 All Doses (N=41) n (%)
Relative Dose Intensity (%)			
n	12	16	41
Mean (StdDev)	0.78 (0.321)	1.06 (0.701)	0.77 (0.514)
Median	0.84	0.94	0.64
Min, Max	0.3, 1.4	0.3, 2.9	0.3, 2.9
Relative Dose Intensity Category, (n (%))			
<75%	5 (41.7)	5 (31.3)	26 (63.4)
>=75% to <90%	1 (8.3)	2 (12.5)	5 (12.2)
>=90% to <120%	5 (41.7)	5 (31.3)	6 (14.6)
>=120% to <150%	1 (8.3)	1 (6.3)	1 (2.4)
>=150%	0	3 (18.8)	3 (7.3)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis

Source (Date): Program: t-35-3-2-1-st.sas Date: 17:10/17SEP2021

Table 35.3.2.1
Summary of Study Treatment
AdvSM Population & Prior Neoplastic Therapy = Yes

Variable	BLU-285-2202 200 mg (N=40) n (%)	BLU-285-2202 <=200 mg (N=42) n (%)	BLU-285-2202 All Doses (N=42) n (%)
Duration of Treatment (Weeks)			
n	40	42	42
Mean (StdDev)	30.64 (20.039)	30.52 (20.325)	30.52 (20.325)
Median	26.57	26.57	26.57
Min, Max	0.9, 77.0	0.9, 77.0	0.9, 77.0
Treatment Interval (Weeks), n (%)			
<=4 Weeks	1 (2.5)	2 (4.8)	2 (4.8)
>4 to <=8 Weeks	3 (7.5)	3 (7.1)	3 (7.1)
>8 to <=12 Weeks	0	0	0
>12 to <=16 Weeks	7 (17.5)	7 (16.7)	7 (16.7)
>16 to <=20 Weeks	5 (12.5)	5 (11.9)	5 (11.9)
>20 to <=24 Weeks	3 (7.5)	3 (7.1)	3 (7.1)
>24 to <=28 Weeks	1 (2.5)	1 (2.4)	1 (2.4)
>28 to <=32 Weeks	4 (10.0)	4 (9.5)	4 (9.5)
>32 to <=36 Weeks	4 (10.0)	4 (9.5)	4 (9.5)
>36 to <=40 Weeks	1 (2.5)	1 (2.4)	1 (2.4)
>40 to <=44 Weeks	3 (7.5)	3 (7.1)	3 (7.1)
>44 to <=48 Weeks	3 (7.5)	3 (7.1)	3 (7.1)
>48 to <=52 Weeks	0	0	0
>52 to <=56 Weeks	0	1 (2.4)	1 (2.4)
>56 Weeks	5 (12.5)	5 (11.9)	5 (11.9)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis

Source (Date): Program: t-35-3-2-1-st.sas Date: 17:10/17SEP2021

Table 35.3.2.1
Summary of Study Treatment
AdvSM Population & Prior Neoplastic Therapy = Yes

	BLU-285-2202		
Variable	200 mg (N=40) n (%)	<=200 mg (N=42) n (%)	All Doses (N=42) n (%)
Cumulative Dose (mg)			
n	40	42	42
Mean (StdDev)	26861.25 (17323.067)	26245.24 (17321.828)	26245.24 (17321.828)
Median	28000.00	26875.00	26875.00
Min, Max	1200.0, 63400.0	1200.0, 63400.0	1200.0, 63400.0
Average Daily Dose (mg)			
n	40	42	42
Mean (StdDev)	146.68 (47.064)	143.78 (47.846)	143.78 (47.846)
Median	143.59	139.12	139.12
Min, Max	37.9, 239.9	37.9, 239.9	37.9, 239.9
Dose Intensity (mg/day)			
n	40	42	42
Mean (StdDev)	134.94 (50.391)	132.54 (50.450)	132.54 (50.450)
Median	124.30	116.83	116.83
Min, Max	35.5, 239.9	35.5, 239.9	35.5, 239.9

Abbreviations: AdvSM = Advanced Systemic Mastocytosis

Source (Date): Program: t-35-3-2-1-st.sas Date: 17:10/17SEP2021

Table 35.3.2.1
Summary of Study Treatment
AdvSM Population & Prior Neoplastic Therapy = Yes

Variable	BLU-285-2202 200 mg (N=40) n (%)	BLU-285-2202 <=200 mg (N=42) n (%)	BLU-285-2202 All Doses (N=42) n (%)
Relative Dose Intensity (%)			
n	40	42	42
Mean (StdDev)	0.67 (0.252)	0.68 (0.251)	0.68 (0.251)
Median	0.62	0.65	0.65
Min, Max	0.2, 1.2	0.2, 1.2	0.2, 1.2
Relative Dose Intensity Category, (n (%))			
<75%	26 (65.0)	27 (64.3)	27 (64.3)
>=75% to <90%	3 (7.5)	3 (7.1)	3 (7.1)
>=90% to <120%	11 (27.5)	12 (28.6)	12 (28.6)
>=120% to <150%	0	0	0
>=150%	0	0	0

Abbreviations: AdvSM = Advanced Systemic Mastocytosis

Source (Date): Program: t-35-3-2-1-st.sas Date: 17:10/17SEP2021

Table 35.3.2.1
Summary of Study Treatment
AdvSM Population & Prior Neoplastic Therapy = Yes

	BLU-285-2101 + BLU-285-2202		
Variable	200 mg (N=52) n (%)	<=200 mg (N=58) n (%)	All Doses (N=83) n (%)
Duration of Treatment (Weeks)			
n	52	58	83
Mean (StdDev)	35.58 (29.241)	46.90 (51.475)	58.75 (53.587)
Median	30.64	32.21	36.86
Min, Max	0.9, 179.3	0.9, 220.0	0.9, 220.0
Treatment Interval (Weeks), n (%)			
<=4 Weeks	1 (1.9)	2 (3.4)	2 (2.4)
>4 to <=8 Weeks	4 (7.7)	4 (6.9)	4 (4.8)
>8 to <=12 Weeks	0	0	0
>12 to <=16 Weeks	8 (15.4)	8 (13.8)	9 (10.8)
>16 to <=20 Weeks	6 (11.5)	6 (10.3)	7 (8.4)
>20 to <=24 Weeks	4 (7.7)	4 (6.9)	5 (6.0)
>24 to <=28 Weeks	1 (1.9)	1 (1.7)	1 (1.2)
>28 to <=32 Weeks	4 (7.7)	4 (6.9)	5 (6.0)
>32 to <=36 Weeks	5 (9.6)	5 (8.6)	8 (9.6)
>36 to <=40 Weeks	2 (3.8)	2 (3.4)	2 (2.4)
>40 to <=44 Weeks	4 (7.7)	4 (6.9)	4 (4.8)
>44 to <=48 Weeks	3 (5.8)	3 (5.2)	4 (4.8)
>48 to <=52 Weeks	1 (1.9)	1 (1.7)	1 (1.2)
>52 to <=56 Weeks	0	1 (1.7)	1 (1.2)
>56 Weeks	9 (17.3)	13 (22.4)	30 (36.1)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis

Source (Date): Program: t-35-3-2-1-st.sas Date: 17:10/17SEP2021

Table 35.3.2.1
Summary of Study Treatment
AdvSM Population & Prior Neoplastic Therapy = Yes

Variable	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	BLU-285-2101 + BLU-285-2202 <=200 mg (N=58) n (%)	BLU-285-2101 + BLU-285-2202 All Doses (N=83) n (%)
Cumulative Dose (mg)			
n	52	58	83
Mean (StdDev)	35677.40 (40120.316)	42805.09 (48878.440)	62207.47 (62788.764)
Median	28000.00	28200.00	35700.00
Min, Max	1200.0, 250000.0	1200.0, 250000.0	1200.0, 256900.0
Average Daily Dose (mg)			
n	52	58	83
Mean (StdDev)	151.65 (50.259)	146.34 (50.551)	161.77 (57.580)
Median	148.90	141.80	159.15
Min, Max	37.9, 281.7	37.9, 281.7	37.9, 316.7
Dose Intensity (mg/day)			
n	52	58	83
Mean (StdDev)	139.87 (53.961)	135.57 (53.027)	150.31 (58.681)
Median	131.29	124.30	144.83
Min, Max	35.5, 278.6	35.5, 278.6	35.5, 316.7

Abbreviations: AdvSM = Advanced Systemic Mastocytosis

Source (Date): Program: t-35-3-2-1-st.sas Date: 17:10/17SEP2021

Table 35.3.2.1
Summary of Study Treatment
AdvSM Population & Prior Neoplastic Therapy = Yes

Variable	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	BLU-285-2101 + BLU-285-2202 <=200 mg (N=58) n (%)	BLU-285-2101 + BLU-285-2202 All Doses (N=83) n (%)
Relative Dose Intensity (%)			
n	52	58	83
Mean (StdDev)	0.70 (0.270)	0.79 (0.451)	0.73 (0.403)
Median	0.66	0.70	0.64
Min, Max	0.2, 1.4	0.2, 2.9	0.2, 2.9
Relative Dose Intensity Category, (n (%))			
<75%	31 (59.6)	32 (55.2)	53 (63.9)
>=75% to <90%	4 (7.7)	5 (8.6)	8 (9.6)
>=90% to <120%	16 (30.8)	17 (29.3)	18 (21.7)
>=120% to <150%	1 (1.9)	1 (1.7)	1 (1.2)
>=150%	0	3 (5.2)	3 (3.6)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis

Source (Date): Program: t-35-3-2-1-st.sas Date: 17:10/17SEP2021

Table 99.1.5.1.1
Summary of Avapritinib Treatment by Prior Antineoplastic Therapy
Study BLU-285-2101, RAC-RE Population
Prior Anti-Neoplastic Therapy = Yes

	Starting Dose (QD)	
	200 mg N=9 n (%)	All Doses N=32 n (%)
Overall		
Duration of Treatment (Months) [1]		
n	9	32
Mean (StdDev)	13.61 (11.814)	20.31 (13.680)
Median	9.46	16.84
Min, Max	1.7, 41.2	1.7, 50.6
Duration of Treatment (Months) (n (%))		
< 12 Months	5 (55.6)	12 (37.5)
12 to < 24 Months	3 (33.3)	8 (25.0)
>= 24 Months	1 (11.1)	12 (37.5)
Cumulative Dose (mg) [2]		
n	9	32
Mean (StdDev)	79122.2 (78469.72)	101630.8 (69823.49)
Median	54200.0	102100.0
Min, Max	6500, 250000	6500, 256900
Average Daily Dose (mg) [3]		
n	9	32
Mean (StdDev)	182.8 (53.69)	186.5 (61.36)
Median	195.0	197.5
Min, Max	106, 282	81, 317

[1] Duration of Treatment is defined as (treatment end date – treatment start date + 1) / 30.4375.
[2] Cumulative Dose (mg) is defined as the sum of all dose actually taken.
[3] Average Daily Dose (mg): cumulative dose / number of days actually dosed.
[4] Dose Intensity (mg/day): cumulative dose / treatment duration (days).
[5] Relative Dose Intensity: dose intensity / planned dose intensity. Planned dose intensity is based on initial assigned daily dose.

Table 99.1.5.1.1
Summary of Avapritinib Treatment by Prior Antineoplastic Therapy
Study BLU-285-2101, RAC-RE Population
Prior Anti-Neoplastic Therapy = Yes

	Starting Dose (QD)	
	200 mg N=9 n (%)	All Doses N=32 n (%)
Overall		
Dose Intensity (mg/day) [4]		
n	9	32
Mean (StdDev)	169.0 (62.79)	170.5 (63.32)
Median	194.0	177.5
Min, Max	82, 279	75, 317
Relative Dose Intensity (%)[5]		
n	9	32
Mean (StdDev)	84.6 (31.28)	76.8 (50.06)
Median	97.0	69.0
Min, Max	41, 139	25, 293
Relative Dose Intensity (n (%))		
<25%	0	0
25% to <50%	2 (22.2)	9 (28.1)
50% to <75%	1 (11.1)	10 (31.3)
75% to <90%	1 (11.1)	4 (12.5)
90% to <120%	4 (44.4)	6 (18.8)
120% to <150%	1 (11.1)	1 (3.1)
>=150%	0	2 (6.3)

[1] Duration of Treatment is defined as (treatment end date – treatment start date + 1) / 30.4375.
[2] Cumulative Dose (mg) is defined as the sum of all dose actually taken.
[3] Average Daily Dose (mg): cumulative dose / number of days actually dosed.
[4] Dose Intensity (mg/day): cumulative dose / treatment duration (days).
[5] Relative Dose Intensity: dose intensity / planned dose intensity. Planned dose intensity is based on initial assigned daily dose.

Table 99.1.5.1.1
Summary of Avapritinib Treatment by Prior Antineoplastic Therapy
Study BLU-285-2101, RAC-RE Population
Prior Anti-Neoplastic Therapy = No

	Starting Dose (QD)	
	200 mg N=4 n (%)	All Doses N=21 n (%)
Overall		
Duration of Treatment (Months) [1]		
n	4	21
Mean (StdDev)	11.51 (8.207)	18.58 (11.722)
Median	7.98	20.76
Min, Max	6.3, 23.8	4.7, 40.9
Duration of Treatment (Months) (n (%))		
< 12 Months	3 (75.0)	9 (42.9)
12 to < 24 Months	1 (25.0)	6 (28.6)
>= 24 Months	0	6 (28.6)
Cumulative Dose (mg) [2]		
n	4	21
Mean (StdDev)	31787.5 (28627.04)	67219.0 (50188.79)
Median	22975.0	65800.0
Min, Max	9400, 71800	5790, 215000
Average Daily Dose (mg) [3]		
n	4	21
Mean (StdDev)	118.5 (55.72)	140.9 (70.97)
Median	100.0	107.0
Min, Max	74, 200	30, 300

[1] Duration of Treatment is defined as (treatment end date – treatment start date + 1) / 30.4375.
[2] Cumulative Dose (mg) is defined as the sum of all dose actually taken.
[3] Average Daily Dose (mg): cumulative dose / number of days actually dosed.
[4] Dose Intensity (mg/day): cumulative dose / treatment duration (days).
[5] Relative Dose Intensity: dose intensity / planned dose intensity. Planned dose intensity is based on initial assigned daily dose.

Table 99.1.5.1.1
Summary of Avapritinib Treatment by Prior Antineoplastic Therapy
Study BLU-285-2101, RAC-RE Population
Prior Anti-Neoplastic Therapy = No

	Starting Dose (QD)	
	200 mg N=4 n (%)	All Doses N=21 n (%)
Overall		
Dose Intensity (mg/day) [4]		
n	4	21
Mean (StdDev)	90.5 (60.07)	127.2 (70.23)
Median	75.0	101.0
Min, Max	40, 172	30, 296
Relative Dose Intensity (%)[5]		
n	4	21
Mean (StdDev)	45.5 (29.95)	73.3 (54.19)
Median	38.0	51.0
Min, Max	20, 86	20, 254
Relative Dose Intensity (n (%))		
<25%	1 (25.0)	1 (4.8)
25% to <50%	1 (25.0)	7 (33.3)
50% to <75%	1 (25.0)	5 (23.8)
75% to <90%	1 (25.0)	1 (4.8)
90% to <120%	0	4 (19.0)
120% to <150%	0	2 (9.5)
>=150%	0	1 (4.8)

[1] Duration of Treatment is defined as (treatment end date – treatment start date + 1) / 30.4375.
[2] Cumulative Dose (mg) is defined as the sum of all dose actually taken.
[3] Average Daily Dose (mg): cumulative dose / number of days actually dosed.
[4] Dose Intensity (mg/day): cumulative dose / treatment duration (days).
[5] Relative Dose Intensity: dose intensity / planned dose intensity. Planned dose intensity is based on initial assigned daily dose.

Table 99.1.5.1.1
Summary of Avapritinib Treatment by Prior Antineoplastic Therapy
Study BLU-285-2202, RAC-RE Population
Prior Anti-Neoplastic Therapy = Yes

	Starting Dose (QD)	
	200 mg N=22 n (%)	All Doses N=23 n (%)
Overall		
Duration of Treatment (Months) [1]		
n	22	23
Mean (StdDev)	9.30 (5.016)	9.43 (4.939)
Median	9.17	9.86
Min, Max	0.2, 17.7	0.2, 17.7
Duration of Treatment (Months) (n (%))		
< 12 Months	17 (77.3)	17 (73.9)
12 to < 24 Months	5 (22.7)	6 (26.1)
>= 24 Months	0	0
Cumulative Dose (mg) [2]		
n	22	23
Mean (StdDev)	31218.2 (18609.51)	30980.4 (18217.36)
Median	32750.0	32700.0
Min, Max	1200, 63400	1200, 63400
Average Daily Dose (mg) [3]		
n	22	23
Mean (StdDev)	128.8 (50.36)	126.3 (50.60)
Median	123.0	122.0
Min, Max	38, 240	38, 240

[1] Duration of Treatment is defined as (treatment end date − treatment start date + 1) / 30.4375.
[2] Cumulative Dose (mg) is defined as the sum of all dose actually taken.
[3] Average Daily Dose (mg): cumulative dose / number of days actually dosed.
[4] Dose Intensity (mg/day): cumulative dose / treatment duration (days).
[5] Relative Dose Intensity: dose intensity / planned dose intensity. Planned dose intensity is based on initial assigned daily dose.

Table 99.1.5.1.1
Summary of Avapritinib Treatment by Prior Antineoplastic Therapy
Study BLU-285-2202, RAC-RE Population
Prior Anti-Neoplastic Therapy = Yes

	Starting Dose (QD)	
	200 mg N=22 n (%)	All Doses N=23 n (%)
Overall		
Dose Intensity (mg/day) [4]		
n	22	23
Mean (StdDev)	118.7 (51.56)	116.6 (51.43)
Median	107.5	106.0
Min, Max	36, 238	36, 238
Relative Dose Intensity (%)[5]		
n	22	23
Mean (StdDev)	59.3 (25.84)	59.7 (25.32)
Median	53.5	54.0
Min, Max	18, 119	18, 119
Relative Dose Intensity (n (%))		
<25%	2 (9.1)	2 (8.7)
25% to <50%	5 (22.7)	5 (21.7)
50% to <75%	10 (45.5)	11 (47.8)
75% to <90%	2 (9.1)	2 (8.7)
90% to <120%	3 (13.6)	3 (13.0)
120% to <150%	0	0
>=150%	0	0

[1] Duration of Treatment is defined as (treatment end date – treatment start date + 1) / 30.4375.
[2] Cumulative Dose (mg) is defined as the sum of all dose actually taken.
[3] Average Daily Dose (mg): cumulative dose / number of days actually dosed.
[4] Dose Intensity (mg/day): cumulative dose / treatment duration (days).
[5] Relative Dose Intensity: dose intensity / planned dose intensity. Planned dose intensity is based on initial assigned daily dose.

Table 99.1.5.1.1
Summary of Avapritinib Treatment by Prior Antineoplastic Therapy
Study BLU-285-2202, RAC-RE Population
Prior Anti-Neoplastic Therapy = No

	Starting Dose (QD)	
	200 mg N=9 n (%)	All Doses N=9 n (%)
Overall		
Duration of Treatment (Months) [1]		
n	9	9
Mean (StdDev)	10.34 (4.919)	10.34 (4.919)
Median	8.11	8.11
Min, Max	5.5, 18.2	5.5, 18.2
Duration of Treatment (Months) (n (%))		
< 12 Months	6 (66.7)	6 (66.7)
12 to < 24 Months	3 (33.3)	3 (33.3)
>= 24 Months	0	0
Cumulative Dose (mg) [2]		
n	9	9
Mean (StdDev)	35555.6 (15201.82)	35555.6 (15201.82)
Median	35100.0	35100.0
Min, Max	17000, 62000	17000, 62000
Average Daily Dose (mg) [3]		
n	9	9
Mean (StdDev)	127.2 (30.48)	127.2 (30.48)
Median	122.0	122.0
Min, Max	72, 179	72, 179

[1] Duration of Treatment is defined as (treatment end date − treatment start date + 1) / 30.4375.
[2] Cumulative Dose (mg) is defined as the sum of all dose actually taken.
[3] Average Daily Dose (mg): cumulative dose / number of days actually dosed.
[4] Dose Intensity (mg/day): cumulative dose / treatment duration (days).
[5] Relative Dose Intensity: dose intensity / planned dose intensity. Planned dose intensity is based on initial assigned daily dose.

Table 99.1.5.1.1
Summary of Avapritinib Treatment by Prior Antineoplastic Therapy
Study BLU-285-2202, RAC-RE Population
Prior Anti-Neoplastic Therapy = No

	Starting Dose (QD)	
	200 mg N=9 n (%)	All Doses N=9 n (%)
Overall		
Dose Intensity (mg/day) [4]		
n	9	9
Mean (StdDev)	118.1 (31.50)	118.1 (31.50)
Median	112.0	112.0
Min, Max	70, 179	70, 179
Relative Dose Intensity (%)[5]		
n	9	9
Mean (StdDev)	59.1 (15.85)	59.1 (15.85)
Median	56.0	56.0
Min, Max	35, 90	35, 90
Relative Dose Intensity (n (%))		
<25%	0	0
25% to <50%	1 (11.1)	1 (11.1)
50% to <75%	7 (77.8)	7 (77.8)
75% to <90%	0	0
90% to <120%	1 (11.1)	1 (11.1)
120% to <150%	0	0
>=150%	0	0

[1] Duration of Treatment is defined as (treatment end date – treatment start date + 1) / 30.4375.
[2] Cumulative Dose (mg) is defined as the sum of all dose actually taken.
[3] Average Daily Dose (mg): cumulative dose / number of days actually dosed.
[4] Dose Intensity (mg/day): cumulative dose / treatment duration (days).
[5] Relative Dose Intensity: dose intensity / planned dose intensity. Planned dose intensity is based on initial assigned daily dose.

Table 99.1.5.1.1
Summary of Avapritinib Treatment by Prior Antineoplastic Therapy
Studies: BLU-285-2101 and BLU-285-2202, RAC-RE Population
Prior Anti-Neoplastic Therapy = Yes

	Starting Dose (QD)	
	200 mg N=31 n (%)	All Doses N=55 n (%)
Overall		
Duration of Treatment (Months) [1]		
n	31	55
Mean (StdDev)	10.55 (7.668)	15.76 (12.113)
Median	9.46	11.01
Min, Max	0.2, 41.2	0.2, 50.6
Duration of Treatment (Months) (n (%))		
< 12 Months	22 (71.0)	29 (52.7)
12 to < 24 Months	8 (25.8)	14 (25.5)
>= 24 Months	1 (3.2)	12 (21.8)
Cumulative Dose (mg) [2]		
n	31	55
Mean (StdDev)	45125.8 (48713.33)	72086.1 (64582.86)
Median	32800.0	44800.0
Min, Max	1200, 250000	1200, 256900
Average Daily Dose (mg) [3]		
n	31	55
Mean (StdDev)	144.5 (56.26)	161.3 (64.05)
Median	129.0	159.0
Min, Max	38, 282	38, 317

[1] Duration of Treatment is defined as (treatment end date – treatment start date + 1) / 30.4375.
[2] Cumulative Dose (mg) is defined as the sum of all dose actually taken.
[3] Average Daily Dose (mg): cumulative dose / number of days actually dosed.
[4] Dose Intensity (mg/day): cumulative dose / treatment duration (days).
[5] Relative Dose Intensity: dose intensity / planned dose intensity. Planned dose intensity is based on initial assigned daily dose.

Table 99.1.5.1.1
Summary of Avapritinib Treatment by Prior Antineoplastic Therapy
Studies: BLU-285-2101 and BLU-285-2202, RAC-RE Population
Prior Anti-Neoplastic Therapy = Yes

	Starting Dose (QD)	
	200 mg N=31 n (%)	All Doses N=55 n (%)
Overall		
Dose Intensity (mg/day) [4]		
n	31	55
Mean (StdDev)	133.3 (58.74)	147.9 (64.02)
Median	122.0	142.0
Min, Max	36, 279	36, 317
Relative Dose Intensity (%)[5]		
n	31	55
Mean (StdDev)	66.6 (29.40)	69.6 (42.09)
Median	61.0	63.0
Min, Max	18, 139	18, 293
Relative Dose Intensity (n (%))		
<25%	2 (6.5)	2 (3.6)
25% to <50%	7 (22.6)	14 (25.5)
50% to <75%	11 (35.5)	21 (38.2)
75% to <90%	3 (9.7)	6 (10.9)
90% to <120%	7 (22.6)	9 (16.4)
120% to <150%	1 (3.2)	1 (1.8)
>=150%	0	2 (3.6)

[1] Duration of Treatment is defined as (treatment end date – treatment start date + 1) / 30.4375.
[2] Cumulative Dose (mg) is defined as the sum of all dose actually taken.
[3] Average Daily Dose (mg): cumulative dose / number of days actually dosed.
[4] Dose Intensity (mg/day): cumulative dose / treatment duration (days).
[5] Relative Dose Intensity: dose intensity / planned dose intensity. Planned dose intensity is based on initial assigned daily dose.

Table 99.1.5.1.1
Summary of Avapritinib Treatment by Prior Antineoplastic Therapy
Studies: BLU-285-2101 and BLU-285-2202, RAC-RE Population
Prior Anti-Neoplastic Therapy = No

	Starting Dose (QD)	
	200 mg N=13 n (%)	All Doses N=30 n (%)
Overall		
Duration of Treatment (Months) [1]		
n	13	30
Mean (StdDev)	10.70 (5.769)	16.11 (10.778)
Median	8.11	12.14
Min, Max	5.5, 23.8	4.7, 40.9
Duration of Treatment (Months) (n (%))		
< 12 Months	9 (69.2)	15 (50.0)
12 to < 24 Months	4 (30.8)	9 (30.0)
>= 24 Months	0	6 (20.0)
Cumulative Dose (mg) [2]		
n	13	30
Mean (StdDev)	34396.2 (19032.00)	57720.0 (44930.33)
Median	34700.0	52300.0
Min, Max	9400, 71800	5790, 215000
Average Daily Dose (mg) [3]		
n	13	30
Mean (StdDev)	124.5 (37.59)	136.8 (61.40)
Median	115.0	118.0
Min, Max	72, 200	30, 300

[1] Duration of Treatment is defined as (treatment end date – treatment start date + 1) / 30.4375.
[2] Cumulative Dose (mg) is defined as the sum of all dose actually taken.
[3] Average Daily Dose (mg): cumulative dose / number of days actually dosed.
[4] Dose Intensity (mg/day): cumulative dose / treatment duration (days).
[5] Relative Dose Intensity: dose intensity / planned dose intensity. Planned dose intensity is based on initial assigned daily dose.

Table 99.1.5.1.1
Summary of Avapritinib Treatment by Prior Antineoplastic Therapy
Studies: BLU-285-2101 and BLU-285-2202, RAC-RE Population
Prior Anti-Neoplastic Therapy = No

	Starting Dose (QD)	
	200 mg N=13 n (%)	All Doses N=30 n (%)
Overall		
Dose Intensity (mg/day) [4]		
n	13	30
Mean (StdDev)	109.6 (41.71)	124.5 (60.77)
Median	104.0	105.5
Min, Max	40, 179	30, 296
Relative Dose Intensity (%)[5]		
n	13	30
Mean (StdDev)	54.9 (20.84)	69.1 (46.24)
Median	52.0	54.0
Min, Max	20, 90	20, 254
Relative Dose Intensity (n (%))		
<25%	1 (7.7)	1 (3.3)
25% to <50%	2 (15.4)	8 (26.7)
50% to <75%	8 (61.5)	12 (40.0)
75% to <90%	1 (7.7)	1 (3.3)
90% to <120%	1 (7.7)	5 (16.7)
120% to <150%	0	2 (6.7)
>=150%	0	1 (3.3)

[1] Duration of Treatment is defined as (treatment end date – treatment start date + 1) / 30.4375.
[2] Cumulative Dose (mg) is defined as the sum of all dose actually taken.
[3] Average Daily Dose (mg): cumulative dose / number of days actually dosed.
[4] Dose Intensity (mg/day): cumulative dose / treatment duration (days).
[5] Relative Dose Intensity: dose intensity / planned dose intensity. Planned dose intensity is based on initial assigned daily dose.

Blueprint Medicines Corporation
Avapritinib Systemic Mastocytosis Integrated Summary of Efficacy
BLU-285 SM Germany HTA Analysis Cutoff date: 27may2020 (2101), 23jun2020 (2202)

Table 35.1.10.1 Prior Therapies
AdvSM Population with at least one prior antineoplastic therapy
Study 2101

	Starting Dose (QD)				
	<200 mg (N=4) n (%)	200 mg (N=12) n (%)	300 mg (N=20) n (%)	<=200 mg (N=16) n (%)	All Doses (N=41) n (%)
Prior Antineoplastic Therapy (n (%))					
No	0	0	0	0	0
Yes	4 (100)	12 (100)	20 (100)	16 (100)	41 (100)
Midostaurin	2 (50.0)	10 (83.3)	10 (50.0)	12 (75.0)	23 (56.1)
Cladribine	0	3 (25.0)	5 (25.0)	3 (18.8)	10 (24.4)
Imatinib	0	2 (16.7)	3 (15.0)	2 (12.5)	5 (12.2)
Interferon	0	2 (16.7)	2 (10.0)	2 (12.5)	4 (9.8)
Hydroxycarbamide	0	0	3 (15.0)	0	3 (7.3)
Azacitidine	0	0	0	0	2 (4.9)
Brentuximab Vedotin	0	0	2 (10.0)	0	2 (4.9)
Dasatinib	0	1 (8.3)	1 (5.0)	1 (6.3)	2 (4.9)
Ibrutinib	1 (25.0)	0	0	1 (6.3)	2 (4.9)
Investigational Antineoplastic Drugs	0	1 (8.3)	1 (5.0)	1 (6.3)	2 (4.9)
Ruxolitinib	0	0	1 (5.0)	0	2 (4.9)
Chlorambucil	0	0	1 (5.0)	0	1 (2.4)
Decitabine	0	0	1 (5.0)	0	1 (2.4)
Nilotinib	0	1 (8.3)	0	1 (6.3)	1 (2.4)

Source: Listings 16.2.4.4, 16.2.4.5, 16.2.4.6
Notes: Prior therapies are coded using WHO DD B2 enhanced, version March 2017. Prior therapy is defined as all treatment that started ended on or before first dose date of avapritinib. If a patient has multiple occurrences of a medication, the patient is presented once in the respective patient count.
[1] Percentages based on total number of patients with Prior Midostaurin.

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Avapritinib Systemic Mastocytosis Integrated Summary of Efficacy
BLU-285 SM Germany HTA Analysis
Cutoff date: 27may2020 (2101), 23jun2020 (2202)

Table 35.1.10.1 Prior Therapies
AdvSM Population with at least one prior antineoplastic therapy
Study 2101

	Starting Dose (QD)				
	<200 mg (N=4) n (%)	200 mg (N=12) n (%)	300 mg (N=20) n (%)	<=200 mg (N=16) n (%)	All Doses (N=41) n (%)
Prior Antineoplastic Therapy (n (%)) (Cnt..)					
Obinutuzumab	0	0	1 (5.0)	0	1 (2.4)
Other Antineoplastic Agents	0	0	1 (5.0)	0	1 (2.4)
Peginterferon Alfa-2a	1 (25.0)	0	0	1 (6.3)	1 (2.4)
Rituximab	0	0	1 (5.0)	0	1 (2.4)
Best Response to Any Prior Antineoplastic Therapy					
CR	0	0	0	0	0
PR	0	1 (8.3)	1 (5.0)	1 (6.3)	2 (4.9)
CI	1 (25.0)	2 (16.7)	1 (5.0)	3 (18.8)	5 (12.2)
SI	0	0	2 (10.0)	0	2 (4.9)
SD	1 (25.0)	5 (41.7)	10 (50.0)	6 (37.5)	18 (43.9)
PD	0	1 (8.3)	3 (15.0)	1 (6.3)	5 (12.2)
NA	0	0	2 (10.0)	0	3 (7.3)
NE	2 (50.0)	3 (25.0)	1 (5.0)	5 (31.3)	6 (14.6)
Prior Tyrosine Kinase (TKI) Therapy (n (%))					
Yes	4 (100)	12 (100)	17 (85.0)	16 (100)	38 (92.7)
No	0	0	3 (15.0)	0	3 (7.3)

Source: Listings 16.2.4.4, 16.2.4.5, 16.2.4.6
Notes: Prior therapies are coded using WHO DD B2 enhanced, version March 2017. Prior therapy is defined as all treatment that started ended on or before first dose date of avapritinib. If a patient has multiple occurrences of a medication, the patient is presented once in the respective patient count.
[1] Percentages based on total number of patients with Prior Midostaurin.

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Blueprint Medicines Corporation
Avapritinib Systemic Mastocytosis Integrated Summary of Efficacy
BLU-285 SM Germany HTA Analysis Cutoff date: 27may2020 (2101), 23jun2020 (2202)

Table 35.1.10.1 Prior Therapies
AdvSM Population with at least one prior antineoplastic therapy
Study 2101

	Starting Dose (QD)				
	<200 mg (N=4) n (%)	200 mg (N=12) n (%)	300 mg (N=20) n (%)	<=200 mg (N=16) n (%)	All Doses (N=41) n (%)
Prior Radiation Therapy (n (%))					
Yes	0	0	0	0	0
No	4 (100)	12 (100)	20 (100)	16 (100)	41 (100)
Prior Cancer Related Surgery-Procedures (n (%))					
Yes	3 (75.0)	8 (66.7)	19 (95.0)	11 (68.8)	34 (82.9)
No	1 (25.0)	4 (33.3)	1 (5.0)	5 (31.3)	7 (17.1)
Prior Midostaurin (n (%))					
Yes	2 (50.0)	10 (83.3)	10 (50.0)	12 (75.0)	23 (56.1)
No	2 (50.0)	2 (16.7)	10 (50.0)	4 (25.0)	18 (43.9)

Source: Listings 16.2.4.4, 16.2.4.5, 16.2.4.6
Notes: Prior therapies are coded using WHO DD B2 enhanced, version March 2017. Prior therapy is defined as all treatment that started ended on or before first dose date of avapritinib. If a patient has multiple occurrences of a medication, the patient is presented once in the respective patient count.
[1] Percentages based on total number of patients with Prior Midostaurin.

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Avapritinib Systemic Mastocytosis Integrated Summary of Efficacy
BLU-285 SM Germany HTA Analysis
Cutoff date: 27may2020 (2101), 23jun2020 (2202)

Table 35.1.10.1 Prior Therapies
AdvSM Population with at least one prior antineoplastic therapy
Study 2101

	Starting Dose (QD)				
	<200 mg (N=4) n (%)	200 mg (N=12) n (%)	300 mg (N=20) n (%)	<=200 mg (N=16) n (%)	All Doses (N=41) n (%)
Best Response to Prior Midostaurin [1] (n (%))					
CR	0	0	0	0	0
PR	0	1 (10.0)	1 (10.0)	1 (8.3)	2 (8.7)
CI	1 (50.0)	0	1 (10.0)	1 (8.3)	2 (8.7)
SI	0	0	2 (20.0)	0	2 (8.7)
SD	0	4 (40.0)	3 (30.0)	4 (33.3)	8 (34.8)
PD	0	2 (20.0)	1 (10.0)	2 (16.7)	3 (13.0)
NA	0	0	2 (20.0)	0	2 (8.7)
NE	1 (50.0)	3 (30.0)	0	4 (33.3)	4 (17.4)
Reason for Discontinuation of Prior Midostaurin [1] (n (%))					
Completed Scheduled Cycles	0	0	0	0	0
PD/Relapse	1 (50.0)	2 (20.0)	5 (50.0)	3 (25.0)	8 (34.8)
Refractory	0	0	0	0	0
Toxicity	1 (50.0)	5 (50.0)	3 (30.0)	6 (50.0)	9 (39.1)
Other	0	2 (20.0)	2 (20.0)	2 (16.7)	4 (17.4)
Unknown	0	1 (10.0)	0	1 (8.3)	2 (8.7)

Source: Listings 16.2.4.4, 16.2.4.5, 16.2.4.6
Notes: Prior therapies are coded using WHO DD B2 enhanced, version March 2017. Prior therapy is defined as all treatment that started ended on or before first dose date of avapritinib. If a patient has multiple occurrences of a medication, the patient is presented once in the respective patient count.
[1] Percentages based on total number of patients with Prior Midostaurin.

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Avapritinib Systemic Mastocytosis Integrated Summary of Efficacy
BLU-285 SM Germany HTA Analysis Cutoff date: 27may2020 (2101), 23jun2020 (2202)

Table 35.1.10.1 Prior Therapies
AdvSM Population with at least one prior antineoplastic therapy
Study 2101

	Starting Dose (QD)				
	<200 mg (N=4) n (%)	200 mg (N=12) n (%)	300 mg (N=20) n (%)	<=200 mg (N=16) n (%)	All Doses (N=41) n (%)
Duration of Treatment on Midostaurin (months)					
n	2	10	10	12	23
Mean (StdDev)	6.1 (5.78)	7.5 (5.22)	13.4 (16.73)	7.3 (5.06)	12.8 (17.75)
Median	6.1	7.5	6.1	7.5	7.0
Min, Max	2, 10	1, 17	2, 58	1, 17	1, 74

Source: Listings 16.2.4.4, 16.2.4.5, 16.2.4.6
Notes: Prior therapies are coded using WHO DD B2 enhanced, version March 2017. Prior therapy is defined as all treatment that started ended on or before first dose date of avapritinib. If a patient has multiple occurrences of a medication, the patient is presented once in the respective patient count.
[1] Percentages based on total number of patients with Prior Midostaurin.

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Cutoff date: 27may2020 (2101), 23jun2020 (2202)

Table 35.1.10.1 Prior Therapies
AdvSM Population with at least one prior antineoplastic therapy
Study 2202

	Starting Dose (QD) 200 mg (N=40) n (%)	All Doses (N=42) n (%)
Prior Antineoplastic Therapy (n (%))		
No	0	0
Yes	40 (100)	42 (100)
Midostaurin	32 (80.0)	34 (81.0)
Cladribine	7 (17.5)	8 (19.0)
Interferon Alfa	5 (12.5)	6 (14.3)
Imatinib	5 (12.5)	5 (11.9)
Dasatinib	4 (10.0)	4 (9.5)
Hydroxycarbamide	4 (10.0)	4 (9.5)
Azacitidine	3 (7.5)	3 (7.1)
Investigational Antineoplastic Drugs	2 (5.0)	2 (4.8)
Decitabine	1 (2.5)	1 (2.4)
Nilotinib	1 (2.5)	1 (2.4)
Peginterferon Alfa-2a	1 (2.5)	1 (2.4)
Protein Kinase Inhibitors	1 (2.5)	1 (2.4)
Purine Analogues	1 (2.5)	1 (2.4)
Stem Cells Nos	1 (2.5)	1 (2.4)

Source: Listings 16.2.4.4, 16.2.4.5, 16.2.4.6
Notes: Prior therapies are coded using WHO DD B2 enhanced, version March 2017. Prior therapy is defined as all treatment that started ended on or before first dose date of avapritinib. If a patient has multiple occurrences of a medication, the patient is presented once in the respective patient count.
[1] Percentages based on total number of patients with Prior Midostaurin.

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Table 35.1.10.1 Prior Therapies
AdvSM Population with at least one prior antineoplastic therapy
Study 2202

	Starting Dose (QD) 200 mg (N=40) n (%)	All Doses (N=42) n (%)
Prior Antineoplastic Therapy (n (%)) (Cnt..)		
Thalidomide	1 (2.5)	1 (2.4)
Best Response to Any Prior Antineoplastic Therapy		
CR	0	0
PR	11 (27.5)	12 (28.6)
CI	6 (15.0)	6 (14.3)
SD	11 (27.5)	12 (28.6)
PD	4 (10.0)	4 (9.5)
Other	6 (15.0)	6 (14.3)
Missing	2 (5.0)	2 (4.8)
Prior Tyrosine Kinase (TKI) Therapy (n (%))		
Yes	39 (97.5)	41 (97.6)
No	1 (2.5)	1 (2.4)
Prior Radiation Therapy (n (%))		
Yes	0	0
No	40 (100)	42 (100)

Source: Listings 16.2.4.4, 16.2.4.5, 16.2.4.6
Notes: Prior therapies are coded using WHO DD B2 enhanced, version March 2017. Prior therapy is defined as all treatment that started ended on or before first dose date of avapritinib. If a patient has multiple occurrences of a medication, the patient is presented once in the respective patient count.
[1] Percentages based on total number of patients with Prior Midostaurin.

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Avapritinib Systemic Mastocytosis Integrated Summary of Efficacy
BLU-285 SM Germany HTA Analysis Cutoff date: 27may2020 (2101), 23jun2020 (2202)

Table 35.1.10.1 Prior Therapies
AdvSM Population with at least one prior antineoplastic therapy
Study 2202

	Starting Dose (QD) 200 mg (N=40) n (%)	All Doses (N=42) n (%)
Prior Midostaurin (n (%))		
Yes	32 (80.0)	34 (81.0)
No	8 (20.0)	8 (19.0)
Best Response to Prior Midostaurin [1] (n (%))		
CR	0	0
PR	8 (25.0)	9 (26.5)
CI	4 (12.5)	4 (11.8)
SD	7 (21.9)	8 (23.5)
PD	2 (6.3)	2 (5.9)
Other	9 (28.1)	9 (26.5)
Missing	2 (6.3)	2 (5.9)

Source: Listings 16.2.4.4, 16.2.4.5, 16.2.4.6
Notes: Prior therapies are coded using WHO DD B2 enhanced, version March 2017. Prior therapy is defined as all treatment that started ended on or before first dose date of avapritinib. If a patient has multiple occurrences of a medication, the patient is presented once in the respective patient count.
[1] Percentages based on total number of patients with Prior Midostaurin.

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Table 35.1.10.1 Prior Therapies
AdvSM Population with at least one prior antineoplastic therapy
Study 2202

	Starting Dose (QD) 200 mg (N=40) n (%)	All Doses (N=42) n (%)
Reason for Discontinuation of Prior Midostaurin [1] (n (%))		
Completed Scheduled Cycles	0	0
PD/Relapse	13 (40.6)	14 (41.2)
Refractory	1 (3.1)	1 (2.9)
Other	6 (18.8)	7 (20.6)
Toxicity	10 (31.3)	10 (29.4)
Unknown	2 (6.3)	2 (5.9)
Duration of Treatment on Midostaurin (months)		
n	33	35
Mean (StdDev)	18.6 (23.96)	21.3 (29.33)
Median	10.0	10.0
Min, Max	0, 122	0, 124

Source: Listings 16.2.4.4, 16.2.4.5, 16.2.4.6
Notes: Prior therapies are coded using WHO DD B2 enhanced, version March 2017. Prior therapy is defined as all treatment that started ended on or before first dose date of avapritinib. If a patient has multiple occurrences of a medication, the patient is presented once in the respective patient count.
[1] Percentages based on total number of patients with Prior Midostaurin.

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Table 35.1.10.1 Prior Therapies
AdvSM Population with at least one prior antineoplastic therapy
Studies 2101 and 2202

	Starting Dose (QD)				
	<200 mg (N=6) n (%)	200 mg (N=52) n (%)	300 mg (N=20) n (%)	<=200 mg (N=58) n (%)	All Doses (N=83) n (%)
Prior Antineoplastic Therapy (n (%))					
No	0	0	0	0	0
Yes	6 (100)	52 (100)	20 (100)	58 (100)	83 (100)
Midostaurin	4 (66.7)	42 (80.8)	10 (50.0)	46 (79.3)	57 (68.7)
Cladribine	1 (16.7)	10 (19.2)	5 (25.0)	11 (19.0)	18 (21.7)
Imatinib	0	7 (13.5)	3 (15.0)	7 (12.1)	10 (12.0)
Hydroxycarbamide	0	4 (7.7)	3 (15.0)	4 (6.9)	7 (8.4)
Dasatinib	0	5 (9.6)	1 (5.0)	5 (8.6)	6 (7.2)
Interferon Alfa	1 (16.7)	5 (9.6)	0	6 (10.3)	6 (7.2)
Azacitidine	0	3 (5.8)	0	3 (5.2)	5 (6.0)
Interferon	0	2 (3.8)	2 (10.0)	2 (3.4)	4 (4.8)
Investigational Antineoplastic Drugs	0	3 (5.8)	1 (5.0)	3 (5.2)	4 (4.8)
Brentuximab Vedotin	0	0	2 (10.0)	0	2 (2.4)
Decitabine	0	1 (1.9)	1 (5.0)	1 (1.7)	2 (2.4)
Ibrutinib	1 (16.7)	0	0	1 (1.7)	2 (2.4)
Nilotinib	0	2 (3.8)	0	2 (3.4)	2 (2.4)
Peginterferon Alfa-2a	1 (16.7)	1 (1.9)	0	2 (3.4)	2 (2.4)

Source: Listings 16.2.4.4, 16.2.4.5, 16.2.4.6
Notes: Prior therapies are coded using WHO DD B2 enhanced, version March 2017. Prior therapy is defined as all treatment that started ended on or before first dose date of avapritinib. If a patient has multiple occurrences of a medication, the patient is presented once in the respective patient count.
[1] Percentages based on total number of patients with Prior Midostaurin.

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Avapritinib Systemic Mastocytosis Integrated Summary of Efficacy
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Table 35.1.10.1 Prior Therapies
AdvSM Population with at least one prior antineoplastic therapy
Studies 2101 and 2202

	Starting Dose (QD)				
	<200 mg (N=6) n (%)	200 mg (N=52) n (%)	300 mg (N=20) n (%)	<=200 mg (N=58) n (%)	All Doses (N=83) n (%)
Prior Antineoplastic Therapy (n (%)) (Cnt..)					
Ruxolitinib	0	0	1 (5.0)	0	2 (2.4)
Chlorambucil	0	0	1 (5.0)	0	1 (1.2)
Obinutuzumab	0	0	1 (5.0)	0	1 (1.2)
Other Antineoplastic Agents	0	0	1 (5.0)	0	1 (1.2)
Protein Kinase Inhibitors	0	1 (1.9)	0	1 (1.7)	1 (1.2)
Purine Analogues	0	1 (1.9)	0	1 (1.7)	1 (1.2)
Rituximab	0	0	1 (5.0)	0	1 (1.2)
Stem Cells Nos	0	1 (1.9)	0	1 (1.7)	1 (1.2)
Thalidomide	0	1 (1.9)	0	1 (1.7)	1 (1.2)

Source: Listings 16.2.4.4, 16.2.4.5, 16.2.4.6
Notes: Prior therapies are coded using WHO DD B2 enhanced, version March 2017. Prior therapy is defined as all treatment that started ended on or before first dose date of avapritinib. If a patient has multiple occurrences of a medication, the patient is presented once in the respective patient count.
[1] Percentages based on total number of patients with Prior Midostaurin.

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Table 35.1.10.1 Prior Therapies
AdvSM Population with at least one prior antineoplastic therapy
Studies 2101 and 2202

	Starting Dose (QD)				
	<200 mg (N=6) n (%)	200 mg (N=52) n (%)	300 mg (N=20) n (%)	<=200 mg (N=58) n (%)	All Doses (N=83) n (%)
Best Response to Any Prior Antineoplastic Therapy					
CR	0	0	0	0	0
PR	1 (16.7)	12 (23.1)	1 (5.0)	13 (22.4)	14 (16.9)
CI	1 (16.7)	8 (15.4)	1 (5.0)	9 (15.5)	11 (13.3)
SI	0	0	2 (10.0)	0	2 (2.4)
SD	2 (33.3)	16 (30.8)	10 (50.0)	18 (31.0)	30 (36.1)
PD	0	5 (9.6)	3 (15.0)	5 (8.6)	9 (10.8)
NA	0	0	2 (10.0)	0	3 (3.6)
NE	2 (33.3)	3 (5.8)	1 (5.0)	5 (8.6)	6 (7.2)
Other	0	6 (11.5)	0	6 (10.3)	6 (7.2)
Missing	0	2 (3.8)	0	2 (3.4)	2 (2.4)
Prior Tyrosine Kinase (TKI) Therapy (n (%))					
Yes	6 (100)	51 (98.1)	17 (85.0)	57 (98.3)	79 (95.2)
No	0	1 (1.9)	3 (15.0)	1 (1.7)	4 (4.8)
Prior Radiation Therapy (n (%))					
Yes	0	0	0	0	0
No	6 (100)	52 (100)	20 (100)	58 (100)	83 (100)

Source: Listings 16.2.4.4, 16.2.4.5, 16.2.4.6
Notes: Prior therapies are coded using WHO DD B2 enhanced, version March 2017. Prior therapy is defined as all treatment that started ended on or before first dose date of avapritinib. If a patient has multiple occurrences of a medication, the patient is presented once in the respective patient count.
[1] Percentages based on total number of patients with Prior Midostaurin.

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Table 35.1.10.1 Prior Therapies
AdvSM Population with at least one prior antineoplastic therapy
Studies 2101 and 2202

	Starting Dose (QD)				
	<200 mg (N=6) n (%)	200 mg (N=52) n (%)	300 mg (N=20) n (%)	<=200 mg (N=58) n (%)	All Doses (N=83) n (%)
Prior Cancer Related Surgery-Procedures (n (%))					
Yes	3 (50.0)	8 (15.4)	19 (95.0)	11 (19.0)	34 (41.0)
No	1 (16.7)	4 (7.7)	1 (5.0)	5 (8.6)	7 (8.4)
Prior Midostaurin (n (%))					
Yes	4 (66.7)	42 (80.8)	10 (50.0)	46 (79.3)	57 (68.7)
No	2 (33.3)	10 (19.2)	10 (50.0)	12 (20.7)	26 (31.3)
Best Response to Prior Midostaurin [1] (n (%))					
CR	0	0	0	0	0
PR	1 (25.0)	9 (21.4)	1 (10.0)	10 (21.7)	11 (19.3)
CI	1 (25.0)	4 (9.5)	1 (10.0)	5 (10.9)	6 (10.5)
SI	0	0	2 (20.0)	0	2 (3.5)
SD	1 (25.0)	11 (26.2)	3 (30.0)	12 (26.1)	16 (28.1)
PD	0	4 (9.5)	1 (10.0)	4 (8.7)	5 (8.8)
NA	0	0	2 (20.0)	0	2 (3.5)
NE	1 (25.0)	3 (7.1)	0	4 (8.7)	4 (7.0)
Other	0	9 (21.4)	0	9 (19.6)	9 (15.8)
Missing	0	2 (4.8)	0	2 (4.3)	2 (3.5)

Source: Listings 16.2.4.4, 16.2.4.5, 16.2.4.6
Notes: Prior therapies are coded using WHO DD B2 enhanced, version March 2017. Prior therapy is defined as all treatment that started ended on or before first dose date of avapritinib. If a patient has multiple occurrences of a medication, the patient is presented once in the respective patient count.
[1] Percentages based on total number of patients with Prior Midostaurin.

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Table 35.1.10.1 Prior Therapies
AdvSM Population with at least one prior antineoplastic therapy
Studies 2101 and 2202

	Starting Dose (QD)				
	<200 mg (N=6) n (%)	200 mg (N=52) n (%)	300 mg (N=20) n (%)	<=200 mg (N=58) n (%)	All Doses (N=83) n (%)
Reason for Discontinuation of Prior Midostaurin [1] (n (%))					
Completed Scheduled Cycles	0	0	0	0	0
PD/Relapse	2 (50.0)	15 (35.7)	5 (50.0)	17 (37.0)	22 (38.6)
Refractory	0	1 (2.4)	0	1 (2.2)	1 (1.8)
Toxicity	1 (25.0)	15 (35.7)	3 (30.0)	16 (34.8)	19 (33.3)
Other	1 (25.0)	8 (19.0)	2 (20.0)	9 (19.6)	11 (19.3)
Unknown	0	3 (7.1)	0	3 (6.5)	4 (7.0)
Duration of Treatment on Midostaurin (months)					
n	4	43	10	47	58
Mean (StdDev)	36.0 (58.53)	16.0 (21.57)	13.4 (16.73)	17.7 (26.08)	17.9 (25.54)
Median	9.1	8.7	6.1	8.7	8.1
Min, Max	2, 124	0, 122	2, 58	0, 124	0, 124

Source: Listings 16.2.4.4, 16.2.4.5, 16.2.4.6
Notes: Prior therapies are coded using WHO DD B2 enhanced, version March 2017. Prior therapy is defined as all treatment that started ended on or before first dose date of avapritinib. If a patient has multiple occurrences of a medication, the patient is presented once in the respective patient count.
[1] Percentages based on total number of patients with Prior Midostaurin.

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Table 35.1.10.1.2 Prior Therapies
RAC-RE Population with at least one prior antineoplastic therapy
Study 2101

	Starting Dose (QD)				
	<200 mg (N=3) n (%)	200 mg (N=9) n (%)	300 mg (N=16) n (%)	<=200 mg (N=12) n (%)	All Doses (N=32) n (%)
Prior Antineoplastic Therapy (n (%))					
No	0	0	0	0	0
Yes	3 (100)	9 (100)	16 (100)	12 (100)	32 (100)
Midostaurin	1 (33.3)	7 (77.8)	9 (56.3)	8 (66.7)	17 (53.1)
Cladribine	0	1 (11.1)	4 (25.0)	1 (8.3)	7 (21.9)
Hydroxycarbamide	0	0	3 (18.8)	0	3 (9.4)
Imatinib	0	1 (11.1)	2 (12.5)	1 (8.3)	3 (9.4)
Interferon	0	2 (22.2)	1 (6.3)	2 (16.7)	3 (9.4)
Azacitidine	0	0	0	0	2 (6.3)
Brentuximab Vedotin	0	0	2 (12.5)	0	2 (6.3)
Ibrutinib	1 (33.3)	0	0	1 (8.3)	2 (6.3)
Investigational Antineoplastic Drugs	0	1 (11.1)	1 (6.3)	1 (8.3)	2 (6.3)
Ruxolitinib	0	0	1 (6.3)	0	2 (6.3)
Chlorambucil	0	0	1 (6.3)	0	1 (3.1)
Decitabine	0	0	1 (6.3)	0	1 (3.1)
Obinutuzumab	0	0	1 (6.3)	0	1 (3.1)
Peginterferon Alfa-2a	1 (33.3)	0	0	1 (8.3)	1 (3.1)

Source: Listings 16.2.4.4, 16.2.4.5, 16.2.4.6
Notes: Prior therapies are coded using WHO DD B2 enhanced, version March 2017. Prior therapy is defined as all treatment that started ended on or before first dose date of avapritinib. If a patient has multiple occurrences of a medication, the patient is presented once in the respective patient count.
[1] Percentages based on total number of patients with Prior Midostaurin.

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Table 35.1.10.1.2 Prior Therapies
RAC-RE Population with at least one prior antineoplastic therapy
Study 2101

	Starting Dose (QD)				
	<200 mg (N=3) n (%)	200 mg (N=9) n (%)	300 mg (N=16) n (%)	<=200 mg (N=12) n (%)	All Doses (N=32) n (%)
Prior Antineoplastic Therapy (n (%)) (Cnt..)					
Rituximab	0	0	1 (6.3)	0	1 (3.1)
Best Response to Any Prior Antineoplastic Therapy					
CR	0	0	0	0	0
PR	0	1 (11.1)	1 (6.3)	1 (8.3)	2 (6.3)
CI	1 (33.3)	1 (11.1)	1 (6.3)	2 (16.7)	4 (12.5)
SI	0	0	2 (12.5)	0	2 (6.3)
SD	1 (33.3)	3 (33.3)	9 (56.3)	4 (33.3)	14 (43.8)
PD	0	1 (11.1)	2 (12.5)	1 (8.3)	4 (12.5)
NA	0	0	1 (6.3)	0	2 (6.3)
NE	1 (33.3)	3 (33.3)	0	4 (33.3)	4 (12.5)
Prior Tyrosine Kinase (TKI) Therapy (n (%))					
Yes	3 (100)	9 (100)	14 (87.5)	12 (100)	30 (93.8)
No	0	0	2 (12.5)	0	2 (6.3)
Prior Radiation Therapy (n (%))					
Yes	0	0	0	0	0
No	3 (100)	9 (100)	16 (100)	12 (100)	32 (100)

Source: Listings 16.2.4.4, 16.2.4.5, 16.2.4.6
Notes: Prior therapies are coded using WHO DD B2 enhanced, version March 2017. Prior therapy is defined as all treatment that started ended on or before first dose date of avapritinib. If a patient has multiple occurrences of a medication, the patient is presented once in the respective patient count.
[1] Percentages based on total number of patients with Prior Midostaurin.

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Table 35.1.10.1.2 Prior Therapies
RAC-RE Population with at least one prior antineoplastic therapy
Study 2101

	Starting Dose (QD)				
	<200 mg (N=3) n (%)	200 mg (N=9) n (%)	300 mg (N=16) n (%)	<=200 mg (N=12) n (%)	All Doses (N=32) n (%)
Prior Cancer Related Surgery-Procedures (n (%))					
Yes	2 (66.7)	7 (77.8)	15 (93.8)	9 (75.0)	27 (84.4)
No	1 (33.3)	2 (22.2)	1 (6.3)	3 (25.0)	5 (15.6)
Prior Midostaurin (n (%))					
Yes	1 (33.3)	7 (77.8)	9 (56.3)	8 (66.7)	17 (53.1)
No	2 (66.7)	2 (22.2)	7 (43.8)	4 (33.3)	15 (46.9)
Best Response to Prior Midostaurin [1] (n (%))					
CR	0	0	0	0	0
PR	0	1 (14.3)	1 (11.1)	1 (12.5)	2 (11.8)
CI	1 (100)	0	1 (11.1)	1 (12.5)	2 (11.8)
SI	0	0	2 (22.2)	0	2 (11.8)
SD	0	3 (42.9)	2 (22.2)	3 (37.5)	5 (29.4)
PD	0	2 (28.6)	1 (11.1)	2 (25.0)	3 (17.6)
NA	0	0	2 (22.2)	0	2 (11.8)
NE	0	1 (14.3)	0	1 (12.5)	1 (5.9)

Source: Listings 16.2.4.4, 16.2.4.5, 16.2.4.6
Notes: Prior therapies are coded using WHO DD B2 enhanced, version March 2017. Prior therapy is defined as all treatment that started ended on or before first dose date of avapritinib. If a patient has multiple occurrences of a medication, the patient is presented once in the respective patient count.
[1] Percentages based on total number of patients with Prior Midostaurin.

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Table 35.1.10.1.2 Prior Therapies
RAC-RE Population with at least one prior antineoplastic therapy
Study 2101

	Starting Dose (QD)				
	<200 mg (N=3) n (%)	200 mg (N=9) n (%)	300 mg (N=16) n (%)	<=200 mg (N=12) n (%)	All Doses (N=32) n (%)
Reason for Discontinuation of Prior Midostaurin [1] (n (%))					
Completed Scheduled Cycles	0	0	0	0	0
PD/Relapse	1 (100)	2 (28.6)	5 (55.6)	3 (37.5)	8 (47.1)
Refractory	0	0	0	0	0
Toxicity	0	3 (42.9)	2 (22.2)	3 (37.5)	5 (29.4)
Other	0	1 (14.3)	2 (22.2)	1 (12.5)	3 (17.6)
Unknown	0	1 (14.3)	0	1 (12.5)	1 (5.9)
Duration of Treatment on Midostaurin (months)					
n	1	7	9	8	17
Mean (StdDev)	10.2 (-)	9.9 (4.32)	14.6 (17.23)	9.9 (4.00)	12.4 (12.70)
Median	10.2	8.7	6.2	8.8	8.0
Min, Max	10, 10	5, 17	5, 58	5, 17	5, 58

Source: Listings 16.2.4.4, 16.2.4.5, 16.2.4.6
Notes: Prior therapies are coded using WHO DD B2 enhanced, version March 2017. Prior therapy is defined as all treatment that started ended on or before first dose date of avapritinib. If a patient has multiple occurrences of a medication, the patient is presented once in the respective patient count.
[1] Percentages based on total number of patients with Prior Midostaurin.

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Table 35.1.10.1.2 Prior Therapies
RAC-RE Population with at least one prior antineoplastic therapy
Study 2202

	Starting Dose (QD) 200 mg (N=22) n (%)	All Doses (N=23) n (%)
Prior Antineoplastic Therapy (n (%))		
No	0	0
Yes	22 (100)	23 (100)
Midostaurin	16 (72.7)	17 (73.9)
Cladribine	3 (13.6)	4 (17.4)
Imatinib	4 (18.2)	4 (17.4)
Hydroxycarbamide	3 (13.6)	3 (13.0)
Azacitidine	2 (9.1)	2 (8.7)
Interferon Alfa	2 (9.1)	2 (8.7)
Dasatinib	1 (4.5)	1 (4.3)
Decitabine	1 (4.5)	1 (4.3)
Investigational Antineoplastic Drugs	1 (4.5)	1 (4.3)
Stem Cells Nos	1 (4.5)	1 (4.3)
Thalidomide	1 (4.5)	1 (4.3)

Source: Listings 16.2.4.4, 16.2.4.5, 16.2.4.6
Notes: Prior therapies are coded using WHO DD B2 enhanced, version March 2017. Prior therapy is defined as all treatment that started ended on or before first dose date of avapritinib. If a patient has multiple occurrences of a medication, the patient is presented once in the respective patient count.
[1] Percentages based on total number of patients with Prior Midostaurin.

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Table 35.1.10.1.2 Prior Therapies
RAC-RE Population with at least one prior antineoplastic therapy
Study 2202

	Starting Dose (QD) 200 mg (N=22) n (%)	All Doses (N=23) n (%)
Best Response to Any Prior Antineoplastic Therapy		
CR	0	0
PR	5 (22.7)	6 (26.1)
CI	3 (13.6)	3 (13.0)
SD	7 (31.8)	7 (30.4)
PD	4 (18.2)	4 (17.4)
Other	2 (9.1)	2 (8.7)
Missing	1 (4.5)	1 (4.3)
Prior Tyrosine Kinase (TKI) Therapy (n (%))		
Yes	21 (95.5)	22 (95.7)
No	1 (4.5)	1 (4.3)
Prior Radiation Therapy (n (%))		
Yes	0	0
No	22 (100)	23 (100)
Prior Midostaurin (n (%))		
Yes	16 (72.7)	17 (73.9)
No	6 (27.3)	6 (26.1)

Source: Listings 16.2.4.4, 16.2.4.5, 16.2.4.6
Notes: Prior therapies are coded using WHO DD B2 enhanced, version March 2017. Prior therapy is defined as all treatment that started ended on or before first dose date of avapritinib. If a patient has multiple occurrences of a medication, the patient is presented once in the respective patient count.
[1] Percentages based on total number of patients with Prior Midostaurin.

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Table 35.1.10.1.2 Prior Therapies
RAC-RE Population with at least one prior antineoplastic therapy
Study 2202

	Starting Dose (QD) 200 mg (N=22) n (%)	All Doses (N=23) n (%)
Best Response to Prior Midostaurin [1] (n (%))		
CR	0	0
PR	4 (25.0)	5 (29.4)
CI	2 (12.5)	2 (11.8)
SD	4 (25.0)	4 (23.5)
PD	2 (12.5)	2 (11.8)
Other	3 (18.8)	3 (17.6)
Missing	1 (6.3)	1 (5.9)
Reason for Discontinuation of Prior Midostaurin [1] (n (%))		
Completed Scheduled Cycles	0	0
PD/Relapse	8 (50.0)	9 (52.9)
Refractory	1 (6.3)	1 (5.9)
Other	4 (25.0)	4 (23.5)
Toxicity	3 (18.8)	3 (17.6)
Unknown	0	0

Source: Listings 16.2.4.4, 16.2.4.5, 16.2.4.6
Notes: Prior therapies are coded using WHO DD B2 enhanced, version March 2017. Prior therapy is defined as all treatment that started ended on or before first dose date of avapritinib. If a patient has multiple occurrences of a medication, the patient is presented once in the respective patient count.
[1] Percentages based on total number of patients with Prior Midostaurin.

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Table 35.1.10.1.2 Prior Therapies
RAC-RE Population with at least one prior antineoplastic therapy
Study 2202

	Starting Dose (QD) 200 mg (N=22) n (%)	All Doses (N=23) n (%)
Duration of Treatment on Midostaurin (months)		
n	17	18
Mean (StdDev)	22.9 (31.33)	28.5 (38.57)
Median	9.0	9.5
Min, Max	2, 122	2, 124

Source: Listings 16.2.4.4, 16.2.4.5, 16.2.4.6
Notes: Prior therapies are coded using WHO DD B2 enhanced, version March 2017. Prior therapy is defined as all treatment that started ended on or before first dose date of avapritinib. If a patient has multiple occurrences of a medication, the patient is presented once in the respective patient count.
[1] Percentages based on total number of patients with Prior Midostaurin.

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Table 35.1.10.1.2 Prior Therapies
RAC-RE Population with at least one prior antineoplastic therapy
Studies 2101 and 2202

	Starting Dose (QD)				
	<200 mg (N=4) n (%)	200 mg (N=31) n (%)	300 mg (N=16) n (%)	<=200 mg (N=35) n (%)	All Doses (N=55) n (%)
Prior Antineoplastic Therapy (n (%))					
No	0	0	0	0	0
Yes	4 (100)	31 (100)	16 (100)	35 (100)	55 (100)
Midostaurin	2 (50.0)	23 (74.2)	9 (56.3)	25 (71.4)	34 (61.8)
Cladribine	1 (25.0)	4 (12.9)	4 (25.0)	5 (14.3)	11 (20.0)
Imatinib	0	5 (16.1)	2 (12.5)	5 (14.3)	7 (12.7)
Hydroxycarbamide	0	3 (9.7)	3 (18.8)	3 (8.6)	6 (10.9)
Azacitidine	0	2 (6.5)	0	2 (5.7)	4 (7.3)
Interferon	0	2 (6.5)	1 (6.3)	2 (5.7)	3 (5.5)
Investigational Antineoplastic Drugs	0	2 (6.5)	1 (6.3)	2 (5.7)	3 (5.5)
Brentuximab Vedotin	0	0	2 (12.5)	0	2 (3.6)
Decitabine	0	1 (3.2)	1 (6.3)	1 (2.9)	2 (3.6)
Ibrutinib	1 (25.0)	0	0	1 (2.9)	2 (3.6)
Interferon Alfa	0	2 (6.5)	0	2 (5.7)	2 (3.6)
Ruxolitinib	0	0	1 (6.3)	0	2 (3.6)
Chlorambucil	0	0	1 (6.3)	0	1 (1.8)
Dasatinib	0	1 (3.2)	0	1 (2.9)	1 (1.8)

Source: Listings 16.2.4.4, 16.2.4.5, 16.2.4.6
Notes: Prior therapies are coded using WHO DD B2 enhanced, version March 2017. Prior therapy is defined as all treatment that started ended on or before first dose date of avapritinib. If a patient has multiple occurrences of a medication, the patient is presented once in the respective patient count.
[1] Percentages based on total number of patients with Prior Midostaurin.

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Table 35.1.10.1.2 Prior Therapies
RAC-RE Population with at least one prior antineoplastic therapy
Studies 2101 and 2202

	Starting Dose (QD)				
	<200 mg (N=4) n (%)	200 mg (N=31) n (%)	300 mg (N=16) n (%)	<=200 mg (N=35) n (%)	All Doses (N=55) n (%)
Prior Antineoplastic Therapy (n (%)) (Cnt..)					
Obinutuzumab	0	0	1 (6.3)	0	1 (1.8)
Peginterferon Alfa-2a	1 (25.0)	0	0	1 (2.9)	1 (1.8)
Rituximab	0	0	1 (6.3)	0	1 (1.8)
Stem Cells Nos	0	1 (3.2)	0	1 (2.9)	1 (1.8)
Thalidomide	0	1 (3.2)	0	1 (2.9)	1 (1.8)
Best Response to Any Prior Antineoplastic Therapy					
CR	0	0	0	0	0
PR	1 (25.0)	6 (19.4)	1 (6.3)	7 (20.0)	8 (14.5)
CI	1 (25.0)	4 (12.9)	1 (6.3)	5 (14.3)	7 (12.7)
SI	0	0	2 (12.5)	0	2 (3.6)
SD	1 (25.0)	10 (32.3)	9 (56.3)	11 (31.4)	21 (38.2)
PD	0	5 (16.1)	2 (12.5)	5 (14.3)	8 (14.5)
NA	0	0	1 (6.3)	0	2 (3.6)
NE	1 (25.0)	3 (9.7)	0	4 (11.4)	4 (7.3)
Other	0	2 (6.5)	0	2 (5.7)	2 (3.6)
Missing	0	1 (3.2)	0	1 (2.9)	1 (1.8)

Source: Listings 16.2.4.4, 16.2.4.5, 16.2.4.6
Notes: Prior therapies are coded using WHO DD B2 enhanced, version March 2017. Prior therapy is defined as all treatment that started ended on or before first dose date of avapritinib. If a patient has multiple occurrences of a medication, the patient is presented once in the respective patient count.
[1] Percentages based on total number of patients with Prior Midostaurin.

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Table 35.1.10.1.2 Prior Therapies
RAC-RE Population with at least one prior antineoplastic therapy
Studies 2101 and 2202

	Starting Dose (QD)				
	<200 mg (N=4) n (%)	200 mg (N=31) n (%)	300 mg (N=16) n (%)	<=200 mg (N=35) n (%)	All Doses (N=55) n (%)
Prior Tyrosine Kinase (TKI) Therapy (n (%))					
Yes	4 (100)	30 (96.8)	14 (87.5)	34 (97.1)	52 (94.5)
No	0	1 (3.2)	2 (12.5)	1 (2.9)	3 (5.5)
Prior Radiation Therapy (n (%))					
Yes	0	0	0	0	0
No	4 (100)	31 (100)	16 (100)	35 (100)	55 (100)
Prior Cancer Related Surgery-Procedures (n (%))					
Yes	2 (50.0)	7 (22.6)	15 (93.8)	9 (25.7)	27 (49.1)
No	1 (25.0)	2 (6.5)	1 (6.3)	3 (8.6)	5 (9.1)
Prior Midostaurin (n (%))					
Yes	2 (50.0)	23 (74.2)	9 (56.3)	25 (71.4)	34 (61.8)
No	2 (50.0)	8 (25.8)	7 (43.8)	10 (28.6)	21 (38.2)

Source: Listings 16.2.4.4, 16.2.4.5, 16.2.4.6
Notes: Prior therapies are coded using WHO DD B2 enhanced, version March 2017. Prior therapy is defined as all treatment that started ended on or before first dose date of avapritinib. If a patient has multiple occurrences of a medication, the patient is presented once in the respective patient count.
[1] Percentages based on total number of patients with Prior Midostaurin.

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Table 35.1.10.1.2 Prior Therapies
RAC-RE Population with at least one prior antineoplastic therapy
Studies 2101 and 2202

	Starting Dose (QD)				
	<200 mg (N=4) n (%)	200 mg (N=31) n (%)	300 mg (N=16) n (%)	<=200 mg (N=35) n (%)	All Doses (N=55) n (%)
Best Response to Prior Midostaurin [1] (n (%))					
CR	0	0	0	0	0
PR	1 (50.0)	5 (21.7)	1 (11.1)	6 (24.0)	7 (20.6)
CI	1 (50.0)	2 (8.7)	1 (11.1)	3 (12.0)	4 (11.8)
SI	0	0	2 (22.2)	0	2 (5.9)
SD	0	7 (30.4)	2 (22.2)	7 (28.0)	9 (26.5)
PD	0	4 (17.4)	1 (11.1)	4 (16.0)	5 (14.7)
NA	0	0	2 (22.2)	0	2 (5.9)
NE	0	1 (4.3)	0	1 (4.0)	1 (2.9)
Other	0	3 (13.0)	0	3 (12.0)	3 (8.8)
Missing	0	1 (4.3)	0	1 (4.0)	1 (2.9)

Source: Listings 16.2.4.4, 16.2.4.5, 16.2.4.6
Notes: Prior therapies are coded using WHO DD B2 enhanced, version March 2017. Prior therapy is defined as all treatment that started ended on or before first dose date of avapritinib. If a patient has multiple occurrences of a medication, the patient is presented once in the respective patient count.
[1] Percentages based on total number of patients with Prior Midostaurin.

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Table 35.1.10.1.2 Prior Therapies
RAC-RE Population with at least one prior antineoplastic therapy
Studies 2101 and 2202

	Starting Dose (QD)				
	<200 mg (N=4) n (%)	200 mg (N=31) n (%)	300 mg (N=16) n (%)	<=200 mg (N=35) n (%)	All Doses (N=55) n (%)
Reason for Discontinuation of Prior Midostaurin [1] (n (%))					
Completed Scheduled Cycles	0	0	0	0	0
PD/Relapse	2 (100)	10 (43.5)	5 (55.6)	12 (48.0)	17 (50.0)
Refractory	0	1 (4.3)	0	1 (4.0)	1 (2.9)
Toxicity	0	6 (26.1)	2 (22.2)	6 (24.0)	8 (23.5)
Other	0	5 (21.7)	2 (22.2)	5 (20.0)	7 (20.6)
Unknown	0	1 (4.3)	0	1 (4.0)	1 (2.9)
Duration of Treatment on Midostaurin (months)					
n	2	24	9	26	35
Mean (StdDev)	66.9 (80.22)	19.1 (26.91)	14.6 (17.23)	22.8 (33.05)	20.7 (29.76)
Median	66.9	8.8	6.2	9.0	8.7
Min, Max	10, 124	2, 122	5, 58	2, 124	2, 124

Source: Listings 16.2.4.4, 16.2.4.5, 16.2.4.6
Notes: Prior therapies are coded using WHO DD B2 enhanced, version March 2017. Prior therapy is defined as all treatment that started ended on or before first dose date of avapritinib. If a patient has multiple occurrences of a medication, the patient is presented once in the respective patient count.
[1] Percentages based on total number of patients with Prior Midostaurin.

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Table 35.3.1.5
Summary of Concomitant Medications
AdvSM Population & Prior Neoplastic Therapy = Yes

	BLU-285-2101		
ATC Class Preferred Drug Name	200 mg (N=12) n (%)	<=200 mg (N=16) n (%)	All Doses (N=41) n (%)
Any Concomitant Medication	12 (100)	16 (100)	41 (100)
ACE INHIBITORS, COMBINATIONS	0	0	1 (2.4)
HYDROCHLOROTHIAZIDE;LISINOPRIL	0	0	1 (2.4)
ACE INHIBITORS, PLAIN	3 (25.0)	3 (18.8)	6 (14.6)
LISINOPRIL	2 (16.7)	2 (12.5)	4 (9.8)
ENALAPRIL	1 (8.3)	1 (6.3)	1 (2.4)
LISINOPRIL DIHYDRATE	0	0	1 (2.4)

Abbreviations: ATC = Anatomic Therapeutic Chemical; AdvSM = Advanced Systemic Mastocytosis
Note 1: Prior medications are excluded from this table. Concomitatnt medications are all medications taken anytime from the first dose of study drug to the last dose of study drug + 30 days.
Note 2: ATC Class and Preferred Drug Term are coded using WHO drug dictionary versions from each patient's respective study, as listed in the Statistical Analysis Plan.
Note 3: If a patient experiences more than 1 treatment within a given ATC Class or Preferred Drug Term, that patient is counted only once under that ATC Class or Preferred Drug Term, respectively.
Note 4: Percentages are based on the number of patients in the Safety Population in each column.
Note 5: ATC Classes are sorted alphabetically and Preferred Drug Terms are subsequently sorted in decreasing order of frequency using the 'All Doses' column.

Source (Date): Program: t-35-3-1-5-cm.sas Date: 16:52/17SEP2021

Table 99.2.4.1.1
Summary of Overall Survival by Prior Antineoplastic Therapy
Study BLU-285-2101, AdvSM Population
Prior Anti-Neoplastic Therapy = No

All Doses

	ASM (N=1)	SM-AHN (N=22)	MCL (N=5)	All AdvSM (N=28)
Events	0	8 (36.4)	1 (20.0)	9 (32.1)
Censors	1 (100.0)	14 (63.6)	4 (80.0)	19 (67.9)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	24.5 (21.4 -NE)	NE (6.9 -NE)	46.9 (21.4 -NE)
25th, 75th percentiles	NE, NE	15.2, 46.9	NE, NE	15.2, NE
3 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	89.9 (76.7 -100.0)	75.0 (32.6 -100.0)	88.0 (75.2 -100.0)
12 Months (95% CIs)	100.0 (100.0 -100.0)	78.3 (59.3 - 97.3)	75.0 (32.6 -100.0)	78.9 (62.4 - 95.4)
18 Months (95% CIs)	100.0 (100.0 -100.0)	72.3 (51.4 - 93.2)	75.0 (32.6 -100.0)	74.3 (56.4 - 92.2)
24 Months (95% CIs)	100.0 (100.0 -100.0)	62.0 (36.0 - 87.9)	75.0 (32.6 -100.0)	67.5 (46.9 - 88.1)
30 Months (95% CIs)		46.5 (13.8 - 79.2)	75.0 (32.6 -100.0)	59.1 (35.3 - 82.8)
36 Months (95% CIs)		46.5 (13.8 - 79.2)	75.0 (32.6 -100.0)	59.1 (35.3 - 82.8)
42 Months (95% CIs)		46.5 (13.8 - 79.2)		59.1 (35.3 - 82.8)
48 Months (95% CIs)				
54 Months (95% CIs)				
Median OS Follow-up[a] (months) (95% CI)	25.6 (NE -NE)	21.0 (18.3 - 43.9)	35.2 (6.3 - 38.7)	22.9 (20.5 - 35.2)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Overall survival is defined as the time in months from the start of treatment to the date of death. Patients who die before or on the data cutoff date will considered to have had an overall survival event. All Patients who do not have a death record prior to or on the cutoff date are censored at the last date known alive.
[a] Median OS Follow-up is calculated from the Kaplan-Meier method switching the OS event/censored status, i.e. OS event as censored and censored as OS event
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Table 99.2.4.1.1
Summary of Overall Survival by Prior Antineoplastic Therapy
Study BLU-285-2101, AdvSM Population
Prior Anti-Neoplastic Therapy = Yes

All Doses

	ASM (N=7)	SM-AHN (N=26)	MCL (N=8)	All AdvSM (N=41)
Events	0	7 (26.9)	1 (12.5)	8 (19.5)
Censors	7 (100.0)	19 (73.1)	7 (87.5)	33 (80.5)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (NE -NE)	NE (31.2 -NE)	NE (NE -NE)
25th, 75th percentiles	NE, NE	18.6, NE	31.2, NE	31.2, NE
3 Months (95% CIs)	100.0 (100.0 -100.0)	96.2 (88.8 -100.0)	100.0 (100.0 -100.0)	97.6 (92.8 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	92.3 (82.1 -100.0)	100.0 (100.0 -100.0)	95.1 (88.5 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	88.3 (75.8 -100.0)	100.0 (100.0 -100.0)	92.6 (84.4 -100.0)
12 Months (95% CIs)	100.0 (100.0 -100.0)	84.3 (70.1 - 98.4)	100.0 (100.0 -100.0)	89.9 (80.5 - 99.3)
18 Months (95% CIs)	100.0 (100.0 -100.0)	75.4 (58.2 - 92.6)	100.0 (100.0 -100.0)	83.9 (72.0 - 95.8)
24 Months (95% CIs)	100.0 (100.0 -100.0)	69.6 (50.3 - 88.9)	100.0 (100.0 -100.0)	80.3 (66.9 - 93.6)
30 Months (95% CIs)	100.0 (100.0 -100.0)	69.6 (50.3 - 88.9)	100.0 (100.0 -100.0)	80.3 (66.9 - 93.6)
36 Months (95% CIs)	100.0 (100.0 -100.0)	69.6 (50.3 - 88.9)	66.7 (13.3 -100.0)	73.6 (56.0 - 91.1)
42 Months (95% CIs)	100.0 (100.0 -100.0)	69.6 (50.3 - 88.9)	66.7 (13.3 -100.0)	73.6 (56.0 - 91.1)
48 Months (95% CIs)	100.0 (100.0 -100.0)	69.6 (50.3 - 88.9)		73.6 (56.0 - 91.1)
54 Months (95% CIs)				
Median OS Follow-up[a] (months) (95% CI)	31.3 (21.5 - 39.4)	24.2 (18.6 - 30.7)	17.1 (9.5 - 31.8)	27.3 (19.0 - 31.3)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Overall survival is defined as the time in months from the start of treatment to the date of death. Patients who die before or on the data cutoff date will considered to have had an overall survival event. All Patients who do not have a death record prior to or on the cutoff date are censored at the last date known alive.
[a] Median OS Follow-up is calculated from the Kaplan-Meier method switching the OS event/censored status, i.e. OS event as censored and censored as OS event
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Table 99.2.4.1.1
Summary of Overall Survival by Prior Antineoplastic Therapy
Study BLU-285-2101, AdvSM Population
Prior Anti-Neoplastic Therapy = No

Starting Dose: < 200 mg	ASM (N=0)	SM-AHN (N=5)	MCL (N=0)	All AdvSM (N=5)
Events		3 (60.0)		3 (60.0)
Censors		2 (40.0)		2 (40.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		46.9 (6.5 -NE)		46.9 (6.5 -NE)
25th, 75th percentiles		24.5, NE		24.5, NE
3 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
6 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
9 Months (95% CIs)		80.0 (44.9 -100.0)		80.0 (44.9 -100.0)
12 Months (95% CIs)		80.0 (44.9 -100.0)		80.0 (44.9 -100.0)
18 Months (95% CIs)		80.0 (44.9 -100.0)		80.0 (44.9 -100.0)
24 Months (95% CIs)		80.0 (44.9 -100.0)		80.0 (44.9 -100.0)
30 Months (95% CIs)		60.0 (17.1 -100.0)		60.0 (17.1 -100.0)
36 Months (95% CIs)		60.0 (17.1 -100.0)		60.0 (17.1 -100.0)
42 Months (95% CIs)		60.0 (17.1 -100.0)		60.0 (17.1 -100.0)
48 Months (95% CIs)				
54 Months (95% CIs)				
Median OS Follow-up[a] (months) (95% CI)		46.9 (43.9 - 46.9)		46.9 (43.9 - 46.9)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Overall survival is defined as the time in months from the start of treatment to the date of death. Patients who die before or on the data cutoff date will considered to have had an overall survival event. All Patients who do not have a death record prior to or on the cutoff date are censored at the last date known alive.
[a] Median OS Follow-up is calculated from the Kaplan-Meier method switching the OS event/censored status, i.e. OS event as censored and censored as OS event
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.4.1.1-os-advsm-nat.sas Date: 10:44/19JAN2021

Table 99.2.4.1.1
Summary of Overall Survival by Prior Antineoplastic Therapy
Study BLU-285-2101, AdvSM Population
Prior Anti-Neoplastic Therapy = Yes

Starting Dose: < 200 mg

	ASM (N=1)	SM-AHN (N=2)	MCL (N=1)	All AdvSM (N=4)
Events	0	0	0	0
Censors	1 (100.0)	2 (100.0)	1 (100.0)	4 (100.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (NE -NE)	NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
12 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
18 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
24 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
30 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
36 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
42 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
48 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
54 Months (95% CIs)				
Median OS Follow-up[a] (months) (95% CI)	48.6 (NE -NE)	46.6 (42.6 - 50.6)	46.3 (NE -NE)	47.4 (42.6 - 50.6)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Overall survival is defined as the time in months from the start of treatment to the date of death. Patients who die before or on the data cutoff date will considered to have had an overall survival event. All Patients who do not have a death record prior to or on the cutoff date are censored at the last date known alive.
[a] Median OS Follow-up is calculated from the Kaplan-Meier method switching the OS event/censored status, i.e. OS event as censored and censored as OS event
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Table 99.2.4.1.1
Summary of Overall Survival by Prior Antineoplastic Therapy
Study BLU-285-2101, AdvSM Population
Prior Anti-Neoplastic Therapy = No

Starting Dose: < 300 mg

	ASM (N=0)	SM-AHN (N=11)	MCL (N=2)	All AdvSM (N=13)
Events		4 (36.4)	0	4 (30.8)
Censors		7 (63.6)	2 (100.0)	9 (69.2)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		46.9 (7.7 -NE)	NE (NE -NE)	46.9 (24.5 -NE)
25th, 75th percentiles		24.5, NE	NE, NE	24.5, NE
3 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)		77.1 (48.9 -100.0)	100.0 (100.0 -100.0)	79.5 (54.0 -100.0)
12 Months (95% CIs)		77.1 (48.9 -100.0)	100.0 (100.0 -100.0)	79.5 (54.0 -100.0)
18 Months (95% CIs)		77.1 (48.9 -100.0)	100.0 (100.0 -100.0)	79.5 (54.0 -100.0)
24 Months (95% CIs)		77.1 (48.9 -100.0)	100.0 (100.0 -100.0)	79.5 (54.0 -100.0)
30 Months (95% CIs)		57.9 (18.9 - 96.9)	100.0 (100.0 -100.0)	63.6 (29.0 - 98.2)
36 Months (95% CIs)		57.9 (18.9 - 96.9)	100.0 (100.0 -100.0)	63.6 (29.0 - 98.2)
42 Months (95% CIs)		57.9 (18.9 - 96.9)		63.6 (29.0 - 98.2)
48 Months (95% CIs)				
54 Months (95% CIs)				
Median OS Follow-up[a] (months) (95% CI)		9.5 (7.5 - 46.9)	22.5 (6.3 - 38.7)	9.5 (7.5 - 46.9)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Overall survival is defined as the time in months from the start of treatment to the date of death. Patients who die before or on the data cutoff date will considered to have had an overall survival event. All Patients who do not have a death record prior to or on the cutoff date are censored at the last date known alive.
[a] Median OS Follow-up is calculated from the Kaplan-Meier method switching the OS event/censored status, i.e. OS event as censored and censored as OS event
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Table 99.2.4.1.1
Summary of Overall Survival by Prior Antineoplastic Therapy
Study BLU-285-2101, AdvSM Population
Prior Anti-Neoplastic Therapy = Yes

Starting Dose: < 300 mg

	ASM (N=2)	SM-AHN (N=9)	MCL (N=5)	All AdvSM (N=16)
Events	0	3 (33.3)	0	3 (18.8)
Censors	2 (100.0)	6 (66.7)	5 (100.0)	13 (81.3)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (13.0 -NE)	NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles	NE, NE	13.0, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0 -100.0)	88.9 (68.4 -100.0)	100.0 (100.0 -100.0)	93.8 (81.9 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	88.9 (68.4 -100.0)	100.0 (100.0 -100.0)	93.8 (81.9 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	77.8 (50.6 -100.0)	100.0 (100.0 -100.0)	87.1 (70.3 -100.0)
12 Months (95% CIs)	100.0 (100.0 -100.0)	77.8 (50.6 -100.0)	100.0 (100.0 -100.0)	87.1 (70.3 -100.0)
18 Months (95% CIs)	100.0 (100.0 -100.0)	62.2 (27.4 - 97.1)	100.0 (100.0 -100.0)	77.4 (54.1 -100.0)
24 Months (95% CIs)	100.0 (100.0 -100.0)	62.2 (27.4 - 97.1)	100.0 (100.0 -100.0)	77.4 (54.1 -100.0)
30 Months (95% CIs)	100.0 (100.0 -100.0)	62.2 (27.4 - 97.1)	100.0 (100.0 -100.0)	77.4 (54.1 -100.0)
36 Months (95% CIs)	100.0 (100.0 -100.0)	62.2 (27.4 - 97.1)	100.0 (100.0 -100.0)	77.4 (54.1 -100.0)
42 Months (95% CIs)	100.0 (100.0 -100.0)	62.2 (27.4 - 97.1)	100.0 (100.0 -100.0)	77.4 (54.1 -100.0)
48 Months (95% CIs)	100.0 (100.0 -100.0)	62.2 (27.4 - 97.1)		77.4 (54.1 -100.0)
54 Months (95% CIs)				
Median OS Follow-up[a] (months) (95% CI)	28.0 (7.5 - 48.6)	41.2 (12.7 - 42.6)	15.2 (9.0 - 46.3)	16.1 (11.6 - 42.6)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Overall survival is defined as the time in months from the start of treatment to the date of death. Patients who die before or on the data cutoff date will considered to have had an overall survival event. All Patients who do not have a death record prior to or on the cutoff date are censored at the last date known alive.
[a] Median OS Follow-up is calculated from the Kaplan-Meier method switching the OS event/censored status, i.e. OS event as censored and censored as OS event
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Table 99.2.4.1.1
Summary of Overall Survival by Prior Antineoplastic Therapy
Study BLU-285-2101, AdvSM Population
Prior Anti-Neoplastic Therapy = No

Starting Dose: 200 mg	ASM (N=0)	SM-AHN (N=6)	MCL (N=2)	All AdvSM (N=8)
Events		1 (16.7)	0	1 (12.5)
Censors		5 (83.3)	2 (100.0)	7 (87.5)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (7.7 -NE)	NE (NE -NE)	NE (7.7 -NE)
25th, 75th percentiles		7.7, NE	NE, NE	NE, NE
3 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)		66.7 (13.3 -100.0)	100.0 (100.0 -100.0)	75.0 (32.6 -100.0)
12 Months (95% CIs)			100.0 (100.0 -100.0)	75.0 (32.6 -100.0)
18 Months (95% CIs)			100.0 (100.0 -100.0)	75.0 (32.6 -100.0)
24 Months (95% CIs)			100.0 (100.0 -100.0)	75.0 (32.6 -100.0)
30 Months (95% CIs)			100.0 (100.0 -100.0)	75.0 (32.6 -100.0)
36 Months (95% CIs)			100.0 (100.0 -100.0)	75.0 (32.6 -100.0)
42 Months (95% CIs)				
48 Months (95% CIs)				
54 Months (95% CIs)				
Median OS Follow-up[a] (months) (95% CI)		7.9 (6.8 - 9.5)	22.5 (6.3 - 38.7)	7.9 (6.3 - 9.5)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Overall survival is defined as the time in months from the start of treatment to the date of death. Patients who die before or on the data cutoff date will considered to have had an overall survival event. All Patients who do not have a death record prior to or on the cutoff date are censored at the last date known alive.
[a] Median OS Follow-up is calculated from the Kaplan-Meier method switching the OS event/censored status, i.e. OS event as censored and censored as OS event
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.4.1.1-os-advsm-nat.sas Date: 10:44/19JAN2021

Table 99.2.4.1.1
Summary of Overall Survival by Prior Antineoplastic Therapy
Study BLU-285-2101, AdvSM Population
Prior Anti-Neoplastic Therapy = Yes

Starting Dose: 200 mg	ASM (N=1)	SM-AHN (N=7)	MCL (N=4)	All AdvSM (N=12)
Events	0	3 (42.9)	0	3 (25.0)
Censors	1 (100.0)	4 (57.1)	4 (100.0)	9 (75.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	13.0 (8.0 -NE)	NE (NE -NE)	NE (13.0 -NE)
25th, 75th percentiles	NE, NE	8.0, NE	NE, NE	13.0, NE
3 Months (95% CIs)	100.0 (100.0 -100.0)	85.7 (59.8 -100.0)	100.0 (100.0 -100.0)	91.7 (76.0 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	85.7 (59.8 -100.0)	100.0 (100.0 -100.0)	91.7 (76.0 -100.0)
9 Months (95% CIs)		71.4 (38.0 -100.0)	100.0 (100.0 -100.0)	82.5 (60.4 -100.0)
12 Months (95% CIs)		71.4 (38.0 -100.0)	100.0 (100.0 -100.0)	82.5 (60.4 -100.0)
18 Months (95% CIs)		47.6 (3.5 - 91.8)	100.0 (100.0 -100.0)	66.0 (32.1 - 99.9)
24 Months (95% CIs)		47.6 (3.5 - 91.8)		66.0 (32.1 - 99.9)
30 Months (95% CIs)		47.6 (3.5 - 91.8)		66.0 (32.1 - 99.9)
36 Months (95% CIs)		47.6 (3.5 - 91.8)		66.0 (32.1 - 99.9)
42 Months (95% CIs)				
48 Months (95% CIs)				
54 Months (95% CIs)				
Median OS Follow-up[a] (months) (95% CI)	7.5 (NE -NE)	16.1 (11.6 - 41.2)	12.3 (9.0 - 19.0)	15.2 (9.5 - 19.0)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Overall survival is defined as the time in months from the start of treatment to the date of death. Patients who die before or on the data cutoff date will considered to have had an overall survival event. All Patients who do not have a death record prior to or on the cutoff date are censored at the last date known alive.
[a] Median OS Follow-up is calculated from the Kaplan-Meier method switching the OS event/censored status, i.e. OS event as censored and censored as OS event
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.4.1.1-os-advsm-nat.sas
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Table 99.2.4.1.1
Summary of Overall Survival by Prior Antineoplastic Therapy
Study BLU-285-2101, AdvSM Population
Prior Anti-Neoplastic Therapy = No

Starting Dose: 300 mg

	ASM (N=1)	SM-AHN (N=11)	MCL (N=2)	All AdvSM (N=14)
Events	0	4 (36.4)	1 (50.0)	5 (35.7)
Censors	1 (100.0)	7 (63.6)	1 (50.0)	9 (64.3)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	21.4 (15.2 -NE)	NE (6.9 -NE)	NE (15.2 -NE)
25th, 75th percentiles	NE, NE	15.2, NE	6.9, NE	15.2, NE
3 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	50.0 (0.0 -100.0)	92.9 (79.4 -100.0)
12 Months (95% CIs)	100.0 (100.0 -100.0)	81.8 (59.0 -100.0)	50.0 (0.0 -100.0)	78.6 (57.1 -100.0)
18 Months (95% CIs)	100.0 (100.0 -100.0)	72.7 (46.4 - 99.0)	50.0 (0.0 -100.0)	71.4 (47.8 - 95.1)
24 Months (95% CIs)	100.0 (100.0 -100.0)		50.0 (0.0 -100.0)	57.1 (25.7 - 88.5)
30 Months (95% CIs)			50.0 (0.0 -100.0)	57.1 (25.7 - 88.5)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				
54 Months (95% CIs)				
Median OS Follow-up[a] (months) (95% CI)	25.6 (NE -NE)	20.9 (20.5 - 22.9)	33.4 (NE -NE)	21.9 (20.5 - 25.6)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Overall survival is defined as the time in months from the start of treatment to the date of death. Patients who die before or on the data cutoff date will considered to have had an overall survival event. All Patients who do not have a death record prior to or on the cutoff date are censored at the last date known alive.
[a] Median OS Follow-up is calculated from the Kaplan-Meier method switching the OS event/censored status, i.e. OS event as censored and censored as OS event
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.4.1.1-os-advsm-nat.sas
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Table 99.2.4.1.1
Summary of Overall Survival by Prior Antineoplastic Therapy
Study BLU-285-2101, AdvSM Population
Prior Anti-Neoplastic Therapy = Yes

Starting Dose: 300 mg	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Events	0	4 (30.8)	1 (33.3)	5 (25.0)
Censors	4 (100.0)	9 (69.2)	2 (66.7)	15 (75.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (18.6 -NE)	NE (31.2 -NE)	NE (31.2 -NE)
25th, 75th percentiles	NE, NE	18.6, NE	31.2, NE	31.2, NE
3 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	92.3 (77.8 -100.0)	100.0 (100.0 -100.0)	95.0 (85.4 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	92.3 (77.8 -100.0)	100.0 (100.0 -100.0)	95.0 (85.4 -100.0)
12 Months (95% CIs)	100.0 (100.0 -100.0)	84.6 (65.0 -100.0)	100.0 (100.0 -100.0)	90.0 (76.9 -100.0)
18 Months (95% CIs)	100.0 (100.0 -100.0)	76.9 (54.0 - 99.8)	100.0 (100.0 -100.0)	84.7 (68.8 -100.0)
24 Months (95% CIs)	100.0 (100.0 -100.0)	67.3 (40.6 - 94.0)	100.0 (100.0 -100.0)	78.7 (59.9 - 97.4)
30 Months (95% CIs)	100.0 (100.0 -100.0)	67.3 (40.6 - 94.0)	100.0 (100.0 -100.0)	78.7 (59.9 - 97.4)
36 Months (95% CIs)	100.0 (100.0 -100.0)			62.9 (31.5 - 94.3)
42 Months (95% CIs)				
48 Months (95% CIs)				
54 Months (95% CIs)				
Median OS Follow-up[a] (months) (95% CI)	31.6 (27.7 - 39.4)	24.2 (22.4 - 30.0)	31.8 (9.6 - 31.8)	29.5 (22.5 - 31.3)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Overall survival is defined as the time in months from the start of treatment to the date of death. Patients who die before or on the data cutoff date will considered to have had an overall survival event. All Patients who do not have a death record prior to or on the cutoff date are censored at the last date known alive.
[a] Median OS Follow-up is calculated from the Kaplan-Meier method switching the OS event/censored status, i.e. OS event as censored and censored as OS event
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Table 99.2.4.1.1
Summary of Overall Survival by Prior Antineoplastic Therapy
Study BLU-285-2101, AdvSM Population
Prior Anti-Neoplastic Therapy = No

Starting Dose: 200 mg and 300 mg

	ASM (N=1)	SM-AHN (N=17)	MCL (N=4)	All AdvSM (N=22)
Events	0	5 (29.4)	1 (25.0)	6 (27.3)
Censors	1 (100.0)	12 (70.6)	3 (75.0)	16 (72.7)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	21.4 (15.2 -NE)	NE (6.9 -NE)	NE (15.2 -NE)
25th, 75th percentiles	NE, NE	15.2, NE	6.9, NE	15.2, NE
3 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	92.9 (79.4 -100.0)	66.7 (13.3 -100.0)	89.2 (75.0 -100.0)
12 Months (95% CIs)	100.0 (100.0 -100.0)	76.6 (53.3 -100.0)	66.7 (13.3 -100.0)	76.8 (56.7 - 96.9)
18 Months (95% CIs)	100.0 (100.0 -100.0)	68.1 (42.1 - 94.1)	66.7 (13.3 -100.0)	70.4 (48.4 - 92.4)
24 Months (95% CIs)	100.0 (100.0 -100.0)		66.7 (13.3 -100.0)	58.7 (30.8 - 86.5)
30 Months (95% CIs)			66.7 (13.3 -100.0)	58.7 (30.8 - 86.5)
36 Months (95% CIs)			66.7 (13.3 -100.0)	58.7 (30.8 - 86.5)
42 Months (95% CIs)				
48 Months (95% CIs)				
54 Months (95% CIs)				
Median OS Follow-up[a] (months) (95% CI)	25.6 (NE -NE)	20.5 (9.5 - 22.9)	33.4 (6.3 - 38.7)	20.8 (18.3 - 22.9)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Overall survival is defined as the time in months from the start of treatment to the date of death. Patients who die before or on the data cutoff date will considered to have had an overall survival event. All Patients who do not have a death record prior to or on the cutoff date are censored at the last date known alive.
[a] Median OS Follow-up is calculated from the Kaplan-Meier method switching the OS event/censored status, i.e. OS event as censored and censored as OS event
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Table 99.2.4.1.1
Summary of Overall Survival by Prior Antineoplastic Therapy
Study BLU-285-2101, AdvSM Population
Prior Anti-Neoplastic Therapy = Yes

Starting Dose: 200 mg and 300 mg

	ASM (N=5)	SM-AHN (N=20)	MCL (N=7)	All AdvSM (N=32)
Events	0	7 (35.0)	1 (14.3)	8 (25.0)
Censors	5 (100.0)	13 (65.0)	6 (85.7)	24 (75.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (13.5 -NE)	NE (31.2 -NE)	NE (31.2 -NE)
25th, 75th percentiles	NE, NE	13.0, NE	31.2, NE	18.6, NE
3 Months (95% CIs)	100.0 (100.0 -100.0)	95.0 (85.4 -100.0)	100.0 (100.0 -100.0)	96.9 (90.8 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	90.0 (76.9 -100.0)	100.0 (100.0 -100.0)	93.8 (85.4 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	85.0 (69.4 -100.0)	100.0 (100.0 -100.0)	90.5 (80.3 -100.0)
12 Months (95% CIs)	100.0 (100.0 -100.0)	80.0 (62.5 - 97.5)	100.0 (100.0 -100.0)	87.2 (75.4 - 98.9)
18 Months (95% CIs)	100.0 (100.0 -100.0)	68.6 (47.6 - 89.6)	100.0 (100.0 -100.0)	79.2 (64.3 - 94.2)
24 Months (95% CIs)	100.0 (100.0 -100.0)	61.0 (37.6 - 84.3)	100.0 (100.0 -100.0)	74.3 (57.4 - 91.2)
30 Months (95% CIs)	100.0 (100.0 -100.0)	61.0 (37.6 - 84.3)	100.0 (100.0 -100.0)	74.3 (57.4 - 91.2)
36 Months (95% CIs)	100.0 (100.0 -100.0)	61.0 (37.6 - 84.3)		61.9 (35.7 - 88.2)
42 Months (95% CIs)				
48 Months (95% CIs)				
54 Months (95% CIs)				
Median OS Follow-up[a] (months) (95% CI)	31.3 (7.5 - 39.4)	22.5 (18.2 - 29.5)	15.2 (9.5 - 31.8)	24.2 (16.1 - 30.0)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Overall survival is defined as the time in months from the start of treatment to the date of death. Patients who die before or on the data cutoff date will considered to have had an overall survival event. All Patients who do not have a death record prior to or on the cutoff date are censored at the last date known alive.
[a] Median OS Follow-up is calculated from the Kaplan-Meier method switching the OS event/censored status, i.e. OS event as censored and censored as OS event
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.4.1.1-os-advsm-nat.sas
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Table 99.2.4.1.1
Summary of Overall Survival by Prior Antineoplastic Therapy
Study BLU-285-2101, AdvSM Population
Prior Anti-Neoplastic Therapy = No

Starting Dose: 400 mg

	ASM (N=0)	SM-AHN (N=0)	MCL (N=1)	All AdvSM (N=1)
Events			0	0
Censors			1 (100.0)	1 (100.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)			NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles			NE, NE	NE, NE
3 Months (95% CIs)			100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)			100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)			100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
12 Months (95% CIs)			100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
18 Months (95% CIs)			100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
24 Months (95% CIs)			100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
30 Months (95% CIs)			100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				
54 Months (95% CIs)				
Median OS Follow-up[a] (months) (95% CI)			35.2 (NE -NE)	35.2 (NE -NE)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Overall survival is defined as the time in months from the start of treatment to the date of death. Patients who die before or on the data cutoff date will considered to have had an overall survival event. All Patients who do not have a death record prior to or on the cutoff date are censored at the last date known alive.
[a] Median OS Follow-up is calculated from the Kaplan-Meier method switching the OS event/censored status, i.e. OS event as censored and censored as OS event
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Table 99.2.4.1.1
Summary of Overall Survival by Prior Antineoplastic Therapy
Study BLU-285-2101, AdvSM Population
Prior Anti-Neoplastic Therapy = Yes

Starting Dose: 400 mg

	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Events	0	0		0
Censors	1 (100.0)	4 (100.0)		5 (100.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (NE -NE)		NE (NE -NE)
25th, 75th percentiles	NE, NE	NE, NE		NE, NE
3 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
12 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
18 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
24 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
30 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
36 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
42 Months (95% CIs)				
48 Months (95% CIs)				
54 Months (95% CIs)				
Median OS Follow-up[a] (months) (95% CI)	21.5 (NE -NE)	26.9 (5.4 - 37.9)		21.5 (5.4 - 37.9)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Overall survival is defined as the time in months from the start of treatment to the date of death. Patients who die before or on the data cutoff date will considered to have had an overall survival event. All Patients who do not have a death record prior to or on the cutoff date are censored at the last date known alive.
[a] Median OS Follow-up is calculated from the Kaplan-Meier method switching the OS event/censored status, i.e. OS event as censored and censored as OS event
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Table 99.2.4.1.1
Summary of Overall Survival by Prior Antineoplastic Therapy
Study BLU-285-2202, AdvSM Population
Prior Anti-Neoplastic Therapy = No

All Doses

	ASM (N=4)	SM-AHN (N=15)	MCL (N=1)	All AdvSM (N=20)
Events	0	1 (6.7)	0	1 (5.0)
Censors	4 (100.0)	14 (93.3)	1 (100.0)	19 (95.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (8.6 -NE)	NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	80.0 (44.9 -100.0)		83.3 (53.5 -100.0)
12 Months (95% CIs)	100.0 (100.0 -100.0)	80.0 (44.9 -100.0)		83.3 (53.5 -100.0)
18 Months (95% CIs)		80.0 (44.9 -100.0)		83.3 (53.5 -100.0)
24 Months (95% CIs)				
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				
54 Months (95% CIs)				
Median OS Follow-up[a] (months) (95% CI)	2.7 (0.4 - 12.7)	7.1 (6.4 - 9.0)	4.6 (NE -NE)	6.7 (5.5 - 9.0)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Overall survival is defined as the time in months from the start of treatment to the date of death. Patients who die before or on the data cutoff date will considered to have had an overall survival event. All Patients who do not have a death record prior to or on the cutoff date are censored at the last date known alive.
[a] Median OS Follow-up is calculated from the Kaplan-Meier method switching the OS event/censored status, i.e. OS event as censored and censored as OS event
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Table 99.2.4.1.1
Summary of Overall Survival by Prior Antineoplastic Therapy
Study BLU-285-2202, AdvSM Population
Prior Anti-Neoplastic Therapy = Yes

All Doses

	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Events	0	3 (10.7)	1 (11.1)	4 (9.5)
Censors	5 (100.0)	25 (89.3)	8 (88.9)	38 (90.5)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (NE -NE)	NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0 -100.0)	96.4 (89.6 -100.0)	100.0 (100.0 -100.0)	97.6 (93.0 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	92.0 (81.4 -100.0)	83.3 (53.5 -100.0)	91.2 (81.4 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	86.3 (71.5 -100.0)	83.3 (53.5 -100.0)	87.0 (74.8 - 99.2)
12 Months (95% CIs)		86.3 (71.5 -100.0)	83.3 (53.5 -100.0)	87.0 (74.8 - 99.2)
18 Months (95% CIs)				
24 Months (95% CIs)				
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				
54 Months (95% CIs)				
Median OS Follow-up[a] (months) (95% CI)	6.7 (0.7 - 9.9)	8.0 (5.1 - 10.4)	5.4 (4.7 - 10.8)	7.1 (5.1 - 8.5)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Overall survival is defined as the time in months from the start of treatment to the date of death. Patients who die before or on the data cutoff date will considered to have had an overall survival event. All Patients who do not have a death record prior to or on the cutoff date are censored at the last date known alive.
[a] Median OS Follow-up is calculated from the Kaplan-Meier method switching the OS event/censored status, i.e. OS event as censored and censored as OS event
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Table 99.2.4.1.1
Summary of Overall Survival by Prior Antineoplastic Therapy
Study BLU-285-2202, AdvSM Population
Prior Anti-Neoplastic Therapy = No

Starting Dose: 200 mg	ASM (N=4)	SM-AHN (N=15)	MCL (N=1)	All AdvSM (N=20)
Events	0	1 (6.7)	0	1 (5.0)
Censors	4 (100.0)	14 (93.3)	1 (100.0)	19 (95.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (8.6 -NE)	NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	80.0 (44.9 -100.0)		83.3 (53.5 -100.0)
12 Months (95% CIs)	100.0 (100.0 -100.0)	80.0 (44.9 -100.0)		83.3 (53.5 -100.0)
18 Months (95% CIs)		80.0 (44.9 -100.0)		83.3 (53.5 -100.0)
24 Months (95% CIs)				
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				
54 Months (95% CIs)				
Median OS Follow-up[a] (months) (95% CI)	2.7 (0.4 - 12.7)	7.1 (6.4 - 9.0)	4.6 (NE -NE)	6.7 (5.5 - 9.0)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Overall survival is defined as the time in months from the start of treatment to the date of death. Patients who die before or on the data cutoff date will considered to have had an overall survival event. All Patients who do not have a death record prior to or on the cutoff date are censored at the last date known alive.
[a] Median OS Follow-up is calculated from the Kaplan-Meier method switching the OS event/censored status, i.e. OS event as censored and censored as OS event
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Table 99.2.4.1.1
Summary of Overall Survival by Prior Antineoplastic Therapy
Study BLU-285-2202, AdvSM Population
Prior Anti-Neoplastic Therapy = Yes

Starting Dose: 200 mg

	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Events	0	3 (11.1)	1 (11.1)	4 (10.0)
Censors	4 (100.0)	24 (88.9)	8 (88.9)	36 (90.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (NE -NE)	NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0 -100.0)	96.3 (89.2 -100.0)	100.0 (100.0 -100.0)	97.5 (92.7 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	91.7 (80.6 -100.0)	83.3 (53.5 -100.0)	90.8 (80.8 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	85.6 (70.1 -100.0)	83.3 (53.5 -100.0)	86.5 (73.8 - 99.1)
12 Months (95% CIs)		85.6 (70.1 -100.0)	83.3 (53.5 -100.0)	86.5 (73.8 - 99.1)
18 Months (95% CIs)				
24 Months (95% CIs)				
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				
54 Months (95% CIs)				
Median OS Follow-up[a] (months) (95% CI)	6.8 (3.4 - 9.9)	8.0 (5.1 - 9.9)	5.4 (4.7 - 10.8)	7.1 (5.1 - 8.5)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Overall survival is defined as the time in months from the start of treatment to the date of death. Patients who die before or on the data cutoff date will considered to have had an overall survival event. All Patients who do not have a death record prior to or on the cutoff date are censored at the last date known alive.
[a] Median OS Follow-up is calculated from the Kaplan-Meier method switching the OS event/censored status, i.e. OS event as censored and censored as OS event
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.4.1.1-os-advsm-nat.sas
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Table 99.2.4.1.1
Summary of Overall Survival by Prior Antineoplastic Therapy
Studies: BLU-285-2101 and BLU-285-2202, AdvSM Population
Prior Anti-Neoplastic Therapy = No

All Doses

	ASM (N=5)	SM-AHN (N=37)	MCL (N=6)	All AdvSM (N=48)
Events	0	9 (24.3)	1 (16.7)	10 (20.8)
Censors	5 (100.0)	28 (75.7)	5 (83.3)	38 (79.2)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	24.5 (21.4 -NE)	NE (6.9 -NE)	46.9 (21.4 -NE)
25th, 75th percentiles	NE, NE	15.2, 46.9	NE, NE	21.4, NE
3 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	88.3 (75.8 -100.0)	75.0 (32.6 -100.0)	87.7 (76.3 - 99.1)
12 Months (95% CIs)	100.0 (100.0 -100.0)	79.0 (62.3 - 95.6)	75.0 (32.6 -100.0)	80.3 (66.0 - 94.6)
18 Months (95% CIs)	100.0 (100.0 -100.0)	73.7 (55.2 - 92.2)	75.0 (32.6 -100.0)	76.1 (60.3 - 91.9)
24 Months (95% CIs)	100.0 (100.0 -100.0)	63.2 (38.4 - 88.0)	75.0 (32.6 -100.0)	69.2 (49.9 - 88.5)
30 Months (95% CIs)		47.4 (14.7 - 80.0)	75.0 (32.6 -100.0)	60.5 (37.4 - 83.7)
36 Months (95% CIs)		47.4 (14.7 - 80.0)	75.0 (32.6 -100.0)	60.5 (37.4 - 83.7)
42 Months (95% CIs)		47.4 (14.7 - 80.0)		60.5 (37.4 - 83.7)
48 Months (95% CIs)				
54 Months (95% CIs)				
Median OS Follow-up[a] (months) (95% CI)	3.4 (0.4 - 25.6)	17.5 (8.1 - 20.5)	33.4 (6.3 - 38.7)	12.7 (8.1 - 20.8)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Overall survival is defined as the time in months from the start of treatment to the date of death. Patients who die before or on the data cutoff date will considered to have had an overall survival event. All Patients who do not have a death record prior to or on the cutoff date are censored at the last date known alive.
[a] Median OS Follow-up is calculated from the Kaplan-Meier method switching the OS event/censored status, i.e. OS event as censored and censored as OS event
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.4.1.1-os-advsm-nat.sas
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Table 99.2.4.1.1
Summary of Overall Survival by Prior Antineoplastic Therapy
Studies: BLU-285-2101 and BLU-285-2202, AdvSM Population
Prior Anti-Neoplastic Therapy = Yes

All Doses

	ASM (N=12)	SM-AHN (N=54)	MCL (N=17)	All AdvSM (N=83)
Events	0	10 (18.5)	2 (11.8)	12 (14.5)
Censors	12 (100.0)	44 (81.5)	15 (88.2)	71 (85.5)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (NE -NE)	NE (31.2 -NE)	NE (NE -NE)
25th, 75th percentiles	NE, NE	18.6, NE	31.2, NE	31.2, NE
3 Months (95% CIs)	100.0 (100.0 -100.0)	96.3 (91.2 -100.0)	100.0 (100.0 -100.0)	97.5 (94.2 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	92.0 (84.5 - 99.6)	92.9 (79.4 -100.0)	93.3 (87.7 - 99.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	87.2 (77.5 - 96.9)	92.9 (79.4 -100.0)	90.0 (83.0 - 97.1)
12 Months (95% CIs)	100.0 (100.0 -100.0)	84.4 (73.5 - 95.2)	92.9 (79.4 -100.0)	88.1 (80.3 - 96.0)
18 Months (95% CIs)	100.0 (100.0 -100.0)	77.0 (63.2 - 90.9)	92.9 (79.4 -100.0)	83.1 (73.1 - 93.1)
24 Months (95% CIs)	100.0 (100.0 -100.0)	71.1 (54.1 - 88.1)	92.9 (79.4 -100.0)	79.5 (67.6 - 91.3)
30 Months (95% CIs)	100.0 (100.0 -100.0)	71.1 (54.1 - 88.1)	92.9 (79.4 -100.0)	79.5 (67.6 - 91.3)
36 Months (95% CIs)	100.0 (100.0 -100.0)	71.1 (54.1 - 88.1)	61.9 (11.6 -100.0)	72.9 (56.4 - 89.4)
42 Months (95% CIs)	100.0 (100.0 -100.0)	71.1 (54.1 - 88.1)	61.9 (11.6 -100.0)	72.9 (56.4 - 89.4)
48 Months (95% CIs)	100.0 (100.0 -100.0)	71.1 (54.1 - 88.1)		72.9 (56.4 - 89.4)
54 Months (95% CIs)				
Median OS Follow-up[a] (months) (95% CI)	15.7 (7.0 - 31.3)	14.8 (10.4 - 18.2)	9.6 (5.4 - 16.3)	12.3 (9.6 - 17.4)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Overall survival is defined as the time in months from the start of treatment to the date of death. Patients who die before or on the data cutoff date will considered to have had an overall survival event. All Patients who do not have a death record prior to or on the cutoff date are censored at the last date known alive.
[a] Median OS Follow-up is calculated from the Kaplan-Meier method switching the OS event/censored status, i.e. OS event as censored and censored as OS event
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.4.1.1-os-advsm-nat.sas
Date: 10:44/19JAN2021

Table 99.2.4.1.1
Summary of Overall Survival by Prior Antineoplastic Therapy
Studies: BLU-285-2101 and BLU-285-2202, AdvSM Population
Prior Anti-Neoplastic Therapy = No

Starting Dose: < 200 mg

	ASM (N=0)	SM-AHN (N=5)	MCL (N=0)	All AdvSM (N=5)
Events		3 (60.0)		3 (60.0)
Censors		2 (40.0)		2 (40.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		46.9 (6.5 -NE)		46.9 (6.5 -NE)
25th, 75th percentiles		24.5, NE		24.5, NE
3 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
6 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
9 Months (95% CIs)		80.0 (44.9 -100.0)		80.0 (44.9 -100.0)
12 Months (95% CIs)		80.0 (44.9 -100.0)		80.0 (44.9 -100.0)
18 Months (95% CIs)		80.0 (44.9 -100.0)		80.0 (44.9 -100.0)
24 Months (95% CIs)		80.0 (44.9 -100.0)		80.0 (44.9 -100.0)
30 Months (95% CIs)		60.0 (17.1 -100.0)		60.0 (17.1 -100.0)
36 Months (95% CIs)		60.0 (17.1 -100.0)		60.0 (17.1 -100.0)
42 Months (95% CIs)		60.0 (17.1 -100.0)		60.0 (17.1 -100.0)
48 Months (95% CIs)				
54 Months (95% CIs)				
Median OS Follow-up[a] (months) (95% CI)		46.9 (43.9 - 46.9)		46.9 (43.9 - 46.9)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Overall survival is defined as the time in months from the start of treatment to the date of death. Patients who die before or on the data cutoff date will considered to have had an overall survival event. All Patients who do not have a death record prior to or on the cutoff date are censored at the last date known alive.
[a] Median OS Follow-up is calculated from the Kaplan-Meier method switching the OS event/censored status, i.e. OS event as censored and censored as OS event
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.4.1.1-os-advsm-nat.sas Date: 10:44/19JAN2021

Table 99.2.4.1.1
Summary of Overall Survival by Prior Antineoplastic Therapy
Studies: BLU-285-2101 and BLU-285-2202, AdvSM Population
Prior Anti-Neoplastic Therapy = Yes

Starting Dose: < 200 mg

	ASM (N=2)	SM-AHN (N=3)	MCL (N=1)	All AdvSM (N=6)
Events	0	0	0	0
Censors	2 (100.0)	3 (100.0)	1 (100.0)	6 (100.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (NE -NE)	NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
12 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
18 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
24 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
30 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
36 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
42 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
48 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
54 Months (95% CIs)				
Median OS Follow-up[a] (months) (95% CI)	24.6 (0.7 - 48.6)	42.6 (12.3 - 50.6)	46.3 (NE -NE)	44.5 (12.3 - 48.6)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Overall survival is defined as the time in months from the start of treatment to the date of death. Patients who die before or on the data cutoff date will considered to have had an overall survival event. All Patients who do not have a death record prior to or on the cutoff date are censored at the last date known alive.
[a] Median OS Follow-up is calculated from the Kaplan-Meier method switching the OS event/censored status, i.e. OS event as censored and censored as OS event
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.4.1.1-os-advsm-nat.sas
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Table 99.2.4.1.1
Summary of Overall Survival by Prior Antineoplastic Therapy
Studies: BLU-285-2101 and BLU-285-2202, AdvSM Population
Prior Anti-Neoplastic Therapy = No

Starting Dose: < 300 mg

	ASM (N=4)	SM-AHN (N=26)	MCL (N=3)	All AdvSM (N=33)
Events	0	5 (19.2)	0	5 (15.2)
Censors	4 (100.0)	21 (80.8)	3 (100.0)	28 (84.8)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	46.9 (24.5 -NE)	NE (NE -NE)	46.9 (24.5 -NE)
25th, 75th percentiles	NE, NE	24.5, NE	NE, NE	24.5, NE
3 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	78.9 (57.0 -100.0)	100.0 (100.0 -100.0)	81.7 (62.4 -100.0)
12 Months (95% CIs)	100.0 (100.0 -100.0)	78.9 (57.0 -100.0)	100.0 (100.0 -100.0)	81.7 (62.4 -100.0)
18 Months (95% CIs)		78.9 (57.0 -100.0)	100.0 (100.0 -100.0)	81.7 (62.4 -100.0)
24 Months (95% CIs)		78.9 (57.0 -100.0)	100.0 (100.0 -100.0)	81.7 (62.4 -100.0)
30 Months (95% CIs)		59.2 (21.9 - 96.5)	100.0 (100.0 -100.0)	65.3 (32.8 - 97.9)
36 Months (95% CIs)		59.2 (21.9 - 96.5)	100.0 (100.0 -100.0)	65.3 (32.8 - 97.9)
42 Months (95% CIs)		59.2 (21.9 - 96.5)		65.3 (32.8 - 97.9)
48 Months (95% CIs)				
54 Months (95% CIs)				
Median OS Follow-up[a] (months) (95% CI)	2.7 (0.4 - 12.7)	8.1 (7.0 - 11.6)	6.3 (4.6 - 38.7)	7.5 (6.5 - 11.6)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Overall survival is defined as the time in months from the start of treatment to the date of death. Patients who die before or on the data cutoff date will considered to have had an overall survival event. All Patients who do not have a death record prior to or on the cutoff date are censored at the last date known alive.
[a] Median OS Follow-up is calculated from the Kaplan-Meier method switching the OS event/censored status, i.e. OS event as censored and censored as OS event
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.4.1.1-os-advsm-nat.sas Date: 10:44/19JAN2021

Table 99.2.4.1.1
Summary of Overall Survival by Prior Antineoplastic Therapy
Studies: BLU-285-2101 and BLU-285-2202, AdvSM Population
Prior Anti-Neoplastic Therapy = Yes

Starting Dose: < 300 mg	ASM (N=7)	SM-AHN (N=37)	MCL (N=14)	All AdvSM (N=58)
Events	0	6 (16.2)	1 (7.1)	7 (12.1)
Censors	7 (100.0)	31 (83.8)	13 (92.9)	51 (87.9)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (NE -NE)	NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles	NE, NE	13.0, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0 -100.0)	94.5 (87.1 -100.0)	100.0 (100.0 -100.0)	96.5 (91.6 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	91.4 (82.0 -100.0)	90.9 (73.9 -100.0)	92.2 (84.8 - 99.6)
9 Months (95% CIs)	100.0 (100.0 -100.0)	83.4 (69.8 - 97.0)	90.9 (73.9 -100.0)	86.7 (76.6 - 96.9)
12 Months (95% CIs)	100.0 (100.0 -100.0)	83.4 (69.8 - 97.0)	90.9 (73.9 -100.0)	86.7 (76.6 - 96.9)
18 Months (95% CIs)	100.0 (100.0 -100.0)	74.1 (53.2 - 95.1)	90.9 (73.9 -100.0)	80.5 (65.5 - 95.6)
24 Months (95% CIs)	100.0 (100.0 -100.0)	74.1 (53.2 - 95.1)	90.9 (73.9 -100.0)	80.5 (65.5 - 95.6)
30 Months (95% CIs)	100.0 (100.0 -100.0)	74.1 (53.2 - 95.1)	90.9 (73.9 -100.0)	80.5 (65.5 - 95.6)
36 Months (95% CIs)	100.0 (100.0 -100.0)	74.1 (53.2 - 95.1)	90.9 (73.9 -100.0)	80.5 (65.5 - 95.6)
42 Months (95% CIs)	100.0 (100.0 -100.0)	74.1 (53.2 - 95.1)	90.9 (73.9 -100.0)	80.5 (65.5 - 95.6)
48 Months (95% CIs)	100.0 (100.0 -100.0)	74.1 (53.2 - 95.1)		80.5 (65.5 - 95.6)
54 Months (95% CIs)				
Median OS Follow-up[a] (months) (95% CI)	7.0 (3.4 - 9.9)	9.9 (7.9 - 12.3)	9.0 (5.1 - 15.2)	8.5 (7.5 - 10.8)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Overall survival is defined as the time in months from the start of treatment to the date of death. Patients who die before or on the data cutoff date will considered to have had an overall survival event. All Patients who do not have a death record prior to or on the cutoff date are censored at the last date known alive.
[a] Median OS Follow-up is calculated from the Kaplan-Meier method switching the OS event/censored status, i.e. OS event as censored and censored as OS event
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.4.1.1-os-advsm-nat.sas Date: 10:44/19JAN2021

Table 99.2.4.1.1
Summary of Overall Survival by Prior Antineoplastic Therapy
Studies: BLU-285-2101 and BLU-285-2202, AdvSM Population
Prior Anti-Neoplastic Therapy = No

Starting Dose: 200 mg

	ASM (N=4)	SM-AHN (N=21)	MCL (N=3)	All AdvSM (N=28)
Events	0	2 (9.5)	0	2 (7.1)
Censors	4 (100.0)	19 (90.5)	3 (100.0)	26 (92.9)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (8.6 -NE)	NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles	NE, NE	8.6, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	74.1 (42.5 -100.0)	100.0 (100.0 -100.0)	79.5 (54.0 -100.0)
12 Months (95% CIs)	100.0 (100.0 -100.0)	74.1 (42.5 -100.0)	100.0 (100.0 -100.0)	79.5 (54.0 -100.0)
18 Months (95% CIs)		74.1 (42.5 -100.0)	100.0 (100.0 -100.0)	79.5 (54.0 -100.0)
24 Months (95% CIs)			100.0 (100.0 -100.0)	79.5 (54.0 -100.0)
30 Months (95% CIs)			100.0 (100.0 -100.0)	79.5 (54.0 -100.0)
36 Months (95% CIs)			100.0 (100.0 -100.0)	79.5 (54.0 -100.0)
42 Months (95% CIs)				
48 Months (95% CIs)				
54 Months (95% CIs)				
Median OS Follow-up[a] (months) (95% CI)	2.7 (0.4 - 12.7)	7.4 (6.5 - 9.0)	6.3 (4.6 - 38.7)	7.0 (6.3 - 8.3)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Overall survival is defined as the time in months from the start of treatment to the date of death. Patients who die before or on the data cutoff date will considered to have had an overall survival event. All Patients who do not have a death record prior to or on the cutoff date are censored at the last date known alive.
[a] Median OS Follow-up is calculated from the Kaplan-Meier method switching the OS event/censored status, i.e. OS event as censored and censored as OS event
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.4.1.1-os-advsm-nat.sas Date: 10:44/19JAN2021

Table 99.2.4.1.1
Summary of Overall Survival by Prior Antineoplastic Therapy
Studies: BLU-285-2101 and BLU-285-2202, AdvSM Population
Prior Anti-Neoplastic Therapy = Yes

Starting Dose: 200 mg

	ASM (N=5)	SM-AHN (N=34)	MCL (N=13)	All AdvSM (N=52)
Events	0	6 (17.6)	1 (7.7)	7 (13.5)
Censors	5 (100.0)	28 (82.4)	12 (92.3)	45 (86.5)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (13.0 -NE)	NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles	NE, NE	13.0, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0 -100.0)	94.0 (86.0 -100.0)	100.0 (100.0 -100.0)	96.1 (90.7 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	90.5 (80.3 -100.0)	90.0 (71.4 -100.0)	91.3 (83.1 - 99.5)
9 Months (95% CIs)	100.0 (100.0 -100.0)	81.4 (66.3 - 96.6)	90.0 (71.4 -100.0)	84.9 (73.4 - 96.4)
12 Months (95% CIs)		81.4 (66.3 - 96.6)	90.0 (71.4 -100.0)	84.9 (73.4 - 96.4)
18 Months (95% CIs)		69.8 (45.0 - 94.6)	90.0 (71.4 -100.0)	76.4 (57.5 - 95.3)
24 Months (95% CIs)		69.8 (45.0 - 94.6)		76.4 (57.5 - 95.3)
30 Months (95% CIs)		69.8 (45.0 - 94.6)		76.4 (57.5 - 95.3)
36 Months (95% CIs)		69.8 (45.0 - 94.6)		76.4 (57.5 - 95.3)
42 Months (95% CIs)				
48 Months (95% CIs)				
54 Months (95% CIs)				
Median OS Follow-up[a] (months) (95% CI)	7.0 (3.4 - 9.9)	8.5 (7.9 - 11.0)	9.0 (5.1 - 15.2)	8.1 (7.0 - 10.4)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Overall survival is defined as the time in months from the start of treatment to the date of death. Patients who die before or on the data cutoff date will considered to have had an overall survival event. All Patients who do not have a death record prior to or on the cutoff date are censored at the last date known alive.
[a] Median OS Follow-up is calculated from the Kaplan-Meier method switching the OS event/censored status, i.e. OS event as censored and censored as OS event
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.4.1.1-os-advsm-nat.sas
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Table 99.2.4.1.1
Summary of Overall Survival by Prior Antineoplastic Therapy
Studies: BLU-285-2101 and BLU-285-2202, AdvSM Population
Prior Anti-Neoplastic Therapy = No

Starting Dose: 300 mg	ASM (N=1)	SM-AHN (N=11)	MCL (N=2)	All AdvSM (N=14)
Events	0	4 (36.4)	1 (50.0)	5 (35.7)
Censors	1 (100.0)	7 (63.6)	1 (50.0)	9 (64.3)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	21.4 (15.2 -NE)	NE (6.9 -NE)	NE (15.2 -NE)
25th, 75th percentiles	NE, NE	15.2, NE	6.9, NE	15.2, NE
3 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	50.0 (0.0 -100.0)	92.9 (79.4 -100.0)
12 Months (95% CIs)	100.0 (100.0 -100.0)	81.8 (59.0 -100.0)	50.0 (0.0 -100.0)	78.6 (57.1 -100.0)
18 Months (95% CIs)	100.0 (100.0 -100.0)	72.7 (46.4 - 99.0)	50.0 (0.0 -100.0)	71.4 (47.8 - 95.1)
24 Months (95% CIs)	100.0 (100.0 -100.0)		50.0 (0.0 -100.0)	57.1 (25.7 - 88.5)
30 Months (95% CIs)			50.0 (0.0 -100.0)	57.1 (25.7 - 88.5)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				
54 Months (95% CIs)				
Median OS Follow-up[a] (months) (95% CI)	25.6 (NE -NE)	20.9 (20.5 - 22.9)	33.4 (NE -NE)	21.9 (20.5 - 25.6)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Overall survival is defined as the time in months from the start of treatment to the date of death. Patients who die before or on the data cutoff date will considered to have had an overall survival event. All Patients who do not have a death record prior to or on the cutoff date are censored at the last date known alive.
[a] Median OS Follow-up is calculated from the Kaplan-Meier method switching the OS event/censored status, i.e. OS event as censored and censored as OS event
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.4.1.1-os-advsm-nat.sas Date: 10:44/19JAN2021

Table 99.2.4.1.1
Summary of Overall Survival by Prior Antineoplastic Therapy
Studies: BLU-285-2101 and BLU-285-2202, AdvSM Population
Prior Anti-Neoplastic Therapy = Yes

Starting Dose: 300 mg	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Events	0	4 (30.8)	1 (33.3)	5 (25.0)
Censors	4 (100.0)	9 (69.2)	2 (66.7)	15 (75.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (18.6 -NE)	NE (31.2 -NE)	NE (31.2 -NE)
25th, 75th percentiles	NE, NE	18.6, NE	31.2, NE	31.2, NE
3 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	92.3 (77.8 -100.0)	100.0 (100.0 -100.0)	95.0 (85.4 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	92.3 (77.8 -100.0)	100.0 (100.0 -100.0)	95.0 (85.4 -100.0)
12 Months (95% CIs)	100.0 (100.0 -100.0)	84.6 (65.0 -100.0)	100.0 (100.0 -100.0)	90.0 (76.9 -100.0)
18 Months (95% CIs)	100.0 (100.0 -100.0)	76.9 (54.0 - 99.8)	100.0 (100.0 -100.0)	84.7 (68.8 -100.0)
24 Months (95% CIs)	100.0 (100.0 -100.0)	67.3 (40.6 - 94.0)	100.0 (100.0 -100.0)	78.7 (59.9 - 97.4)
30 Months (95% CIs)	100.0 (100.0 -100.0)	67.3 (40.6 - 94.0)	100.0 (100.0 -100.0)	78.7 (59.9 - 97.4)
36 Months (95% CIs)	100.0 (100.0 -100.0)			62.9 (31.5 - 94.3)
42 Months (95% CIs)				
48 Months (95% CIs)				
54 Months (95% CIs)				
Median OS Follow-up[a] (months) (95% CI)	31.6 (27.7 - 39.4)	24.2 (22.4 - 30.0)	31.8 (9.6 - 31.8)	29.5 (22.5 - 31.3)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Overall survival is defined as the time in months from the start of treatment to the date of death. Patients who die before or on the data cutoff date will considered to have had an overall survival event. All Patients who do not have a death record prior to or on the cutoff date are censored at the last date known alive.
[a] Median OS Follow-up is calculated from the Kaplan-Meier method switching the OS event/censored status, i.e. OS event as censored and censored as OS event
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.4.1.1-os-advsm-nat.sas
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Table 99.2.4.1.1
Summary of Overall Survival by Prior Antineoplastic Therapy
Studies: BLU-285-2101 and BLU-285-2202, AdvSM Population
Prior Anti-Neoplastic Therapy = No

Starting Dose: 200 mg and 300 mg

	ASM (N=5)	SM-AHN (N=32)	MCL (N=5)	All AdvSM (N=42)
Events	0	6 (18.8)	1 (20.0)	7 (16.7)
Censors	5 (100.0)	26 (81.3)	4 (80.0)	35 (83.3)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	21.4 (15.2 -NE)	NE (6.9 -NE)	NE (21.4 -NE)
25th, 75th percentiles	NE, NE	15.2, NE	6.9, NE	15.2, NE
3 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	89.4 (75.5 -100.0)	66.7 (13.3 -100.0)	88.1 (75.4 -100.0)
12 Months (95% CIs)	100.0 (100.0 -100.0)	77.4 (57.7 - 97.1)	66.7 (13.3 -100.0)	78.8 (62.1 - 95.5)
18 Months (95% CIs)	100.0 (100.0 -100.0)	70.3 (48.1 - 92.6)	66.7 (13.3 -100.0)	73.2 (54.3 - 92.0)
24 Months (95% CIs)	100.0 (100.0 -100.0)		66.7 (13.3 -100.0)	61.0 (34.1 - 87.8)
30 Months (95% CIs)			66.7 (13.3 -100.0)	61.0 (34.1 - 87.8)
36 Months (95% CIs)			66.7 (13.3 -100.0)	61.0 (34.1 - 87.8)
42 Months (95% CIs)				
48 Months (95% CIs)				
54 Months (95% CIs)				
Median OS Follow-up[a] (months) (95% CI)	3.4 (0.4 - 25.6)	9.5 (7.4 - 18.3)	33.4 (4.6 - 38.7)	9.5 (7.1 - 18.3)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Overall survival is defined as the time in months from the start of treatment to the date of death. Patients who die before or on the data cutoff date will considered to have had an overall survival event. All Patients who do not have a death record prior to or on the cutoff date are censored at the last date known alive.
[a] Median OS Follow-up is calculated from the Kaplan-Meier method switching the OS event/censored status, i.e. OS event as censored and censored as OS event
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Table 99.2.4.1.1
Summary of Overall Survival by Prior Antineoplastic Therapy
Studies: BLU-285-2101 and BLU-285-2202, AdvSM Population
Prior Anti-Neoplastic Therapy = Yes

Starting Dose: 200 mg and 300 mg

	ASM (N=9)	SM-AHN (N=47)	MCL (N=16)	All AdvSM (N=72)
Events	0	10 (21.3)	2 (12.5)	12 (16.7)
Censors	9 (100.0)	37 (78.7)	14 (87.5)	60 (83.3)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (18.6 -NE)	31.2 (31.2 -NE)	NE (31.2 -NE)
25th, 75th percentiles	NE, NE	13.5, NE	31.2, NE	18.6, NE
3 Months (95% CIs)	100.0 (100.0 -100.0)	95.7 (89.9 -100.0)	100.0 (100.0 -100.0)	97.2 (93.3 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	90.7 (82.0 - 99.4)	92.3 (77.8 -100.0)	92.3 (85.8 - 98.8)
9 Months (95% CIs)	100.0 (100.0 -100.0)	85.0 (73.9 - 96.2)	92.3 (77.8 -100.0)	88.4 (80.2 - 96.6)
12 Months (95% CIs)	100.0 (100.0 -100.0)	81.6 (69.1 - 94.2)	92.3 (77.8 -100.0)	86.1 (77.0 - 95.2)
18 Months (95% CIs)	100.0 (100.0 -100.0)	72.6 (56.3 - 88.8)	92.3 (77.8 -100.0)	79.7 (67.7 - 91.7)
24 Months (95% CIs)	100.0 (100.0 -100.0)	64.5 (43.7 - 85.3)	92.3 (77.8 -100.0)	74.7 (60.0 - 89.4)
30 Months (95% CIs)	100.0 (100.0 -100.0)	64.5 (43.7 - 85.3)	92.3 (77.8 -100.0)	74.7 (60.0 - 89.4)
36 Months (95% CIs)	100.0 (100.0 -100.0)	64.5 (43.7 - 85.3)		62.3 (36.8 - 87.7)
42 Months (95% CIs)				
48 Months (95% CIs)				
54 Months (95% CIs)				
Median OS Follow-up[a] (months) (95% CI)	9.9 (7.0 - 31.3)	11.6 (8.5 - 17.4)	9.5 (5.4 - 15.2)	10.8 (8.5 - 16.1)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Overall survival is defined as the time in months from the start of treatment to the date of death. Patients who die before or on the data cutoff date will considered to have had an overall survival event. All Patients who do not have a death record prior to or on the cutoff date are censored at the last date known alive.
[a] Median OS Follow-up is calculated from the Kaplan-Meier method switching the OS event/censored status, i.e. OS event as censored and censored as OS event
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Table 99.2.4.1.1
Summary of Overall Survival by Prior Antineoplastic Therapy
Studies: BLU-285-2101 and BLU-285-2202, AdvSM Population
Prior Anti-Neoplastic Therapy = No

Starting Dose: 400 mg

	ASM (N=0)	SM-AHN (N=0)	MCL (N=1)	All AdvSM (N=1)
Events			0	0
Censors			1 (100.0)	1 (100.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)			NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles			NE, NE	NE, NE
3 Months (95% CIs)			100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)			100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)			100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
12 Months (95% CIs)			100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
18 Months (95% CIs)			100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
24 Months (95% CIs)			100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
30 Months (95% CIs)			100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				
54 Months (95% CIs)				
Median OS Follow-up[a] (months) (95% CI)			35.2 (NE -NE)	35.2 (NE -NE)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Overall survival is defined as the time in months from the start of treatment to the date of death. Patients who die before or on the data cutoff date will considered to have had an overall survival event. All Patients who do not have a death record prior to or on the cutoff date are censored at the last date known alive.
[a] Median OS Follow-up is calculated from the Kaplan-Meier method switching the OS event/censored status, i.e. OS event as censored and censored as OS event
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Table 99.2.4.1.1
Summary of Overall Survival by Prior Antineoplastic Therapy
Studies: BLU-285-2101 and BLU-285-2202, AdvSM Population
Prior Anti-Neoplastic Therapy = Yes

Starting Dose: 400 mg	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Events	0	0		0
Censors	1 (100.0)	4 (100.0)		5 (100.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (NE -NE)		NE (NE -NE)
25th, 75th percentiles	NE, NE	NE, NE		NE, NE
3 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
12 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
18 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
24 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
30 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
36 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
42 Months (95% CIs)				
48 Months (95% CIs)				
54 Months (95% CIs)				
Median OS Follow-up[a] (months) (95% CI)	21.5 (NE -NE)	26.9 (5.4 - 37.9)		21.5 (5.4 - 37.9)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Overall survival is defined as the time in months from the start of treatment to the date of death. Patients who die before or on the data cutoff date will considered to have had an overall survival event. All Patients who do not have a death record prior to or on the cutoff date are censored at the last date known alive.
[a] Median OS Follow-up is calculated from the Kaplan-Meier method switching the OS event/censored status, i.e. OS event as censored and censored as OS event
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Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Starting Dose: Overall & Prior Antineoplastic Therapy = Positive

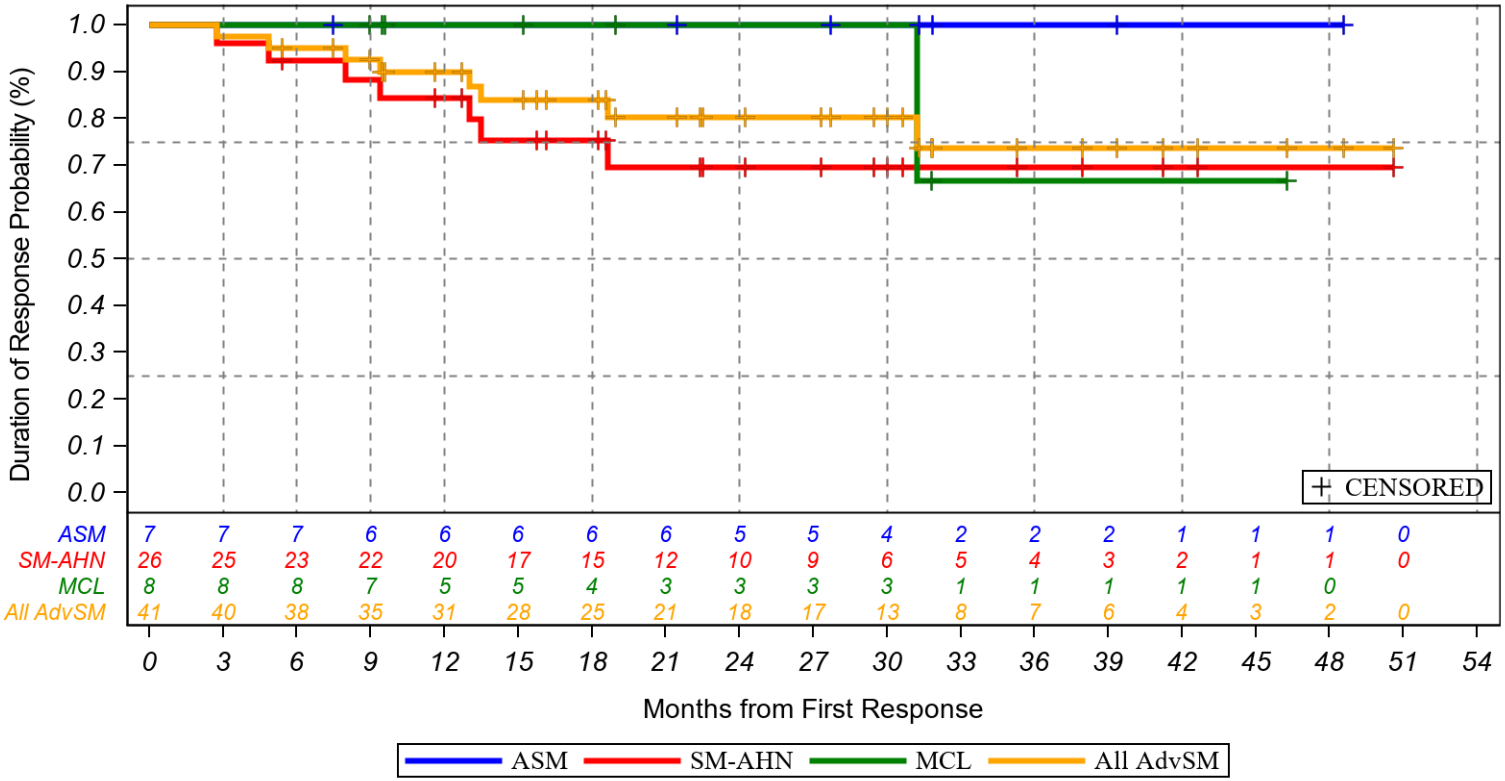

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Starting Dose: Overall & Prior Antineoplastic Therapy = Negative

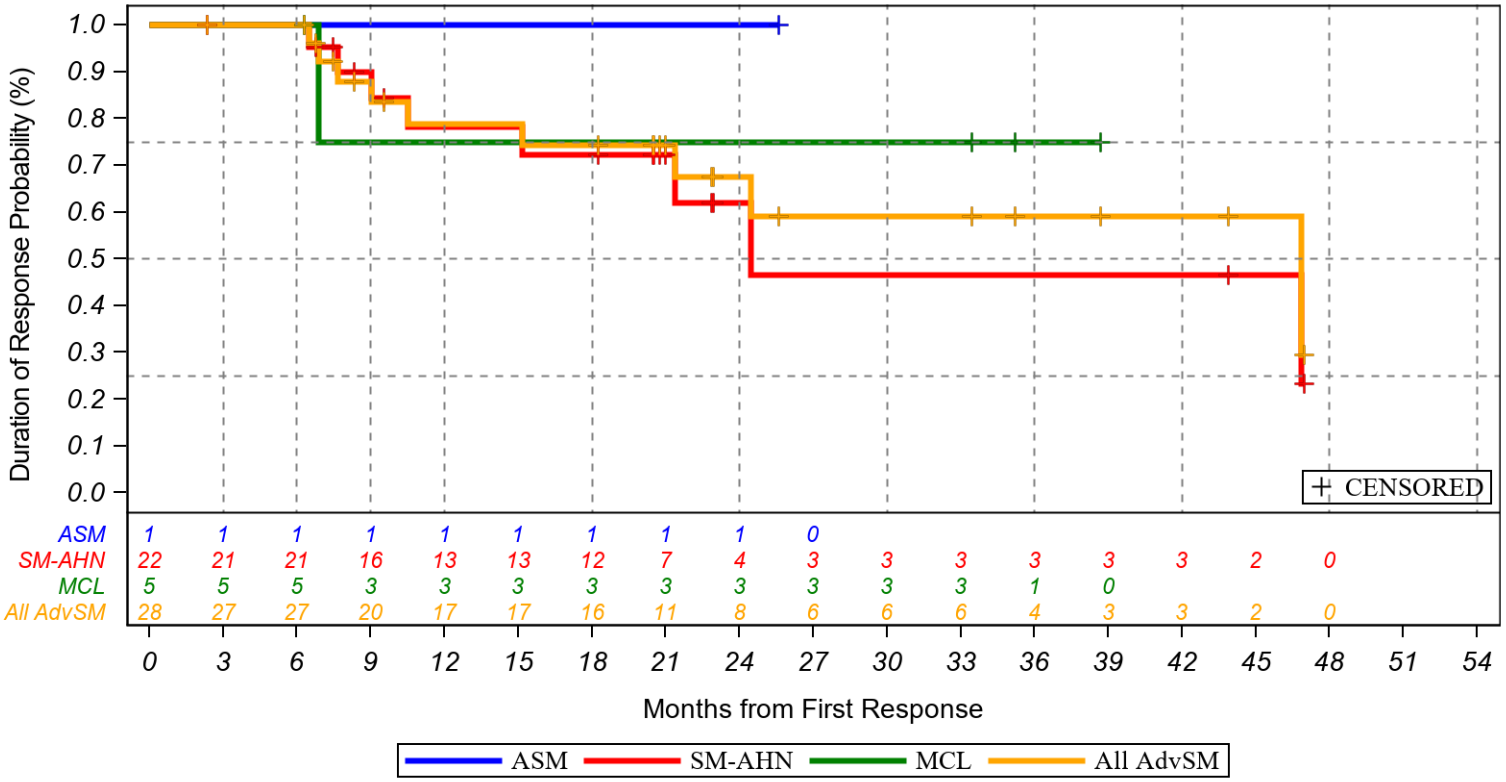

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Starting Dose: < 200 mg & Prior Antineoplastic Therapy = Positive

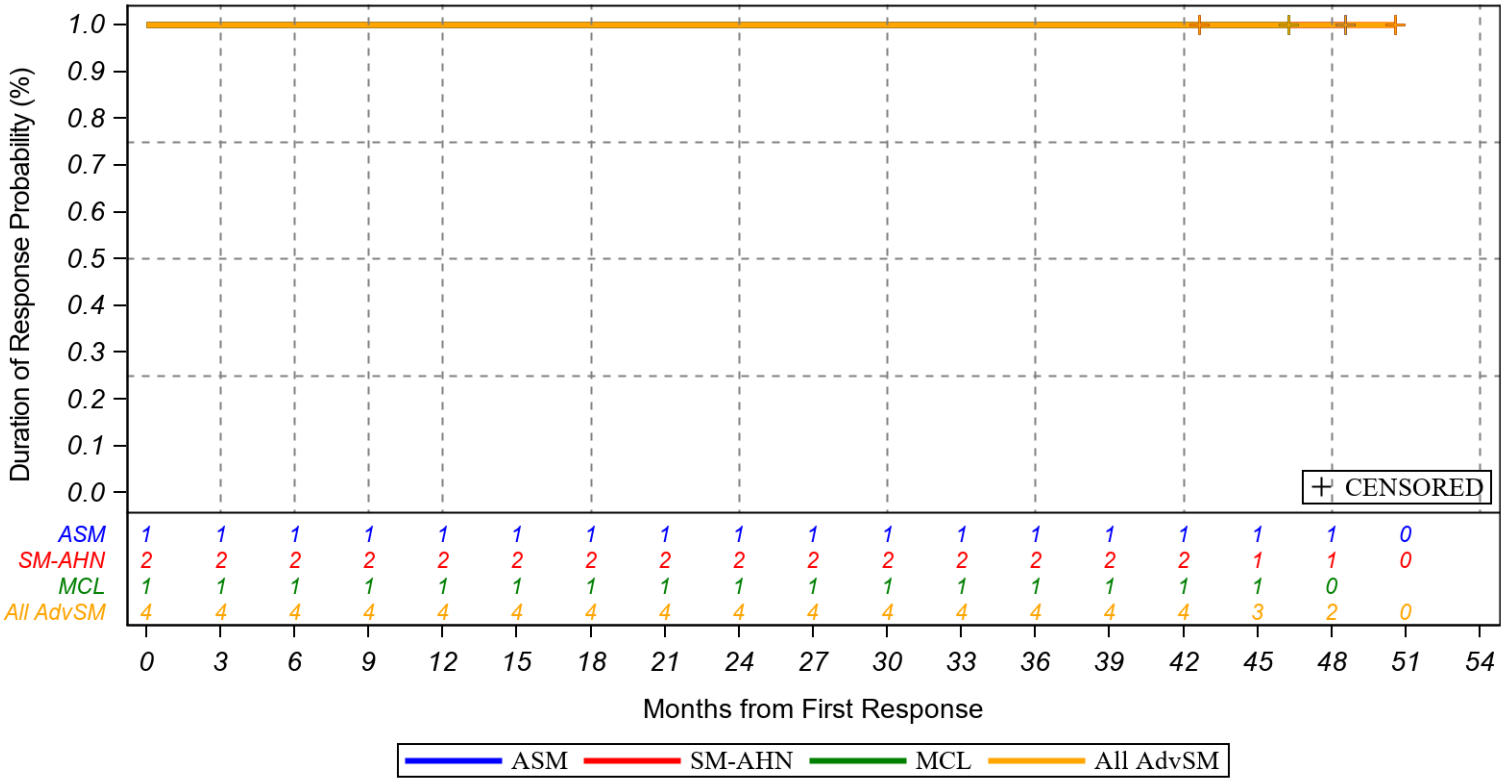

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Starting Dose: < 200 mg & Prior Antineoplastic Therapy = Negative

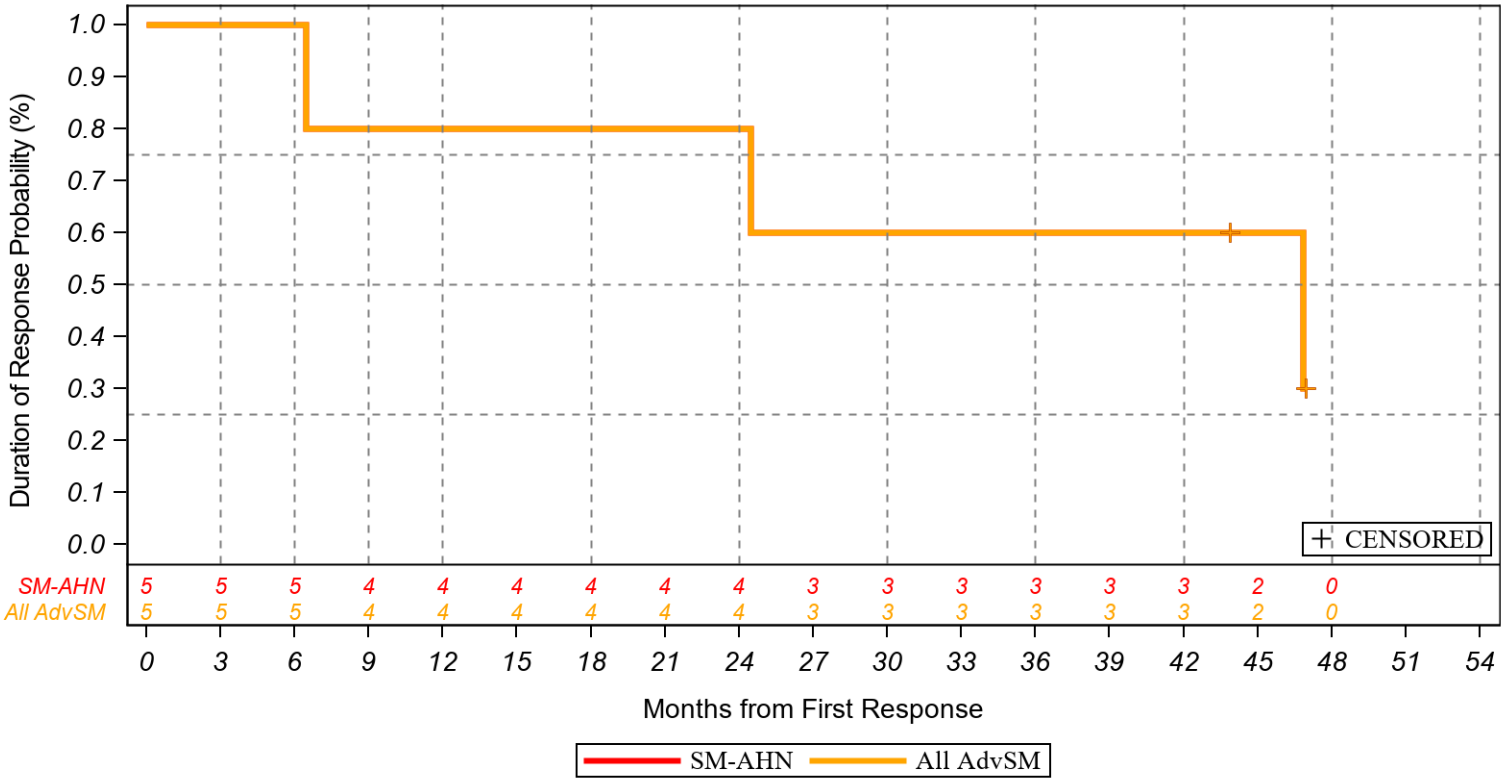

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Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Starting Dose: < 300 mg & Prior Antineoplastic Therapy = Positive

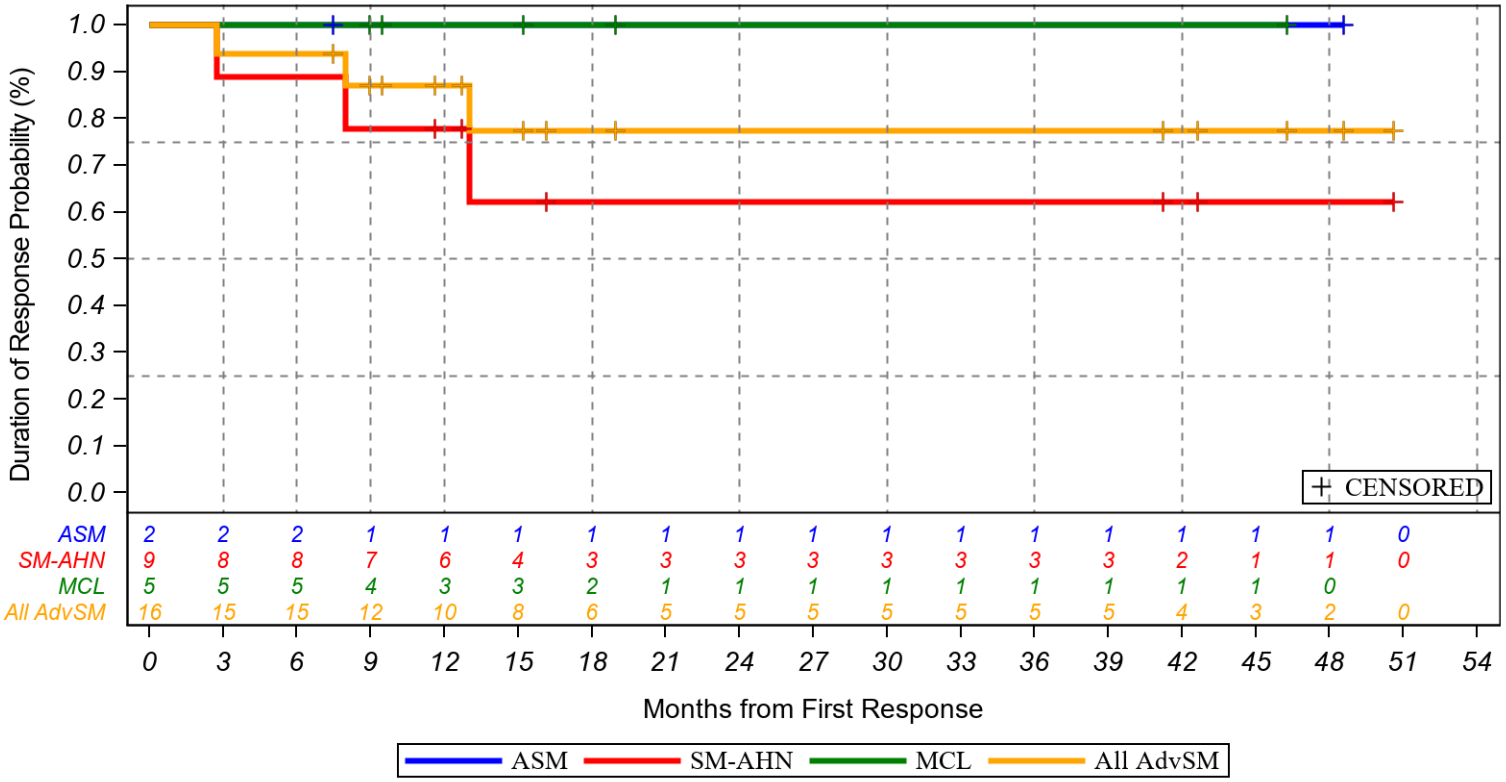

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Starting Dose: < 300 mg & Prior Antineoplastic Therapy = Negative

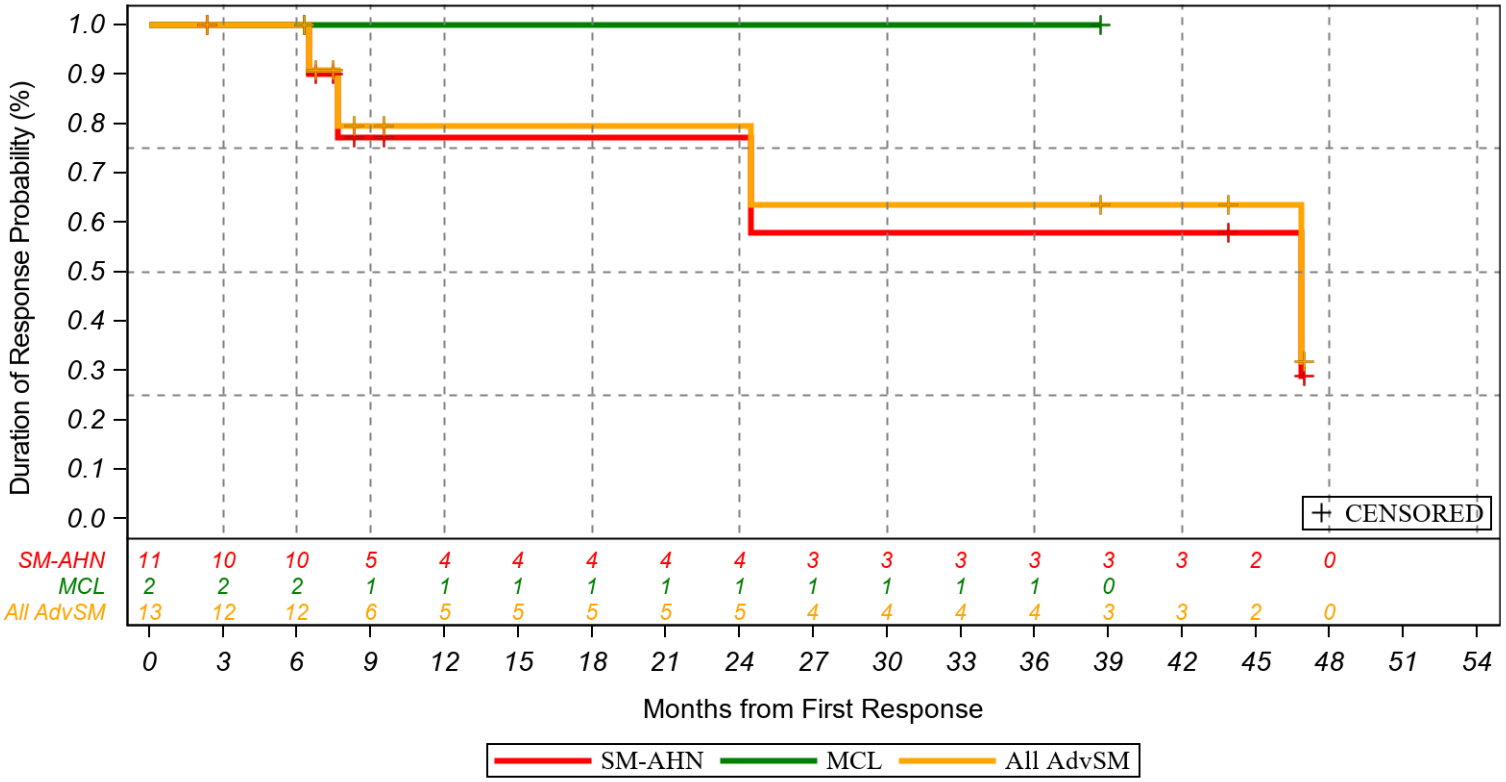

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Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Starting Dose: 200 mg & Prior Antineoplastic Therapy = Positive

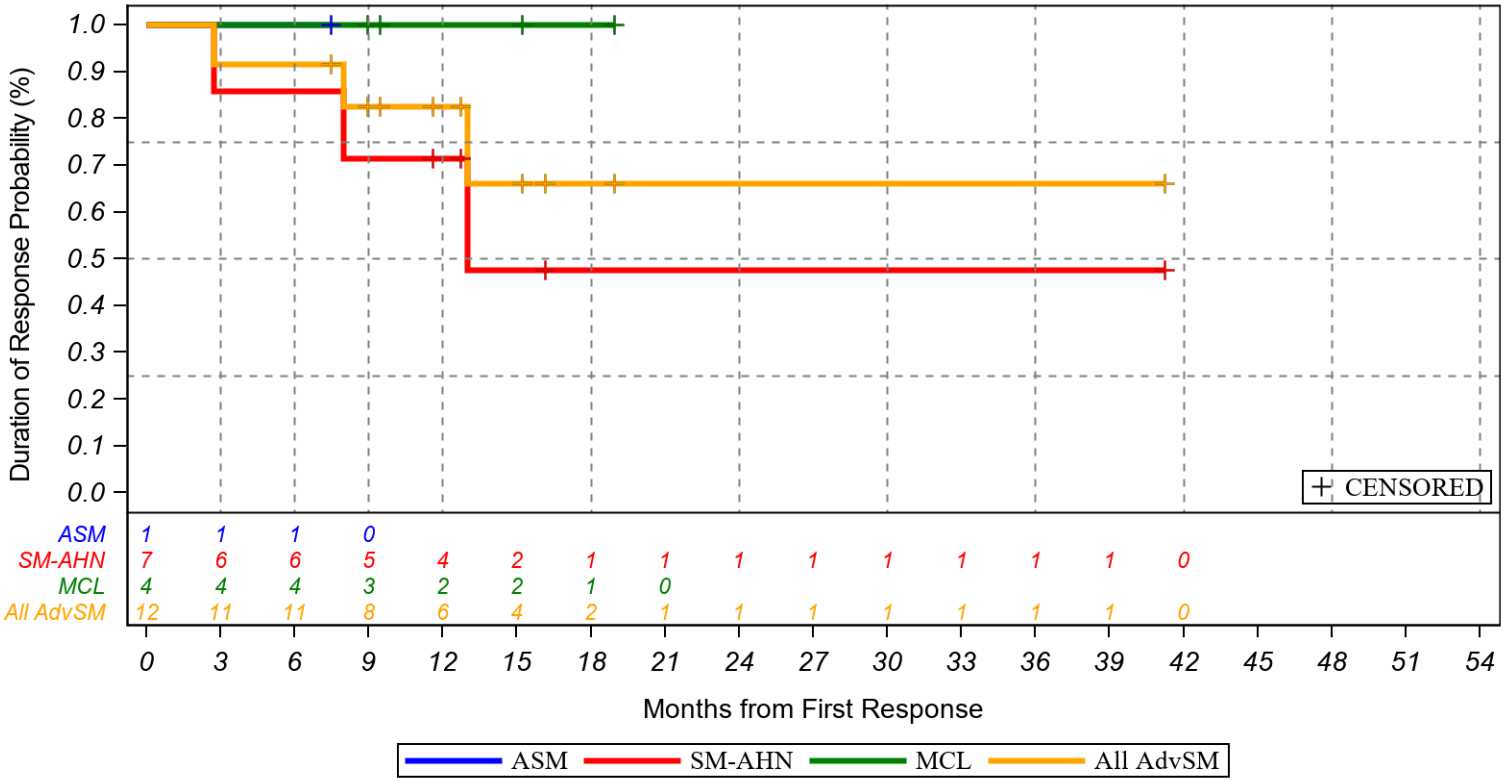

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Starting Dose: 200 mg & Prior Antineoplastic Therapy = Negative

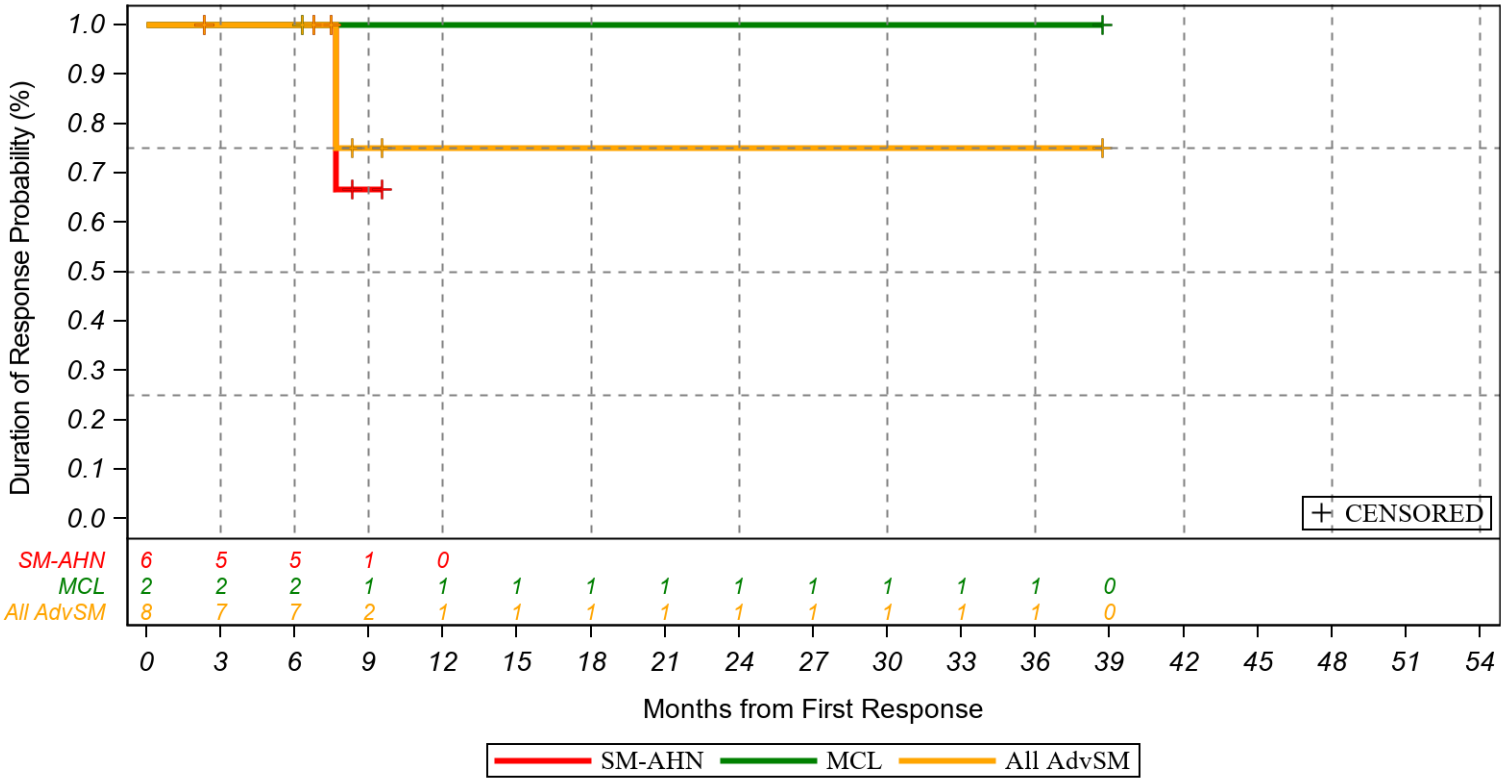

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Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Starting Dose: 300 mg & Prior Antineoplastic Therapy = Positive

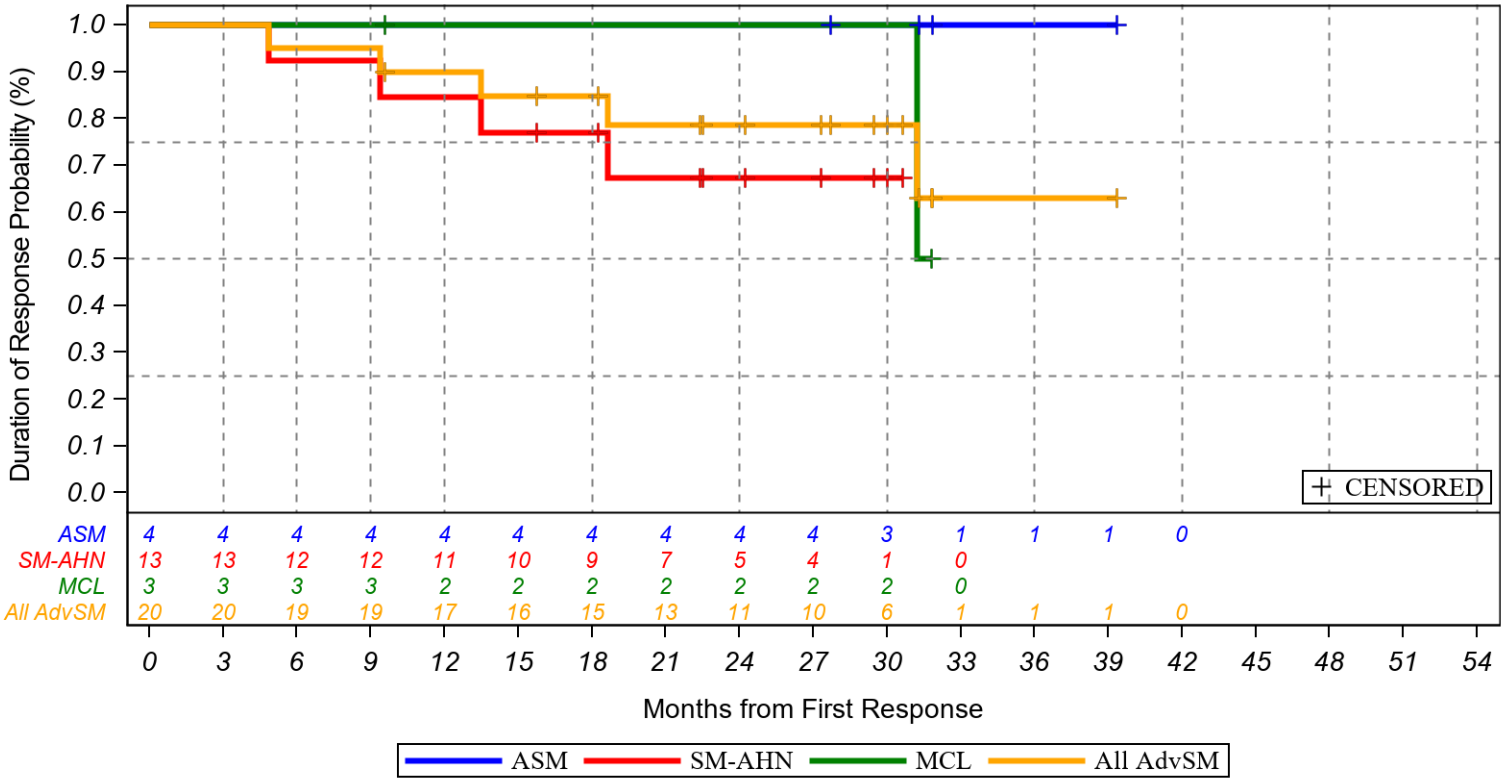

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Starting Dose: 300 mg & Prior Antineoplastic Therapy = Negative

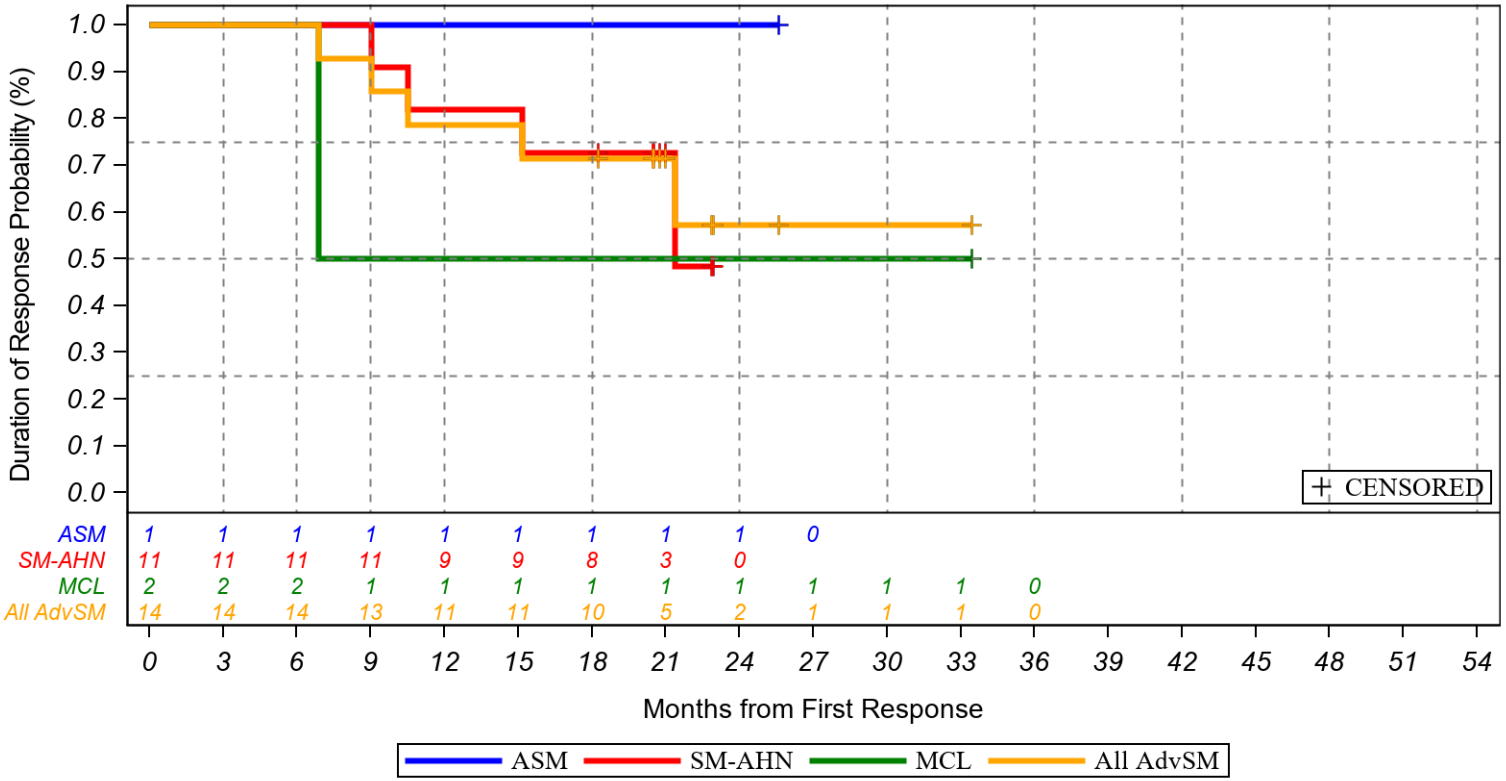

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Starting Dose: 200 mg and 300 mg & Prior Antineoplastic Therapy = Positive

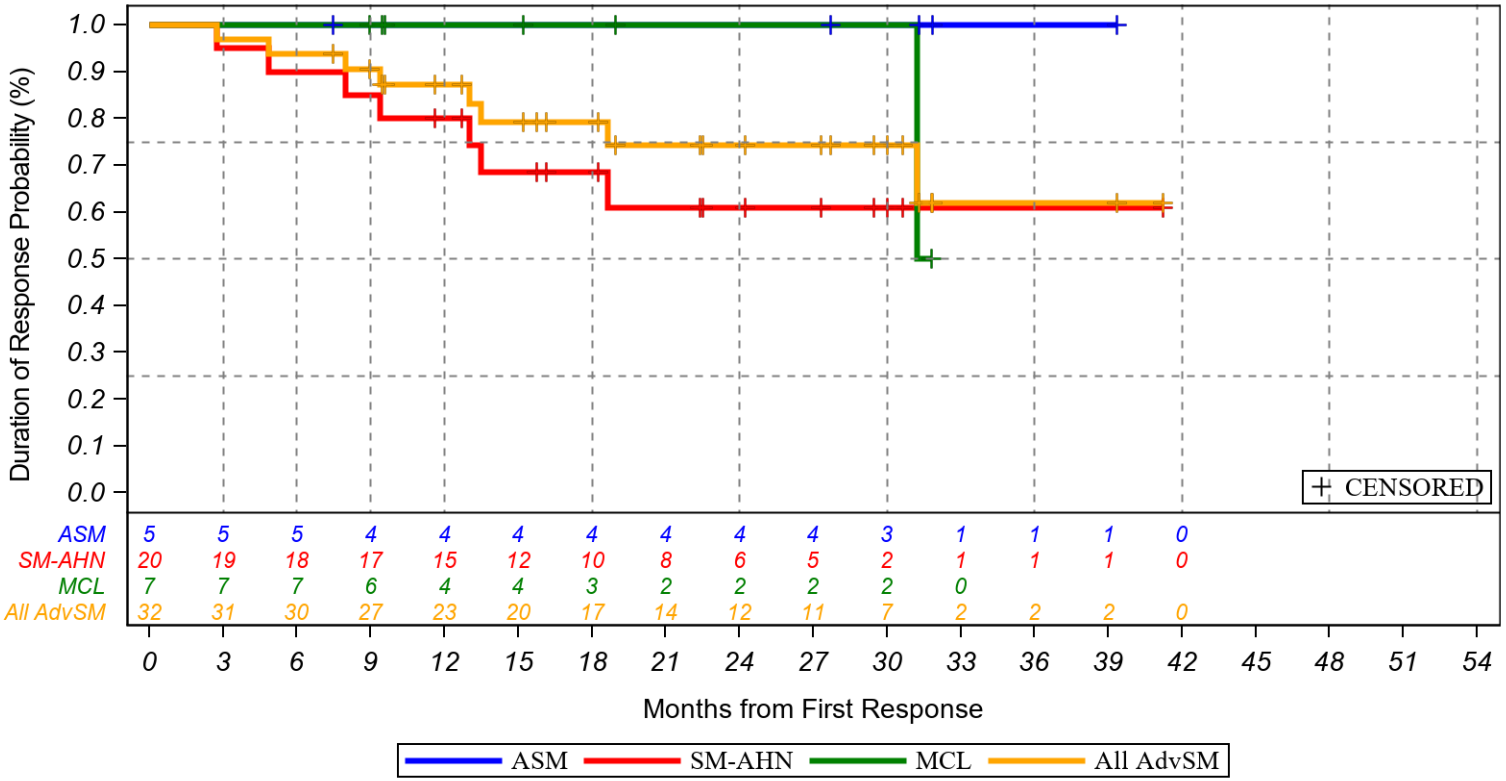

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Starting Dose: 200 mg and 300 mg & Prior Antineoplastic Therapy = Negative

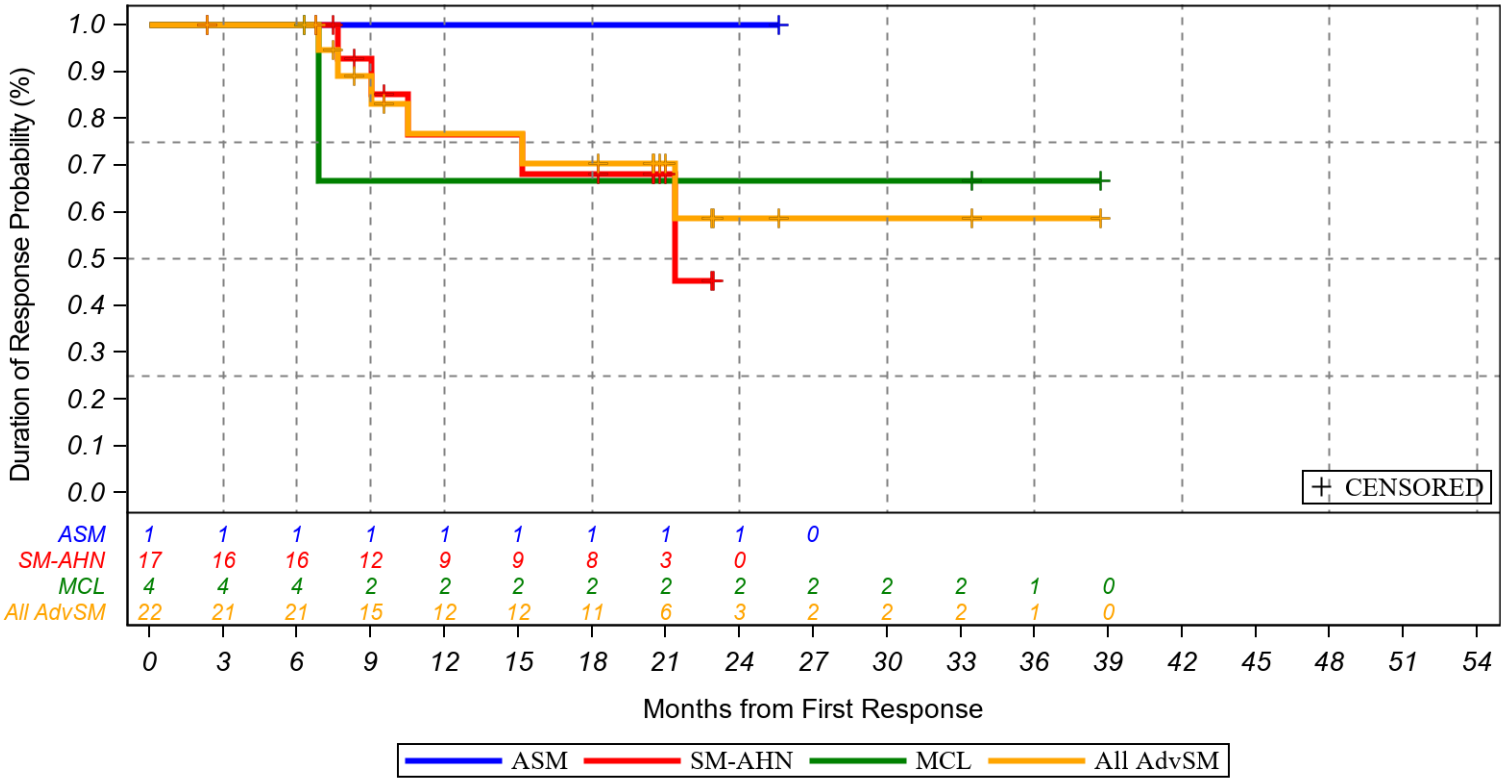

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Starting Dose: 400 mg & Prior Antineoplastic Therapy = Positive

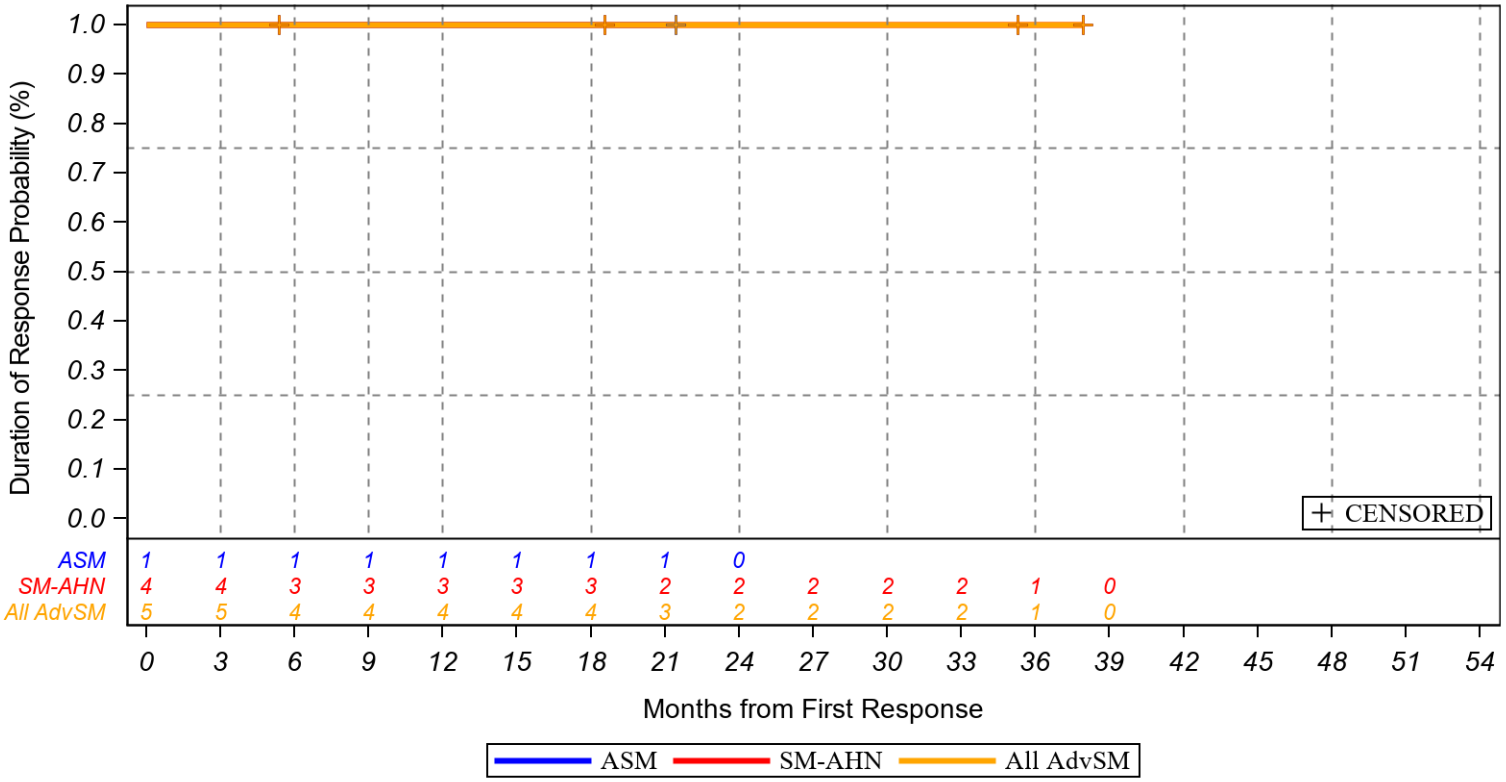

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Starting Dose: 400 mg & Prior Antineoplastic Therapy = Negative

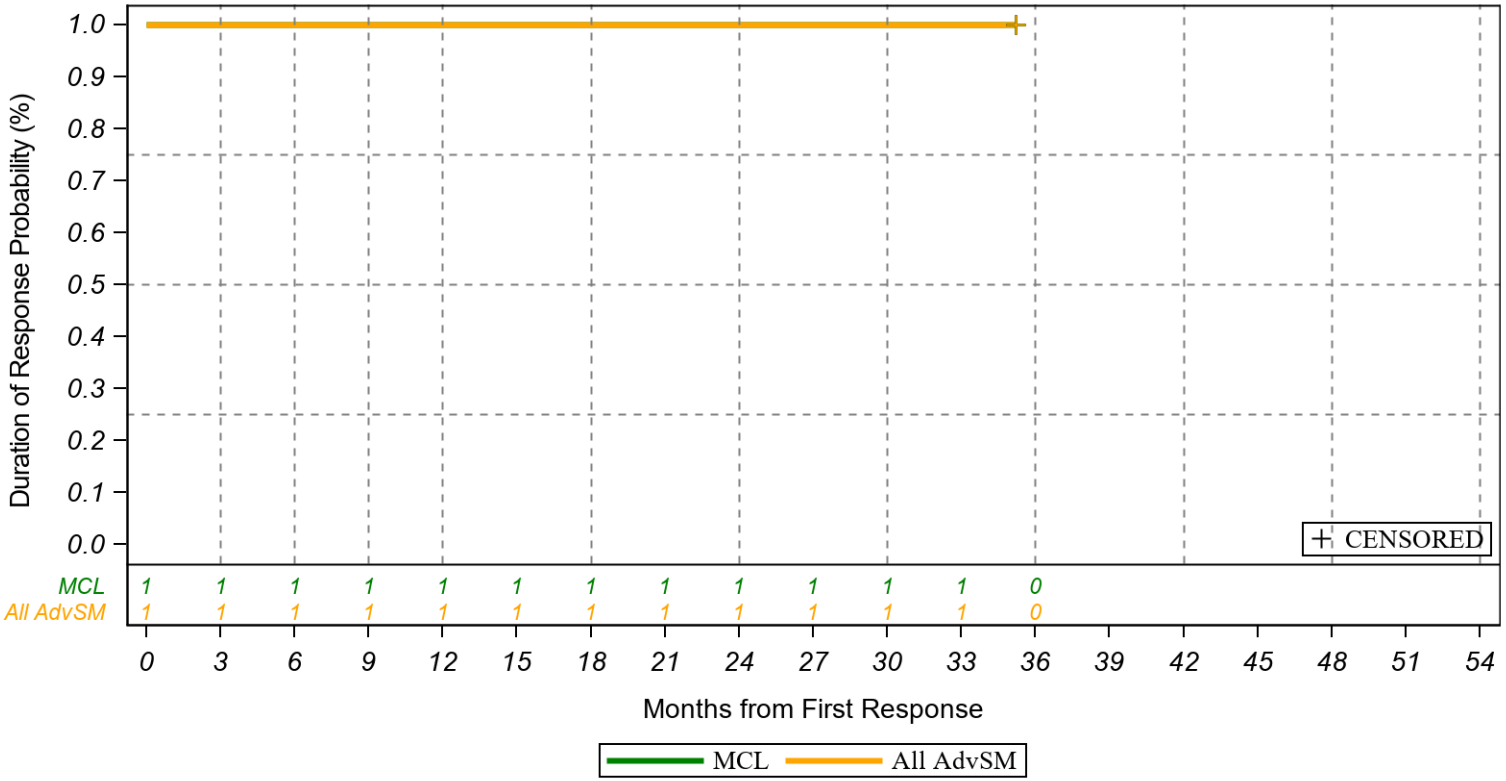

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Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2202
Starting Dose: Overall & Prior Antineoplastic Therapy = Positive

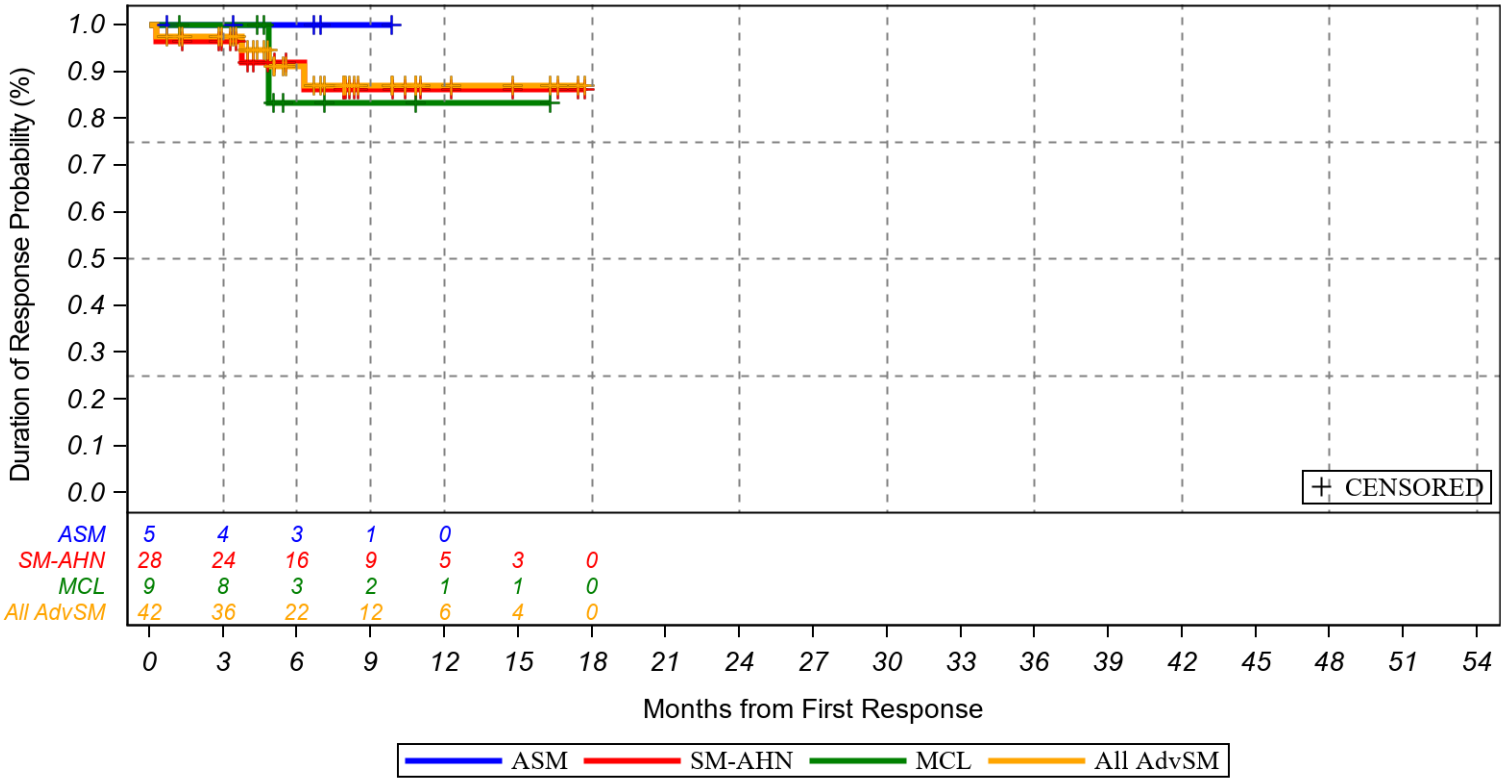

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Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2202
Starting Dose: Overall & Prior Antineoplastic Therapy = Negative

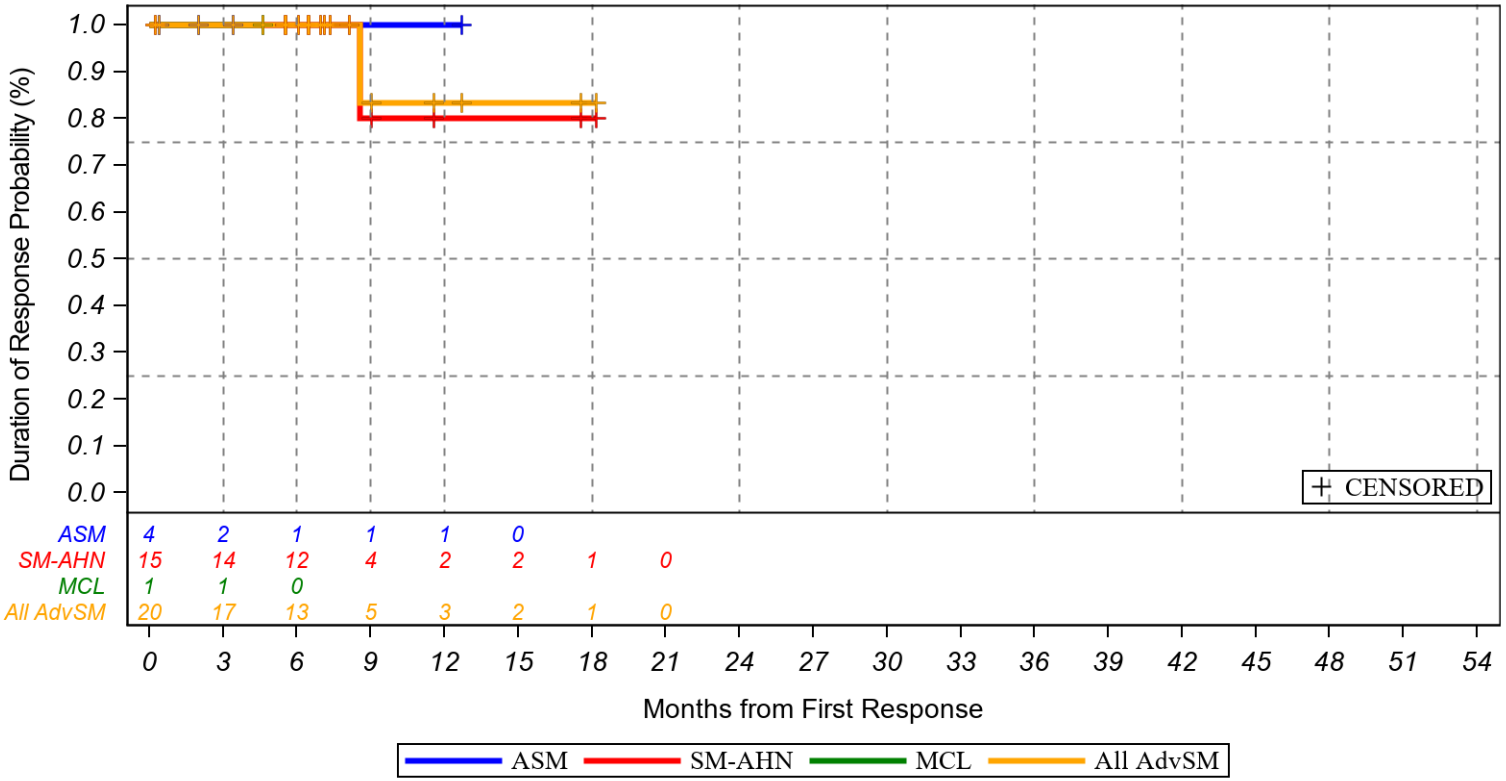

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2202
Starting Dose: 200 mg & Prior Antineoplastic Therapy = Positive

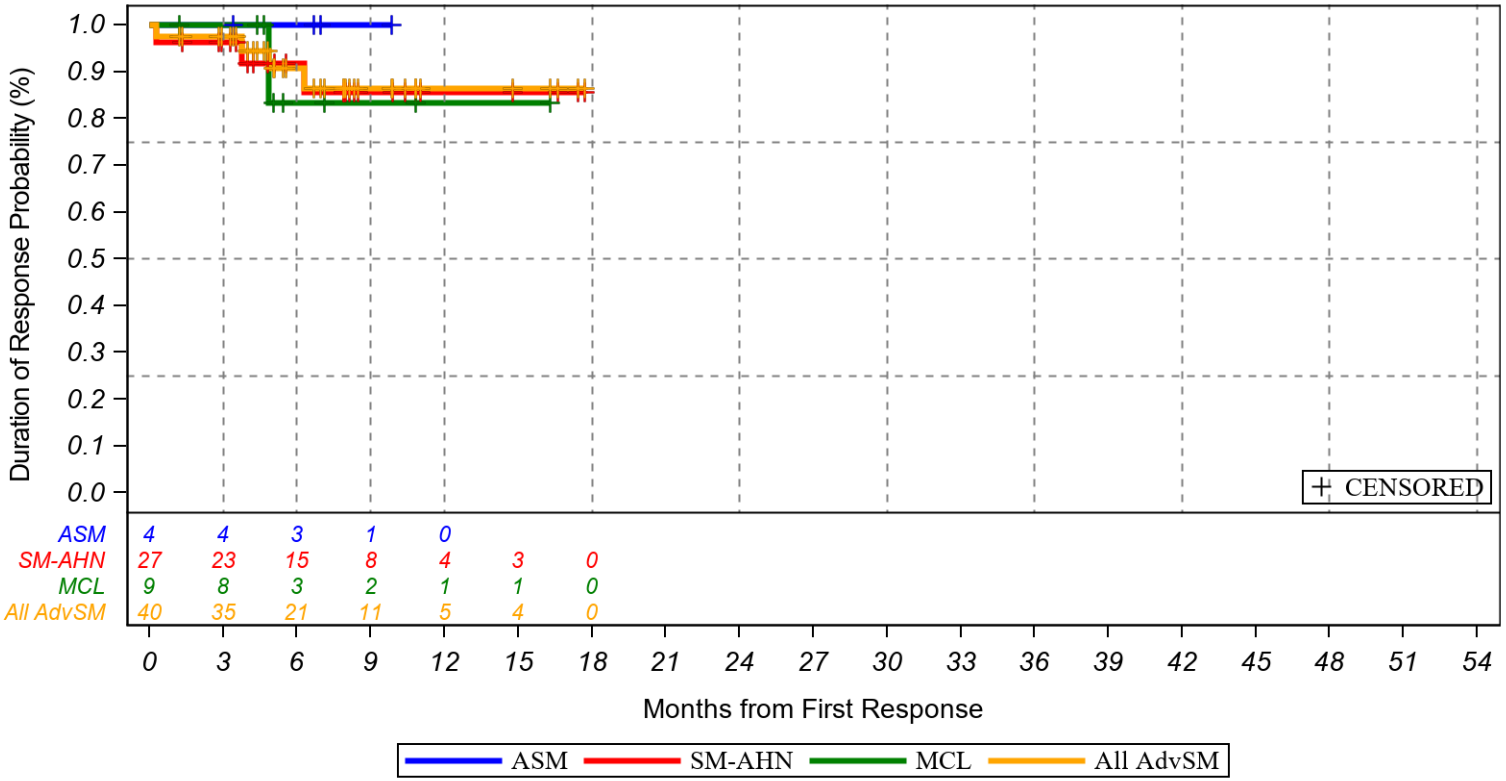

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Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2202
Starting Dose: 200 mg & Prior Antineoplastic Therapy = Negative

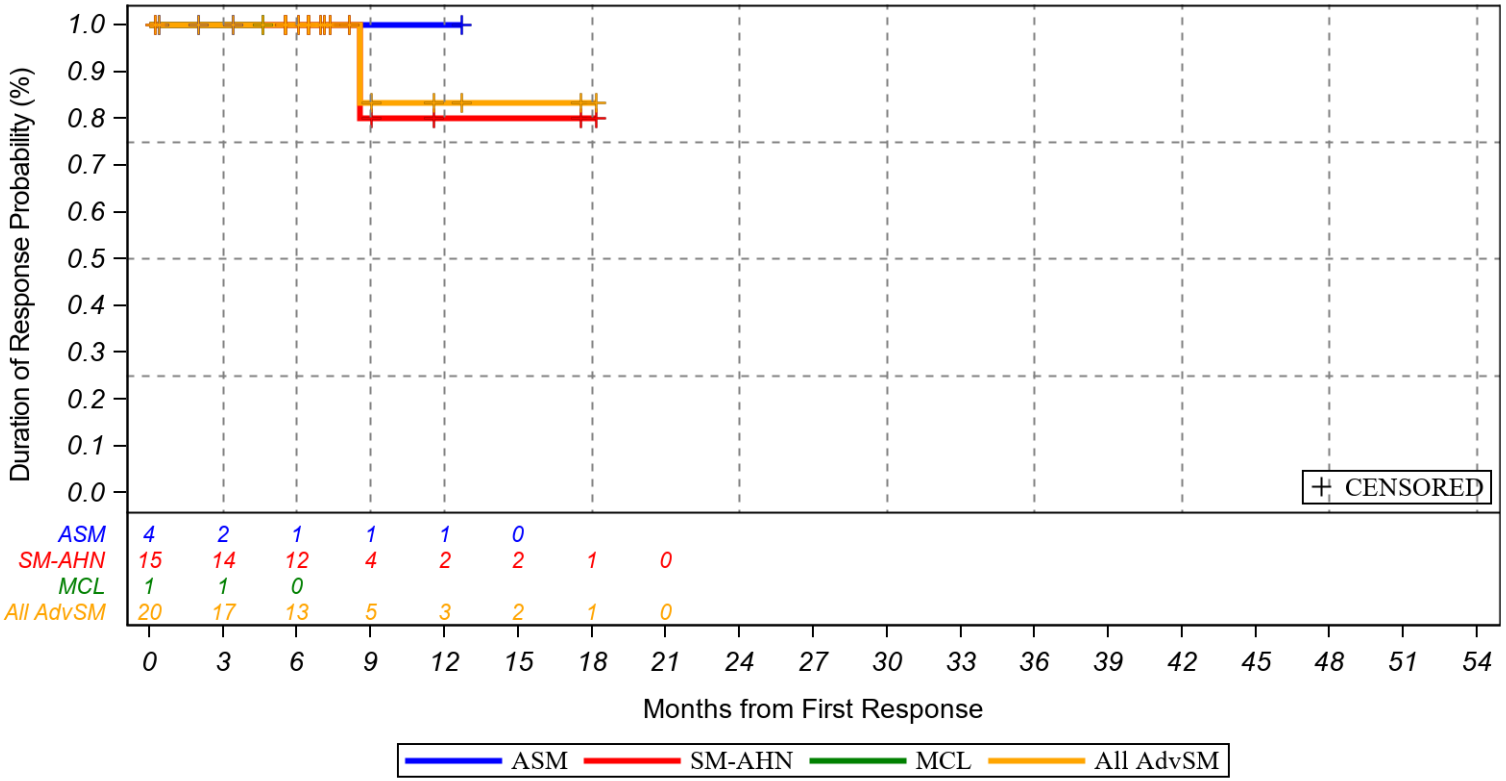

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall & Prior Antineoplastic Therapy = Positive

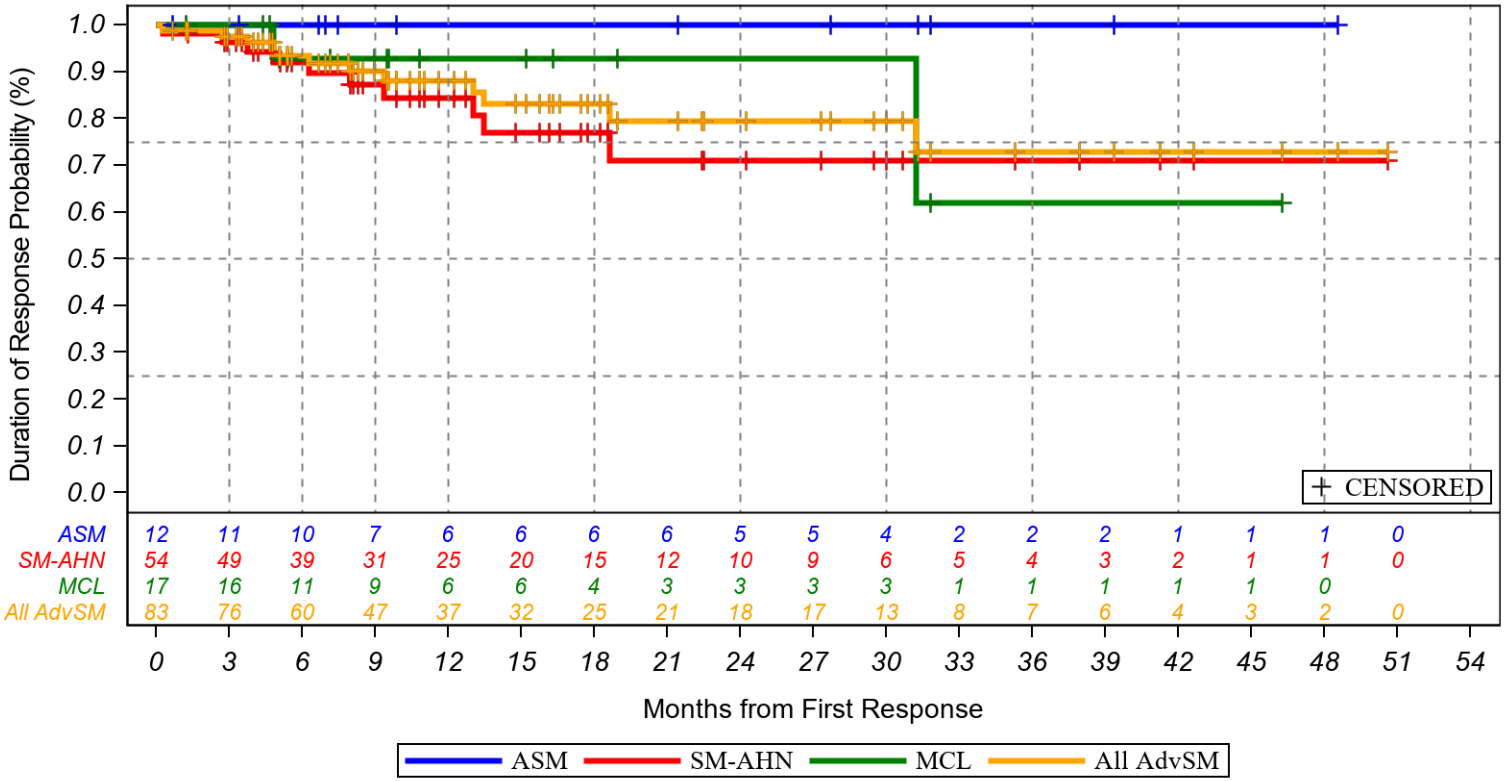

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall & Prior Antineoplastic Therapy = Negative

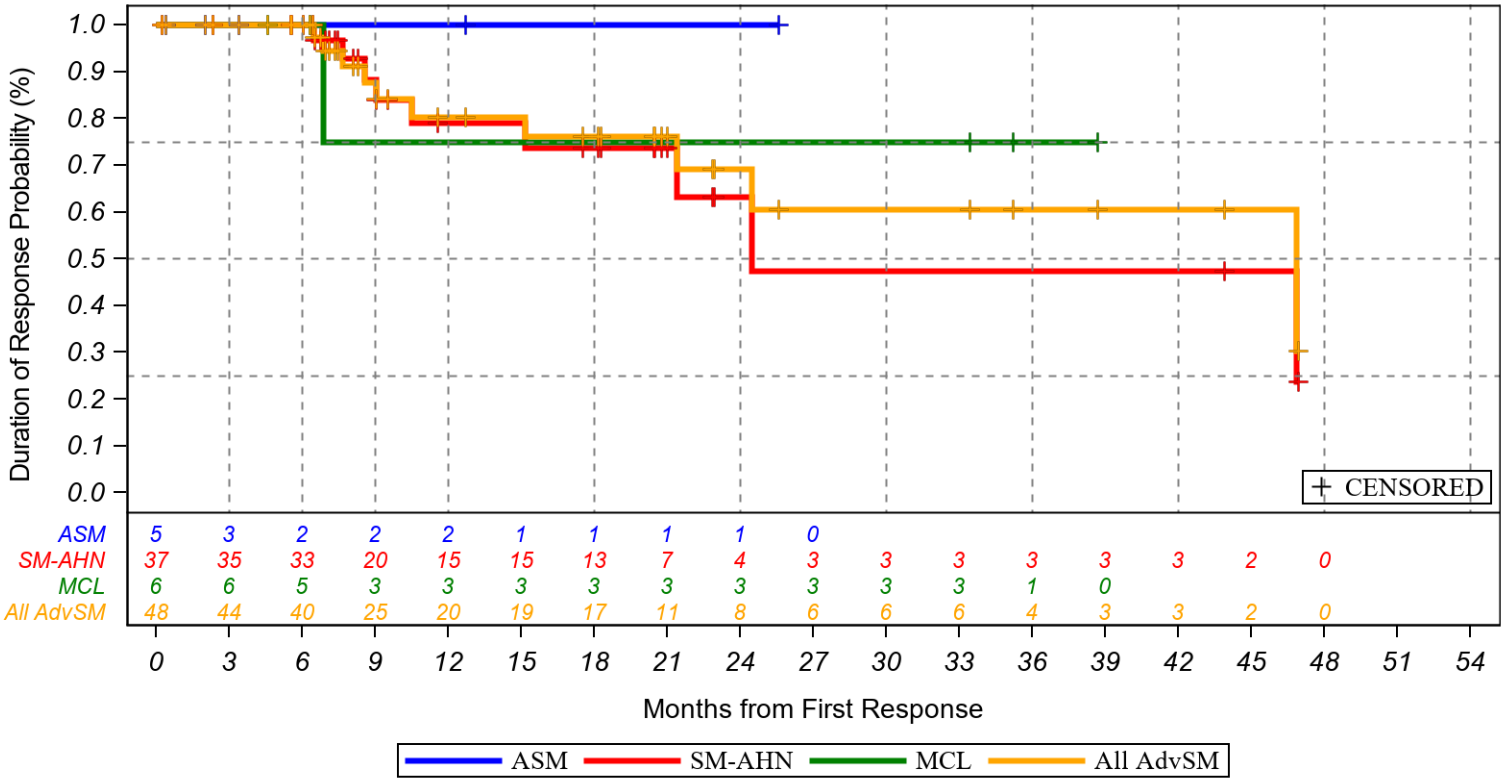

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg & Prior Antineoplastic Therapy = Positive

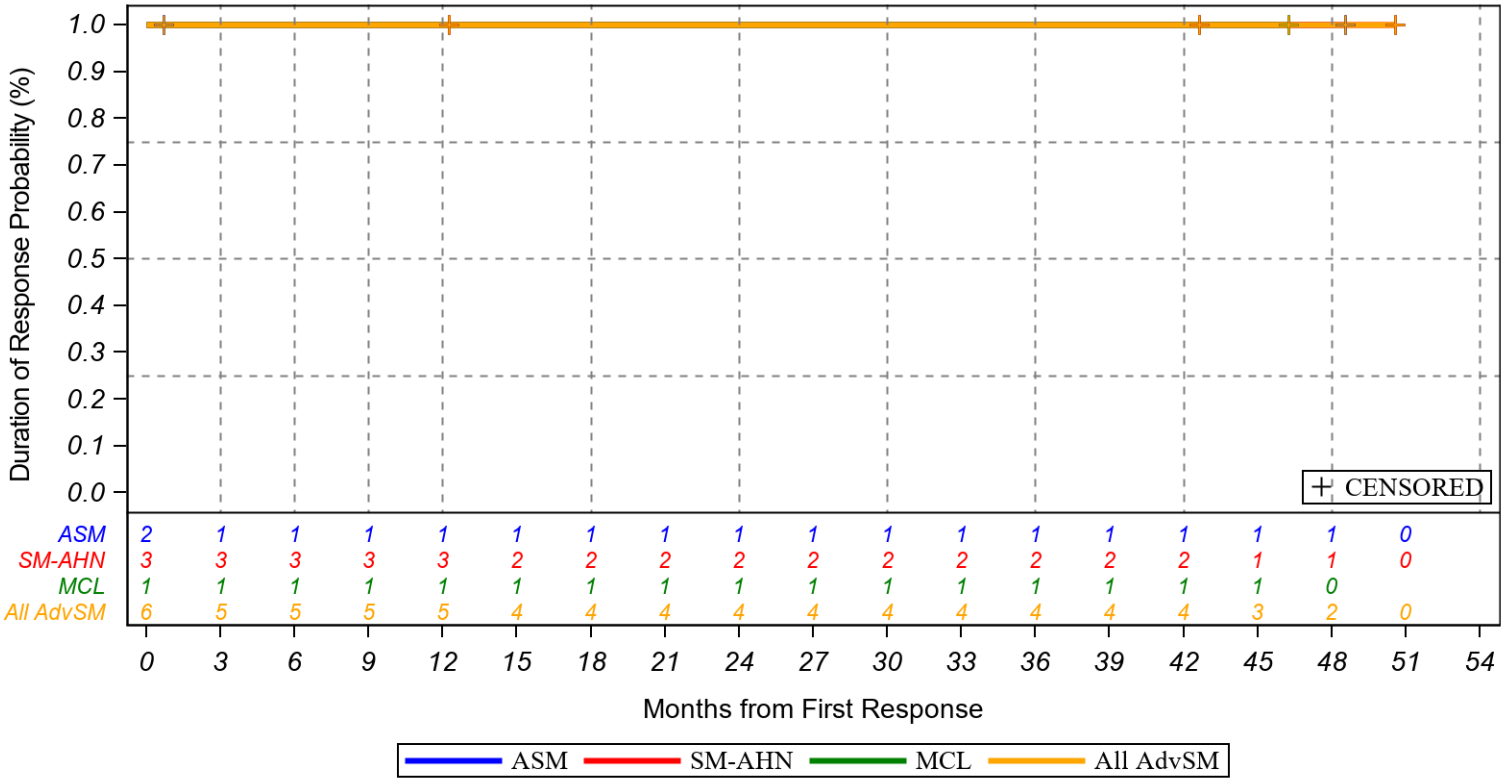

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg & Prior Antineoplastic Therapy = Negative

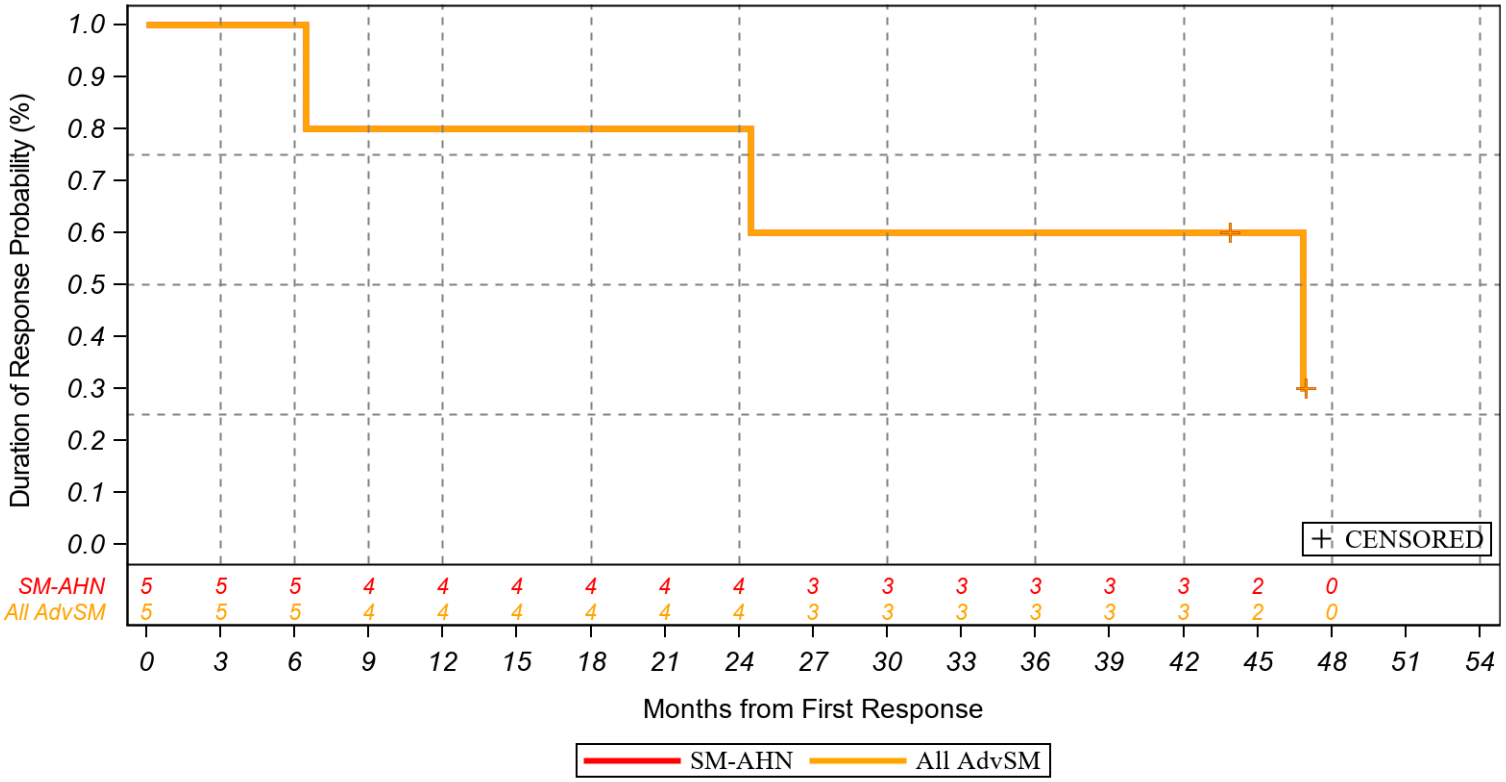

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Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg & Prior Antineoplastic Therapy = Positive

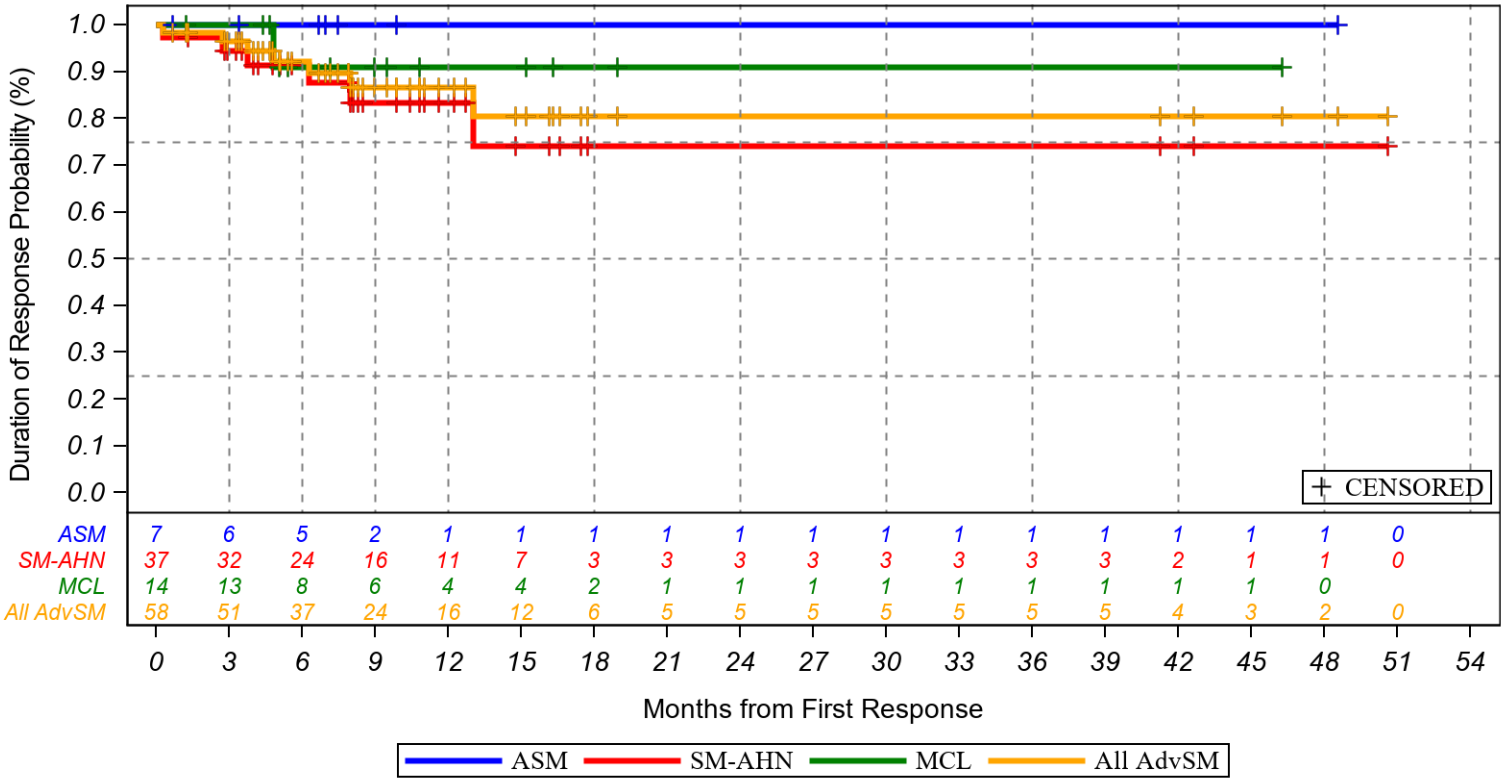

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg & Prior Antineoplastic Therapy = Negative

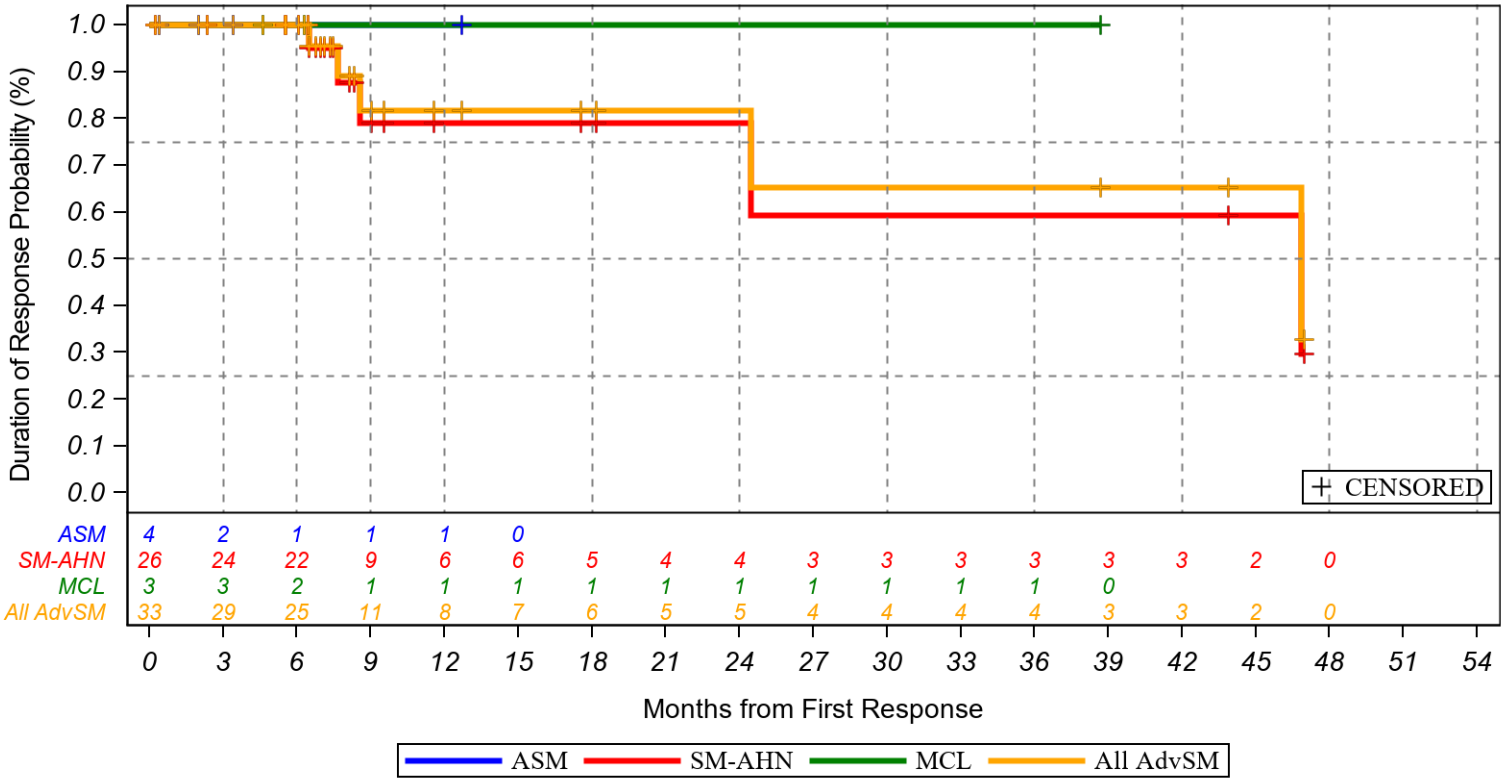

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg & Prior Antineoplastic Therapy = Positive

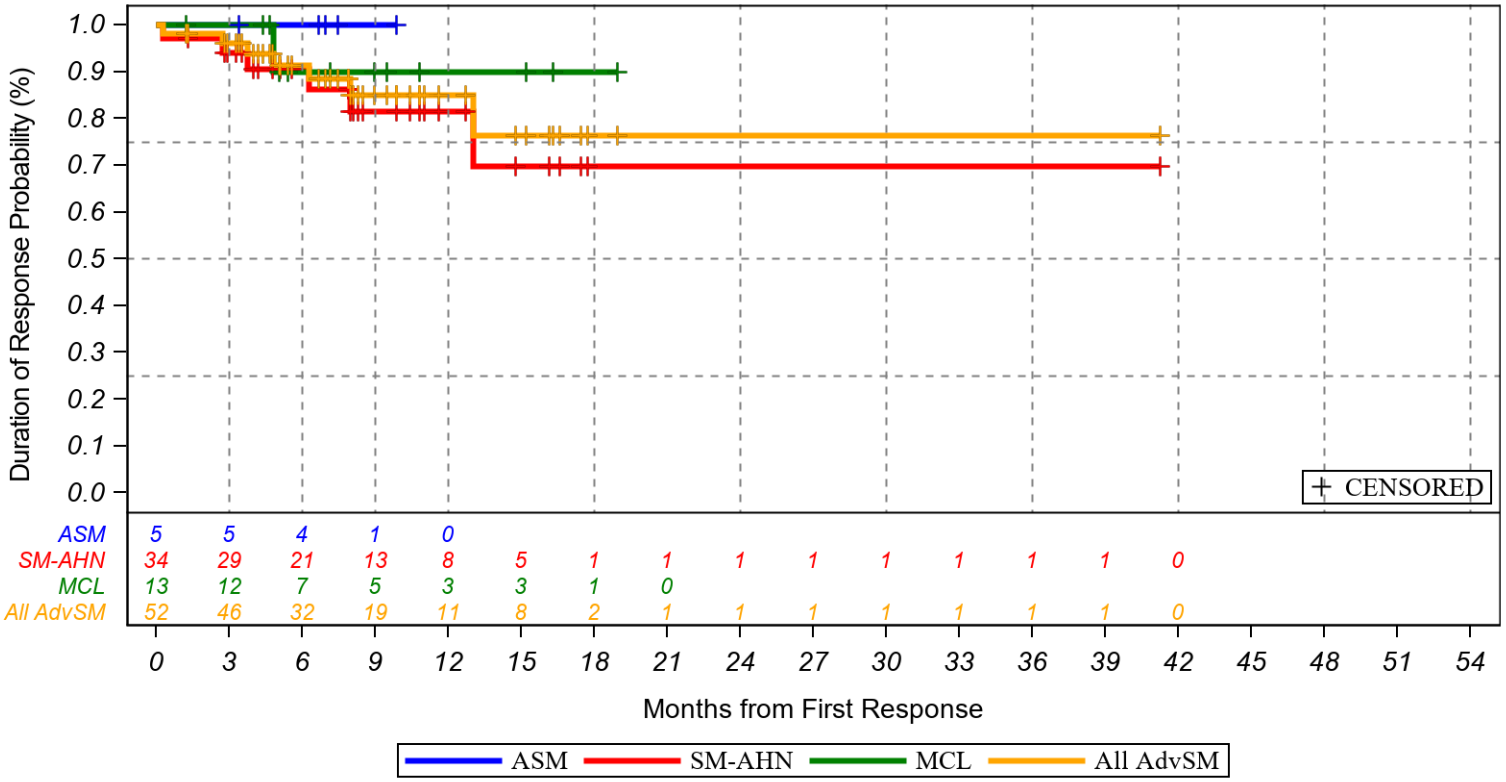

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Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg & Prior Antineoplastic Therapy = Negative

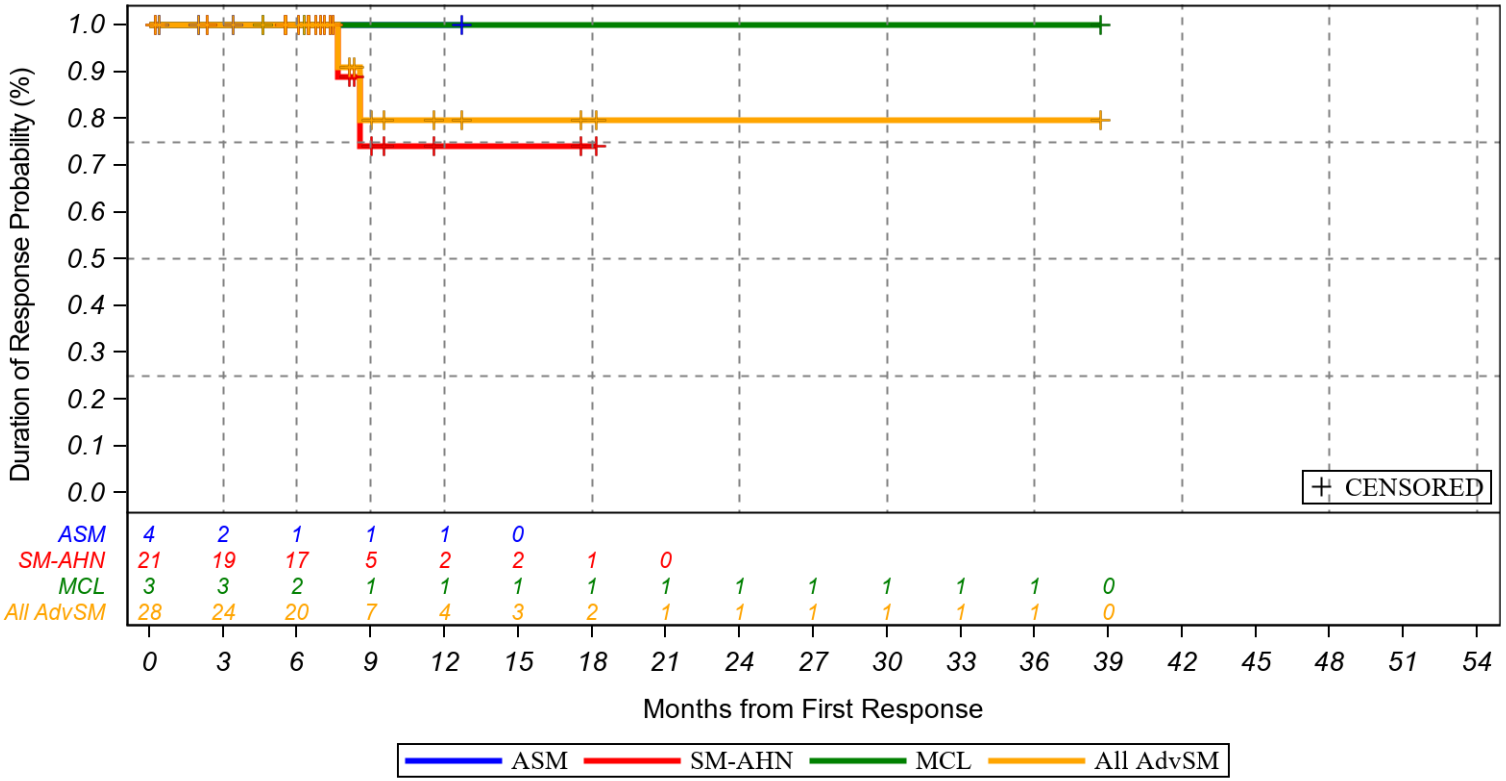

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg & Prior Antineoplastic Therapy = Positive

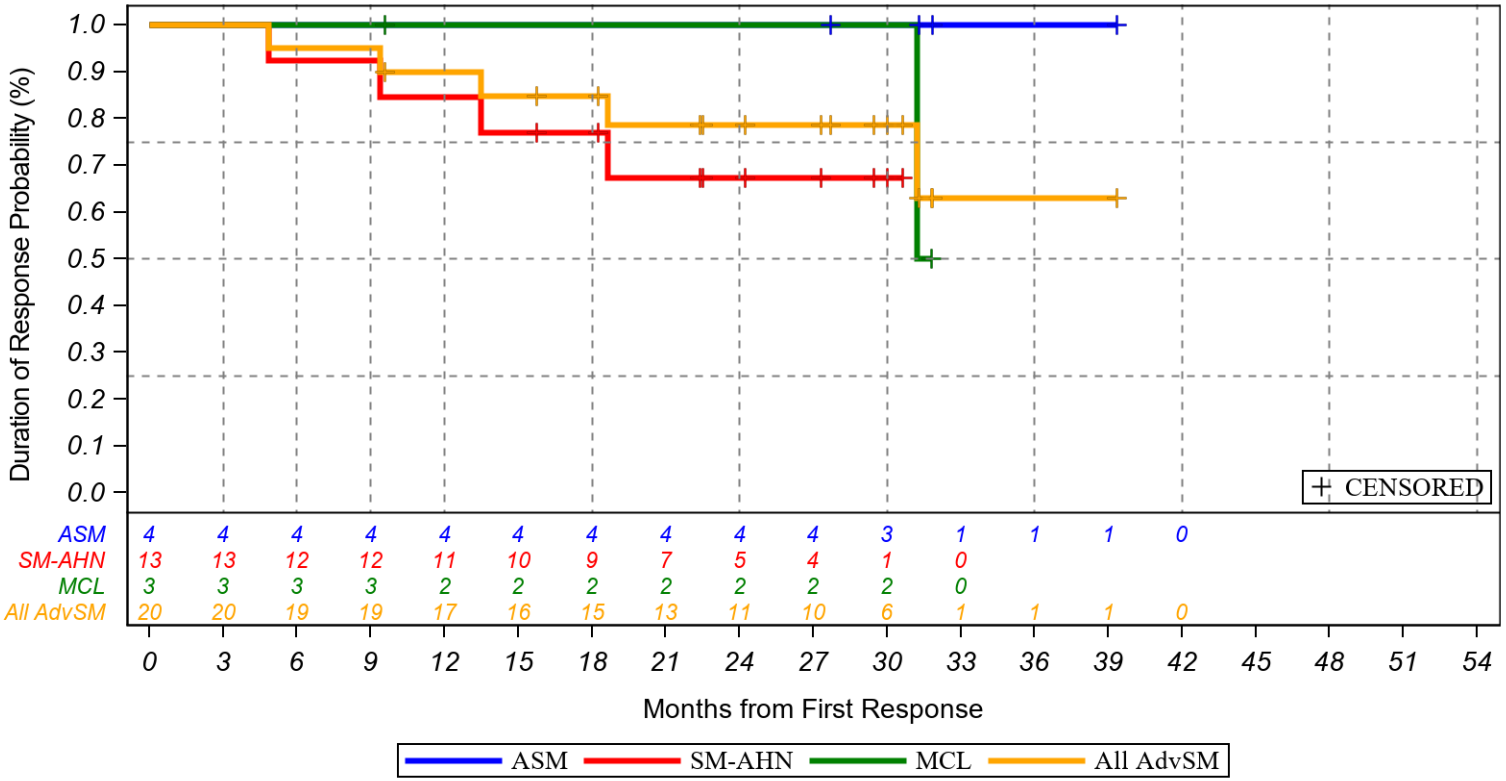

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg & Prior Antineoplastic Therapy = Negative

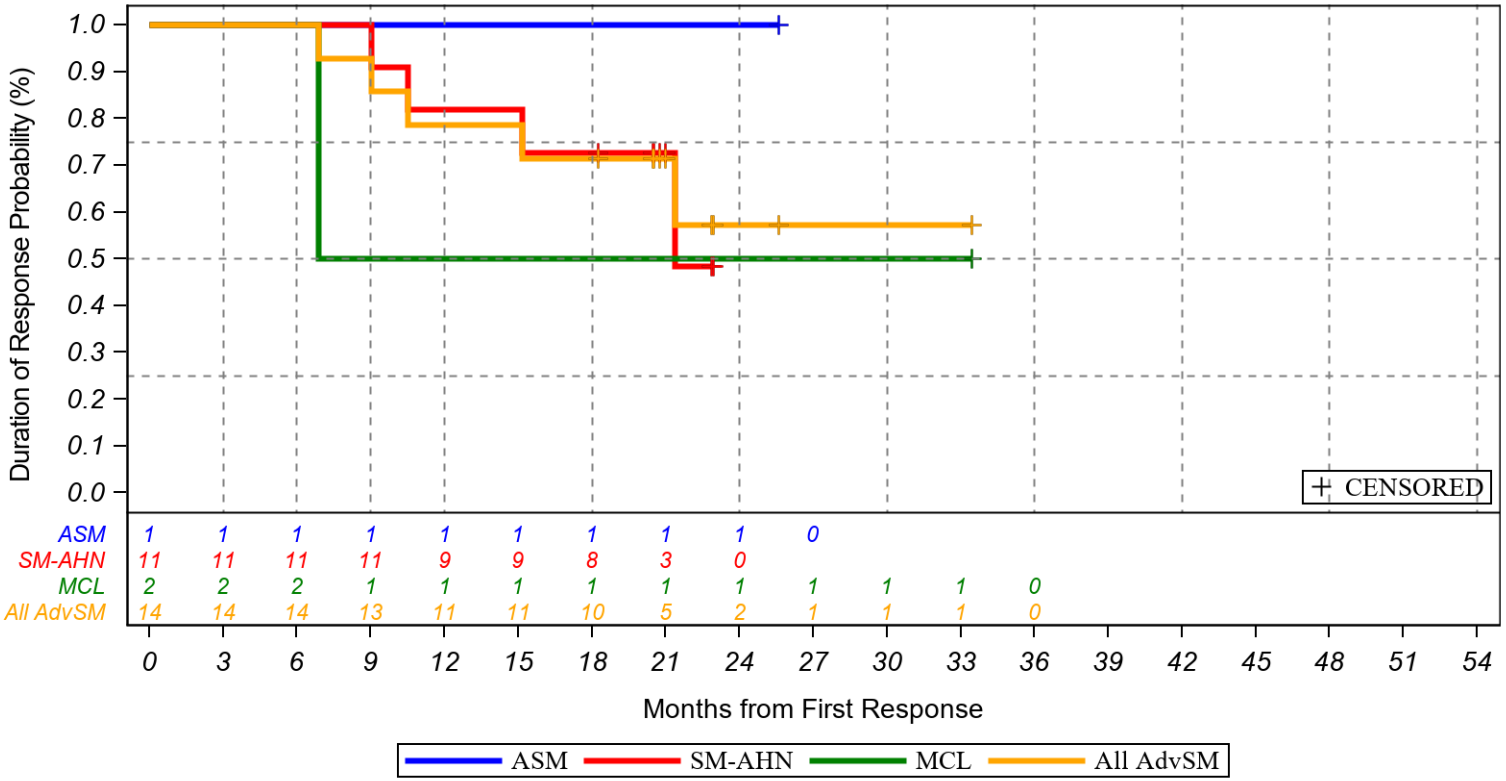

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg & Prior Antineoplastic Therapy = Positive

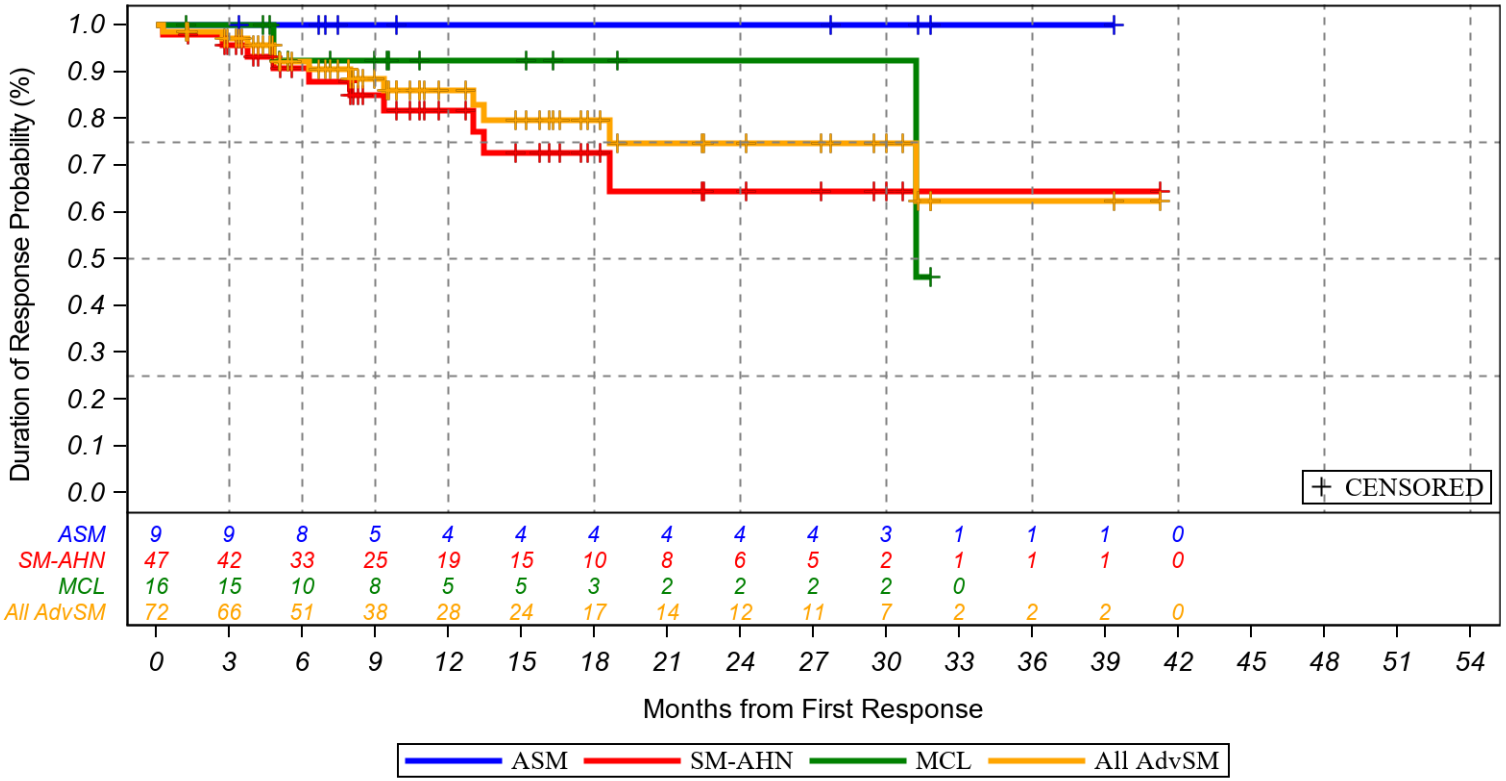

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg & Prior Antineoplastic Therapy = Negative

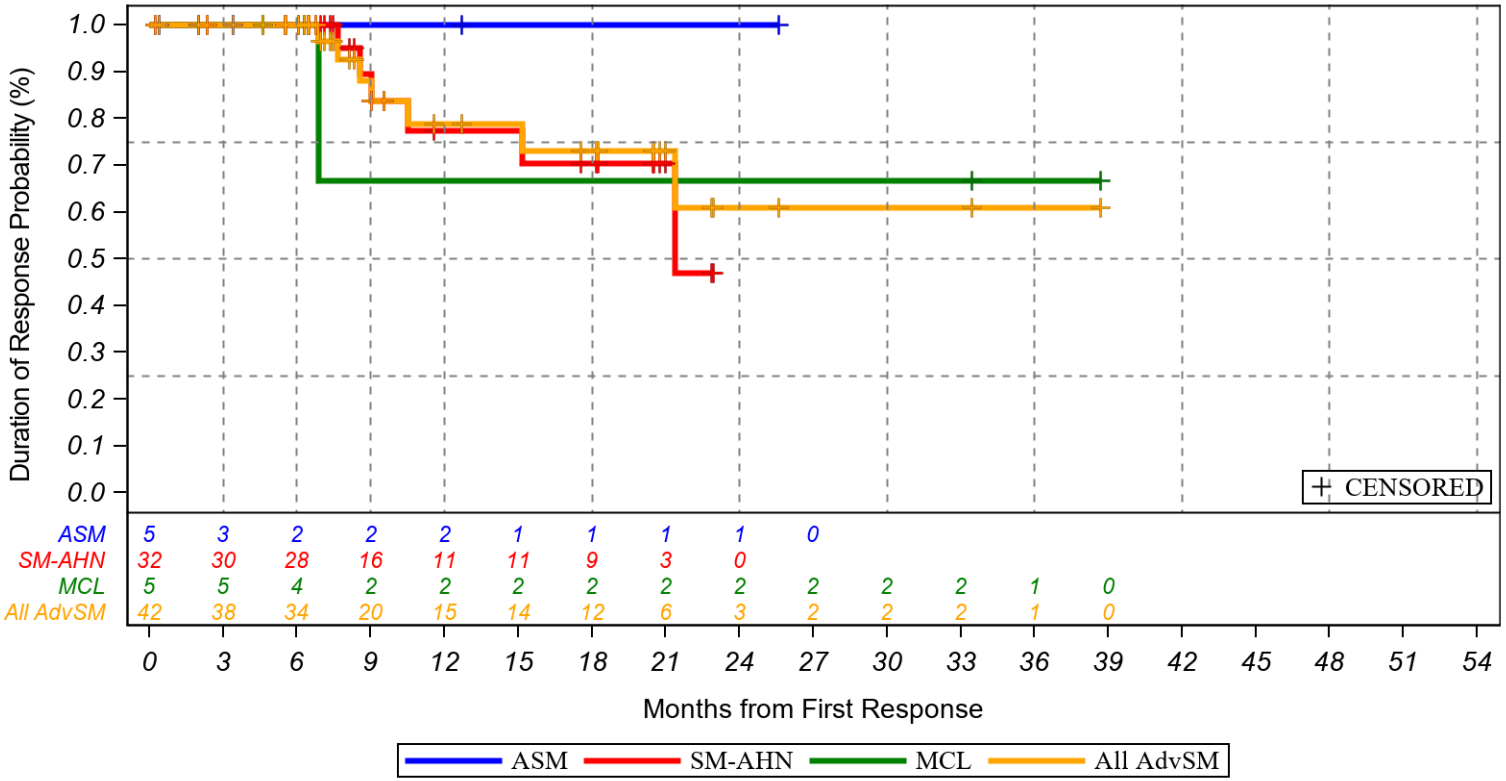

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg & Prior Antineoplastic Therapy = Positive

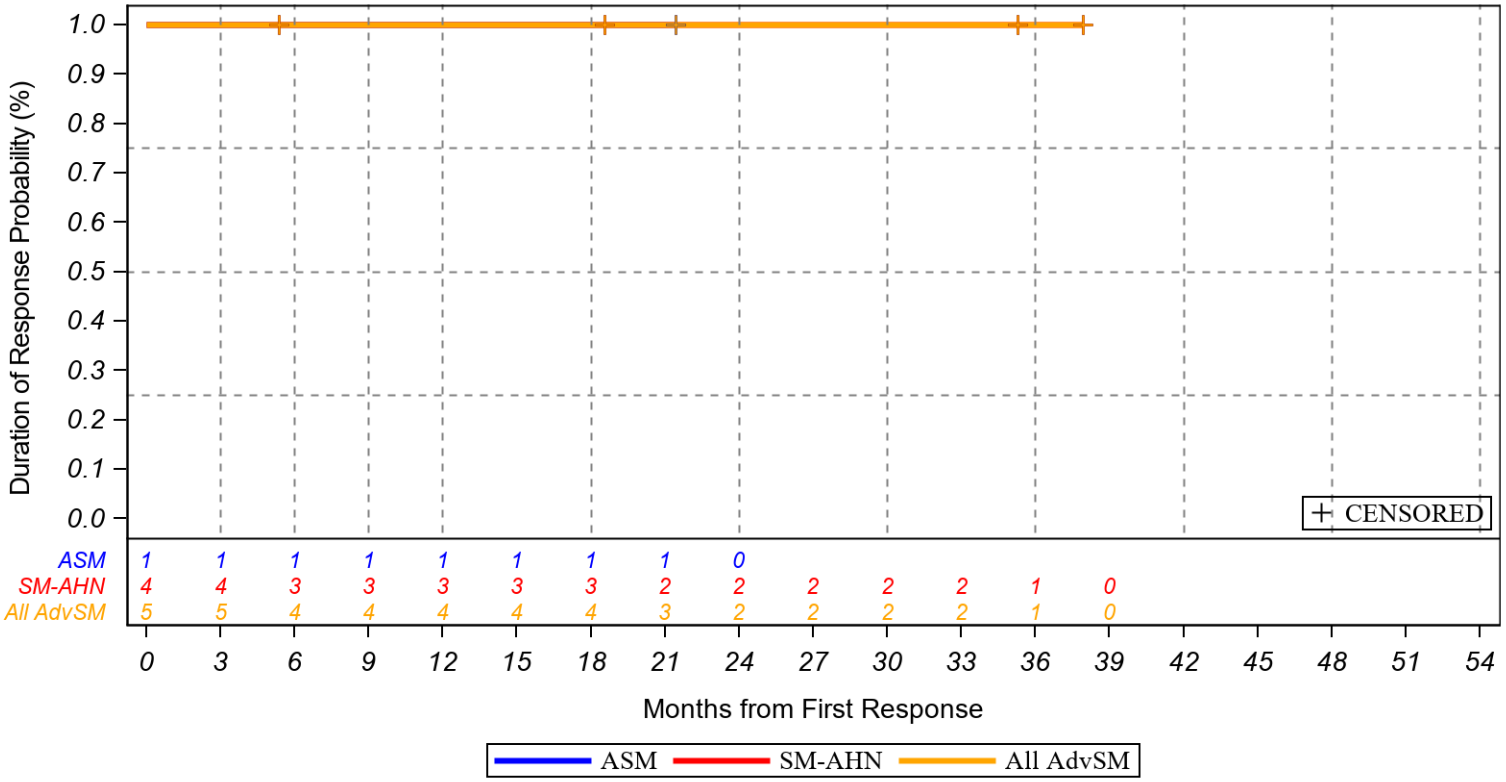

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg & Prior Antineoplastic Therapy = Negative

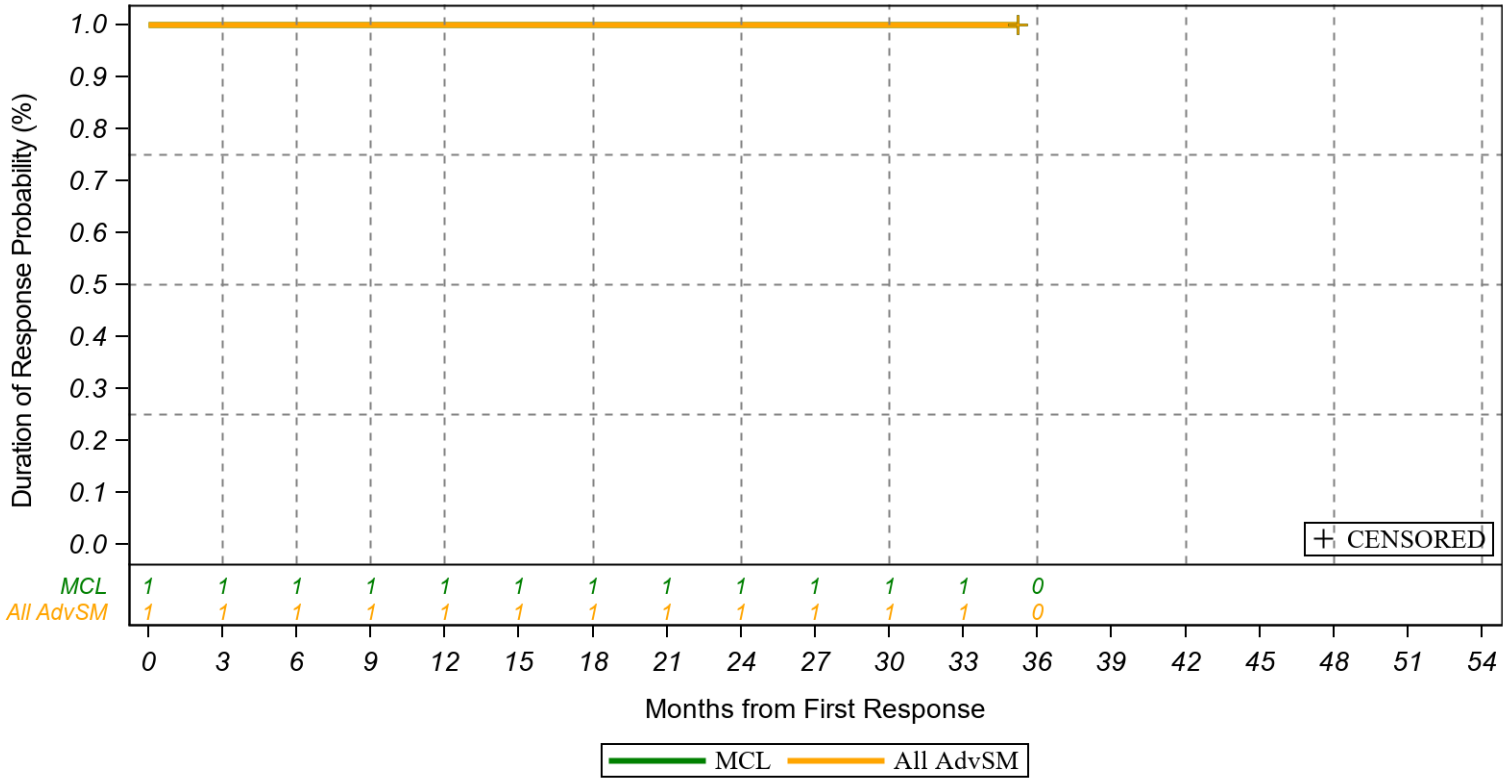

Table 14.2.1.1f
Summary of Adjudicated Best Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Overall & Prior Antineoplastic Therapy = Yes

Best Response	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=22) n (%) (95% CIs)	MCL (N=8) n (%) (95% CIs)	All AdvSM (N=32) n (%) (95% CIs)
CR	0	3 (13.6)	1 (12.5)	4 (12.5)
CRh	1 (50.0)	4 (18.2)	0	5 (15.6)
PR	1 (50.0)	8 (36.4)	2 (25.0)	11 (34.4)
CI	0	1 (4.5)	1 (12.5)	2 (6.3)
SD	0	5 (22.7)	4 (50.0)	9 (28.1)
PD	0	0	0	0
NE	0	1 (4.5)	0	1 (3.1)
CR+CRh	1 (50.0) (1.3- 98.7)	7 (31.8) (13.9- 54.9)	1 (12.5) (0.3- 52.7)	9 (28.1) (13.7- 46.7)
CR+CRh+PR	2 (100) (15.8-100.0)	15 (68.2) (45.1- 86.1)	3 (37.5) (8.5- 75.5)	20 (62.5) (43.7- 78.9)
CR+CRh+PR+CI (ORR)	2 (100) (15.8-100.0)	16 (72.7) (49.8- 89.3)	4 (50.0) (15.7- 84.3)	22 (68.8) (50.0- 83.9)
CR+CRh+PR+CI+SD	2 (100) (15.8-100.0)	21 (95.5) (77.2- 99.9)	8 (100) (63.1-100.0)	31 (96.9) (83.8- 99.9)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
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Table 14.2.1.1f
Summary of Adjudicated Best Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: <200 mg & Prior Antineoplastic Therapy = Yes

Best Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=2) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=3) n (%) (95% CIs)
CR		1 (50.0)	1 (100)	2 (66.7)
CRh		1 (50.0)	0	1 (33.3)
PR		0	0	0
CI		0	0	0
SD		0	0	0
PD		0	0	0
NE		0	0	0
CR+CRh		2 (100) (15.8-100.0)	1 (100) (2.5-100.0)	3 (100) (29.2-100.0)
CR+CRh+PR		2 (100) (15.8-100.0)	1 (100) (2.5-100.0)	3 (100) (29.2-100.0)
CR+CRh+PR+CI (ORR)		2 (100) (15.8-100.0)	1 (100) (2.5-100.0)	3 (100) (29.2-100.0)
CR+CRh+PR+CI+SD		2 (100) (15.8-100.0)	1 (100) (2.5-100.0)	3 (100) (29.2-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-resp-tpy-racDate: 20:38/02NOV2020

Table 14.2.1.1f
Summary of Adjudicated Best Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: <300 mg & Prior Antineoplastic Therapy = Yes

Best Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=7) n (%) (95% CIs)	MCL (N=5) n (%) (95% CIs)	All AdvSM (N=12) n (%) (95% CIs)
CR		1 (14.3)	1 (20.0)	2 (16.7)
CRh		3 (42.9)	0	3 (25.0)
PR		1 (14.3)	1 (20.0)	2 (16.7)
CI		0	0	0
SD		1 (14.3)	3 (60.0)	4 (33.3)
PD		0	0	0
NE		1 (14.3)	0	1 (8.3)
CR+CRh		4 (57.1) (18.4- 90.1)	1 (20.0) (0.5- 71.6)	5 (41.7) (15.2- 72.3)
CR+CRh+PR		5 (71.4) (29.0- 96.3)	2 (40.0) (5.3- 85.3)	7 (58.3) (27.7- 84.8)
CR+CRh+PR+CI (ORR)		5 (71.4) (29.0- 96.3)	2 (40.0) (5.3- 85.3)	7 (58.3) (27.7- 84.8)
CR+CRh+PR+CI+SD		6 (85.7) (42.1- 99.6)	5 (100) (47.8-100.0)	11 (91.7) (61.5- 99.8)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-resp-tpy-racDate: 20:38/02NOV2020

Table 14.2.1.1f
Summary of Adjudicated Best Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: 200 mg & Prior Antineoplastic Therapy = Yes

Best Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=5) n (%) (95% CIs)	MCL (N=4) n (%) (95% CIs)	All AdvSM (N=9) n (%) (95% CIs)
CR		0	0	0
CRh		2 (40.0)	0	2 (22.2)
PR		1 (20.0)	1 (25.0)	2 (22.2)
CI		0	0	0
SD		1 (20.0)	3 (75.0)	4 (44.4)
PD		0	0	0
NE		1 (20.0)	0	1 (11.1)
CR+CRh		2 (40.0) (5.3- 85.3)	0	2 (22.2) (2.8- 60.0)
CR+CRh+PR		3 (60.0) (14.7- 94.7)	1 (25.0) (0.6- 80.6)	4 (44.4) (13.7- 78.8)
CR+CRh+PR+CI (ORR)		3 (60.0) (14.7- 94.7)	1 (25.0) (0.6- 80.6)	4 (44.4) (13.7- 78.8)
CR+CRh+PR+CI+SD		4 (80.0) (28.4- 99.5)	4 (100) (39.8-100.0)	8 (88.9) (51.8- 99.7)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-resp-tpy-racDate: 20:38/02NOV2020

Table 14.2.1.1f
Summary of Adjudicated Best Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: 300 mg & Prior Antineoplastic Therapy = Yes

Best Response	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=11) n (%) (95% CIs)	MCL (N=3) n (%) (95% CIs)	All AdvSM (N=16) n (%) (95% CIs)
CR	0	2 (18.2)	0	2 (12.5)
CRh	1 (50.0)	0	0	1 (6.3)
PR	1 (50.0)	6 (54.5)	1 (33.3)	8 (50.0)
CI	0	1 (9.1)	1 (33.3)	2 (12.5)
SD	0	2 (18.2)	1 (33.3)	3 (18.8)
PD	0	0	0	0
NE	0	0	0	0
CR+CRh	1 (50.0) (1.3- 98.7)	2 (18.2) (2.3- 51.8)	0	3 (18.8) (4.0- 45.6)
CR+CRh+PR	2 (100) (15.8-100.0)	8 (72.7) (39.0- 94.0)	1 (33.3) (0.8- 90.6)	11 (68.8) (41.3- 89.0)
CR+CRh+PR+CI (ORR)	2 (100) (15.8-100.0)	9 (81.8) (48.2- 97.7)	2 (66.7) (9.4- 99.2)	13 (81.3) (54.4- 96.0)
CR+CRh+PR+CI+SD	2 (100) (15.8-100.0)	11 (100) (71.5-100.0)	3 (100) (29.2-100.0)	16 (100) (79.4-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-resp-tpy-racDate: 20:38/02NOV2020

Table 14.2.1.1f
Summary of Adjudicated Best Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg & Prior Antineoplastic Therapy = Yes

Best Response	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=16) n (%) (95% CIs)	MCL (N=7) n (%) (95% CIs)	All AdvSM (N=25) n (%) (95% CIs)
CR	0	2 (12.5)	0	2 (8.0)
CRh	1 (50.0)	2 (12.5)	0	3 (12.0)
PR	1 (50.0)	7 (43.8)	2 (28.6)	10 (40.0)
CI	0	1 (6.3)	1 (14.3)	2 (8.0)
SD	0	3 (18.8)	4 (57.1)	7 (28.0)
PD	0	0	0	0
NE	0	1 (6.3)	0	1 (4.0)
CR+CRh	1 (50.0) (1.3- 98.7)	4 (25.0) (7.3- 52.4)	0	5 (20.0) (6.8- 40.7)
CR+CRh+PR	2 (100) (15.8-100.0)	11 (68.8) (41.3- 89.0)	2 (28.6) (3.7- 71.0)	15 (60.0) (38.7- 78.9)
CR+CRh+PR+CI (ORR)	2 (100) (15.8-100.0)	12 (75.0) (47.6- 92.7)	3 (42.9) (9.9- 81.6)	17 (68.0) (46.5- 85.1)
CR+CRh+PR+CI+SD	2 (100) (15.8-100.0)	15 (93.8) (69.8- 99.8)	7 (100) (59.0-100.0)	24 (96.0) (79.6- 99.9)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-resp-tpy-racDate: 20:38/02NOV2020

Table 14.2.1.1f
Summary of Adjudicated Best Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: 400 mg & Prior Antineoplastic Therapy = Yes

Best Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=4) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=4) n (%) (95% CIs)
CR		0		0
CRh		1 (25.0)		1 (25.0)
PR		1 (25.0)		1 (25.0)
CI		0		0
SD		2 (50.0)		2 (50.0)
PD		0		0
NE		0		0
CR+CRh		1 (25.0) (0.6- 80.6)		1 (25.0) (0.6- 80.6)
CR+CRh+PR		2 (50.0) (6.8- 93.2)		2 (50.0) (6.8- 93.2)
CR+CRh+PR+CI (ORR)		2 (50.0) (6.8- 93.2)		2 (50.0) (6.8- 93.2)
CR+CRh+PR+CI+SD		4 (100) (39.8-100.0)		4 (100) (39.8-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-resp-tpy-racDate: 20:38/02NOV2020

Table 14.2.1.1f
Summary of Adjudicated Best Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Overall & Prior Antineoplastic Therapy = No

Best Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=15) n (%) (95% CIs)	MCL (N=5) n (%) (95% CIs)	All AdvSM (N=21) n (%) (95% CIs)
CR	0	2 (13.3)	2 (40.0)	4 (19.0)
CRh	1 (100)	5 (33.3)	0	6 (28.6)
PR	0	5 (33.3)	2 (40.0)	7 (33.3)
CI	0	0	1 (20.0)	1 (4.8)
SD	0	3 (20.0)	0	3 (14.3)
PD	0	0	0	0
NE	0	0	0	0
CR+CRh	1 (100) (2.5-100.0)	7 (46.7) (21.3- 73.4)	2 (40.0) (5.3- 85.3)	10 (47.6) (25.7- 70.2)
CR+CRh+PR	1 (100) (2.5-100.0)	12 (80.0) (51.9- 95.7)	4 (80.0) (28.4- 99.5)	17 (81.0) (58.1- 94.6)
CR+CRh+PR+CI (ORR)	1 (100) (2.5-100.0)	12 (80.0) (51.9- 95.7)	5 (100) (47.8-100.0)	18 (85.7) (63.7- 97.0)
CR+CRh+PR+CI+SD	1 (100) (2.5-100.0)	15 (100) (78.2-100.0)	5 (100) (47.8-100.0)	21 (100) (83.9-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-resp-tpy-racDate: 20:38/02NOV2020

Table 14.2.1.1f
Summary of Adjudicated Best Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: <200 mg & Prior Antineoplastic Therapy = No

Best Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=5) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=5) n (%) (95% CIs)
CR		1 (20.0)		1 (20.0)
CRh		3 (60.0)		3 (60.0)
PR		0		0
CI		0		0
SD		1 (20.0)		1 (20.0)
PD		0		0
NE		0		0
CR+CRh		4 (80.0) (28.4- 99.5)		4 (80.0) (28.4- 99.5)
CR+CRh+PR		4 (80.0) (28.4- 99.5)		4 (80.0) (28.4- 99.5)
CR+CRh+PR+CI (ORR)		4 (80.0) (28.4- 99.5)		4 (80.0) (28.4- 99.5)
CR+CRh+PR+CI+SD		5 (100) (47.8-100.0)		5 (100) (47.8-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-resp-tpy-racDate: 20:38/02NOV2020

Table 14.2.1.1f
Summary of Adjudicated Best Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: <300 mg & Prior Antineoplastic Therapy = No

Best Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=7) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=9) n (%) (95% CIs)
CR		1 (14.3)	0	1 (11.1)
CRh		3 (42.9)	0	3 (33.3)
PR		1 (14.3)	2 (100)	3 (33.3)
CI		0	0	0
SD		2 (28.6)	0	2 (22.2)
PD		0	0	0
NE		0	0	0
CR+CRh		4 (57.1) (18.4- 90.1)	0	4 (44.4) (13.7- 78.8)
CR+CRh+PR		5 (71.4) (29.0- 96.3)	2 (100) (15.8-100.0)	7 (77.8) (40.0- 97.2)
CR+CRh+PR+CI (ORR)		5 (71.4) (29.0- 96.3)	2 (100) (15.8-100.0)	7 (77.8) (40.0- 97.2)
CR+CRh+PR+CI+SD		7 (100) (59.0-100.0)	2 (100) (15.8-100.0)	9 (100) (66.4-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-resp-tpy-racDate: 20:38/02NOV2020

Table 14.2.1.1f
Summary of Adjudicated Best Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: 200 mg & Prior Antineoplastic Therapy = No

Best Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=2) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=4) n (%) (95% CIs)
CR		0	0	0
CRh		0	0	0
PR		1 (50.0)	2 (100)	3 (75.0)
CI		0	0	0
SD		1 (50.0)	0	1 (25.0)
PD		0	0	0
NE		0	0	0
CR+CRh		0	0	0
CR+CRh+PR		1 (50.0) (1.3- 98.7)	2 (100) (15.8-100.0)	3 (75.0) (19.4- 99.4)
CR+CRh+PR+CI (ORR)		1 (50.0) (1.3- 98.7)	2 (100) (15.8-100.0)	3 (75.0) (19.4- 99.4)
CR+CRh+PR+CI+SD		2 (100) (15.8-100.0)	2 (100) (15.8-100.0)	4 (100) (39.8-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-resp-tpy-racDate: 20:38/02NOV2020

Table 14.2.1.1f
Summary of Adjudicated Best Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: 300 mg & Prior Antineoplastic Therapy = No

Best Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=8) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=11) n (%) (95% CIs)
CR	0	1 (12.5)	1 (50.0)	2 (18.2)
CRh	1 (100)	2 (25.0)	0	3 (27.3)
PR	0	4 (50.0)	0	4 (36.4)
CI	0	0	1 (50.0)	1 (9.1)
SD	0	1 (12.5)	0	1 (9.1)
PD	0	0	0	0
NE	0	0	0	0
CR+CRh	1 (100) (2.5-100.0)	3 (37.5) (8.5- 75.5)	1 (50.0) (1.3- 98.7)	5 (45.5) (16.7- 76.6)
CR+CRh+PR	1 (100) (2.5-100.0)	7 (87.5) (47.3- 99.7)	1 (50.0) (1.3- 98.7)	9 (81.8) (48.2- 97.7)
CR+CRh+PR+CI (ORR)	1 (100) (2.5-100.0)	7 (87.5) (47.3- 99.7)	2 (100) (15.8-100.0)	10 (90.9) (58.7- 99.8)
CR+CRh+PR+CI+SD	1 (100) (2.5-100.0)	8 (100) (63.1-100.0)	2 (100) (15.8-100.0)	11 (100) (71.5-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-resp-tpy-racDate: 20:38/02NOV2020

Table 14.2.1.1f
Summary of Adjudicated Best Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg & Prior Antineoplastic Therapy = No

Best Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=10) n (%) (95% CIs)	MCL (N=4) n (%) (95% CIs)	All AdvSM (N=15) n (%) (95% CIs)
CR	0	1 (10.0)	1 (25.0)	2 (13.3)
CRh	1 (100)	2 (20.0)	0	3 (20.0)
PR	0	5 (50.0)	2 (50.0)	7 (46.7)
CI	0	0	1 (25.0)	1 (6.7)
SD	0	2 (20.0)	0	2 (13.3)
PD	0	0	0	0
NE	0	0	0	0
CR+CRh	1 (100) (2.5-100.0)	3 (30.0) (6.7- 65.2)	1 (25.0) (0.6- 80.6)	5 (33.3) (11.8- 61.6)
CR+CRh+PR	1 (100) (2.5-100.0)	8 (80.0) (44.4- 97.5)	3 (75.0) (19.4- 99.4)	12 (80.0) (51.9- 95.7)
CR+CRh+PR+CI (ORR)	1 (100) (2.5-100.0)	8 (80.0) (44.4- 97.5)	4 (100) (39.8-100.0)	13 (86.7) (59.5- 98.3)
CR+CRh+PR+CI+SD	1 (100) (2.5-100.0)	10 (100) (69.2-100.0)	4 (100) (39.8-100.0)	15 (100) (78.2-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-resp-tpy-racDate: 20:38/02NOV2020

Table 14.2.1.1f
Summary of Adjudicated Best Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: 400 mg & Prior Antineoplastic Therapy = No

Best Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=0) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=1) n (%) (95% CIs)
CR			1 (100)	1 (100)
CRh			0	0
PR			0	0
CI			0	0
SD			0	0
PD			0	0
NE			0	0
CR+CRh			1 (100) (2.5-100.0)	1 (100) (2.5-100.0)
CR+CRh+PR			1 (100) (2.5-100.0)	1 (100) (2.5-100.0)
CR+CRh+PR+CI (ORR)			1 (100) (2.5-100.0)	1 (100) (2.5-100.0)
CR+CRh+PR+CI+SD			1 (100) (2.5-100.0)	1 (100) (2.5-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-resp-tpy-racDate: 20:38/02NOV2020

Table 14.2.1.1f
Summary of Adjudicated Best Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202

Overall & Prior Antineoplastic Therapy = Yes

Best Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=18) n (%) (95% CIs)	MCL (N=4) n (%) (95% CIs)	All AdvSM (N=23) n (%) (95% CIs)
CR	0	0	0	0
CRh	1 (100)	2 (11.1)	0	3 (13.0)
PR	0	6 (33.3)	1 (25.0)	7 (30.4)
CI	0	7 (38.9)	0	7 (30.4)
SD	0	0	2 (50.0)	2 (8.7)
PD	0	0	1 (25.0)	1 (4.3)
NE	0	3 (16.7)	0	3 (13.0)
CR+CRh	1 (100) (2.5-100.0)	2 (11.1) (1.4- 34.7)	0	3 (13.0) (2.8- 33.6)
CR+CRh+PR	1 (100) (2.5-100.0)	8 (44.4) (21.5- 69.2)	1 (25.0) (0.6- 80.6)	10 (43.5) (23.2- 65.5)
CR+CRh+PR+CI (ORR)	1 (100) (2.5-100.0)	15 (83.3) (58.6- 96.4)	1 (25.0) (0.6- 80.6)	17 (73.9) (51.6- 89.8)
CR+CRh+PR+CI+SD	1 (100) (2.5-100.0)	15 (83.3) (58.6- 96.4)	3 (75.0) (19.4- 99.4)	19 (82.6) (61.2- 95.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-resp-tpy-racDate: 20:38/02NOV2020

Table 14.2.1.1f
Summary of Adjudicated Best Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202

Starting Dose: 200 mg & Prior Antineoplastic Therapy = Yes

Best Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=17) n (%) (95% CIs)	MCL (N=4) n (%) (95% CIs)	All AdvSM (N=22) n (%) (95% CIs)
CR	0	0	0	0
CRh	1 (100)	2 (11.8)	0	3 (13.6)
PR	0	6 (35.3)	1 (25.0)	7 (31.8)
CI	0	6 (35.3)	0	6 (27.3)
SD	0	0	2 (50.0)	2 (9.1)
PD	0	0	1 (25.0)	1 (4.5)
NE	0	3 (17.6)	0	3 (13.6)
CR+CRh	1 (100) (2.5-100.0)	2 (11.8) (1.5- 36.4)	0	3 (13.6) (2.9- 34.9)
CR+CRh+PR	1 (100) (2.5-100.0)	8 (47.1) (23.0- 72.2)	1 (25.0) (0.6- 80.6)	10 (45.5) (24.4- 67.8)
CR+CRh+PR+CI (ORR)	1 (100) (2.5-100.0)	14 (82.4) (56.6- 96.2)	1 (25.0) (0.6- 80.6)	16 (72.7) (49.8- 89.3)
CR+CRh+PR+CI+SD	1 (100) (2.5-100.0)	14 (82.4) (56.6- 96.2)	3 (75.0) (19.4- 99.4)	18 (81.8) (59.7- 94.8)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-resp-tpy-racDate: 20:38/02NOV2020

Table 14.2.1.1f
Summary of Adjudicated Best Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202

Overall & Prior Antineoplastic Therapy = No

Best Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=8) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=9) n (%) (95% CIs)
CR	0	0		0
CRh	0	3 (37.5)		3 (33.3)
PR	1 (100)	2 (25.0)		3 (33.3)
CI	0	1 (12.5)		1 (11.1)
SD	0	2 (25.0)		2 (22.2)
PD	0	0		0
NE	0	0		0
CR+CRh	0	3 (37.5) (8.5- 75.5)		3 (33.3) (7.5- 70.1)
CR+CRh+PR	1 (100) (2.5-100.0)	5 (62.5) (24.5- 91.5)		6 (66.7) (29.9- 92.5)
CR+CRh+PR+CI (ORR)	1 (100) (2.5-100.0)	6 (75.0) (34.9- 96.8)		7 (77.8) (40.0- 97.2)
CR+CRh+PR+CI+SD	1 (100) (2.5-100.0)	8 (100) (63.1-100.0)		9 (100) (66.4-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-resp-tpy-racDate: 20:38/02NOV2020

Table 14.2.1.1f
Summary of Adjudicated Best Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202

Starting Dose: 200 mg & Prior Antineoplastic Therapy = No

Best Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=8) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=9) n (%) (95% CIs)
CR	0	0		0
CRh	0	3 (37.5)		3 (33.3)
PR	1 (100)	2 (25.0)		3 (33.3)
CI	0	1 (12.5)		1 (11.1)
SD	0	2 (25.0)		2 (22.2)
PD	0	0		0
NE	0	0		0
CR+CRh	0	3 (37.5) (8.5- 75.5)		3 (33.3) (7.5- 70.1)
CR+CRh+PR	1 (100) (2.5-100.0)	5 (62.5) (24.5- 91.5)		6 (66.7) (29.9- 92.5)
CR+CRh+PR+CI (ORR)	1 (100) (2.5-100.0)	6 (75.0) (34.9- 96.8)		7 (77.8) (40.0- 97.2)
CR+CRh+PR+CI+SD	1 (100) (2.5-100.0)	8 (100) (63.1-100.0)		9 (100) (66.4-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-resp-tpy-racDate: 20:38/02NOV2020

Table 14.2.1.1f
Summary of Adjudicated Best Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Overall & Prior Antineoplastic Therapy = Yes

Best Response	ASM (N=3) n (%) (95% CIs)	SM-AHN (N=40) n (%) (95% CIs)	MCL (N=12) n (%) (95% CIs)	All AdvSM (N=55) n (%) (95% CIs)
CR	0	3 (7.5)	1 (8.3)	4 (7.3)
CRh	2 (66.7)	6 (15.0)	0	8 (14.5)
PR	1 (33.3)	14 (35.0)	3 (25.0)	18 (32.7)
CI	0	8 (20.0)	1 (8.3)	9 (16.4)
SD	0	5 (12.5)	6 (50.0)	11 (20.0)
PD	0	0	1 (8.3)	1 (1.8)
NE	0	4 (10.0)	0	4 (7.3)
CR+CRh	2 (66.7) (9.4- 99.2)	9 (22.5) (10.8- 38.5)	1 (8.3) (0.2- 38.5)	12 (21.8) (11.8- 35.0)
CR+CRh+PR	3 (100) (29.2-100.0)	23 (57.5) (40.9- 73.0)	4 (33.3) (9.9- 65.1)	30 (54.5) (40.6- 68.0)
CR+CRh+PR+CI (ORR)	3 (100) (29.2-100.0)	31 (77.5) (61.5- 89.2)	5 (41.7) (15.2- 72.3)	39 (70.9) (57.1- 82.4)
CR+CRh+PR+CI+SD	3 (100) (29.2-100.0)	36 (90.0) (76.3- 97.2)	11 (91.7) (61.5- 99.8)	50 (90.9) (80.0- 97.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-resp-tpy-racDate: 20:38/02NOV2020

Table 14.2.1.1f
Summary of Adjudicated Best Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg & Prior Antineoplastic Therapy = Yes

Best Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=3) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=4) n (%) (95% CIs)
CR		1 (33.3)	1 (100)	2 (50.0)
CRh		1 (33.3)	0	1 (25.0)
PR		0	0	0
CI		1 (33.3)	0	1 (25.0)
SD		0	0	0
PD		0	0	0
NE		0	0	0
CR+CRh		2 (66.7) (9.4- 99.2)	1 (100) (2.5-100.0)	3 (75.0) (19.4- 99.4)
CR+CRh+PR		2 (66.7) (9.4- 99.2)	1 (100) (2.5-100.0)	3 (75.0) (19.4- 99.4)
CR+CRh+PR+CI (ORR)		3 (100) (29.2-100.0)	1 (100) (2.5-100.0)	4 (100) (39.8-100.0)
CR+CRh+PR+CI+SD		3 (100) (29.2-100.0)	1 (100) (2.5-100.0)	4 (100) (39.8-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-resp-tpy-racDate: 20:38/02NOV2020

Table 14.2.1.1f
Summary of Adjudicated Best Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg & Prior Antineoplastic Therapy = Yes

Best Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=25) n (%) (95% CIs)	MCL (N=9) n (%) (95% CIs)	All AdvSM (N=35) n (%) (95% CIs)
CR	0	1 (4.0)	1 (11.1)	2 (5.7)
CRh	1 (100)	5 (20.0)	0	6 (17.1)
PR	0	7 (28.0)	2 (22.2)	9 (25.7)
CI	0	7 (28.0)	0	7 (20.0)
SD	0	1 (4.0)	5 (55.6)	6 (17.1)
PD	0	0	1 (11.1)	1 (2.9)
NE	0	4 (16.0)	0	4 (11.4)
CR+CRh	1 (100)	6 (24.0)	1 (11.1)	8 (22.9)
	(2.5-100.0)	(9.4- 45.1)	(0.3- 48.2)	(10.4- 40.1)
CR+CRh+PR	1 (100)	13 (52.0)	3 (33.3)	17 (48.6)
	(2.5-100.0)	(31.3- 72.2)	(7.5- 70.1)	(31.4- 66.0)
CR+CRh+PR+CI (ORR)	1 (100)	20 (80.0)	3 (33.3)	24 (68.6)
	(2.5-100.0)	(59.3- 93.2)	(7.5- 70.1)	(50.7- 83.1)
CR+CRh+PR+CI+SD	1 (100)	21 (84.0)	8 (88.9)	30 (85.7)
	(2.5-100.0)	(63.9- 95.5)	(51.8- 99.7)	(69.7- 95.2)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-resp-tpy-racDate: 20:38/02NOV2020

Table 14.2.1.1f
Summary of Adjudicated Best Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg & Prior Antineoplastic Therapy = Yes

Best Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=22) n (%) (95% CIs)	MCL (N=8) n (%) (95% CIs)	All AdvSM (N=31) n (%) (95% CIs)
CR	0	0	0	0
CRh	1 (100)	4 (18.2)	0	5 (16.1)
PR	0	7 (31.8)	2 (25.0)	9 (29.0)
CI	0	6 (27.3)	0	6 (19.4)
SD	0	1 (4.5)	5 (62.5)	6 (19.4)
PD	0	0	1 (12.5)	1 (3.2)
NE	0	4 (18.2)	0	4 (12.9)
CR+CRh	1 (100)	4 (18.2)	0	5 (16.1)
	(2.5-100.0)	(5.2- 40.3)		(5.5- 33.7)
CR+CRh+PR	1 (100)	11 (50.0)	2 (25.0)	14 (45.2)
	(2.5-100.0)	(28.2- 71.8)	(3.2- 65.1)	(27.3- 64.0)
CR+CRh+PR+CI (ORR)	1 (100)	17 (77.3)	2 (25.0)	20 (64.5)
	(2.5-100.0)	(54.6- 92.2)	(3.2- 65.1)	(45.4- 80.8)
CR+CRh+PR+CI+SD	1 (100)	18 (81.8)	7 (87.5)	26 (83.9)
	(2.5-100.0)	(59.7- 94.8)	(47.3- 99.7)	(66.3- 94.5)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-resp-tpy-racDate: 20:38/02NOV2020

Table 14.2.1.1f
Summary of Adjudicated Best Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg & Prior Antineoplastic Therapy = Yes

Best Response	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=11) n (%) (95% CIs)	MCL (N=3) n (%) (95% CIs)	All AdvSM (N=16) n (%) (95% CIs)
CR	0	2 (18.2)	0	2 (12.5)
CRh	1 (50.0)	0	0	1 (6.3)
PR	1 (50.0)	6 (54.5)	1 (33.3)	8 (50.0)
CI	0	1 (9.1)	1 (33.3)	2 (12.5)
SD	0	2 (18.2)	1 (33.3)	3 (18.8)
PD	0	0	0	0
NE	0	0	0	0
CR+CRh	1 (50.0) (1.3- 98.7)	2 (18.2) (2.3- 51.8)	0	3 (18.8) (4.0- 45.6)
CR+CRh+PR	2 (100) (15.8-100.0)	8 (72.7) (39.0- 94.0)	1 (33.3) (0.8- 90.6)	11 (68.8) (41.3- 89.0)
CR+CRh+PR+CI (ORR)	2 (100) (15.8-100.0)	9 (81.8) (48.2- 97.7)	2 (66.7) (9.4- 99.2)	13 (81.3) (54.4- 96.0)
CR+CRh+PR+CI+SD	2 (100) (15.8-100.0)	11 (100) (71.5-100.0)	3 (100) (29.2-100.0)	16 (100) (79.4-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-resp-tpy-racDate: 20:38/02NOV2020

Table 14.2.1.1f
Summary of Adjudicated Best Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg & Prior Antineoplastic Therapy = Yes

Best Response	ASM (N=3) n (%) (95% CIs)	SM-AHN (N=33) n (%) (95% CIs)	MCL (N=11) n (%) (95% CIs)	All AdvSM (N=47) n (%) (95% CIs)
CR	0	2 (6.1)	0	2 (4.3)
CRh	2 (66.7)	4 (12.1)	0	6 (12.8)
PR	1 (33.3)	13 (39.4)	3 (27.3)	17 (36.2)
CI	0	7 (21.2)	1 (9.1)	8 (17.0)
SD	0	3 (9.1)	6 (54.5)	9 (19.1)
PD	0	0	1 (9.1)	1 (2.1)
NE	0	4 (12.1)	0	4 (8.5)
CR+CRh	2 (66.7) (9.4- 99.2)	6 (18.2) (7.0- 35.5)	0	8 (17.0) (7.6- 30.8)
CR+CRh+PR	3 (100) (29.2-100.0)	19 (57.6) (39.2- 74.5)	3 (27.3) (6.0- 61.0)	25 (53.2) (38.1- 67.9)
CR+CRh+PR+CI (ORR)	3 (100) (29.2-100.0)	26 (78.8) (61.1- 91.0)	4 (36.4) (10.9- 69.2)	33 (70.2) (55.1- 82.7)
CR+CRh+PR+CI+SD	3 (100) (29.2-100.0)	29 (87.9) (71.8- 96.6)	10 (90.9) (58.7- 99.8)	42 (89.4) (76.9- 96.5)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-resp-tpy-racDate: 20:38/02NOV2020

Table 14.2.1.1f
Summary of Adjudicated Best Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg & Prior Antineoplastic Therapy = Yes

Best Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=4) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=4) n (%) (95% CIs)
CR		0		0
CRh		1 (25.0)		1 (25.0)
PR		1 (25.0)		1 (25.0)
CI		0		0
SD		2 (50.0)		2 (50.0)
PD		0		0
NE		0		0
CR+CRh		1 (25.0) (0.6- 80.6)		1 (25.0) (0.6- 80.6)
CR+CRh+PR		2 (50.0) (6.8- 93.2)		2 (50.0) (6.8- 93.2)
CR+CRh+PR+CI (ORR)		2 (50.0) (6.8- 93.2)		2 (50.0) (6.8- 93.2)
CR+CRh+PR+CI+SD		4 (100) (39.8-100.0)		4 (100) (39.8-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-resp-tpy-racDate: 20:38/02NOV2020

Table 14.2.1.1f
Summary of Adjudicated Best Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Overall & Prior Antineoplastic Therapy = No

Best Response	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=23) n (%) (95% CIs)	MCL (N=5) n (%) (95% CIs)	All AdvSM (N=30) n (%) (95% CIs)
CR	0	2 (8.7)	2 (40.0)	4 (13.3)
CRh	1 (50.0)	8 (34.8)	0	9 (30.0)
PR	1 (50.0)	7 (30.4)	2 (40.0)	10 (33.3)
CI	0	1 (4.3)	1 (20.0)	2 (6.7)
SD	0	5 (21.7)	0	5 (16.7)
PD	0	0	0	0
NE	0	0	0	0
CR+CRh	1 (50.0) (1.3- 98.7)	10 (43.5) (23.2- 65.5)	2 (40.0) (5.3- 85.3)	13 (43.3) (25.5- 62.6)
CR+CRh+PR	2 (100) (15.8-100.0)	17 (73.9) (51.6- 89.8)	4 (80.0) (28.4- 99.5)	23 (76.7) (57.7- 90.1)
CR+CRh+PR+CI (ORR)	2 (100) (15.8-100.0)	18 (78.3) (56.3- 92.5)	5 (100) (47.8-100.0)	25 (83.3) (65.3- 94.4)
CR+CRh+PR+CI+SD	2 (100) (15.8-100.0)	23 (100) (85.2-100.0)	5 (100) (47.8-100.0)	30 (100) (88.4-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-resp-tpy-racDate: 20:38/02NOV2020

Table 14.2.1.1f
Summary of Adjudicated Best Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg & Prior Antineoplastic Therapy = No

Best Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=5) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=5) n (%) (95% CIs)
CR		1 (20.0)		1 (20.0)
CRh		3 (60.0)		3 (60.0)
PR		0		0
CI		0		0
SD		1 (20.0)		1 (20.0)
PD		0		0
NE		0		0
CR+CRh		4 (80.0) (28.4- 99.5)		4 (80.0) (28.4- 99.5)
CR+CRh+PR		4 (80.0) (28.4- 99.5)		4 (80.0) (28.4- 99.5)
CR+CRh+PR+CI (ORR)		4 (80.0) (28.4- 99.5)		4 (80.0) (28.4- 99.5)
CR+CRh+PR+CI+SD		5 (100) (47.8-100.0)		5 (100) (47.8-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-resp-tpy-racDate: 20:38/02NOV2020

Table 14.2.1.1f
Summary of Adjudicated Best Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg & Prior Antineoplastic Therapy = No

Best Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=15) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=18) n (%) (95% CIs)
CR	0	1 (6.7)	0	1 (5.6)
CRh	0	6 (40.0)	0	6 (33.3)
PR	1 (100)	3 (20.0)	2 (100)	6 (33.3)
CI	0	1 (6.7)	0	1 (5.6)
SD	0	4 (26.7)	0	4 (22.2)
PD	0	0	0	0
NE	0	0	0	0
CR+CRh	0	7 (46.7) (21.3- 73.4)	0	7 (38.9) (17.3- 64.3)
CR+CRh+PR	1 (100) (2.5-100.0)	10 (66.7) (38.4- 88.2)	2 (100) (15.8-100.0)	13 (72.2) (46.5- 90.3)
CR+CRh+PR+CI (ORR)	1 (100) (2.5-100.0)	11 (73.3) (44.9- 92.2)	2 (100) (15.8-100.0)	14 (77.8) (52.4- 93.6)
CR+CRh+PR+CI+SD	1 (100) (2.5-100.0)	15 (100) (78.2-100.0)	2 (100) (15.8-100.0)	18 (100) (81.5-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-resp-tpy-racDate: 20:38/02NOV2020

Table 14.2.1.1f
Summary of Adjudicated Best Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg & Prior Antineoplastic Therapy = No

Best Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=10) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=13) n (%) (95% CIs)
CR	0	0	0	0
CRh	0	3 (30.0)	0	3 (23.1)
PR	1 (100)	3 (30.0)	2 (100)	6 (46.2)
CI	0	1 (10.0)	0	1 (7.7)
SD	0	3 (30.0)	0	3 (23.1)
PD	0	0	0	0
NE	0	0	0	0
CR+CRh	0	3 (30.0) (6.7- 65.2)	0	3 (23.1) (5.0- 53.8)
CR+CRh+PR	1 (100) (2.5-100.0)	6 (60.0) (26.2- 87.8)	2 (100) (15.8-100.0)	9 (69.2) (38.6- 90.9)
CR+CRh+PR+CI (ORR)	1 (100) (2.5-100.0)	7 (70.0) (34.8- 93.3)	2 (100) (15.8-100.0)	10 (76.9) (46.2- 95.0)
CR+CRh+PR+CI+SD	1 (100) (2.5-100.0)	10 (100) (69.2-100.0)	2 (100) (15.8-100.0)	13 (100) (75.3-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-resp-tpy-racDate: 20:38/02NOV2020

Table 14.2.1.1f
Summary of Adjudicated Best Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg & Prior Antineoplastic Therapy = No

Best Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=8) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=11) n (%) (95% CIs)
CR	0	1 (12.5)	1 (50.0)	2 (18.2)
CRh	1 (100)	2 (25.0)	0	3 (27.3)
PR	0	4 (50.0)	0	4 (36.4)
CI	0	0	1 (50.0)	1 (9.1)
SD	0	1 (12.5)	0	1 (9.1)
PD	0	0	0	0
NE	0	0	0	0
CR+CRh	1 (100) (2.5-100.0)	3 (37.5) (8.5- 75.5)	1 (50.0) (1.3- 98.7)	5 (45.5) (16.7- 76.6)
CR+CRh+PR	1 (100) (2.5-100.0)	7 (87.5) (47.3- 99.7)	1 (50.0) (1.3- 98.7)	9 (81.8) (48.2- 97.7)
CR+CRh+PR+CI (ORR)	1 (100) (2.5-100.0)	7 (87.5) (47.3- 99.7)	2 (100) (15.8-100.0)	10 (90.9) (58.7- 99.8)
CR+CRh+PR+CI+SD	1 (100) (2.5-100.0)	8 (100) (63.1-100.0)	2 (100) (15.8-100.0)	11 (100) (71.5-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-resp-tpy-racDate: 20:38/02NOV2020

Table 14.2.1.1f
Summary of Adjudicated Best Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg & Prior Antineoplastic Therapy = No

Best Response	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=18) n (%) (95% CIs)	MCL (N=4) n (%) (95% CIs)	All AdvSM (N=24) n (%) (95% CIs)
CR	0	1 (5.6)	1 (25.0)	2 (8.3)
CRh	1 (50.0)	5 (27.8)	0	6 (25.0)
PR	1 (50.0)	7 (38.9)	2 (50.0)	10 (41.7)
CI	0	1 (5.6)	1 (25.0)	2 (8.3)
SD	0	4 (22.2)	0	4 (16.7)
PD	0	0	0	0
NE	0	0	0	0
CR+CRh	1 (50.0) (1.3- 98.7)	6 (33.3) (13.3- 59.0)	1 (25.0) (0.6- 80.6)	8 (33.3) (15.6- 55.3)
CR+CRh+PR	2 (100) (15.8-100.0)	13 (72.2) (46.5- 90.3)	3 (75.0) (19.4- 99.4)	18 (75.0) (53.3- 90.2)
CR+CRh+PR+CI (ORR)	2 (100) (15.8-100.0)	14 (77.8) (52.4- 93.6)	4 (100) (39.8-100.0)	20 (83.3) (62.6- 95.3)
CR+CRh+PR+CI+SD	2 (100) (15.8-100.0)	18 (100) (81.5-100.0)	4 (100) (39.8-100.0)	24 (100) (85.8-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-resp-tpy-racDate: 20:38/02NOV2020

Table 14.2.1.1f
Summary of Adjudicated Best Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg & Prior Antineoplastic Therapy = No

Best Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=0) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=1) n (%) (95% CIs)
CR			1 (100)	1 (100)
CRh			0	0
PR			0	0
CI			0	0
SD			0	0
PD			0	0
NE			0	0
CR+CRh			1 (100) (2.5-100.0)	1 (100) (2.5-100.0)
CR+CRh+PR			1 (100) (2.5-100.0)	1 (100) (2.5-100.0)
CR+CRh+PR+CI (ORR)			1 (100) (2.5-100.0)	1 (100) (2.5-100.0)
CR+CRh+PR+CI+SD			1 (100) (2.5-100.0)	1 (100) (2.5-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-resp-tpy-racDate: 20:38/02NOV2020

Table 35.2.1.2
Summary of Investigator Assessed Best Response
RAC-RE Population with at least one prior antineoplastic therapy
Study 2101

All Doses

Best Response	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=22) n (%) (95% CIs)	MCL (N=8) n (%) (95% CIs)	All (N=32) n (%) (95% CIs)
CR	0	4 (18.2)	1 (12.5)	5 (15.6)
CRh	1 (50.0)	2 (9.1)	0	3 (9.4)
PR	1 (50.0)	7 (31.8)	2 (25.0)	10 (31.3)
CI	0	2 (9.1)	1 (12.5)	3 (9.4)
SD	0	7 (31.8)	4 (50.0)	11 (34.4)
PD	0	0	0	0
NE	0	0	0	0
CR+CRh	1 (50.0) (1.3-98.7)	6 (27.3) (10.7-50.2)	1 (12.5) (0.3-52.7)	8 (25.0) (11.5-43.4)
CR+CRh+PR	2 (100) (15.8-100.0)	13 (59.1) (36.4-79.3)	3 (37.5) (8.5-75.5)	18 (56.3) (37.7-73.6)
CR+CRh+PR+CI (ORR)	2 (100) (15.8-100.0)	15 (68.2) (45.1-86.1)	4 (50.0) (15.7-84.3)	21 (65.6) (46.8-81.4)
CR+CRh+PR+CI+SD	2 (100) (15.8-100.0)	22 (100) (84.6-100.0)	8 (100) (63.1-100.0)	32 (100) (89.1-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-resp-advsm.sas Date: 14:58/18OCT2021

Table 35.2.1.2
Summary of Investigator Assessed Best Response
RAC-RE Population with at least one prior antineoplastic therapy
Study 2101

Starting Dose: < 200 mg

Best Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=2) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All (N=3) n (%) (95% CIs)
CR	-	1 (50.0)	1 (100)	2 (66.7)
CRh	-	0	0	0
PR	-	0	0	0
CI	-	1 (50.0)	0	1 (33.3)
SD	-	0	0	0
PD	-	0	0	0
NE	-	0	0	0
CR+CRh	-	1 (50.0) (1.3-98.7)	1 (100) (2.5-100.0)	2 (66.7) (9.4-99.2)
CR+CRh+PR	-	1 (50.0) (1.3-98.7)	1 (100) (2.5-100.0)	2 (66.7) (9.4-99.2)
CR+CRh+PR+CI (ORR)	-	2 (100) (15.8-100.0)	1 (100) (2.5-100.0)	3 (100) (29.2-100.0)
CR+CRh+PR+CI+SD	-	2 (100) (15.8-100.0)	1 (100) (2.5-100.0)	3 (100) (29.2-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-resp-advsm.sas Date: 14:58/18OCT2021

Table 35.2.1.2
Summary of Investigator Assessed Best Response
RAC-RE Population with at least one prior antineoplastic therapy
Study 2101

Starting Dose: < 300 mg

Best Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=7) n (%) (95% CIs)	MCL (N=5) n (%) (95% CIs)	All (N=12) n (%) (95% CIs)
CR	-	2 (28.6)	1 (20.0)	3 (25.0)
CRh	-	1 (14.3)	0	1 (8.3)
PR	-	0	1 (20.0)	1 (8.3)
CI	-	2 (28.6)	1 (20.0)	3 (25.0)
SD	-	2 (28.6)	2 (40.0)	4 (33.3)
PD	-	0	0	0
NE	-	0	0	0
CR+CRh	-	3 (42.9) (9.9-81.6)	1 (20.0) (0.5-71.6)	4 (33.3) (9.9-65.1)
CR+CRh+PR	-	3 (42.9) (9.9-81.6)	2 (40.0) (5.3-85.3)	5 (41.7) (15.2-72.3)
CR+CRh+PR+CI (ORR)	-	5 (71.4) (29.0-96.3)	3 (60.0) (14.7-94.7)	8 (66.7) (34.9-90.1)
CR+CRh+PR+CI+SD	-	7 (100) (59.0-100.0)	5 (100) (47.8-100.0)	12 (100) (73.5-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-resp-advsm.sas
Date: 14:58/18OCT2021

Table 35.2.1.2
Summary of Investigator Assessed Best Response
RAC-RE Population with at least one prior antineoplastic therapy
Study 2101

Starting Dose: 200 mg

Best Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=5) n (%) (95% CIs)	MCL (N=4) n (%) (95% CIs)	All (N=9) n (%) (95% CIs)
CR	-	1 (20.0)	0	1 (11.1)
CRh	-	1 (20.0)	0	1 (11.1)
PR	-	0	1 (25.0)	1 (11.1)
CI	-	1 (20.0)	1 (25.0)	2 (22.2)
SD	-	2 (40.0)	2 (50.0)	4 (44.4)
PD	-	0	0	0
NE	-	0	0	0
CR+CRh	-	2 (40.0) (5.3-85.3)	0	2 (22.2) (2.8-60.0)
CR+CRh+PR	-	2 (40.0) (5.3-85.3)	1 (25.0) (0.6-80.6)	3 (33.3) (7.5-70.1)
CR+CRh+PR+CI (ORR)	-	3 (60.0) (14.7-94.7)	2 (50.0) (6.8-93.2)	5 (55.6) (21.2-86.3)
CR+CRh+PR+CI+SD	-	5 (100) (47.8-100.0)	4 (100) (39.8-100.0)	9 (100) (66.4-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-resp-advsm.sas Date: 14:58/18OCT2021

Table 35.2.1.2
Summary of Investigator Assessed Best Response
RAC-RE Population with at least one prior antineoplastic therapy
Study 2101

Starting Dose: 300 mg

Best Response	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=11) n (%) (95% CIs)	MCL (N=3) n (%) (95% CIs)	All (N=16) n (%) (95% CIs)
CR	0	1 (9.1)	0	1 (6.3)
CRh	1 (50.0)	0	0	1 (6.3)
PR	1 (50.0)	7 (63.6)	1 (33.3)	9 (56.3)
CI	0	0	0	0
SD	0	3 (27.3)	2 (66.7)	5 (31.3)
PD	0	0	0	0
NE	0	0	0	0
CR+CRh	1 (50.0) (1.3-98.7)	1 (9.1) (0.2-41.3)	0	2 (12.5) (1.6-38.3)
CR+CRh+PR	2 (100) (15.8-100.0)	8 (72.7) (39.0-94.0)	1 (33.3) (0.8-90.6)	11 (68.8) (41.3-89.0)
CR+CRh+PR+CI (ORR)	2 (100) (15.8-100.0)	8 (72.7) (39.0-94.0)	1 (33.3) (0.8-90.6)	11 (68.8) (41.3-89.0)
CR+CRh+PR+CI+SD	2 (100) (15.8-100.0)	11 (100) (71.5-100.0)	3 (100) (29.2-100.0)	16 (100) (79.4-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate

Table 35.2.1.2
Summary of Investigator Assessed Best Response
RAC-RE Population with at least one prior antineoplastic therapy
Study 2101

Starting Dose: 200 mg and 300 mg

Best Response	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=16) n (%) (95% CIs)	MCL (N=7) n (%) (95% CIs)	All (N=25) n (%) (95% CIs)
CR	0	2 (12.5)	0	2 (8.0)
CRh	1 (50.0)	1 (6.3)	0	2 (8.0)
PR	1 (50.0)	7 (43.8)	2 (28.6)	10 (40.0)
CI	0	1 (6.3)	1 (14.3)	2 (8.0)
SD	0	5 (31.3)	4 (57.1)	9 (36.0)
PD	0	0	0	0
NE	0	0	0	0
CR+CRh	1 (50.0) (1.3-98.7)	3 (18.8) (4.0-45.6)	0	4 (16.0) (4.5-36.1)
CR+CRh+PR	2 (100) (15.8-100.0)	10 (62.5) (35.4-84.8)	2 (28.6) (3.7-71.0)	14 (56.0) (34.9-75.6)
CR+CRh+PR+CI (ORR)	2 (100) (15.8-100.0)	11 (68.8) (41.3-89.0)	3 (42.9) (9.9-81.6)	16 (64.0) (42.5-82.0)
CR+CRh+PR+CI+SD	2 (100) (15.8-100.0)	16 (100) (79.4-100.0)	7 (100) (59.0-100.0)	25 (100) (86.3-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-resp-advsm.sas Date: 14:58/18OCT2021

Table 35.2.1.2
Summary of Investigator Assessed Best Response
RAC-RE Population with at least one prior antineoplastic therapy
Study 2101

Starting Dose: 400 mg

Best Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=4) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All (N=4) n (%) (95% CIs)
CR	-	1 (25.0)	-	1 (25.0)
CRh	-	1 (25.0)	-	1 (25.0)
PR	-	0	-	0
CI	-	0	-	0
SD	-	2 (50.0)	-	2 (50.0)
PD	-	0	-	0
NE	-	0	-	0
CR+CRh	-	2 (50.0) (6.8-93.2)	-	2 (50.0) (6.8-93.2)
CR+CRh+PR	-	2 (50.0) (6.8-93.2)	-	2 (50.0) (6.8-93.2)
CR+CRh+PR+CI (ORR)	-	2 (50.0) (6.8-93.2)	-	2 (50.0) (6.8-93.2)
CR+CRh+PR+CI+SD	-	4 (100) (39.8-100.0)	-	4 (100) (39.8-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-resp-advsm.sas Date: 14:58/18OCT2021

Table 35.2.1.2
Summary of Investigator Assessed Best Response
RAC-RE Population with at least one prior antineoplastic therapy
Study 2202

All Doses

Best Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=18) n (%) (95% CIs)	MCL (N=4) n (%) (95% CIs)	All (N=23) n (%) (95% CIs)
CR	0	0	0	0
CRh	0	2 (11.1)	0	2 (8.7)
PR	0	5 (27.8)	1 (25.0)	6 (26.1)
CI	0	5 (27.8)	0	5 (21.7)
SD	0	4 (22.2)	3 (75.0)	7 (30.4)
PD	0	0	0	0
NE	1 (100)	2 (11.1)	0	3 (13.0)
CR+CRh	0	2 (11.1) (1.4-34.7)	0	2 (8.7) (1.1-28.0)
CR+CRh+PR	0	7 (38.9) (17.3-64.3)	1 (25.0) (0.6-80.6)	8 (34.8) (16.4-57.3)
CR+CRh+PR+CI (ORR)	0	12 (66.7) (41.0-86.7)	1 (25.0) (0.6-80.6)	13 (56.5) (34.5-76.8)
CR+CRh+PR+CI+SD	0	16 (88.9) (65.3-98.6)	4 (100) (39.8-100.0)	20 (87.0) (66.4-97.2)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-resp-advsm.sas Date: 14:58/18OCT2021

Table 35.2.1.2
Summary of Investigator Assessed Best Response
RAC-RE Population with at least one prior antineoplastic therapy
Study 2202

Starting Dose: 200 mg

Best Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=17) n (%) (95% CIs)	MCL (N=4) n (%) (95% CIs)	All (N=22) n (%) (95% CIs)
CR	0	0	0	0
CRh	0	2 (11.8)	0	2 (9.1)
PR	0	4 (23.5)	1 (25.0)	5 (22.7)
CI	0	5 (29.4)	0	5 (22.7)
SD	0	4 (23.5)	3 (75.0)	7 (31.8)
PD	0	0	0	0
NE	1 (100)	2 (11.8)	0	3 (13.6)
CR+CRh	0	2 (11.8) (1.5-36.4)	0	2 (9.1) (1.1-29.2)
CR+CRh+PR	0	6 (35.3) (14.2-61.7)	1 (25.0) (0.6-80.6)	7 (31.8) (13.9-54.9)
CR+CRh+PR+CI (ORR)	0	11 (64.7) (38.3-85.8)	1 (25.0) (0.6-80.6)	12 (54.5) (32.2-75.6)
CR+CRh+PR+CI+SD	0	15 (88.2) (63.6-98.5)	4 (100) (39.8-100.0)	19 (86.4) (65.1-97.1)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-resp-advsm.sas Date: 14:58/18OCT2021

Table 35.2.1.2
Summary of Investigator Assessed Best Response
RAC-RE Population with at least one prior antineoplastic therapy
Studies 2101 and 2202

All Doses

Best Response	ASM (N=3) n (%) (95% CIs)	SM-AHN (N=40) n (%) (95% CIs)	MCL (N=12) n (%) (95% CIs)	All (N=55) n (%) (95% CIs)
CR	0	4 (10.0)	1 (8.3)	5 (9.1)
CRh	1 (33.3)	4 (10.0)	0	5 (9.1)
PR	1 (33.3)	12 (30.0)	3 (25.0)	16 (29.1)
CI	0	7 (17.5)	1 (8.3)	8 (14.5)
SD	0	11 (27.5)	7 (58.3)	18 (32.7)
PD	0	0	0	0
NE	1 (33.3)	2 (5.0)	0	3 (5.5)
CR+CRh	1 (33.3) (0.8-90.6)	8 (20.0) (9.1-35.6)	1 (8.3) (0.2-38.5)	10 (18.2) (9.1-30.9)
CR+CRh+PR	2 (66.7) (9.4-99.2)	20 (50.0) (33.8-66.2)	4 (33.3) (9.9-65.1)	26 (47.3) (33.7-61.2)
CR+CRh+PR+CI (ORR)	2 (66.7) (9.4-99.2)	27 (67.5) (50.9-81.4)	5 (41.7) (15.2-72.3)	34 (61.8) (47.7-74.6)
CR+CRh+PR+CI+SD	2 (66.7) (9.4-99.2)	38 (95.0) (83.1-99.4)	12 (100) (73.5-100.0)	52 (94.5) (84.9-98.9)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-resp-advsm.sas Date: 14:58/18OCT2021

Table 35.2.1.2
Summary of Investigator Assessed Best Response
RAC-RE Population with at least one prior antineoplastic therapy
Studies 2101 and 2202

Starting Dose: < 200 mg

Best Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=3) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All (N=4) n (%) (95% CIs)
CR	-	1 (33.3)	1 (100)	2 (50.0)
CRh	-	0	0	0
PR	-	1 (33.3)	0	1 (25.0)
CI	-	1 (33.3)	0	1 (25.0)
SD	-	0	0	0
PD	-	0	0	0
NE	-	0	0	0
CR+CRh	-	1 (33.3) (0.8-90.6)	1 (100) (2.5-100.0)	2 (50.0) (6.8-93.2)
CR+CRh+PR	-	2 (66.7) (9.4-99.2)	1 (100) (2.5-100.0)	3 (75.0) (19.4-99.4)
CR+CRh+PR+CI (ORR)	-	3 (100) (29.2-100.0)	1 (100) (2.5-100.0)	4 (100) (39.8-100.0)
CR+CRh+PR+CI+SD	-	3 (100) (29.2-100.0)	1 (100) (2.5-100.0)	4 (100) (39.8-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-resp-advsm.sas Date: 14:58/18OCT2021

Table 35.2.1.2
Summary of Investigator Assessed Best Response
RAC-RE Population with at least one prior antineoplastic therapy
Studies 2101 and 2202

Starting Dose: < 300 mg

Best Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=25) n (%) (95% CIs)	MCL (N=9) n (%) (95% CIs)	All (N=35) n (%) (95% CIs)
CR	0	2 (8.0)	1 (11.1)	3 (8.6)
CRh	0	3 (12.0)	0	3 (8.6)
PR	0	5 (20.0)	2 (22.2)	7 (20.0)
CI	0	7 (28.0)	1 (11.1)	8 (22.9)
SD	0	6 (24.0)	5 (55.6)	11 (31.4)
PD	0	0	0	0
NE	1 (100)	2 (8.0)	0	3 (8.6)
CR+CRh	0	5 (20.0) (6.8-40.7)	1 (11.1) (0.3-48.2)	6 (17.1) (6.6-33.6)
CR+CRh+PR	0	10 (40.0) (21.1-61.3)	3 (33.3) (7.5-70.1)	13 (37.1) (21.5-55.1)
CR+CRh+PR+CI (ORR)	0	17 (68.0) (46.5-85.1)	4 (44.4) (13.7-78.8)	21 (60.0) (42.1-76.1)
CR+CRh+PR+CI+SD	0	23 (92.0) (74.0-99.0)	9 (100) (66.4-100.0)	32 (91.4) (76.9-98.2)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-resp-advsm.sas Date: 14:58/18OCT2021

Table 35.2.1.2
Summary of Investigator Assessed Best Response
RAC-RE Population with at least one prior antineoplastic therapy
Studies 2101 and 2202

Starting Dose: 200 mg

Best Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=22) n (%) (95% CIs)	MCL (N=8) n (%) (95% CIs)	All (N=31) n (%) (95% CIs)
CR	0	1 (4.5)	0	1 (3.2)
CRh	0	3 (13.6)	0	3 (9.7)
PR	0	4 (18.2)	2 (25.0)	6 (19.4)
CI	0	6 (27.3)	1 (12.5)	7 (22.6)
SD	0	6 (27.3)	5 (62.5)	11 (35.5)
PD	0	0	0	0
NE	1 (100)	2 (9.1)	0	3 (9.7)
CR+CRh	0	4 (18.2) (5.2-40.3)	0	4 (12.9) (3.6-29.8)
CR+CRh+PR	0	8 (36.4) (17.2-59.3)	2 (25.0) (3.2-65.1)	10 (32.3) (16.7-51.4)
CR+CRh+PR+CI (ORR)	0	14 (63.6) (40.7-82.8)	3 (37.5) (8.5-75.5)	17 (54.8) (36.0-72.7)
CR+CRh+PR+CI+SD	0	20 (90.9) (70.8-98.9)	8 (100) (63.1-100.0)	28 (90.3) (74.2-98.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-resp-advsm.sas
Date: 14:58/18OCT2021

Table 35.2.1.2
Summary of Investigator Assessed Best Response
RAC-RE Population with at least one prior antineoplastic therapy
Studies 2101 and 2202

Starting Dose: 300 mg

Best Response	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=11) n (%) (95% CIs)	MCL (N=3) n (%) (95% CIs)	All (N=16) n (%) (95% CIs)
CR	0	1 (9.1)	0	1 (6.3)
CRh	1 (50.0)	0	0	1 (6.3)
PR	1 (50.0)	7 (63.6)	1 (33.3)	9 (56.3)
CI	0	0	0	0
SD	0	3 (27.3)	2 (66.7)	5 (31.3)
PD	0	0	0	0
NE	0	0	0	0
CR+CRh	1 (50.0) (1.3-98.7)	1 (9.1) (0.2-41.3)	0	2 (12.5) (1.6-38.3)
CR+CRh+PR	2 (100) (15.8-100.0)	8 (72.7) (39.0-94.0)	1 (33.3) (0.8-90.6)	11 (68.8) (41.3-89.0)
CR+CRh+PR+CI (ORR)	2 (100) (15.8-100.0)	8 (72.7) (39.0-94.0)	1 (33.3) (0.8-90.6)	11 (68.8) (41.3-89.0)
CR+CRh+PR+CI+SD	2 (100) (15.8-100.0)	11 (100) (71.5-100.0)	3 (100) (29.2-100.0)	16 (100) (79.4-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-resp-advsm.sas Date: 14:58/18OCT2021

Table 35.2.1.2
Summary of Investigator Assessed Best Response
RAC-RE Population with at least one prior antineoplastic therapy
Studies 2101 and 2202

Starting Dose: 200 mg and 300 mg

Best Response	ASM (N=3) n (%) (95% CIs)	SM-AHN (N=33) n (%) (95% CIs)	MCL (N=11) n (%) (95% CIs)	All (N=47) n (%) (95% CIs)
CR	0	2 (6.1)	0	2 (4.3)
CRh	1 (33.3)	3 (9.1)	0	4 (8.5)
PR	1 (33.3)	11 (33.3)	3 (27.3)	15 (31.9)
CI	0	6 (18.2)	1 (9.1)	7 (14.9)
SD	0	9 (27.3)	7 (63.6)	16 (34.0)
PD	0	0	0	0
NE	1 (33.3)	2 (6.1)	0	3 (6.4)
CR+CRh	1 (33.3) (0.8-90.6)	5 (15.2) (5.1-31.9)	0	6 (12.8) (4.8-25.7)
CR+CRh+PR	2 (66.7) (9.4-99.2)	16 (48.5) (30.8-66.5)	3 (27.3) (6.0-61.0)	21 (44.7) (30.2-59.9)
CR+CRh+PR+CI (ORR)	2 (66.7) (9.4-99.2)	22 (66.7) (48.2-82.0)	4 (36.4) (10.9-69.2)	28 (59.6) (44.3-73.6)
CR+CRh+PR+CI+SD	2 (66.7) (9.4-99.2)	31 (93.9) (79.8-99.3)	11 (100) (71.5-100.0)	44 (93.6) (82.5-98.7)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-resp-advsm.sas Date: 14:58/18OCT2021

Table 35.2.1.2
Summary of Investigator Assessed Best Response
RAC-RE Population with at least one prior antineoplastic therapy
Studies 2101 and 2202

Starting Dose: 400 mg

Best Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=4) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All (N=4) n (%) (95% CIs)
CR	-	1 (25.0)	-	1 (25.0)
CRh	-	1 (25.0)	-	1 (25.0)
PR	-	0	-	0
CI	-	0	-	0
SD	-	2 (50.0)	-	2 (50.0)
PD	-	0	-	0
NE	-	0	-	0
CR+CRh	-	2 (50.0) (6.8-93.2)	-	2 (50.0) (6.8-93.2)
CR+CRh+PR	-	2 (50.0) (6.8-93.2)	-	2 (50.0) (6.8-93.2)
CR+CRh+PR+CI (ORR)	-	2 (50.0) (6.8-93.2)	-	2 (50.0) (6.8-93.2)
CR+CRh+PR+CI+SD	-	4 (100) (39.8-100.0)	-	4 (100) (39.8-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, NE=Not Evaluable, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-resp-advsm.sas Date: 14:58/18OCT2021

Table 14.2.1.4b
Summary of Algorithm Best Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Overall & Prior Antineoplastic Therapy = Yes

Best Response	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=20) n (%) (95% CIs)	MCL (N=8) n (%) (95% CIs)	All AdvSM (N=30) n (%) (95% CIs)
CR	0	4 (20.0)	3 (37.5)	7 (23.3)
PR	2 (100)	8 (40.0)	1 (12.5)	11 (36.7)
CI	0	0	1 (12.5)	1 (3.3)
SD	0	8 (40.0)	3 (37.5)	11 (36.7)
PD	0	0	0	0
NE	0	0	0	0
CR+PR	2 (100) (15.8-100.0)	12 (60.0) (36.1- 80.9)	4 (50.0) (15.7- 84.3)	18 (60.0) (40.6- 77.3)
CR+PR+CI (ORR)	2 (100) (15.8-100.0)	12 (60.0) (36.1- 80.9)	5 (62.5) (24.5- 91.5)	19 (63.3) (43.9- 80.1)
CR+PR+CI+SD	2 (100) (15.8-100.0)	20 (100) (83.2-100.0)	8 (100) (63.1-100.0)	30 (100) (88.4-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-resp-rac-tpy.sDate: 20:50/02NOV2020

Table 14.2.1.4b
Summary of Algorithm Best Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: <200 mg & Prior Antineoplastic Therapy = Yes

Best Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=1) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=2) n (%) (95% CIs)
CR		1 (100)	1 (100)	2 (100)
PR		0	0	0
CI		0	0	0
SD		0	0	0
PD		0	0	0
NE		0	0	0
CR+PR		1 (100) (2.5-100.0)	1 (100) (2.5-100.0)	2 (100) (15.8-100.0)
CR+PR+CI (ORR)		1 (100) (2.5-100.0)	1 (100) (2.5-100.0)	2 (100) (15.8-100.0)
CR+PR+CI+SD		1 (100) (2.5-100.0)	1 (100) (2.5-100.0)	2 (100) (15.8-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-resp-rac-tpy.sDate: 20:50/02NOV2020

Table 14.2.1.4b
Summary of Algorithm Best Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: <300 mg & Prior Antineoplastic Therapy = Yes

Best Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=6) n (%) (95% CIs)	MCL (N=5) n (%) (95% CIs)	All AdvSM (N=11) n (%) (95% CIs)
CR		1 (16.7)	2 (40.0)	3 (27.3)
PR		1 (16.7)	1 (20.0)	2 (18.2)
CI		0	0	0
SD		4 (66.7)	2 (40.0)	6 (54.5)
PD		0	0	0
NE		0	0	0
CR+PR		2 (33.3) (4.3- 77.7)	3 (60.0) (14.7- 94.7)	5 (45.5) (16.7- 76.6)
CR+PR+CI (ORR)		2 (33.3) (4.3- 77.7)	3 (60.0) (14.7- 94.7)	5 (45.5) (16.7- 76.6)
CR+PR+CI+SD		6 (100) (54.1-100.0)	5 (100) (47.8-100.0)	11 (100) (71.5-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-resp-rac-tpy.sDate: 20:50/02NOV2020

Table 14.2.1.4b
Summary of Algorithm Best Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: 200 mg & Prior Antineoplastic Therapy = Yes

Best Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=5) n (%) (95% CIs)	MCL (N=4) n (%) (95% CIs)	All AdvSM (N=9) n (%) (95% CIs)
CR		0	1 (25.0)	1 (11.1)
PR		1 (20.0)	1 (25.0)	2 (22.2)
CI		0	0	0
SD		4 (80.0)	2 (50.0)	6 (66.7)
PD		0	0	0
NE		0	0	0
CR+PR		1 (20.0) (0.5- 71.6)	2 (50.0) (6.8- 93.2)	3 (33.3) (7.5- 70.1)
CR+PR+CI (ORR)		1 (20.0) (0.5- 71.6)	2 (50.0) (6.8- 93.2)	3 (33.3) (7.5- 70.1)
CR+PR+CI+SD		5 (100) (47.8-100.0)	4 (100) (39.8-100.0)	9 (100) (66.4-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-resp-rac-tpy.sDate: 20:50/02NOV2020

Table 14.2.1.4b
Summary of Algorithm Best Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: 300 mg & Prior Antineoplastic Therapy = Yes

Best Response	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=10) n (%) (95% CIs)	MCL (N=3) n (%) (95% CIs)	All AdvSM (N=15) n (%) (95% CIs)
CR	0	2 (20.0)	1 (33.3)	3 (20.0)
PR	2 (100)	5 (50.0)	0	7 (46.7)
CI	0	0	1 (33.3)	1 (6.7)
SD	0	3 (30.0)	1 (33.3)	4 (26.7)
PD	0	0	0	0
NE	0	0	0	0
CR+PR	2 (100) (15.8-100.0)	7 (70.0) (34.8- 93.3)	1 (33.3) (0.8- 90.6)	10 (66.7) (38.4- 88.2)
CR+PR+CI (ORR)	2 (100) (15.8-100.0)	7 (70.0) (34.8- 93.3)	2 (66.7) (9.4- 99.2)	11 (73.3) (44.9- 92.2)
CR+PR+CI+SD	2 (100) (15.8-100.0)	10 (100) (69.2-100.0)	3 (100) (29.2-100.0)	15 (100) (78.2-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-resp-rac-tpy.sDate: 20:50/02NOV2020

Table 14.2.1.4b
Summary of Algorithm Best Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg & Prior Antineoplastic Therapy = Yes

Best Response	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=15) n (%) (95% CIs)	MCL (N=7) n (%) (95% CIs)	All AdvSM (N=24) n (%) (95% CIs)
CR	0	2 (13.3)	2 (28.6)	4 (16.7)
PR	2 (100)	6 (40.0)	1 (14.3)	9 (37.5)
CI	0	0	1 (14.3)	1 (4.2)
SD	0	7 (46.7)	3 (42.9)	10 (41.7)
PD	0	0	0	0
NE	0	0	0	0
CR+PR	2 (100) (15.8-100.0)	8 (53.3) (26.6- 78.7)	3 (42.9) (9.9- 81.6)	13 (54.2) (32.8- 74.4)
CR+PR+CI (ORR)	2 (100) (15.8-100.0)	8 (53.3) (26.6- 78.7)	4 (57.1) (18.4- 90.1)	14 (58.3) (36.6- 77.9)
CR+PR+CI+SD	2 (100) (15.8-100.0)	15 (100) (78.2-100.0)	7 (100) (59.0-100.0)	24 (100) (85.8-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-resp-rac-tpy.sDate: 20:50/02NOV2020

Table 14.2.1.4b
Summary of Algorithm Best Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: 400 mg & Prior Antineoplastic Therapy = Yes

Best Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=4) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=4) n (%) (95% CIs)
CR		1 (25.0)		1 (25.0)
PR		2 (50.0)		2 (50.0)
CI		0		0
SD		1 (25.0)		1 (25.0)
PD		0		0
NE		0		0
CR+PR		3 (75.0) (19.4- 99.4)		3 (75.0) (19.4- 99.4)
CR+PR+CI (ORR)		3 (75.0) (19.4- 99.4)		3 (75.0) (19.4- 99.4)
CR+PR+CI+SD		4 (100) (39.8-100.0)		4 (100) (39.8-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-resp-rac-tpy.sDate: 20:50/02NOV2020

Table 14.2.1.4b
Summary of Algorithm Best Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Overall & Prior Antineoplastic Therapy = No

Best Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=12) n (%) (95% CIs)	MCL (N=5) n (%) (95% CIs)	All AdvSM (N=18) n (%) (95% CIs)
CR	0	1 (8.3)	2 (40.0)	3 (16.7)
PR	1 (100)	8 (66.7)	2 (40.0)	11 (61.1)
CI	0	1 (8.3)	1 (20.0)	2 (11.1)
SD	0	2 (16.7)	0	2 (11.1)
PD	0	0	0	0
NE	0	0	0	0
CR+PR	1 (100) (2.5-100.0)	9 (75.0) (42.8- 94.5)	4 (80.0) (28.4- 99.5)	14 (77.8) (52.4- 93.6)
CR+PR+CI (ORR)	1 (100) (2.5-100.0)	10 (83.3) (51.6- 97.9)	5 (100) (47.8-100.0)	16 (88.9) (65.3- 98.6)
CR+PR+CI+SD	1 (100) (2.5-100.0)	12 (100) (73.5-100.0)	5 (100) (47.8-100.0)	18 (100) (81.5-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-resp-rac-tpy.sDate: 20:50/02NOV2020

Table 14.2.1.4b
Summary of Algorithm Best Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: <200 mg & Prior Antineoplastic Therapy = No

Best Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=3) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=3) n (%) (95% CIs)
CR		0		0
PR		3 (100)		3 (100)
CI		0		0
SD		0		0
PD		0		0
NE		0		0
CR+PR		3 (100) (29.2-100.0)		3 (100) (29.2-100.0)
CR+PR+CI (ORR)		3 (100) (29.2-100.0)		3 (100) (29.2-100.0)
CR+PR+CI+SD		3 (100) (29.2-100.0)		3 (100) (29.2-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-resp-rac-tpy.sDate: 20:50/02NOV2020

Table 14.2.1.4b
Summary of Algorithm Best Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: <300 mg & Prior Antineoplastic Therapy = No

Best Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=4) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=6) n (%) (95% CIs)
CR		0	0	0
PR		3 (75.0)	2 (100)	5 (83.3)
CI		0	0	0
SD		1 (25.0)	0	1 (16.7)
PD		0	0	0
NE		0	0	0
CR+PR		3 (75.0) (19.4- 99.4)	2 (100) (15.8-100.0)	5 (83.3) (35.9- 99.6)
CR+PR+CI (ORR)		3 (75.0) (19.4- 99.4)	2 (100) (15.8-100.0)	5 (83.3) (35.9- 99.6)
CR+PR+CI+SD		4 (100) (39.8-100.0)	2 (100) (15.8-100.0)	6 (100) (54.1-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-resp-rac-tpy.sDate: 20:50/02NOV2020

Table 14.2.1.4b
Summary of Algorithm Best Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: 200 mg & Prior Antineoplastic Therapy = No

Best Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=1) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=3) n (%) (95% CIs)
CR		0	0	0
PR		0	2 (100)	2 (66.7)
CI		0	0	0
SD		1 (100)	0	1 (33.3)
PD		0	0	0
NE		0	0	0
CR+PR		0	2 (100) (15.8-100.0)	2 (66.7) (9.4- 99.2)
CR+PR+CI (ORR)		0	2 (100) (15.8-100.0)	2 (66.7) (9.4- 99.2)
CR+PR+CI+SD		1 (100) (2.5-100.0)	2 (100) (15.8-100.0)	3 (100) (29.2-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-resp-rac-tpy.sDate: 20:50/02NOV2020

Table 14.2.1.4b
Summary of Algorithm Best Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: 300 mg & Prior Antineoplastic Therapy = No

Best Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=8) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=11) n (%) (95% CIs)
CR	0	1 (12.5)	1 (50.0)	2 (18.2)
PR	1 (100)	5 (62.5)	0	6 (54.5)
CI	0	1 (12.5)	1 (50.0)	2 (18.2)
SD	0	1 (12.5)	0	1 (9.1)
PD	0	0	0	0
NE	0	0	0	0
CR+PR	1 (100) (2.5-100.0)	6 (75.0) (34.9- 96.8)	1 (50.0) (1.3- 98.7)	8 (72.7) (39.0- 94.0)
CR+PR+CI (ORR)	1 (100) (2.5-100.0)	7 (87.5) (47.3- 99.7)	2 (100) (15.8-100.0)	10 (90.9) (58.7- 99.8)
CR+PR+CI+SD	1 (100) (2.5-100.0)	8 (100) (63.1-100.0)	2 (100) (15.8-100.0)	11 (100) (71.5-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-resp-rac-tpy.sDate: 20:50/02NOV2020

Table 14.2.1.4b
Summary of Algorithm Best Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg & Prior Antineoplastic Therapy = No

Best Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=9) n (%) (95% CIs)	MCL (N=4) n (%) (95% CIs)	All AdvSM (N=14) n (%) (95% CIs)
CR	0	1 (11.1)	1 (25.0)	2 (14.3)
PR	1 (100)	5 (55.6)	2 (50.0)	8 (57.1)
CI	0	1 (11.1)	1 (25.0)	2 (14.3)
SD	0	2 (22.2)	0	2 (14.3)
PD	0	0	0	0
NE	0	0	0	0
CR+PR	1 (100) (2.5-100.0)	6 (66.7) (29.9- 92.5)	3 (75.0) (19.4- 99.4)	10 (71.4) (41.9- 91.6)
CR+PR+CI (ORR)	1 (100) (2.5-100.0)	7 (77.8) (40.0- 97.2)	4 (100) (39.8-100.0)	12 (85.7) (57.2- 98.2)
CR+PR+CI+SD	1 (100) (2.5-100.0)	9 (100) (66.4-100.0)	4 (100) (39.8-100.0)	14 (100) (76.8-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-resp-rac-tpy.sDate: 20:50/02NOV2020

Table 14.2.1.4b
Summary of Algorithm Best Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: 400 mg & Prior Antineoplastic Therapy = No

Best Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=0) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=1) n (%) (95% CIs)
CR			1 (100)	1 (100)
PR			0	0
CI			0	0
SD			0	0
PD			0	0
NE			0	0
CR+PR			1 (100) (2.5-100.0)	1 (100) (2.5-100.0)
CR+PR+CI (ORR)			1 (100) (2.5-100.0)	1 (100) (2.5-100.0)
CR+PR+CI+SD			1 (100) (2.5-100.0)	1 (100) (2.5-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-resp-rac-tpy.sDate: 20:50/02NOV2020

Table 14.2.1.4b
Summary of Algorithm Best Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202

Overall & Prior Antineoplastic Therapy = Yes

Best Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=18) n (%) (95% CIs)	MCL (N=4) n (%) (95% CIs)	All AdvSM (N=23) n (%) (95% CIs)
CR	0	0	0	0
PR	1 (100)	6 (33.3)	1 (25.0)	8 (34.8)
CI	0	6 (33.3)	1 (25.0)	7 (30.4)
SD	0	5 (27.8)	2 (50.0)	7 (30.4)
PD	0	0	0	0
NE	0	1 (5.6)	0	1 (4.3)
CR+PR	1 (100)	6 (33.3)	1 (25.0)	8 (34.8)
	(2.5-100.0)	(13.3- 59.0)	(0.6- 80.6)	(16.4- 57.3)
CR+PR+CI (ORR)	1 (100)	12 (66.7)	2 (50.0)	15 (65.2)
	(2.5-100.0)	(41.0- 86.7)	(6.8- 93.2)	(42.7- 83.6)
CR+PR+CI+SD	1 (100)	17 (94.4)	4 (100)	22 (95.7)
	(2.5-100.0)	(72.7- 99.9)	(39.8-100.0)	(78.1- 99.9)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-resp-rac-tpy.sDate: 20:50/02NOV2020

Table 14.2.1.4b
Summary of Algorithm Best Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202

Starting Dose: 200 mg & Prior Antineoplastic Therapy = Yes

Best Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=17) n (%) (95% CIs)	MCL (N=4) n (%) (95% CIs)	All AdvSM (N=22) n (%) (95% CIs)
CR	0	0	0	0
PR	1 (100)	5 (29.4)	1 (25.0)	7 (31.8)
CI	0	6 (35.3)	1 (25.0)	7 (31.8)
SD	0	5 (29.4)	2 (50.0)	7 (31.8)
PD	0	0	0	0
NE	0	1 (5.9)	0	1 (4.5)
CR+PR	1 (100)	5 (29.4)	1 (25.0)	7 (31.8)
	(2.5-100.0)	(10.3- 56.0)	(0.6- 80.6)	(13.9- 54.9)
CR+PR+CI (ORR)	1 (100)	11 (64.7)	2 (50.0)	14 (63.6)
	(2.5-100.0)	(38.3- 85.8)	(6.8- 93.2)	(40.7- 82.8)
CR+PR+CI+SD	1 (100)	16 (94.1)	4 (100)	21 (95.5)
	(2.5-100.0)	(71.3- 99.9)	(39.8-100.0)	(77.2- 99.9)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-resp-rac-tpy.sDate: 20:50/02NOV2020

Table 14.2.1.4b
Summary of Algorithm Best Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202

Overall & Prior Antineoplastic Therapy = No

Best Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=7) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=8) n (%) (95% CIs)
CR	0	0		0
PR	1 (100)	3 (42.9)		4 (50.0)
CI	0	0		0
SD	0	4 (57.1)		4 (50.0)
PD	0	0		0
NE	0	0		0
CR+PR	1 (100) (2.5-100.0)	3 (42.9) (9.9- 81.6)		4 (50.0) (15.7- 84.3)
CR+PR+CI (ORR)	1 (100) (2.5-100.0)	3 (42.9) (9.9- 81.6)		4 (50.0) (15.7- 84.3)
CR+PR+CI+SD	1 (100) (2.5-100.0)	7 (100) (59.0-100.0)		8 (100) (63.1-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-resp-rac-tpy.sDate: 20:50/02NOV2020

Table 14.2.1.4b
Summary of Algorithm Best Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202

Starting Dose: 200 mg & Prior Antineoplastic Therapy = No

Best Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=7) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=8) n (%) (95% CIs)
CR	0	0		0
PR	1 (100)	3 (42.9)		4 (50.0)
CI	0	0		0
SD	0	4 (57.1)		4 (50.0)
PD	0	0		0
NE	0	0		0
CR+PR	1 (100) (2.5-100.0)	3 (42.9) (9.9- 81.6)		4 (50.0) (15.7- 84.3)
CR+PR+CI (ORR)	1 (100) (2.5-100.0)	3 (42.9) (9.9- 81.6)		4 (50.0) (15.7- 84.3)
CR+PR+CI+SD	1 (100) (2.5-100.0)	7 (100) (59.0-100.0)		8 (100) (63.1-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-resp-rac-tpy.sDate: 20:50/02NOV2020

Table 14.2.1.4b
Summary of Algorithm Best Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Overall & Prior Antineoplastic Therapy = Yes

Best Response	ASM (N=3) n (%) (95% CIs)	SM-AHN (N=38) n (%) (95% CIs)	MCL (N=12) n (%) (95% CIs)	All AdvSM (N=53) n (%) (95% CIs)
CR	0	4 (10.5)	3 (25.0)	7 (13.2)
PR	3 (100)	14 (36.8)	2 (16.7)	19 (35.8)
CI	0	6 (15.8)	2 (16.7)	8 (15.1)
SD	0	13 (34.2)	5 (41.7)	18 (34.0)
PD	0	0	0	0
NE	0	1 (2.6)	0	1 (1.9)
CR+PR	3 (100) (29.2-100.0)	18 (47.4) (31.0- 64.2)	5 (41.7) (15.2- 72.3)	26 (49.1) (35.1- 63.2)
CR+PR+CI (ORR)	3 (100) (29.2-100.0)	24 (63.2) (46.0- 78.2)	7 (58.3) (27.7- 84.8)	34 (64.2) (49.8- 76.9)
CR+PR+CI+SD	3 (100) (29.2-100.0)	37 (97.4) (86.2- 99.9)	12 (100) (73.5-100.0)	52 (98.1) (89.9-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-resp-rac-tpy.sDate: 20:50/02NOV2020

Table 14.2.1.4b
Summary of Algorithm Best Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg & Prior Antineoplastic Therapy = Yes

Best Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=2) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=3) n (%) (95% CIs)
CR		1 (50.0)	1 (100)	2 (66.7)
PR		1 (50.0)	0	1 (33.3)
CI		0	0	0
SD		0	0	0
PD		0	0	0
NE		0	0	0
CR+PR		2 (100) (15.8-100.0)	1 (100) (2.5-100.0)	3 (100) (29.2-100.0)
CR+PR+CI (ORR)		2 (100) (15.8-100.0)	1 (100) (2.5-100.0)	3 (100) (29.2-100.0)
CR+PR+CI+SD		2 (100) (15.8-100.0)	1 (100) (2.5-100.0)	3 (100) (29.2-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-resp-rac-tpy.sDate: 20:50/02NOV2020

Table 14.2.1.4b
Summary of Algorithm Best Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg & Prior Antineoplastic Therapy = Yes

Best Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=24) n (%) (95% CIs)	MCL (N=9) n (%) (95% CIs)	All AdvSM (N=34) n (%) (95% CIs)
CR	0	1 (4.2)	2 (22.2)	3 (8.8)
PR	1 (100)	7 (29.2)	2 (22.2)	10 (29.4)
CI	0	6 (25.0)	1 (11.1)	7 (20.6)
SD	0	9 (37.5)	4 (44.4)	13 (38.2)
PD	0	0	0	0
NE	0	1 (4.2)	0	1 (2.9)
CR+PR	1 (100) (2.5-100.0)	8 (33.3) (15.6- 55.3)	4 (44.4) (13.7- 78.8)	13 (38.2) (22.2- 56.4)
CR+PR+CI (ORR)	1 (100) (2.5-100.0)	14 (58.3) (36.6- 77.9)	5 (55.6) (21.2- 86.3)	20 (58.8) (40.7- 75.4)
CR+PR+CI+SD	1 (100) (2.5-100.0)	23 (95.8) (78.9- 99.9)	9 (100) (66.4-100.0)	33 (97.1) (84.7- 99.9)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-resp-rac-tpy.sDate: 20:50/02NOV2020

Table 14.2.1.4b
Summary of Algorithm Best Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg & Prior Antineoplastic Therapy = Yes

Best Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=22) n (%) (95% CIs)	MCL (N=8) n (%) (95% CIs)	All AdvSM (N=31) n (%) (95% CIs)
CR	0	0	1 (12.5)	1 (3.2)
PR	1 (100)	6 (27.3)	2 (25.0)	9 (29.0)
CI	0	6 (27.3)	1 (12.5)	7 (22.6)
SD	0	9 (40.9)	4 (50.0)	13 (41.9)
PD	0	0	0	0
NE	0	1 (4.5)	0	1 (3.2)
CR+PR	1 (100) (2.5-100.0)	6 (27.3) (10.7- 50.2)	3 (37.5) (8.5- 75.5)	10 (32.3) (16.7- 51.4)
CR+PR+CI (ORR)	1 (100) (2.5-100.0)	12 (54.5) (32.2- 75.6)	4 (50.0) (15.7- 84.3)	17 (54.8) (36.0- 72.7)
CR+PR+CI+SD	1 (100) (2.5-100.0)	21 (95.5) (77.2- 99.9)	8 (100) (63.1-100.0)	30 (96.8) (83.3- 99.9)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-resp-rac-tpy.sDate: 20:50/02NOV2020

Table 14.2.1.4b
Summary of Algorithm Best Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg & Prior Antineoplastic Therapy = Yes

Best Response	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=10) n (%) (95% CIs)	MCL (N=3) n (%) (95% CIs)	All AdvSM (N=15) n (%) (95% CIs)
CR	0	2 (20.0)	1 (33.3)	3 (20.0)
PR	2 (100)	5 (50.0)	0	7 (46.7)
CI	0	0	1 (33.3)	1 (6.7)
SD	0	3 (30.0)	1 (33.3)	4 (26.7)
PD	0	0	0	0
NE	0	0	0	0
CR+PR	2 (100) (15.8-100.0)	7 (70.0) (34.8- 93.3)	1 (33.3) (0.8- 90.6)	10 (66.7) (38.4- 88.2)
CR+PR+CI (ORR)	2 (100) (15.8-100.0)	7 (70.0) (34.8- 93.3)	2 (66.7) (9.4- 99.2)	11 (73.3) (44.9- 92.2)
CR+PR+CI+SD	2 (100) (15.8-100.0)	10 (100) (69.2-100.0)	3 (100) (29.2-100.0)	15 (100) (78.2-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-resp-rac-tpy.sDate: 20:50/02NOV2020

Table 14.2.1.4b
Summary of Algorithm Best Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg & Prior Antineoplastic Therapy = Yes

Best Response	ASM (N=3) n (%) (95% CIs)	SM-AHN (N=32) n (%) (95% CIs)	MCL (N=11) n (%) (95% CIs)	All AdvSM (N=46) n (%) (95% CIs)
CR	0	2 (6.3)	2 (18.2)	4 (8.7)
PR	3 (100)	11 (34.4)	2 (18.2)	16 (34.8)
CI	0	6 (18.8)	2 (18.2)	8 (17.4)
SD	0	12 (37.5)	5 (45.5)	17 (37.0)
PD	0	0	0	0
NE	0	1 (3.1)	0	1 (2.2)
CR+PR	3 (100) (29.2-100.0)	13 (40.6) (23.7- 59.4)	4 (36.4) (10.9- 69.2)	20 (43.5) (28.9- 58.9)
CR+PR+CI (ORR)	3 (100) (29.2-100.0)	19 (59.4) (40.6- 76.3)	6 (54.5) (23.4- 83.3)	28 (60.9) (45.4- 74.9)
CR+PR+CI+SD	3 (100) (29.2-100.0)	31 (96.9) (83.8- 99.9)	11 (100) (71.5-100.0)	45 (97.8) (88.5- 99.9)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-resp-rac-tpy.sDate: 20:50/02NOV2020

Table 14.2.1.4b
Summary of Algorithm Best Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg & Prior Antineoplastic Therapy = Yes

Best Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=4) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=4) n (%) (95% CIs)
CR		1 (25.0)		1 (25.0)
PR		2 (50.0)		2 (50.0)
CI		0		0
SD		1 (25.0)		1 (25.0)
PD		0		0
NE		0		0
CR+PR		3 (75.0) (19.4- 99.4)		3 (75.0) (19.4- 99.4)
CR+PR+CI (ORR)		3 (75.0) (19.4- 99.4)		3 (75.0) (19.4- 99.4)
CR+PR+CI+SD		4 (100) (39.8-100.0)		4 (100) (39.8-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-resp-rac-tpy.sDate: 20:50/02NOV2020

Table 14.2.1.4b
Summary of Algorithm Best Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Overall & Prior Antineoplastic Therapy = No

Best Response	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=19) n (%) (95% CIs)	MCL (N=5) n (%) (95% CIs)	All AdvSM (N=26) n (%) (95% CIs)
CR	0	1 (5.3)	2 (40.0)	3 (11.5)
PR	2 (100)	11 (57.9)	2 (40.0)	15 (57.7)
CI	0	1 (5.3)	1 (20.0)	2 (7.7)
SD	0	6 (31.6)	0	6 (23.1)
PD	0	0	0	0
NE	0	0	0	0
CR+PR	2 (100) (15.8-100.0)	12 (63.2) (38.4- 83.7)	4 (80.0) (28.4- 99.5)	18 (69.2) (48.2- 85.7)
CR+PR+CI (ORR)	2 (100) (15.8-100.0)	13 (68.4) (43.4- 87.4)	5 (100) (47.8-100.0)	20 (76.9) (56.4- 91.0)
CR+PR+CI+SD	2 (100) (15.8-100.0)	19 (100) (82.4-100.0)	5 (100) (47.8-100.0)	26 (100) (86.8-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-resp-rac-tpy.sDate: 20:50/02NOV2020

Table 14.2.1.4b
Summary of Algorithm Best Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg & Prior Antineoplastic Therapy = No

Best Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=3) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=3) n (%) (95% CIs)
CR		0		0
PR		3 (100)		3 (100)
CI		0		0
SD		0		0
PD		0		0
NE		0		0
CR+PR		3 (100) (29.2-100.0)		3 (100) (29.2-100.0)
CR+PR+CI (ORR)		3 (100) (29.2-100.0)		3 (100) (29.2-100.0)
CR+PR+CI+SD		3 (100) (29.2-100.0)		3 (100) (29.2-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-resp-rac-tpy.sDate: 20:50/02NOV2020

Table 14.2.1.4b
Summary of Algorithm Best Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg & Prior Antineoplastic Therapy = No

Best Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=11) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=14) n (%) (95% CIs)
CR	0	0	0	0
PR	1 (100)	6 (54.5)	2 (100)	9 (64.3)
CI	0	0	0	0
SD	0	5 (45.5)	0	5 (35.7)
PD	0	0	0	0
NE	0	0	0	0
CR+PR	1 (100) (2.5-100.0)	6 (54.5) (23.4- 83.3)	2 (100) (15.8-100.0)	9 (64.3) (35.1- 87.2)
CR+PR+CI (ORR)	1 (100) (2.5-100.0)	6 (54.5) (23.4- 83.3)	2 (100) (15.8-100.0)	9 (64.3) (35.1- 87.2)
CR+PR+CI+SD	1 (100) (2.5-100.0)	11 (100) (71.5-100.0)	2 (100) (15.8-100.0)	14 (100) (76.8-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-resp-rac-tpy.sDate: 20:50/02NOV2020

Table 14.2.1.4b
Summary of Algorithm Best Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg & Prior Antineoplastic Therapy = No

Best Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=8) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=11) n (%) (95% CIs)
CR	0	0	0	0
PR	1 (100)	3 (37.5)	2 (100)	6 (54.5)
CI	0	0	0	0
SD	0	5 (62.5)	0	5 (45.5)
PD	0	0	0	0
NE	0	0	0	0
CR+PR	1 (100) (2.5-100.0)	3 (37.5) (8.5- 75.5)	2 (100) (15.8-100.0)	6 (54.5) (23.4- 83.3)
CR+PR+CI (ORR)	1 (100) (2.5-100.0)	3 (37.5) (8.5- 75.5)	2 (100) (15.8-100.0)	6 (54.5) (23.4- 83.3)
CR+PR+CI+SD	1 (100) (2.5-100.0)	8 (100) (63.1-100.0)	2 (100) (15.8-100.0)	11 (100) (71.5-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-resp-rac-tpy.sDate: 20:50/02NOV2020

Table 14.2.1.4b
Summary of Algorithm Best Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg & Prior Antineoplastic Therapy = No

Best Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=8) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=11) n (%) (95% CIs)
CR	0	1 (12.5)	1 (50.0)	2 (18.2)
PR	1 (100)	5 (62.5)	0	6 (54.5)
CI	0	1 (12.5)	1 (50.0)	2 (18.2)
SD	0	1 (12.5)	0	1 (9.1)
PD	0	0	0	0
NE	0	0	0	0
CR+PR	1 (100) (2.5-100.0)	6 (75.0) (34.9- 96.8)	1 (50.0) (1.3- 98.7)	8 (72.7) (39.0- 94.0)
CR+PR+CI (ORR)	1 (100) (2.5-100.0)	7 (87.5) (47.3- 99.7)	2 (100) (15.8-100.0)	10 (90.9) (58.7- 99.8)
CR+PR+CI+SD	1 (100) (2.5-100.0)	8 (100) (63.1-100.0)	2 (100) (15.8-100.0)	11 (100) (71.5-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-resp-rac-tpy.sDate: 20:50/02NOV2020

Table 14.2.1.4b
Summary of Algorithm Best Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg & Prior Antineoplastic Therapy = No

Best Response	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=16) n (%) (95% CIs)	MCL (N=4) n (%) (95% CIs)	All AdvSM (N=22) n (%) (95% CIs)
CR	0	1 (6.3)	1 (25.0)	2 (9.1)
PR	2 (100)	8 (50.0)	2 (50.0)	12 (54.5)
CI	0	1 (6.3)	1 (25.0)	2 (9.1)
SD	0	6 (37.5)	0	6 (27.3)
PD	0	0	0	0
NE	0	0	0	0
CR+PR	2 (100) (15.8-100.0)	9 (56.3) (29.9- 80.2)	3 (75.0) (19.4- 99.4)	14 (63.6) (40.7- 82.8)
CR+PR+CI (ORR)	2 (100) (15.8-100.0)	10 (62.5) (35.4- 84.8)	4 (100) (39.8-100.0)	16 (72.7) (49.8- 89.3)
CR+PR+CI+SD	2 (100) (15.8-100.0)	16 (100) (79.4-100.0)	4 (100) (39.8-100.0)	22 (100) (84.6-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-resp-rac-tpy.sDate: 20:50/02NOV2020

Table 14.2.1.4b
Summary of Algorithm Best Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg & Prior Antineoplastic Therapy = No

Best Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=0) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=1) n (%) (95% CIs)
CR			1 (100)	1 (100)
PR			0	0
CI			0	0
SD			0	0
PD			0	0
NE			0	0
CR+PR			1 (100) (2.5-100.0)	1 (100) (2.5-100.0)
CR+PR+CI (ORR)			1 (100) (2.5-100.0)	1 (100) (2.5-100.0)
CR+PR+CI+SD			1 (100) (2.5-100.0)	1 (100) (2.5-100.0)

Abbreviations: CI=Clinical improvement, CIs=Confidence intervals, CR=Complete remission, PD=Progressive disease, PR=Partial remission, SD=Stable disease, ORR=Overall response rate
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-resp-rac-tpy.sDate: 20:50/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101

Overall & Prior antineoplastic therapy = Yes

Duration of Response	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=16) n (%) (95% CIs)	MCL (N=4) n (%) (95% CIs)	All AdvSM (N=22) n (%) (95% CIs)
Events	0	3 (18.8)	1 (25.0)	4 (18.2)
Censors	2 (100)	13 (81.3)	3 (75.0)	18 (81.8)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)	NE (9.2 - NE)	NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	93.8 (81.9-100.0)	100.0 (100.0-100.0)	95.5 (86.8-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	93.8 (81.9-100.0)	100.0 (100.0-100.0)	95.5 (86.8-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	87.5 (71.3-100.0)	100.0 (100.0-100.0)	90.9 (78.9-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	80.2 (60.0-100.0)	75.0 (32.6-100.0)	81.1 (64.3- 97.8)
18 Months (95% CIs)	100.0 (100.0-100.0)	80.2 (60.0-100.0)	75.0 (32.6-100.0)	81.1 (64.3- 97.8)
24 Months (95% CIs)	100.0 (100.0-100.0)	80.2 (60.0-100.0)	75.0 (32.6-100.0)	81.1 (64.3- 97.8)
30 Months (95% CIs)		80.2 (60.0-100.0)		81.1 (64.3- 97.8)
36 Months (95% CIs)		80.2 (60.0-100.0)		81.1 (64.3- 97.8)
42 Months (95% CIs)		80.2 (60.0-100.0)		81.1 (64.3- 97.8)
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101

Overall & Prior antineoplastic therapy = Yes

Duration of CR+CRh+PR	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=15) n (%) (95% CIs)	MCL (N=3) n (%) (95% CIs)	All AdvSM (N=20) n (%) (95% CIs)
Events	0	3 (20.0)	0	3 (15.0)
Censors	2 (100)	12 (80.0)	3 (100)	17 (85.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	93.3 (80.7-100.0)	100.0 (100.0-100.0)	95.0 (85.4-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	93.3 (80.7-100.0)	100.0 (100.0-100.0)	95.0 (85.4-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	86.7 (69.5-100.0)	100.0 (100.0-100.0)	90.0 (76.9-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	78.8 (57.3-100.0)	100.0 (100.0-100.0)	84.4 (68.1-100.0)
18 Months (95% CIs)	100.0 (100.0-100.0)	78.8 (57.3-100.0)	100.0 (100.0-100.0)	84.4 (68.1-100.0)
24 Months (95% CIs)	100.0 (100.0-100.0)	78.8 (57.3-100.0)	100.0 (100.0-100.0)	84.4 (68.1-100.0)
30 Months (95% CIs)		78.8 (57.3-100.0)		84.4 (68.1-100.0)
36 Months (95% CIs)		78.8 (57.3-100.0)		84.4 (68.1-100.0)
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101

Overall & Prior antineoplastic therapy = No

Duration of Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=12) n (%) (95% CIs)	MCL (N=5) n (%) (95% CIs)	All AdvSM (N=18) n (%) (95% CIs)
Events	0	6 (50.0)	2 (40.0)	8 (44.4)
Censors	1 (100)	6 (50.0)	3 (60.0)	10 (55.6)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	21.7 (18.4 - 38.3)	NE (5.6 - NE)	28.6 (21.0 - 38.3)
25th, 75th percentiles	NE, NE	21.0, 38.3	13.6, NE	21.0, 38.3
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	90.9 (73.9-100.0)	75.0 (32.6-100.0)	87.5 (71.3-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	90.9 (73.9-100.0)	75.0 (32.6-100.0)	87.5 (71.3-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	90.9 (73.9-100.0)	75.0 (32.6-100.0)	87.5 (71.3-100.0)
18 Months (95% CIs)	100.0 (100.0-100.0)	90.9 (73.9-100.0)	75.0 (32.6-100.0)	87.5 (71.3-100.0)
24 Months (95% CIs)		45.5 (8.1- 82.8)	50.0 (1.0- 99.0)	52.5 (24.2- 80.8)
30 Months (95% CIs)		30.3 (0.0- 65.1)	50.0 (1.0- 99.0)	42.0 (12.8- 71.2)
36 Months (95% CIs)		30.3 (0.0- 65.1)		42.0 (12.8- 71.2)
42 Months (95% CIs)		0.0 (0.0- 0.0)		0.0 (0.0- 0.0)
48 Months (95% CIs)		0.0 (0.0- 0.0)		0.0 (0.0- 0.0)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101

Overall & Prior antineoplastic therapy = No

Duration of CR+CRh+PR	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=12) n (%) (95% CIs)	MCL (N=4) n (%) (95% CIs)	All AdvSM (N=17) n (%) (95% CIs)
Events	0	6 (50.0)	1 (25.0)	7 (41.2)
Censors	1 (100)	6 (50.0)	3 (75.0)	10 (58.8)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	19.4 (15.9 - 38.3)	NE (21.6 - NE)	21.6 (19.4 - 38.3)
25th, 75th percentiles	NE, NE	15.9, 38.3	21.6, NE	19.4, 38.3
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	90.9 (73.9-100.0)	100.0 (100.0-100.0)	93.3 (80.7-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	90.9 (73.9-100.0)	100.0 (100.0-100.0)	93.3 (80.7-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	90.9 (73.9-100.0)	100.0 (100.0-100.0)	93.3 (80.7-100.0)
18 Months (95% CIs)	100.0 (100.0-100.0)	64.9 (32.2- 97.7)	100.0 (100.0-100.0)	76.4 (52.7-100.0)
24 Months (95% CIs)		32.5 (0.0- 68.3)	66.7 (13.3-100.0)	47.7 (18.2- 77.3)
30 Months (95% CIs)		32.5 (0.0- 68.3)	66.7 (13.3-100.0)	47.7 (18.2- 77.3)
36 Months (95% CIs)		32.5 (0.0- 68.3)		47.7 (18.2- 77.3)
42 Months (95% CIs)		0.0 (0.0- 0.0)		0.0 (0.0- 0.0)
48 Months (95% CIs)		0.0 (0.0- 0.0)		0.0 (0.0- 0.0)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101

Starting Dose: <200 mg & Prior antineoplastic therapy = Yes

Duration of Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=2) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=3) n (%) (95% CIs)
Events		0	0	0
Censors		2 (100)	1 (100)	3 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles		NE, NE	NE, NE	NE, NE
3 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
18 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
24 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
30 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
36 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
42 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101

Starting Dose: <200 mg & Prior antineoplastic therapy = Yes

Duration of CR+CRh+PR	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=2) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=3) n (%) (95% CIs)
Events		0	0	0
Censors		2 (100)	1 (100)	3 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles		NE, NE	NE, NE	NE, NE
3 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
18 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
24 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
30 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
36 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101

Starting Dose: <200 mg & Prior antineoplastic therapy = No

Duration of Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=4) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=4) n (%) (95% CIs)
Events		3 (75.0)		3 (75.0)
Censors		1 (25.0)		1 (25.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		33.5 (21.7 - 38.3)		33.5 (21.7 - 38.3)
25th, 75th percentiles		25.1, 38.3		25.1, 38.3
3 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
18 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
24 Months (95% CIs)		75.0 (32.6-100.0)		75.0 (32.6-100.0)
30 Months (95% CIs)		50.0 (1.0- 99.0)		50.0 (1.0- 99.0)
36 Months (95% CIs)		50.0 (1.0- 99.0)		50.0 (1.0- 99.0)
42 Months (95% CIs)		0.0 (0.0- 0.0)		0.0 (0.0- 0.0)
48 Months (95% CIs)		0.0 (0.0- 0.0)		0.0 (0.0- 0.0)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
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Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101

Starting Dose: <200 mg & Prior antineoplastic therapy = No

Duration of CR+CRh+PR	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=4) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=4) n (%) (95% CIs)
Events		3 (75.0)		3 (75.0)
Censors		1 (25.0)		1 (25.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		28.8 (14.8 - 38.3)		28.8 (14.8 - 38.3)
25th, 75th percentiles		17.1, 38.3		17.1, 38.3
3 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
18 Months (95% CIs)		75.0 (32.6-100.0)		75.0 (32.6-100.0)
24 Months (95% CIs)		50.0 (1.0- 99.0)		50.0 (1.0- 99.0)
30 Months (95% CIs)		50.0 (1.0- 99.0)		50.0 (1.0- 99.0)
36 Months (95% CIs)		50.0 (1.0- 99.0)		50.0 (1.0- 99.0)
42 Months (95% CIs)		0.0 (0.0- 0.0)		0.0 (0.0- 0.0)
48 Months (95% CIs)		0.0 (0.0- 0.0)		0.0 (0.0- 0.0)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101

Starting Dose: <300 mg & Prior antineoplastic therapy = Yes

Duration of Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=5) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=7) n (%) (95% CIs)
Events		1 (20.0)	0	1 (14.3)
Censors		4 (80.0)	2 (100)	6 (85.7)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (11.2 - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles		NE, NE	NE, NE	NE, NE
3 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)		75.0 (32.6-100.0)	100.0 (100.0-100.0)	83.3 (53.5-100.0)
18 Months (95% CIs)		75.0 (32.6-100.0)	100.0 (100.0-100.0)	83.3 (53.5-100.0)
24 Months (95% CIs)		75.0 (32.6-100.0)		83.3 (53.5-100.0)
30 Months (95% CIs)		75.0 (32.6-100.0)		83.3 (53.5-100.0)
36 Months (95% CIs)		75.0 (32.6-100.0)		83.3 (53.5-100.0)
42 Months (95% CIs)		75.0 (32.6-100.0)		83.3 (53.5-100.0)
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
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Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101

Starting Dose: <300 mg & Prior antineoplastic therapy = Yes

Duration of CR+CRh+PR	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=5) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=7) n (%) (95% CIs)
Events		1 (20.0)	0	1 (14.3)
Censors		4 (80.0)	2 (100)	6 (85.7)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (11.2 - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles		NE, NE	NE, NE	NE, NE
3 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)		75.0 (32.6-100.0)	100.0 (100.0-100.0)	83.3 (53.5-100.0)
18 Months (95% CIs)		75.0 (32.6-100.0)	100.0 (100.0-100.0)	83.3 (53.5-100.0)
24 Months (95% CIs)		75.0 (32.6-100.0)		83.3 (53.5-100.0)
30 Months (95% CIs)		75.0 (32.6-100.0)		83.3 (53.5-100.0)
36 Months (95% CIs)		75.0 (32.6-100.0)		83.3 (53.5-100.0)
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101

Starting Dose: <300 mg & Prior antineoplastic therapy = No

Duration of Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=5) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=7) n (%) (95% CIs)
Events		3 (60.0)	1 (50.0)	4 (57.1)
Censors		2 (40.0)	1 (50.0)	3 (42.9)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		33.5 (21.7 - 38.3)	21.6 (NE - NE)	28.6 (21.6 - 38.3)
25th, 75th percentiles		25.1, 38.3	21.6, 21.6	21.7, 38.3
3 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
18 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
24 Months (95% CIs)		75.0 (32.6-100.0)	0.0 (0.0- 0.0)	60.0 (17.1-100.0)
30 Months (95% CIs)		50.0 (1.0- 99.0)	0.0 (0.0- 0.0)	40.0 (0.0- 82.9)
36 Months (95% CIs)		50.0 (1.0- 99.0)	0.0 (0.0- 0.0)	40.0 (0.0- 82.9)
42 Months (95% CIs)		0.0 (0.0- 0.0)	0.0 (0.0- 0.0)	0.0 (0.0- 0.0)
48 Months (95% CIs)		0.0 (0.0- 0.0)	0.0 (0.0- 0.0)	0.0 (0.0- 0.0)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
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Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101

Starting Dose: <300 mg & Prior antineoplastic therapy = No

Duration of CR+CRh+PR	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=5) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=7) n (%) (95% CIs)
Events		3 (60.0)	1 (50.0)	4 (57.1)
Censors		2 (40.0)	1 (50.0)	3 (42.9)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		28.8 (14.8 - 38.3)	21.6 (NE - NE)	21.6 (14.8 - 38.3)
25th, 75th percentiles		17.1, 38.3	21.6, 21.6	19.4, 38.3
3 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
18 Months (95% CIs)		75.0 (32.6-100.0)	100.0 (100.0-100.0)	80.0 (44.9-100.0)
24 Months (95% CIs)		50.0 (1.0- 99.0)	0.0 (0.0- 0.0)	40.0 (0.0- 82.9)
30 Months (95% CIs)		50.0 (1.0- 99.0)	0.0 (0.0- 0.0)	40.0 (0.0- 82.9)
36 Months (95% CIs)		50.0 (1.0- 99.0)	0.0 (0.0- 0.0)	40.0 (0.0- 82.9)
42 Months (95% CIs)		0.0 (0.0- 0.0)	0.0 (0.0- 0.0)	0.0 (0.0- 0.0)
48 Months (95% CIs)		0.0 (0.0- 0.0)	0.0 (0.0- 0.0)	0.0 (0.0- 0.0)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101

Starting Dose: 200 mg & Prior antineoplastic therapy = Yes

Duration of Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=3) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=4) n (%) (95% CIs)
Events		1 (33.3)	0	1 (25.0)
Censors		2 (66.7)	1 (100)	3 (75.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (11.2 - NE)	NE (NE - NE)	NE (11.2 - NE)
25th, 75th percentiles		11.2, NE	NE, NE	11.2, NE
3 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)		50.0 (0.0-100.0)	100.0 (100.0-100.0)	66.7 (13.3-100.0)
18 Months (95% CIs)				
24 Months (95% CIs)				
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
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Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101

Starting Dose: 200 mg & Prior antineoplastic therapy = Yes

Duration of CR+CRh+PR	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=3) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=4) n (%) (95% CIs)
Events		1 (33.3)	0	1 (25.0)
Censors		2 (66.7)	1 (100)	3 (75.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (11.2 - NE)	NE (NE - NE)	NE (11.2 - NE)
25th, 75th percentiles		11.2, NE	NE, NE	11.2, NE
3 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)		50.0 (0.0-100.0)	100.0 (100.0-100.0)	66.7 (13.3-100.0)
18 Months (95% CIs)				
24 Months (95% CIs)				
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
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Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101

Starting Dose: 200 mg & Prior antineoplastic therapy = No

Duration of Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=1) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=3) n (%) (95% CIs)
Events		0	1 (50.0)	1 (33.3)
Censors		1 (100)	1 (50.0)	2 (66.7)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE - NE)	21.6 (NE - NE)	21.6 (NE - NE)
25th, 75th percentiles		NE, NE	21.6, 21.6	21.6, 21.6
3 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
18 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
24 Months (95% CIs)			0.0 (0.0- 0.0)	0.0 (0.0- 0.0)
30 Months (95% CIs)			0.0 (0.0- 0.0)	0.0 (0.0- 0.0)
36 Months (95% CIs)			0.0 (0.0- 0.0)	0.0 (0.0- 0.0)
42 Months (95% CIs)			0.0 (0.0- 0.0)	0.0 (0.0- 0.0)
48 Months (95% CIs)			0.0 (0.0- 0.0)	0.0 (0.0- 0.0)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
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Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101

Starting Dose: 200 mg & Prior antineoplastic therapy = No

Duration of CR+CRh+PR	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=1) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=3) n (%) (95% CIs)
Events		0	1 (50.0)	1 (33.3)
Censors		1 (100)	1 (50.0)	2 (66.7)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE - NE)	21.6 (NE - NE)	21.6 (NE - NE)
25th, 75th percentiles		NE, NE	21.6, 21.6	21.6, 21.6
3 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
18 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
24 Months (95% CIs)			0.0 (0.0- 0.0)	0.0 (0.0- 0.0)
30 Months (95% CIs)			0.0 (0.0- 0.0)	0.0 (0.0- 0.0)
36 Months (95% CIs)			0.0 (0.0- 0.0)	0.0 (0.0- 0.0)
42 Months (95% CIs)			0.0 (0.0- 0.0)	0.0 (0.0- 0.0)
48 Months (95% CIs)			0.0 (0.0- 0.0)	0.0 (0.0- 0.0)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101

Starting Dose: 300 mg & Prior antineoplastic therapy = Yes

Duration of Response	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=9) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=13) n (%) (95% CIs)
Events	0	2 (22.2)	1 (50.0)	3 (23.1)
Censors	2 (100)	7 (77.8)	1 (50.0)	10 (76.9)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)	NE (9.2 - NE)	NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE	9.2, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	88.9 (68.4-100.0)	100.0 (100.0-100.0)	92.3 (77.8-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	88.9 (68.4-100.0)	100.0 (100.0-100.0)	92.3 (77.8-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	77.8 (50.6-100.0)	100.0 (100.0-100.0)	84.6 (65.0-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	77.8 (50.6-100.0)	50.0 (0.0-100.0)	76.2 (52.5- 99.8)
18 Months (95% CIs)	100.0 (100.0-100.0)	77.8 (50.6-100.0)	50.0 (0.0-100.0)	76.2 (52.5- 99.8)
24 Months (95% CIs)	100.0 (100.0-100.0)	77.8 (50.6-100.0)	50.0 (0.0-100.0)	76.2 (52.5- 99.8)
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101

Starting Dose: 300 mg & Prior antineoplastic therapy = Yes

Duration of CR+CRh+PR	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=8) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=11) n (%) (95% CIs)
Events	0	2 (25.0)	0	2 (18.2)
Censors	2 (100)	6 (75.0)	1 (100)	9 (81.8)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (7.5 - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	87.5 (64.6-100.0)	100.0 (100.0-100.0)	90.9 (73.9-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	87.5 (64.6-100.0)	100.0 (100.0-100.0)	90.9 (73.9-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	75.0 (45.0-100.0)	100.0 (100.0-100.0)	81.8 (59.0-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	75.0 (45.0-100.0)	100.0 (100.0-100.0)	81.8 (59.0-100.0)
18 Months (95% CIs)	100.0 (100.0-100.0)	75.0 (45.0-100.0)	100.0 (100.0-100.0)	81.8 (59.0-100.0)
24 Months (95% CIs)	100.0 (100.0-100.0)		100.0 (100.0-100.0)	81.8 (59.0-100.0)
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101

Starting Dose: 300 mg & Prior antineoplastic therapy = No

Duration of Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=7) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=10) n (%) (95% CIs)
Events	0	3 (42.9)	1 (50.0)	4 (40.0)
Censors	1 (100)	4 (57.1)	1 (50.0)	6 (60.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	18.4 (18.4 - 21.0)	NE (5.6 - NE)	21.0 (18.4 - NE)
25th, 75th percentiles	NE, NE	18.4, 21.0	5.6, NE	18.4, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	83.3 (53.5-100.0)	50.0 (0.0-100.0)	77.8 (50.6-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	83.3 (53.5-100.0)	50.0 (0.0-100.0)	77.8 (50.6-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	83.3 (53.5-100.0)	50.0 (0.0-100.0)	77.8 (50.6-100.0)
18 Months (95% CIs)	100.0 (100.0-100.0)	83.3 (53.5-100.0)	50.0 (0.0-100.0)	77.8 (50.6-100.0)
24 Months (95% CIs)		0.0 (0.0- 0.0)	50.0 (0.0-100.0)	38.9 (0.0- 79.3)
30 Months (95% CIs)		0.0 (0.0- 0.0)	50.0 (0.0-100.0)	38.9 (0.0- 79.3)
36 Months (95% CIs)		0.0 (0.0- 0.0)		
42 Months (95% CIs)		0.0 (0.0- 0.0)		
48 Months (95% CIs)		0.0 (0.0- 0.0)		

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101

Starting Dose: 300 mg & Prior antineoplastic therapy = No

Duration of CR+CRh+PR	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=7) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=9) n (%) (95% CIs)
Events	0	3 (42.9)	0	3 (33.3)
Censors	1 (100)	4 (57.1)	1 (100)	6 (66.7)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	21.0 (15.9 - 21.0)	NE (NE - NE)	21.0 (15.9 - NE)
25th, 75th percentiles	NE, NE	15.9, 21.0	NE, NE	15.9, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	83.3 (53.5-100.0)	100.0 (100.0-100.0)	87.5 (64.6-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	83.3 (53.5-100.0)	100.0 (100.0-100.0)	87.5 (64.6-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	83.3 (53.5-100.0)	100.0 (100.0-100.0)	87.5 (64.6-100.0)
18 Months (95% CIs)	100.0 (100.0-100.0)	55.6 (6.9-100.0)	100.0 (100.0-100.0)	70.0 (34.3-100.0)
24 Months (95% CIs)		0.0 (0.0- 0.0)	100.0 (100.0-100.0)	46.7 (2.4- 91.0)
30 Months (95% CIs)		0.0 (0.0- 0.0)	100.0 (100.0-100.0)	46.7 (2.4- 91.0)
36 Months (95% CIs)		0.0 (0.0- 0.0)		
42 Months (95% CIs)		0.0 (0.0- 0.0)		
48 Months (95% CIs)		0.0 (0.0- 0.0)		

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg & Prior antineoplastic therapy = Yes

Duration of Response	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=12) n (%) (95% CIs)	MCL (N=3) n (%) (95% CIs)	All AdvSM (N=17) n (%) (95% CIs)
Events	0	3 (25.0)	1 (33.3)	4 (23.5)
Censors	2 (100)	9 (75.0)	2 (66.7)	13 (76.5)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (11.2 - NE)	NE (9.2 - NE)	NE (NE - NE)
25th, 75th percentiles	NE, NE	11.2, NE	9.2, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	91.7 (76.0-100.0)	100.0 (100.0-100.0)	94.1 (82.9-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	91.7 (76.0-100.0)	100.0 (100.0-100.0)	94.1 (82.9-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	83.3 (62.2-100.0)	100.0 (100.0-100.0)	88.2 (72.9-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	72.9 (46.4- 99.5)	66.7 (13.3-100.0)	75.1 (53.8- 96.4)
18 Months (95% CIs)	100.0 (100.0-100.0)	72.9 (46.4- 99.5)	66.7 (13.3-100.0)	75.1 (53.8- 96.4)
24 Months (95% CIs)	100.0 (100.0-100.0)	72.9 (46.4- 99.5)	66.7 (13.3-100.0)	75.1 (53.8- 96.4)
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg & Prior antineoplastic therapy = Yes

Duration of CR+CRh+PR	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=11) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=15) n (%) (95% CIs)
Events	0	3 (27.3)	0	3 (20.0)
Censors	2 (100)	8 (72.7)	2 (100)	12 (80.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (11.2 - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles	NE, NE	11.2, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	90.9 (73.9-100.0)	100.0 (100.0-100.0)	93.3 (80.7-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	90.9 (73.9-100.0)	100.0 (100.0-100.0)	93.3 (80.7-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	81.8 (59.0-100.0)	100.0 (100.0-100.0)	86.7 (69.5-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	70.1 (41.3- 99.0)	100.0 (100.0-100.0)	78.8 (57.3-100.0)
18 Months (95% CIs)	100.0 (100.0-100.0)	70.1 (41.3- 99.0)	100.0 (100.0-100.0)	78.8 (57.3-100.0)
24 Months (95% CIs)	100.0 (100.0-100.0)		100.0 (100.0-100.0)	78.8 (57.3-100.0)
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg & Prior antineoplastic therapy = No

Duration of Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=8) n (%) (95% CIs)	MCL (N=4) n (%) (95% CIs)	All AdvSM (N=13) n (%) (95% CIs)
Events	0	3 (37.5)	2 (50.0)	5 (38.5)
Censors	1 (100)	5 (62.5)	2 (50.0)	8 (61.5)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	18.4 (18.4 - 21.0)	21.6 (5.6 - NE)	21.0 (18.4 - NE)
25th, 75th percentiles	NE, NE	18.4, 21.0	5.6, NE	18.4, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	85.7 (59.8-100.0)	66.7 (13.3-100.0)	81.8 (59.0-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	85.7 (59.8-100.0)	66.7 (13.3-100.0)	81.8 (59.0-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	85.7 (59.8-100.0)	66.7 (13.3-100.0)	81.8 (59.0-100.0)
18 Months (95% CIs)	100.0 (100.0-100.0)	85.7 (59.8-100.0)	66.7 (13.3-100.0)	81.8 (59.0-100.0)
24 Months (95% CIs)		0.0 (0.0- 0.0)	33.3 (0.0- 86.7)	32.7 (0.0- 69.0)
30 Months (95% CIs)		0.0 (0.0- 0.0)	33.3 (0.0- 86.7)	32.7 (0.0- 69.0)
36 Months (95% CIs)		0.0 (0.0- 0.0)		
42 Months (95% CIs)		0.0 (0.0- 0.0)		
48 Months (95% CIs)		0.0 (0.0- 0.0)		

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
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Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg & Prior antineoplastic therapy = No

Duration of CR+CRh+PR	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=8) n (%) (95% CIs)	MCL (N=3) n (%) (95% CIs)	All AdvSM (N=12) n (%) (95% CIs)
Events	0	3 (37.5)	1 (33.3)	4 (33.3)
Censors	1 (100)	5 (62.5)	2 (66.7)	8 (66.7)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	21.0 (15.9 - 21.0)	NE (21.6 - NE)	21.6 (15.9 - NE)
25th, 75th percentiles	NE, NE	15.9, 21.0	21.6, NE	18.4, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	85.7 (59.8-100.0)	100.0 (100.0-100.0)	90.0 (71.4-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	85.7 (59.8-100.0)	100.0 (100.0-100.0)	90.0 (71.4-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	85.7 (59.8-100.0)	100.0 (100.0-100.0)	90.0 (71.4-100.0)
18 Months (95% CIs)	100.0 (100.0-100.0)	57.1 (8.3-100.0)	100.0 (100.0-100.0)	75.0 (44.0-100.0)
24 Months (95% CIs)		0.0 (0.0- 0.0)	50.0 (0.0-100.0)	37.5 (0.0- 77.4)
30 Months (95% CIs)		0.0 (0.0- 0.0)	50.0 (0.0-100.0)	37.5 (0.0- 77.4)
36 Months (95% CIs)		0.0 (0.0- 0.0)		
42 Months (95% CIs)		0.0 (0.0- 0.0)		
48 Months (95% CIs)		0.0 (0.0- 0.0)		

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101

Starting Dose: 400 mg & Prior antineoplastic therapy = Yes

Duration of Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=2) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=2) n (%) (95% CIs)
Events		0		0
Censors		2 (100)		2 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE - NE)		NE (NE - NE)
25th, 75th percentiles		NE, NE		NE, NE
3 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
18 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
24 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
30 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101

Starting Dose: 400 mg & Prior antineoplastic therapy = Yes

Duration of CR+CRh+PR	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=2) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=2) n (%) (95% CIs)
Events		0		0
Censors		2 (100)		2 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE - NE)		NE (NE - NE)
25th, 75th percentiles		NE, NE		NE, NE
3 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
18 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
24 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
30 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101

Starting Dose: 400 mg & Prior antineoplastic therapy = No

Duration of Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=0) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=1) n (%) (95% CIs)
Events			0	0
Censors			1 (100)	1 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)			NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles			NE, NE	NE, NE
3 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
18 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
24 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
30 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101

Starting Dose: 400 mg & Prior antineoplastic therapy = No

Duration of CR+CRh+PR	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=0) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=1) n (%) (95% CIs)
Events			0	0
Censors			1 (100)	1 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)			NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles			NE, NE	NE, NE
3 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
18 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
24 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
30 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2202

Overall & Prior antineoplastic therapy = Yes

Duration of Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=15) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=17) n (%) (95% CIs)
Events	0	0	0	0
Censors	1 (100)	15 (100)	1 (100)	17 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
18 Months (95% CIs)				
24 Months (95% CIs)				
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2202

Overall & Prior antineoplastic therapy = Yes

Duration of CR+CRh+PR	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=8) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=10) n (%) (95% CIs)
Events	0	0	0	0
Censors	1 (100)	8 (100)	1 (100)	10 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
18 Months (95% CIs)				
24 Months (95% CIs)				
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2202

Overall & Prior antineoplastic therapy = No

Duration of Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=6) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=7) n (%) (95% CIs)
Events	0	0		0
Censors	1 (100)	6 (100)		7 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)		NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE		NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)		100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)		100.0 (100.0-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)		100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
18 Months (95% CIs)				
24 Months (95% CIs)				
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2202

Overall & Prior antineoplastic therapy = No

Duration of CR+CRh+PR	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=5) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=6) n (%) (95% CIs)
Events	0	0		0
Censors	1 (100)	5 (100)		6 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)		NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE		NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)		100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)		100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
18 Months (95% CIs)				
24 Months (95% CIs)				
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2202

Starting Dose: 200 mg & Prior antineoplastic therapy = Yes

Duration of Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=14) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=16) n (%) (95% CIs)
Events	0	0	0	0
Censors	1 (100)	14 (100)	1 (100)	16 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
18 Months (95% CIs)				
24 Months (95% CIs)				
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2202

Starting Dose: 200 mg & Prior antineoplastic therapy = Yes

Duration of CR+CRh+PR	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=8) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=10) n (%) (95% CIs)
Events	0	0	0	0
Censors	1 (100)	8 (100)	1 (100)	10 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
18 Months (95% CIs)				
24 Months (95% CIs)				
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2202

Starting Dose: 200 mg & Prior antineoplastic therapy = No

Duration of Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=6) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=7) n (%) (95% CIs)
Events	0	0		0
Censors	1 (100)	6 (100)		7 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)		NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE		NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)		100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)		100.0 (100.0-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)		100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
18 Months (95% CIs)				
24 Months (95% CIs)				
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2202

Starting Dose: 200 mg & Prior antineoplastic therapy = No

Duration of CR+CRh+PR	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=5) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=6) n (%) (95% CIs)
Events	0	0		0
Censors	1 (100)	5 (100)		6 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)		NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE		NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)		100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)		100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
18 Months (95% CIs)				
24 Months (95% CIs)				
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202

Overall & Prior antineoplastic therapy = Yes

Duration of Response	ASM (N=3) n (%) (95% CIs)	SM-AHN (N=31) n (%) (95% CIs)	MCL (N=5) n (%) (95% CIs)	All AdvSM (N=39) n (%) (95% CIs)
Events	0	3 (9.7)	1 (20.0)	4 (10.3)
Censors	3 (100)	28 (90.3)	4 (80.0)	35 (89.7)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)	NE (9.2 - NE)	NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	96.8 (90.6-100.0)	100.0 (100.0-100.0)	97.4 (92.5-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	96.8 (90.6-100.0)	100.0 (100.0-100.0)	97.4 (92.5-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	91.9 (81.0-100.0)	100.0 (100.0-100.0)	93.7 (85.0-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	85.8 (70.3-100.0)	75.0 (32.6-100.0)	85.0 (71.0- 98.9)
18 Months (95% CIs)	100.0 (100.0-100.0)	85.8 (70.3-100.0)	75.0 (32.6-100.0)	85.0 (71.0- 98.9)
24 Months (95% CIs)	100.0 (100.0-100.0)	85.8 (70.3-100.0)	75.0 (32.6-100.0)	85.0 (71.0- 98.9)
30 Months (95% CIs)		85.8 (70.3-100.0)		85.0 (71.0- 98.9)
36 Months (95% CIs)		85.8 (70.3-100.0)		85.0 (71.0- 98.9)
42 Months (95% CIs)		85.8 (70.3-100.0)		85.0 (71.0- 98.9)
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202

Overall & Prior antineoplastic therapy = Yes

Duration of CR+CRh+PR	ASM (N=3) n (%) (95% CIs)	SM-AHN (N=23) n (%) (95% CIs)	MCL (N=4) n (%) (95% CIs)	All AdvSM (N=30) n (%) (95% CIs)
Events	0	3 (13.0)	0	3 (10.0)
Censors	3 (100)	20 (87.0)	4 (100)	27 (90.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	95.7 (87.3-100.0)	100.0 (100.0-100.0)	96.7 (90.2-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	95.7 (87.3-100.0)	100.0 (100.0-100.0)	96.7 (90.2-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	90.0 (76.8-100.0)	100.0 (100.0-100.0)	92.3 (81.9-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	83.1 (65.2-100.0)	100.0 (100.0-100.0)	87.1 (73.3-100.0)
18 Months (95% CIs)	100.0 (100.0-100.0)	83.1 (65.2-100.0)	100.0 (100.0-100.0)	87.1 (73.3-100.0)
24 Months (95% CIs)	100.0 (100.0-100.0)	83.1 (65.2-100.0)	100.0 (100.0-100.0)	87.1 (73.3-100.0)
30 Months (95% CIs)		83.1 (65.2-100.0)		87.1 (73.3-100.0)
36 Months (95% CIs)		83.1 (65.2-100.0)		87.1 (73.3-100.0)
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202

Overall & Prior antineoplastic therapy = No

Duration of Response	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=18) n (%) (95% CIs)	MCL (N=5) n (%) (95% CIs)	All AdvSM (N=25) n (%) (95% CIs)
Events	0	6 (33.3)	2 (40.0)	8 (32.0)
Censors	2 (100)	12 (66.7)	3 (60.0)	17 (68.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	21.7 (18.4 - 38.3)	NE (5.6 - NE)	28.6 (21.0 - 38.3)
25th, 75th percentiles	NE, NE	21.0, 38.3	13.6, NE	21.0, 38.3
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	93.3 (80.7-100.0)	75.0 (32.6-100.0)	90.5 (77.9-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	93.3 (80.7-100.0)	75.0 (32.6-100.0)	90.5 (77.9-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	93.3 (80.7-100.0)	75.0 (32.6-100.0)	90.5 (77.9-100.0)
18 Months (95% CIs)	100.0 (100.0-100.0)	93.3 (80.7-100.0)	75.0 (32.6-100.0)	90.5 (77.9-100.0)
24 Months (95% CIs)		46.7 (8.8- 84.5)	50.0 (1.0- 99.0)	54.3 (25.8- 82.8)
30 Months (95% CIs)		31.1 (0.0- 66.6)	50.0 (1.0- 99.0)	43.4 (13.7- 73.1)
36 Months (95% CIs)		31.1 (0.0- 66.6)		43.4 (13.7- 73.1)
42 Months (95% CIs)		0.0 (0.0- 0.0)		0.0 (0.0- 0.0)
48 Months (95% CIs)		0.0 (0.0- 0.0)		0.0 (0.0- 0.0)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202

Overall & Prior antineoplastic therapy = No

Duration of CR+CRh+PR	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=17) n (%) (95% CIs)	MCL (N=4) n (%) (95% CIs)	All AdvSM (N=23) n (%) (95% CIs)
Events	0	6 (35.3)	1 (25.0)	7 (30.4)
Censors	2 (100)	11 (64.7)	3 (75.0)	16 (69.6)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	21.0 (15.9 - 38.3)	NE (21.6 - NE)	21.6 (19.4 - 38.3)
25th, 75th percentiles	NE, NE	15.9, 38.3	21.6, NE	19.4, 38.3
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	92.9 (79.4-100.0)	100.0 (100.0-100.0)	94.7 (84.7-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	92.9 (79.4-100.0)	100.0 (100.0-100.0)	94.7 (84.7-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	92.9 (79.4-100.0)	100.0 (100.0-100.0)	94.7 (84.7-100.0)
18 Months (95% CIs)	100.0 (100.0-100.0)	67.7 (36.1- 99.3)	100.0 (100.0-100.0)	78.2 (55.6-100.0)
24 Months (95% CIs)		33.9 (0.0- 70.6)	66.7 (13.3-100.0)	48.8 (19.1- 78.6)
30 Months (95% CIs)		33.9 (0.0- 70.6)	66.7 (13.3-100.0)	48.8 (19.1- 78.6)
36 Months (95% CIs)		33.9 (0.0- 70.6)		48.8 (19.1- 78.6)
42 Months (95% CIs)		0.0 (0.0- 0.0)		0.0 (0.0- 0.0)
48 Months (95% CIs)		0.0 (0.0- 0.0)		0.0 (0.0- 0.0)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg & Prior antineoplastic therapy = Yes

Duration of Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=3) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=4) n (%) (95% CIs)
Events		0	0	0
Censors		3 (100)	1 (100)	4 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles		NE, NE	NE, NE	NE, NE
3 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
18 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
24 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
30 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
36 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
42 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg & Prior antineoplastic therapy = Yes

Duration of CR+CRh+PR	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=2) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=3) n (%) (95% CIs)
Events		0	0	0
Censors		2 (100)	1 (100)	3 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles		NE, NE	NE, NE	NE, NE
3 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
18 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
24 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
30 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
36 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg & Prior antineoplastic therapy = No

Duration of Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=4) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=4) n (%) (95% CIs)
Events		3 (75.0)		3 (75.0)
Censors		1 (25.0)		1 (25.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		33.5 (21.7 - 38.3)		33.5 (21.7 - 38.3)
25th, 75th percentiles		25.1, 38.3		25.1, 38.3
3 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
18 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
24 Months (95% CIs)		75.0 (32.6-100.0)		75.0 (32.6-100.0)
30 Months (95% CIs)		50.0 (1.0- 99.0)		50.0 (1.0- 99.0)
36 Months (95% CIs)		50.0 (1.0- 99.0)		50.0 (1.0- 99.0)
42 Months (95% CIs)		0.0 (0.0- 0.0)		0.0 (0.0- 0.0)
48 Months (95% CIs)		0.0 (0.0- 0.0)		0.0 (0.0- 0.0)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg & Prior antineoplastic therapy = No

Duration of CR+CRh+PR	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=4) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=4) n (%) (95% CIs)
Events		3 (75.0)		3 (75.0)
Censors		1 (25.0)		1 (25.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		28.8 (14.8 - 38.3)		28.8 (14.8 - 38.3)
25th, 75th percentiles		17.1, 38.3		17.1, 38.3
3 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
18 Months (95% CIs)		75.0 (32.6-100.0)		75.0 (32.6-100.0)
24 Months (95% CIs)		50.0 (1.0- 99.0)		50.0 (1.0- 99.0)
30 Months (95% CIs)		50.0 (1.0- 99.0)		50.0 (1.0- 99.0)
36 Months (95% CIs)		50.0 (1.0- 99.0)		50.0 (1.0- 99.0)
42 Months (95% CIs)		0.0 (0.0- 0.0)		0.0 (0.0- 0.0)
48 Months (95% CIs)		0.0 (0.0- 0.0)		0.0 (0.0- 0.0)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg & Prior antineoplastic therapy = Yes

Duration of Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=20) n (%) (95% CIs)	MCL (N=3) n (%) (95% CIs)	All AdvSM (N=24) n (%) (95% CIs)
Events	0	1 (5.0)	0	1 (4.2)
Censors	1 (100)	19 (95.0)	3 (100)	23 (95.8)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)		85.7 (59.8-100.0)	100.0 (100.0-100.0)	88.9 (68.4-100.0)
18 Months (95% CIs)		85.7 (59.8-100.0)	100.0 (100.0-100.0)	88.9 (68.4-100.0)
24 Months (95% CIs)		85.7 (59.8-100.0)		88.9 (68.4-100.0)
30 Months (95% CIs)		85.7 (59.8-100.0)		88.9 (68.4-100.0)
36 Months (95% CIs)		85.7 (59.8-100.0)		88.9 (68.4-100.0)
42 Months (95% CIs)		85.7 (59.8-100.0)		88.9 (68.4-100.0)
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg & Prior antineoplastic therapy = Yes

Duration of CR+CRh+PR	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=13) n (%) (95% CIs)	MCL (N=3) n (%) (95% CIs)	All AdvSM (N=17) n (%) (95% CIs)
Events	0	1 (7.7)	0	1 (5.9)
Censors	1 (100)	12 (92.3)	3 (100)	16 (94.1)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)		83.3 (53.5-100.0)	100.0 (100.0-100.0)	87.5 (64.6-100.0)
18 Months (95% CIs)		83.3 (53.5-100.0)	100.0 (100.0-100.0)	87.5 (64.6-100.0)
24 Months (95% CIs)		83.3 (53.5-100.0)		87.5 (64.6-100.0)
30 Months (95% CIs)		83.3 (53.5-100.0)		87.5 (64.6-100.0)
36 Months (95% CIs)		83.3 (53.5-100.0)		87.5 (64.6-100.0)
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg & Prior antineoplastic therapy = No

Duration of Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=11) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=14) n (%) (95% CIs)
Events	0	3 (27.3)	1 (50.0)	4 (28.6)
Censors	1 (100)	8 (72.7)	1 (50.0)	10 (71.4)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	33.5 (21.7 - 38.3)	21.6 (NE - NE)	28.6 (21.6 - 38.3)
25th, 75th percentiles	NE, NE	25.1, 38.3	21.6, 21.6	21.7, 38.3
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
18 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
24 Months (95% CIs)		75.0 (32.6-100.0)	0.0 (0.0- 0.0)	60.0 (17.1-100.0)
30 Months (95% CIs)		50.0 (1.0- 99.0)	0.0 (0.0- 0.0)	40.0 (0.0- 82.9)
36 Months (95% CIs)		50.0 (1.0- 99.0)	0.0 (0.0- 0.0)	40.0 (0.0- 82.9)
42 Months (95% CIs)		0.0 (0.0- 0.0)	0.0 (0.0- 0.0)	0.0 (0.0- 0.0)
48 Months (95% CIs)		0.0 (0.0- 0.0)	0.0 (0.0- 0.0)	0.0 (0.0- 0.0)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg & Prior antineoplastic therapy = No

Duration of CR+CRh+PR	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=10) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=13) n (%) (95% CIs)
Events	0	3 (30.0)	1 (50.0)	4 (30.8)
Censors	1 (100)	7 (70.0)	1 (50.0)	9 (69.2)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	38.3 (14.8 - 38.3)	21.6 (NE - NE)	21.6 (19.4 - 38.3)
25th, 75th percentiles	NE, NE	19.4, 38.3	21.6, 21.6	19.4, 38.3
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
18 Months (95% CIs)		80.0 (44.9-100.0)	100.0 (100.0-100.0)	83.3 (53.5-100.0)
24 Months (95% CIs)		53.3 (4.7-100.0)	0.0 (0.0- 0.0)	41.7 (0.0- 85.1)
30 Months (95% CIs)		53.3 (4.7-100.0)	0.0 (0.0- 0.0)	41.7 (0.0- 85.1)
36 Months (95% CIs)		53.3 (4.7-100.0)	0.0 (0.0- 0.0)	41.7 (0.0- 85.1)
42 Months (95% CIs)		0.0 (0.0- 0.0)	0.0 (0.0- 0.0)	0.0 (0.0- 0.0)
48 Months (95% CIs)		0.0 (0.0- 0.0)	0.0 (0.0- 0.0)	0.0 (0.0- 0.0)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg & Prior antineoplastic therapy = Yes				
	ASM (N=1)	SM-AHN (N=17)	MCL (N=2)	All AdvSM (N=20)
Duration of Response	n (%) (95% CIs)	n (%) (95% CIs)	n (%) (95% CIs)	n (%) (95% CIs)
Events	0	1 (5.9)	0	1 (5.0)
Censors	1 (100)	16 (94.1)	2 (100)	19 (95.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (11.2 - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)		80.0 (44.9-100.0)	100.0 (100.0-100.0)	83.3 (53.5-100.0)
18 Months (95% CIs)				
24 Months (95% CIs)				
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg & Prior antineoplastic therapy = Yes

Duration of CR+CRh+PR	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=11) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=14) n (%) (95% CIs)
Events	0	1 (9.1)	0	1 (7.1)
Censors	1 (100)	10 (90.9)	2 (100)	13 (92.9)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (11.2 - NE)	NE (NE - NE)	NE (11.2 - NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)		75.0 (32.6-100.0)	100.0 (100.0-100.0)	80.0 (44.9-100.0)
18 Months (95% CIs)				
24 Months (95% CIs)				
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg & Prior antineoplastic therapy = No

Duration of Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=7) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=10) n (%) (95% CIs)
Events	0	0	1 (50.0)	1 (10.0)
Censors	1 (100)	7 (100)	1 (50.0)	9 (90.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)	21.6 (NE - NE)	21.6 (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE	21.6, 21.6	21.6, 21.6
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
18 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
24 Months (95% CIs)			0.0 (0.0- 0.0)	0.0 (0.0- 0.0)
30 Months (95% CIs)			0.0 (0.0- 0.0)	0.0 (0.0- 0.0)
36 Months (95% CIs)			0.0 (0.0- 0.0)	0.0 (0.0- 0.0)
42 Months (95% CIs)			0.0 (0.0- 0.0)	0.0 (0.0- 0.0)
48 Months (95% CIs)			0.0 (0.0- 0.0)	0.0 (0.0- 0.0)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg & Prior antineoplastic therapy = No

Duration of CR+CRh+PR	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=6) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=9) n (%) (95% CIs)
Events	0	0	1 (50.0)	1 (11.1)
Censors	1 (100)	6 (100)	1 (50.0)	8 (88.9)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)	21.6 (NE - NE)	21.6 (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE	21.6, 21.6	21.6, 21.6
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
18 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
24 Months (95% CIs)			0.0 (0.0- 0.0)	0.0 (0.0- 0.0)
30 Months (95% CIs)			0.0 (0.0- 0.0)	0.0 (0.0- 0.0)
36 Months (95% CIs)			0.0 (0.0- 0.0)	0.0 (0.0- 0.0)
42 Months (95% CIs)			0.0 (0.0- 0.0)	0.0 (0.0- 0.0)
48 Months (95% CIs)			0.0 (0.0- 0.0)	0.0 (0.0- 0.0)

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg & Prior antineoplastic therapy = Yes

Duration of Response	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=9) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=13) n (%) (95% CIs)
Events	0	2 (22.2)	1 (50.0)	3 (23.1)
Censors	2 (100)	7 (77.8)	1 (50.0)	10 (76.9)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)	NE (9.2 - NE)	NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE	9.2, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	88.9 (68.4-100.0)	100.0 (100.0-100.0)	92.3 (77.8-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	88.9 (68.4-100.0)	100.0 (100.0-100.0)	92.3 (77.8-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	77.8 (50.6-100.0)	100.0 (100.0-100.0)	84.6 (65.0-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	77.8 (50.6-100.0)	50.0 (0.0-100.0)	76.2 (52.5- 99.8)
18 Months (95% CIs)	100.0 (100.0-100.0)	77.8 (50.6-100.0)	50.0 (0.0-100.0)	76.2 (52.5- 99.8)
24 Months (95% CIs)	100.0 (100.0-100.0)	77.8 (50.6-100.0)	50.0 (0.0-100.0)	76.2 (52.5- 99.8)
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg & Prior antineoplastic therapy = Yes

Duration of CR+CRh+PR	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=8) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=11) n (%) (95% CIs)
Events	0	2 (25.0)	0	2 (18.2)
Censors	2 (100)	6 (75.0)	1 (100)	9 (81.8)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (7.5 - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	87.5 (64.6-100.0)	100.0 (100.0-100.0)	90.9 (73.9-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	87.5 (64.6-100.0)	100.0 (100.0-100.0)	90.9 (73.9-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	75.0 (45.0-100.0)	100.0 (100.0-100.0)	81.8 (59.0-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	75.0 (45.0-100.0)	100.0 (100.0-100.0)	81.8 (59.0-100.0)
18 Months (95% CIs)	100.0 (100.0-100.0)	75.0 (45.0-100.0)	100.0 (100.0-100.0)	81.8 (59.0-100.0)
24 Months (95% CIs)	100.0 (100.0-100.0)		100.0 (100.0-100.0)	81.8 (59.0-100.0)
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg & Prior antineoplastic therapy = No

Duration of Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=7) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=10) n (%) (95% CIs)
Events	0	3 (42.9)	1 (50.0)	4 (40.0)
Censors	1 (100)	4 (57.1)	1 (50.0)	6 (60.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	18.4 (18.4 - 21.0)	NE (5.6 - NE)	21.0 (18.4 - NE)
25th, 75th percentiles	NE, NE	18.4, 21.0	5.6, NE	18.4, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	83.3 (53.5-100.0)	50.0 (0.0-100.0)	77.8 (50.6-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	83.3 (53.5-100.0)	50.0 (0.0-100.0)	77.8 (50.6-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	83.3 (53.5-100.0)	50.0 (0.0-100.0)	77.8 (50.6-100.0)
18 Months (95% CIs)	100.0 (100.0-100.0)	83.3 (53.5-100.0)	50.0 (0.0-100.0)	77.8 (50.6-100.0)
24 Months (95% CIs)		0.0 (0.0- 0.0)	50.0 (0.0-100.0)	38.9 (0.0- 79.3)
30 Months (95% CIs)		0.0 (0.0- 0.0)	50.0 (0.0-100.0)	38.9 (0.0- 79.3)
36 Months (95% CIs)		0.0 (0.0- 0.0)		
42 Months (95% CIs)		0.0 (0.0- 0.0)		
48 Months (95% CIs)		0.0 (0.0- 0.0)		

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg & Prior antineoplastic therapy = No

Duration of CR+CRh+PR	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=7) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=9) n (%) (95% CIs)
Events	0	3 (42.9)	0	3 (33.3)
Censors	1 (100)	4 (57.1)	1 (100)	6 (66.7)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	21.0 (15.9 - 21.0)	NE (NE - NE)	21.0 (15.9 - NE)
25th, 75th percentiles	NE, NE	15.9, 21.0	NE, NE	15.9, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	83.3 (53.5-100.0)	100.0 (100.0-100.0)	87.5 (64.6-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	83.3 (53.5-100.0)	100.0 (100.0-100.0)	87.5 (64.6-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	83.3 (53.5-100.0)	100.0 (100.0-100.0)	87.5 (64.6-100.0)
18 Months (95% CIs)	100.0 (100.0-100.0)	55.6 (6.9-100.0)	100.0 (100.0-100.0)	70.0 (34.3-100.0)
24 Months (95% CIs)		0.0 (0.0- 0.0)	100.0 (100.0-100.0)	46.7 (2.4- 91.0)
30 Months (95% CIs)		0.0 (0.0- 0.0)	100.0 (100.0-100.0)	46.7 (2.4- 91.0)
36 Months (95% CIs)		0.0 (0.0- 0.0)		
42 Months (95% CIs)		0.0 (0.0- 0.0)		
48 Months (95% CIs)		0.0 (0.0- 0.0)		

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg & Prior antineoplastic therapy = Yes

Duration of Response	ASM (N=3) n (%) (95% CIs)	SM-AHN (N=26) n (%) (95% CIs)	MCL (N=4) n (%) (95% CIs)	All AdvSM (N=33) n (%) (95% CIs)
Events	0	3 (11.5)	1 (25.0)	4 (12.1)
Censors	3 (100)	23 (88.5)	3 (75.0)	29 (87.9)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)	NE (9.2 - NE)	NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE	9.2, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	96.2 (88.8-100.0)	100.0 (100.0-100.0)	97.0 (91.1-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	96.2 (88.8-100.0)	100.0 (100.0-100.0)	97.0 (91.1-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	90.1 (76.8-100.0)	100.0 (100.0-100.0)	92.4 (81.9-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	81.9 (62.4-100.0)	66.7 (13.3-100.0)	81.1 (63.9- 98.4)
18 Months (95% CIs)	100.0 (100.0-100.0)	81.9 (62.4-100.0)	66.7 (13.3-100.0)	81.1 (63.9- 98.4)
24 Months (95% CIs)	100.0 (100.0-100.0)	81.9 (62.4-100.0)	66.7 (13.3-100.0)	81.1 (63.9- 98.4)
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg & Prior antineoplastic therapy = Yes

Duration of CR+CRh+PR	ASM (N=3) n (%) (95% CIs)	SM-AHN (N=19) n (%) (95% CIs)	MCL (N=3) n (%) (95% CIs)	All AdvSM (N=25) n (%) (95% CIs)
Events	0	3 (15.8)	0	3 (12.0)
Censors	3 (100)	16 (84.2)	3 (100)	22 (88.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	94.7 (84.7-100.0)	100.0 (100.0-100.0)	96.0 (88.3-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	94.7 (84.7-100.0)	100.0 (100.0-100.0)	96.0 (88.3-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	87.4 (70.9-100.0)	100.0 (100.0-100.0)	90.4 (77.4-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	77.7 (54.5-100.0)	100.0 (100.0-100.0)	83.4 (65.7-100.0)
18 Months (95% CIs)	100.0 (100.0-100.0)	77.7 (54.5-100.0)	100.0 (100.0-100.0)	83.4 (65.7-100.0)
24 Months (95% CIs)	100.0 (100.0-100.0)		100.0 (100.0-100.0)	83.4 (65.7-100.0)
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg & Prior antineoplastic therapy = No

Duration of Response	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=14) n (%) (95% CIs)	MCL (N=4) n (%) (95% CIs)	All AdvSM (N=20) n (%) (95% CIs)
Events	0	3 (21.4)	2 (50.0)	5 (25.0)
Censors	2 (100)	11 (78.6)	2 (50.0)	15 (75.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	18.4 (18.4 - 21.0)	21.6 (5.6 - NE)	21.6 (18.4 - NE)
25th, 75th percentiles	NE, NE	18.4, 21.0	5.6, NE	18.4, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	90.9 (73.9-100.0)	66.7 (13.3-100.0)	87.5 (71.3-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	90.9 (73.9-100.0)	66.7 (13.3-100.0)	87.5 (71.3-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	90.9 (73.9-100.0)	66.7 (13.3-100.0)	87.5 (71.3-100.0)
18 Months (95% CIs)	100.0 (100.0-100.0)	90.9 (73.9-100.0)	66.7 (13.3-100.0)	87.5 (71.3-100.0)
24 Months (95% CIs)		0.0 (0.0- 0.0)	33.3 (0.0- 86.7)	35.0 (0.0- 73.1)
30 Months (95% CIs)		0.0 (0.0- 0.0)	33.3 (0.0- 86.7)	35.0 (0.0- 73.1)
36 Months (95% CIs)		0.0 (0.0- 0.0)		
42 Months (95% CIs)		0.0 (0.0- 0.0)		
48 Months (95% CIs)		0.0 (0.0- 0.0)		

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg & Prior antineoplastic therapy = No

Duration of CR+CRh+PR	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=13) n (%) (95% CIs)	MCL (N=3) n (%) (95% CIs)	All AdvSM (N=18) n (%) (95% CIs)
Events	0	3 (23.1)	1 (33.3)	4 (22.2)
Censors	2 (100)	10 (76.9)	2 (66.7)	14 (77.8)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	21.0 (15.9 - 21.0)	NE (21.6 - NE)	21.6 (15.9 - NE)
25th, 75th percentiles	NE, NE	15.9, 21.0	21.6, NE	21.0, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	90.0 (71.4-100.0)	100.0 (100.0-100.0)	92.9 (79.4-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	90.0 (71.4-100.0)	100.0 (100.0-100.0)	92.9 (79.4-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	90.0 (71.4-100.0)	100.0 (100.0-100.0)	92.9 (79.4-100.0)
18 Months (95% CIs)	100.0 (100.0-100.0)	60.0 (10.4-100.0)	100.0 (100.0-100.0)	77.4 (47.5-100.0)
24 Months (95% CIs)		0.0 (0.0- 0.0)	50.0 (0.0-100.0)	38.7 (0.0- 79.4)
30 Months (95% CIs)		0.0 (0.0- 0.0)	50.0 (0.0-100.0)	38.7 (0.0- 79.4)
36 Months (95% CIs)		0.0 (0.0- 0.0)		
42 Months (95% CIs)		0.0 (0.0- 0.0)		
48 Months (95% CIs)		0.0 (0.0- 0.0)		

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg & Prior antineoplastic therapy = Yes

Duration of Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=2) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=2) n (%) (95% CIs)
Events		0		0
Censors		2 (100)		2 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE - NE)		NE (NE - NE)
25th, 75th percentiles		NE, NE		NE, NE
3 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
18 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
24 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
30 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg & Prior antineoplastic therapy = Yes

Duration of CR+CRh+PR	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=2) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=2) n (%) (95% CIs)
Events		0		0
Censors		2 (100)		2 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE - NE)		NE (NE - NE)
25th, 75th percentiles		NE, NE		NE, NE
3 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
18 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
24 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
30 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg & Prior antineoplastic therapy = No

Duration of Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=0) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=1) n (%) (95% CIs)
Events			0	0
Censors			1 (100)	1 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)			NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles			NE, NE	NE, NE
3 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
18 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
24 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
30 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Table 14.2.2.1b
Summary of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg & Prior antineoplastic therapy = No

Duration of CR+CRh+PR	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=0) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=1) n (%) (95% CIs)
Events			0	0
Censors			1 (100)	1 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)			NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles			NE, NE	NE, NE
3 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
18 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
24 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
30 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, NE=Not Evaluable
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-adj-m-dur-rac-tpy.Date: 20:59/02NOV2020

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: Overall
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR+CI)

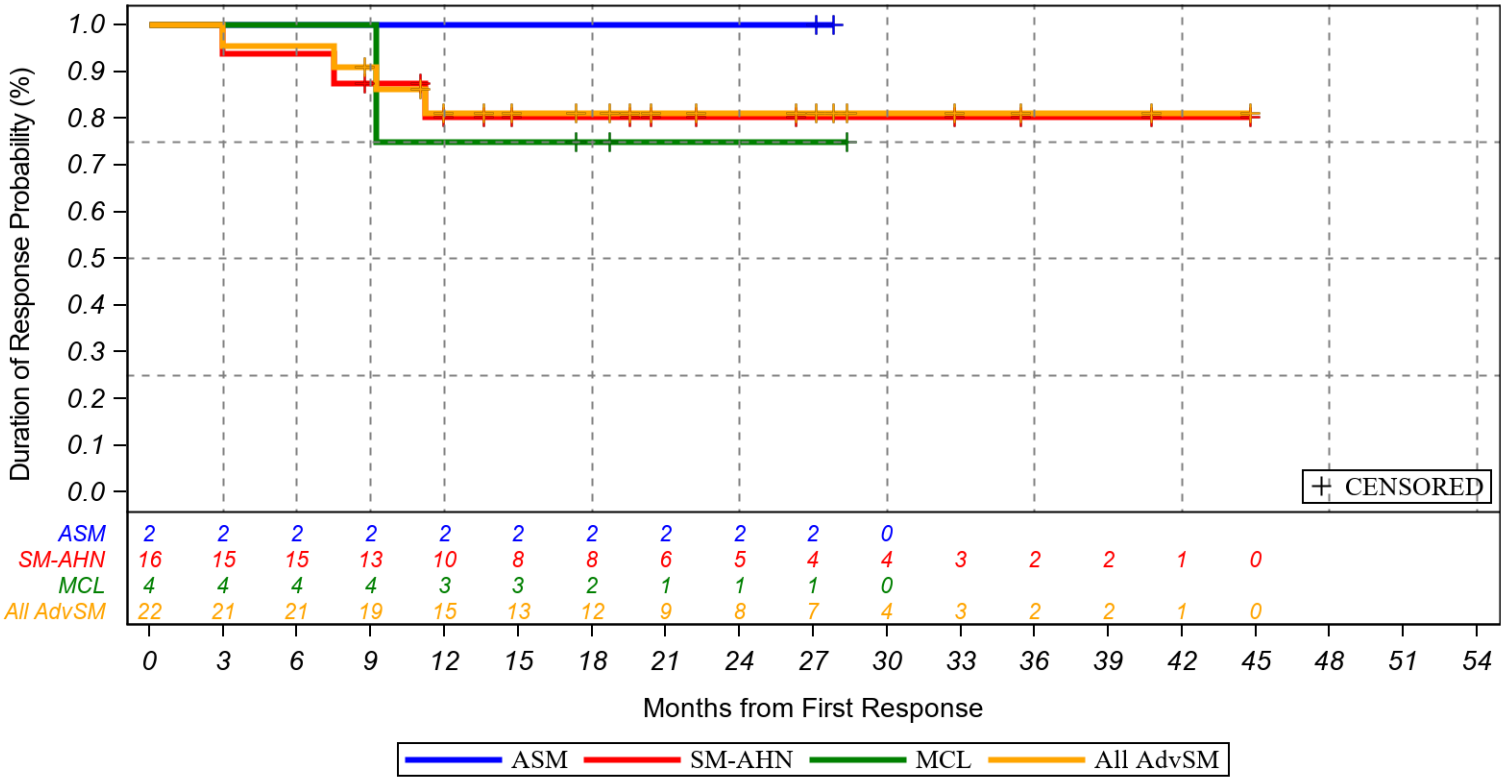

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: Overall
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR)

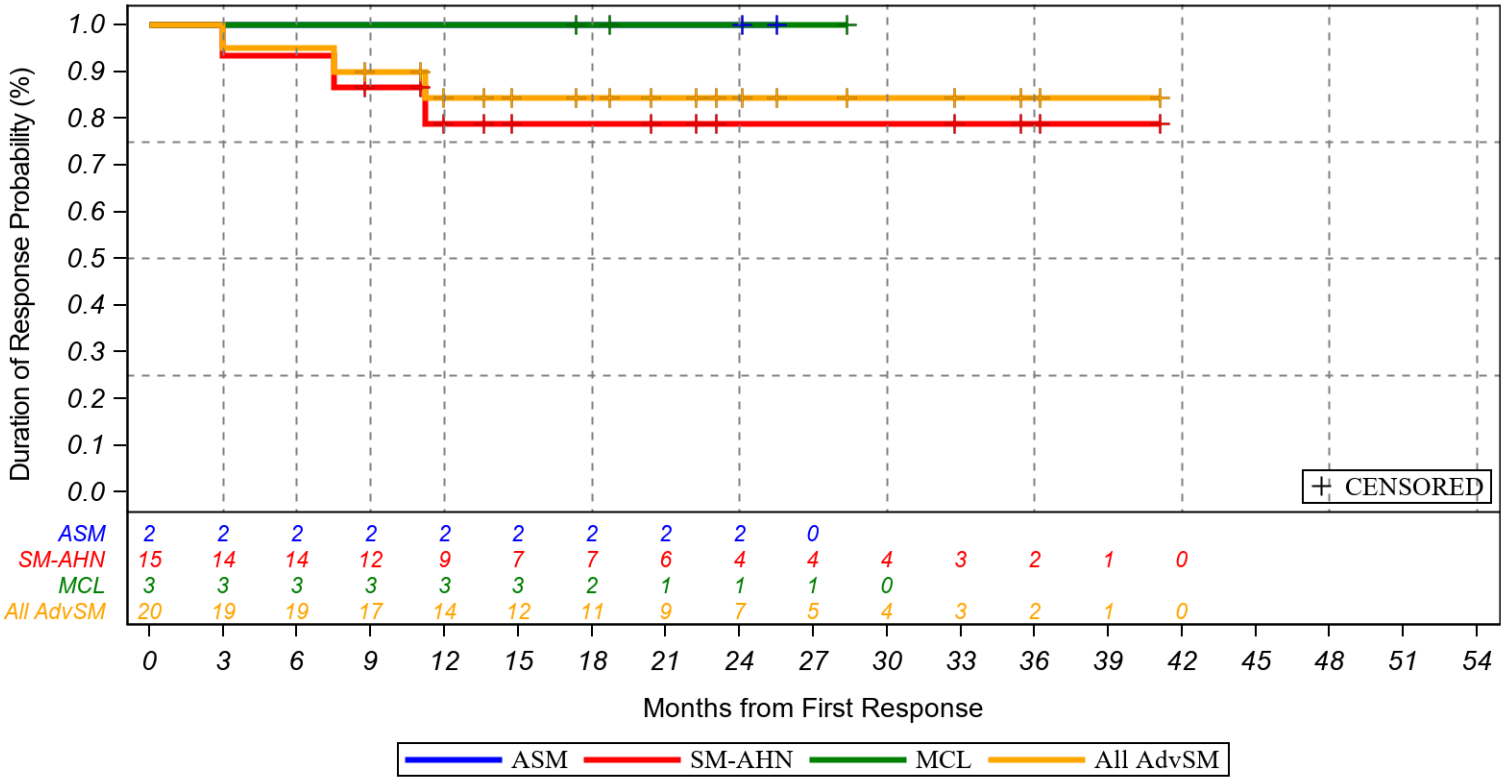

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: Overall
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR+CI)

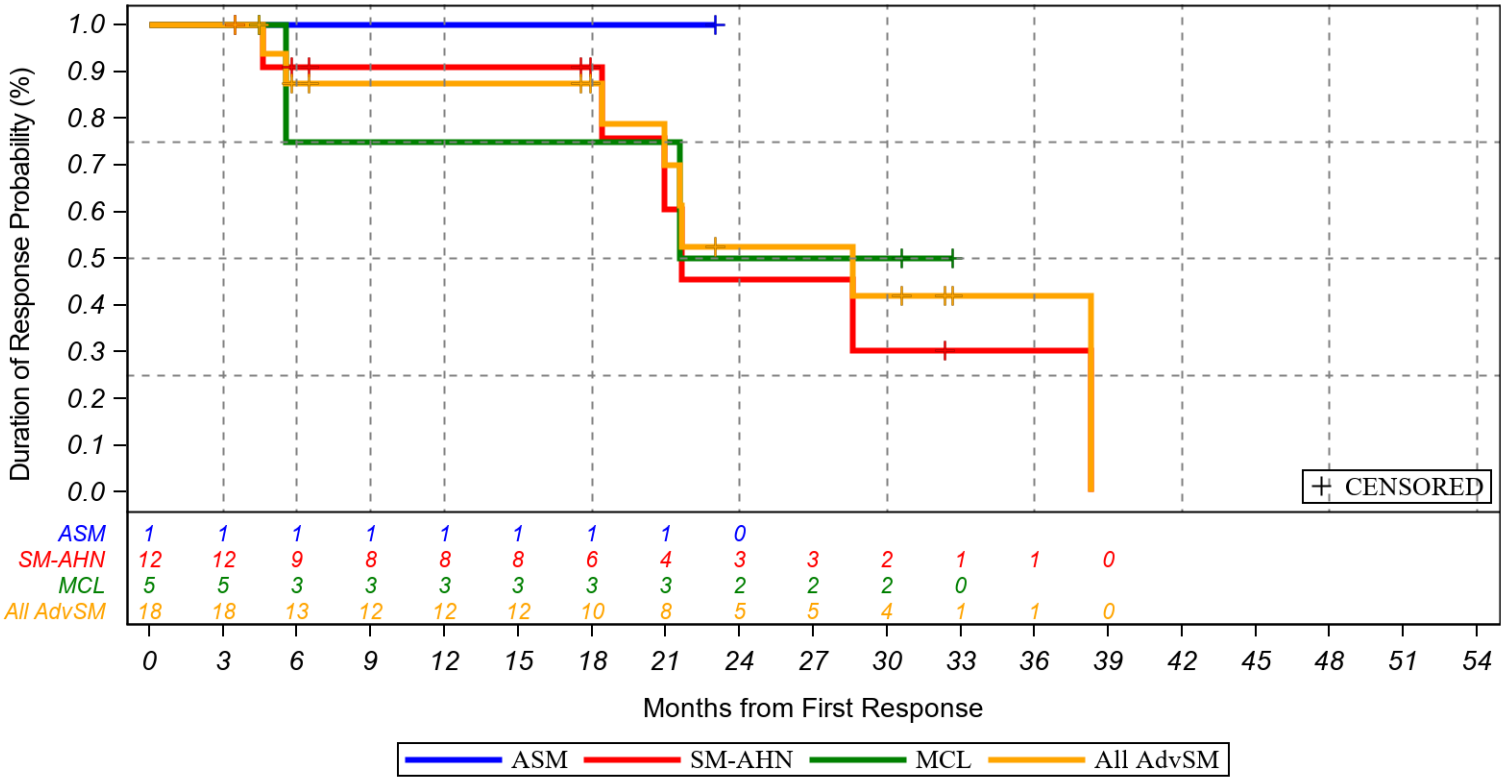

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: Overall
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR)

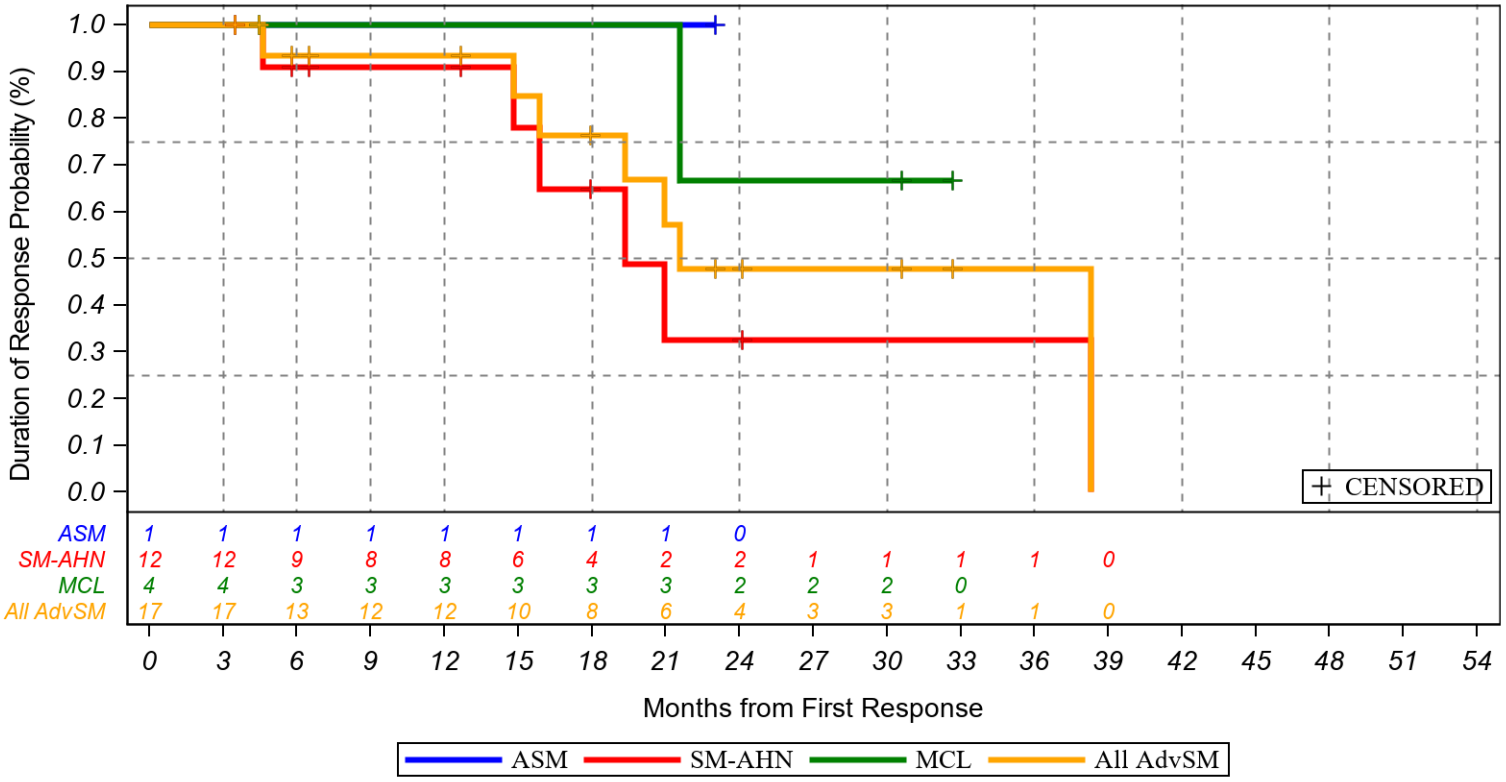

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: < 200 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR+CI)

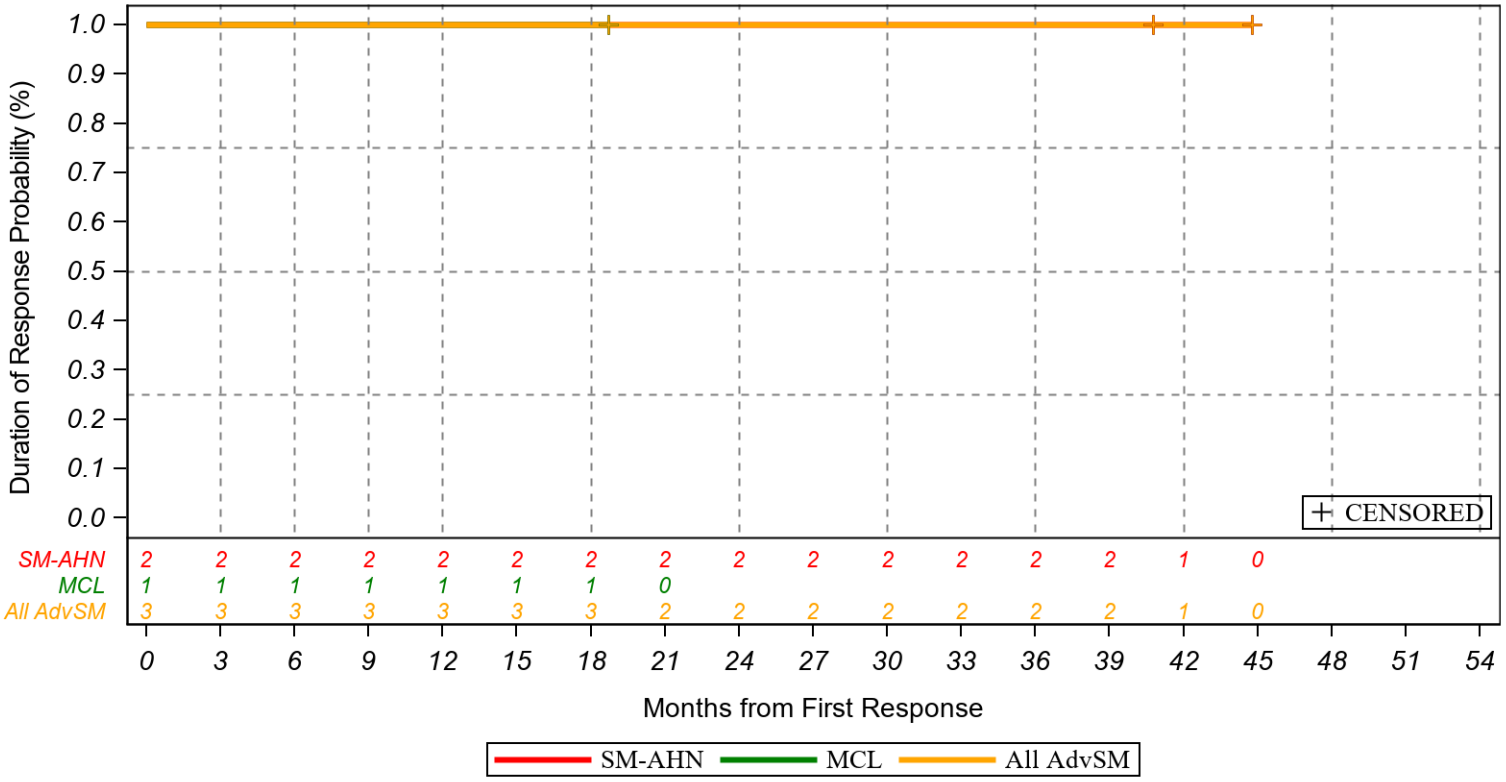

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: < 200 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR)

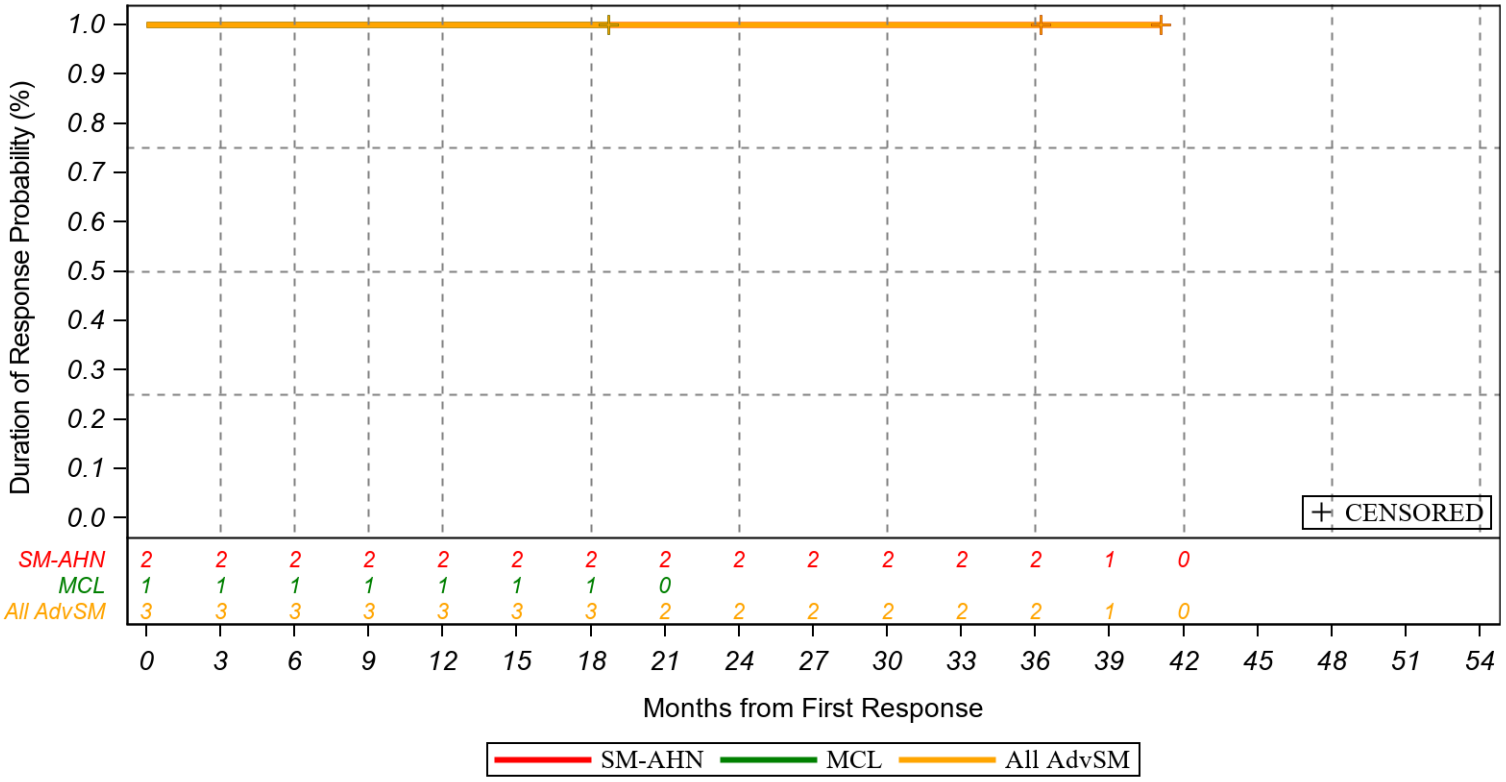

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: < 200 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR+CI)

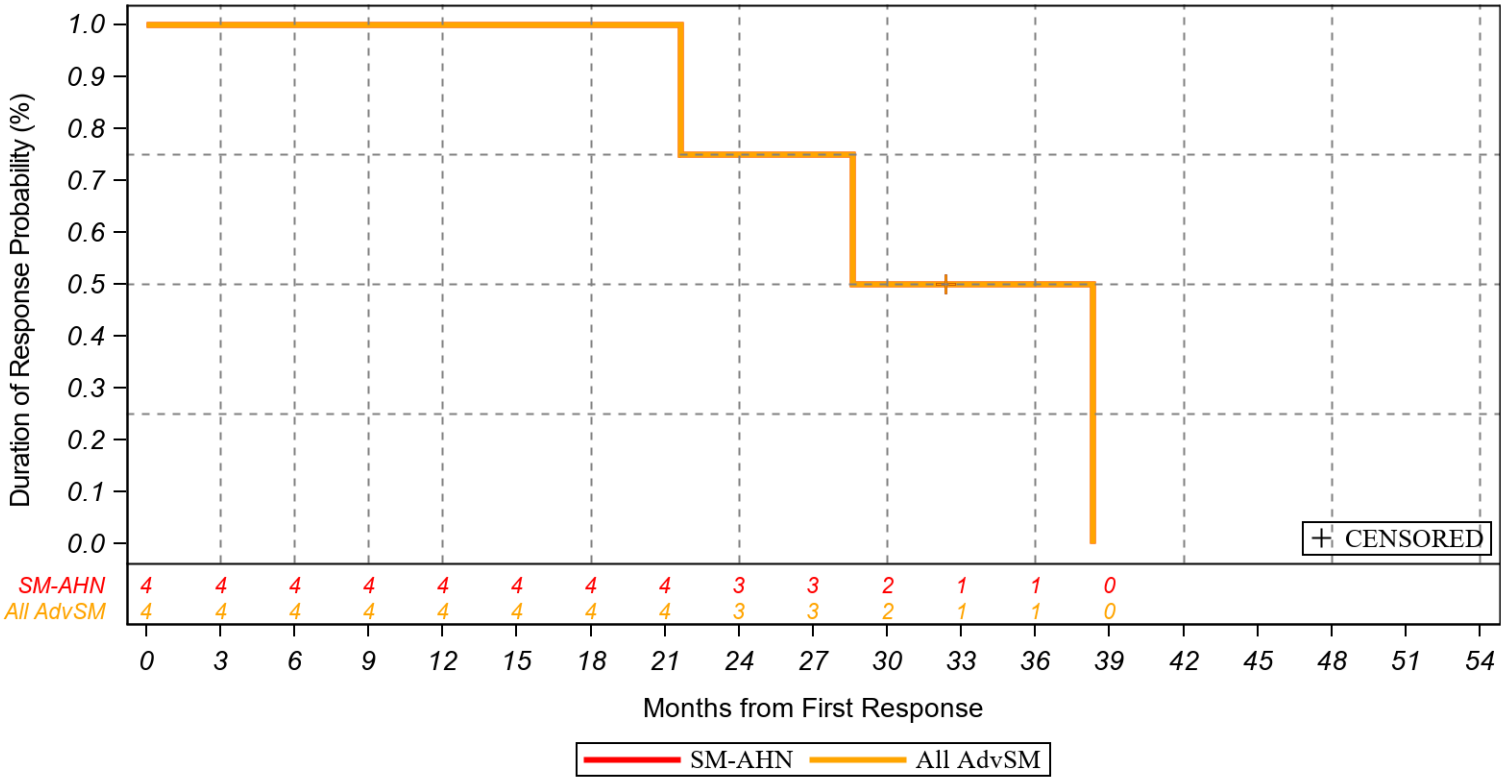

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: < 200 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR)

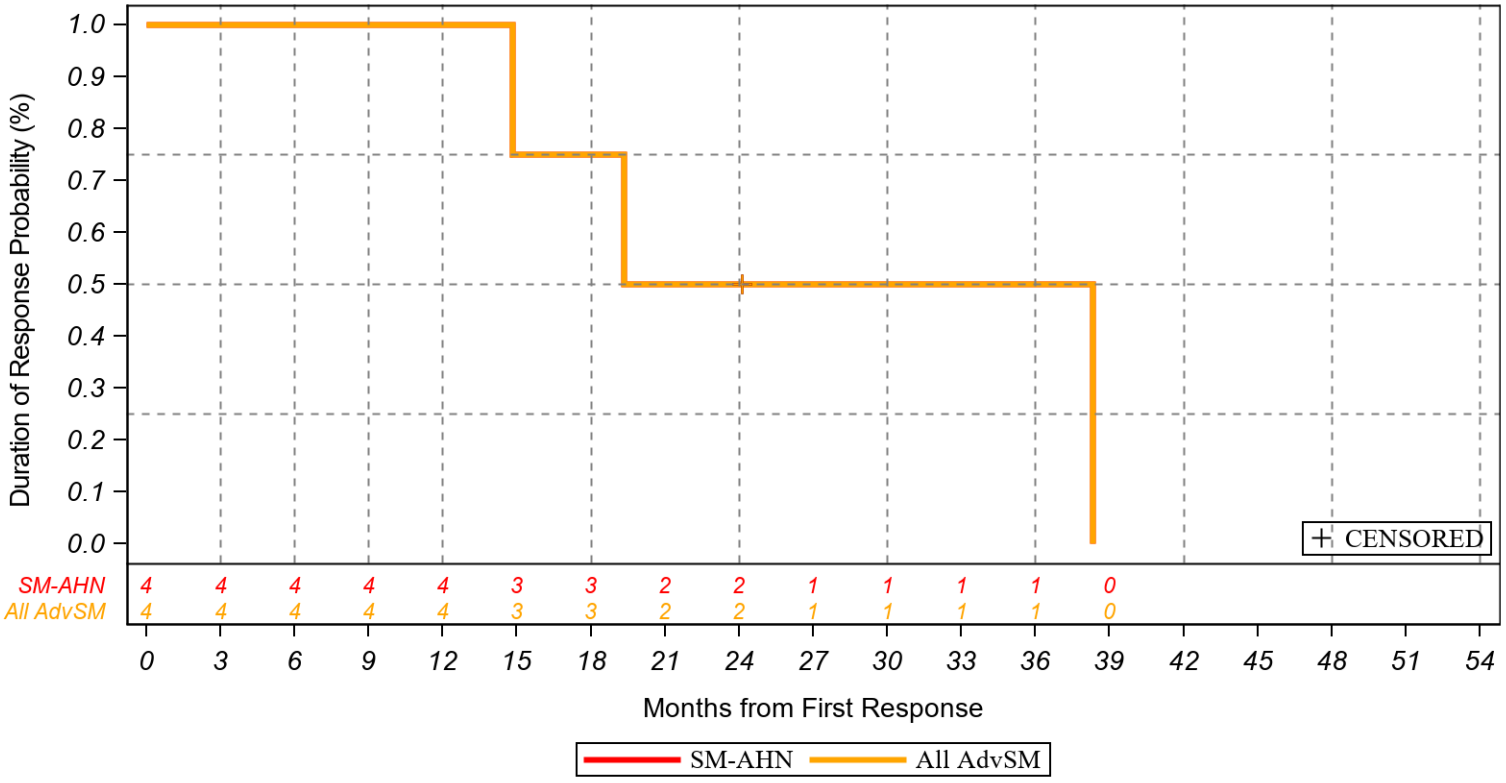

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: < 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR+CI)

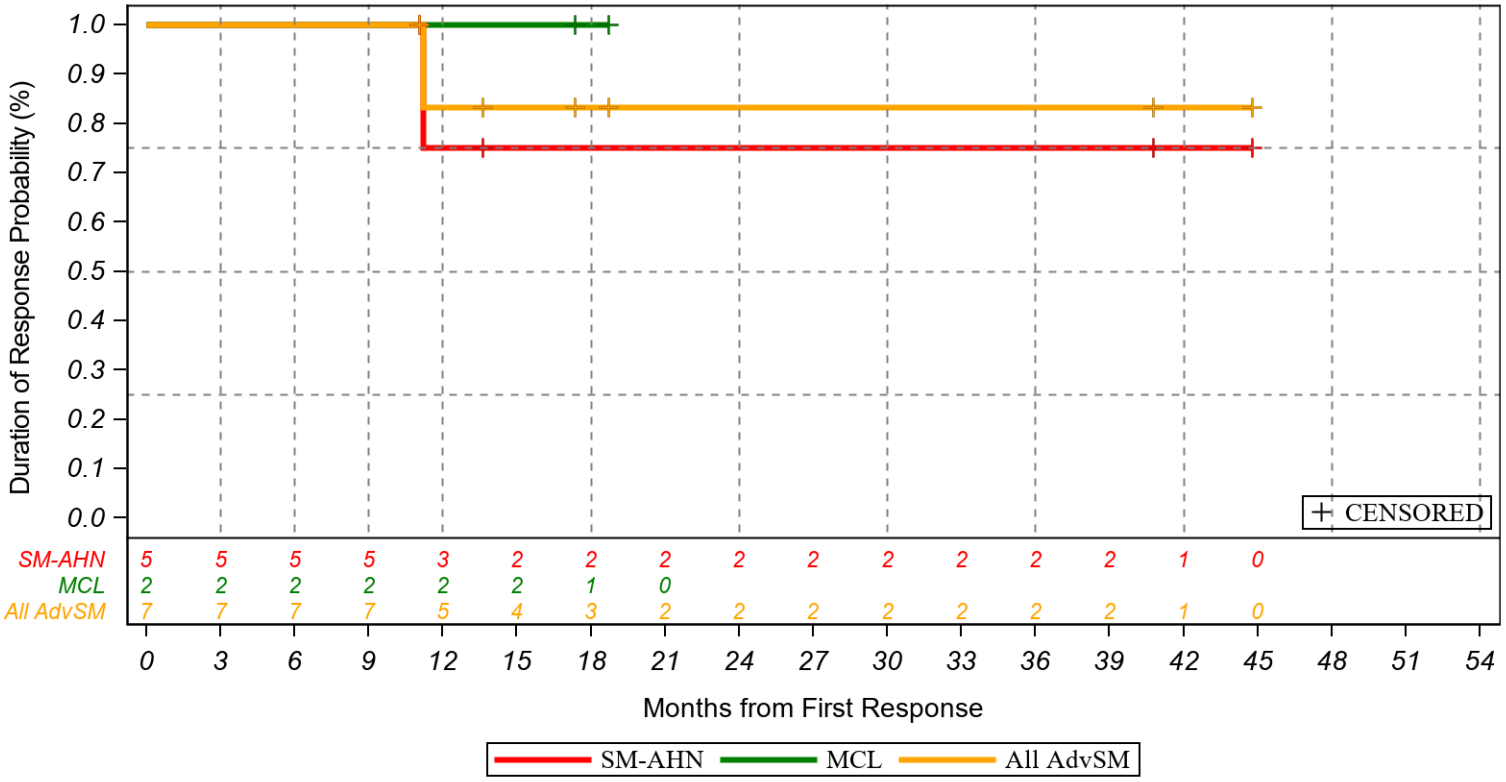

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: < 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR)

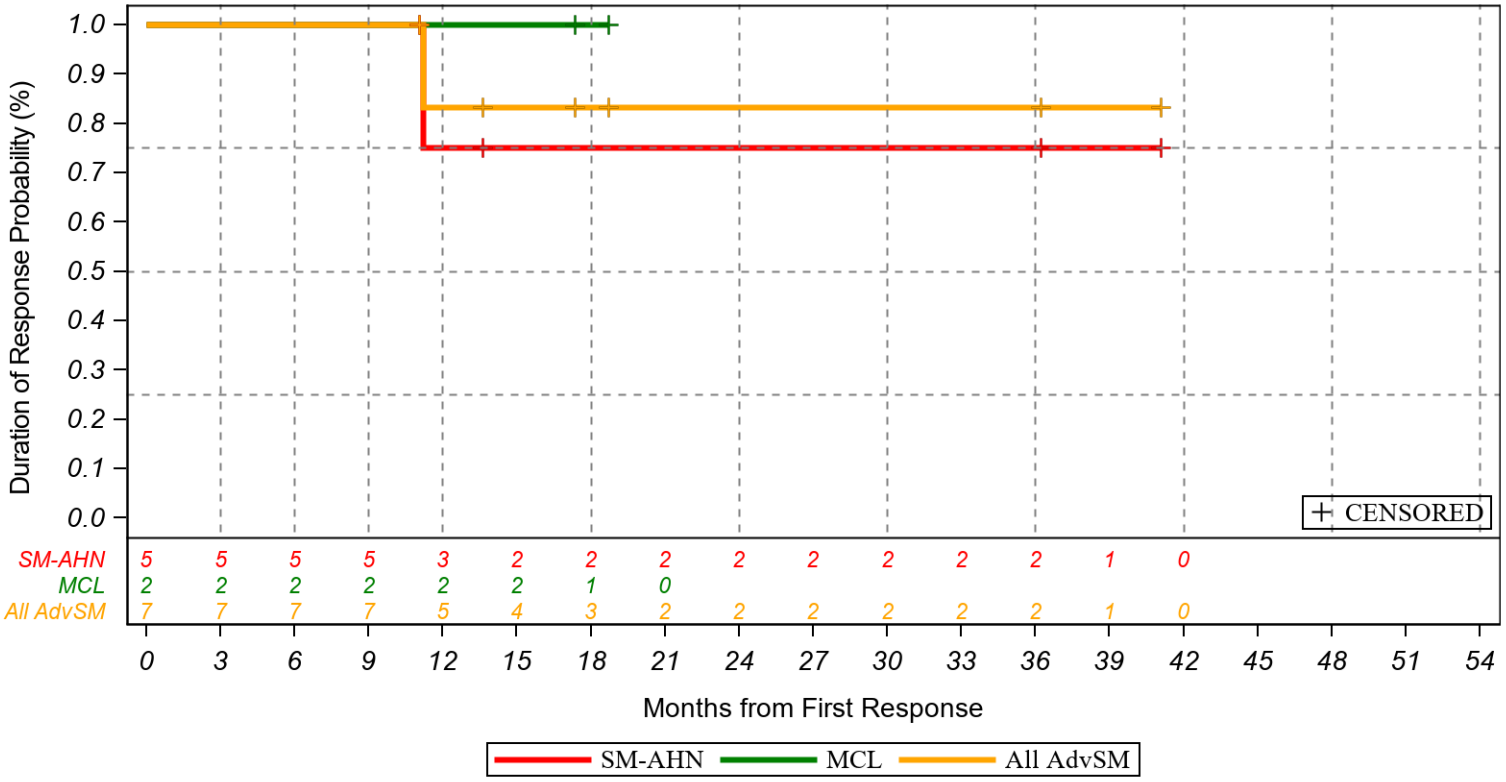

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: < 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR+CI)

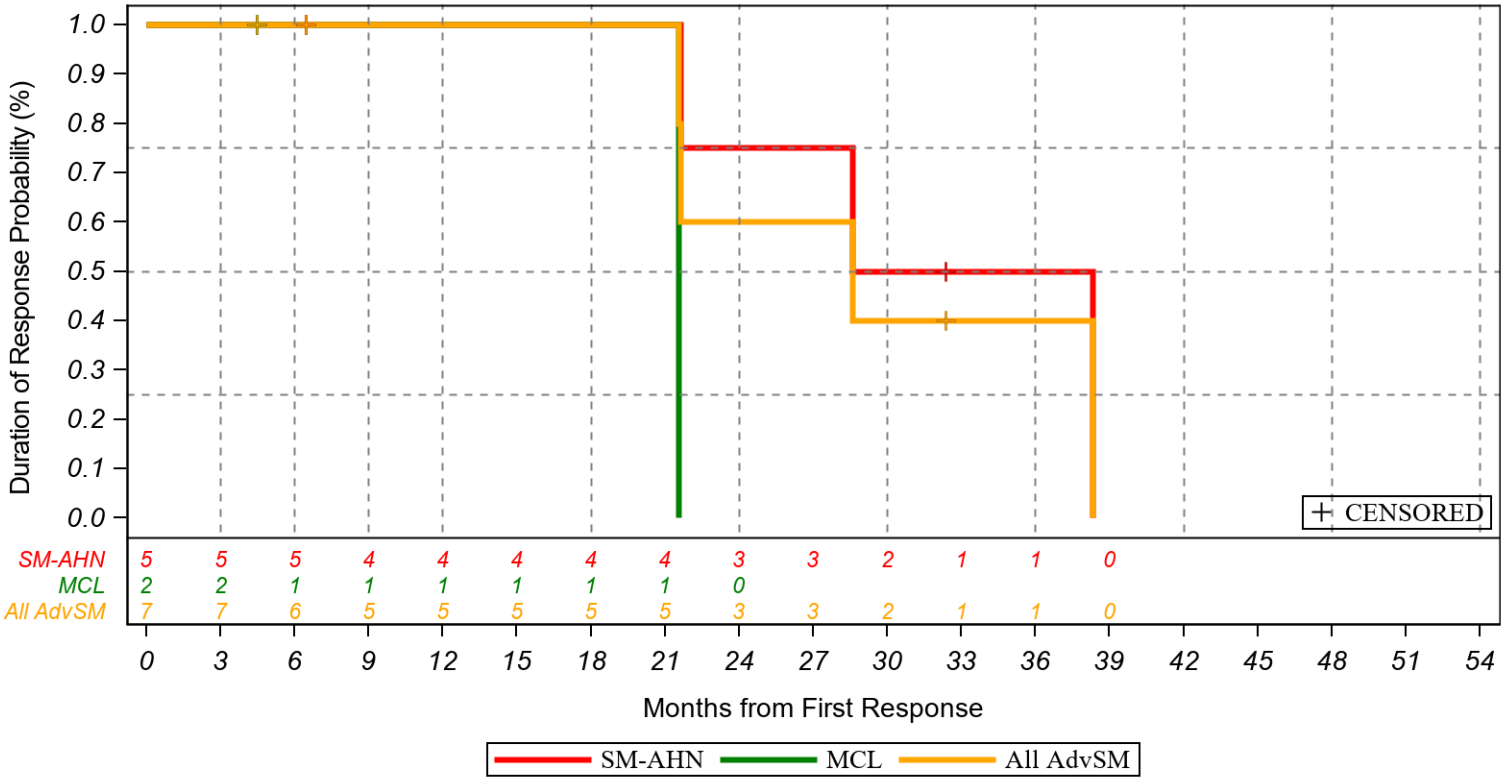

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: < 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR)

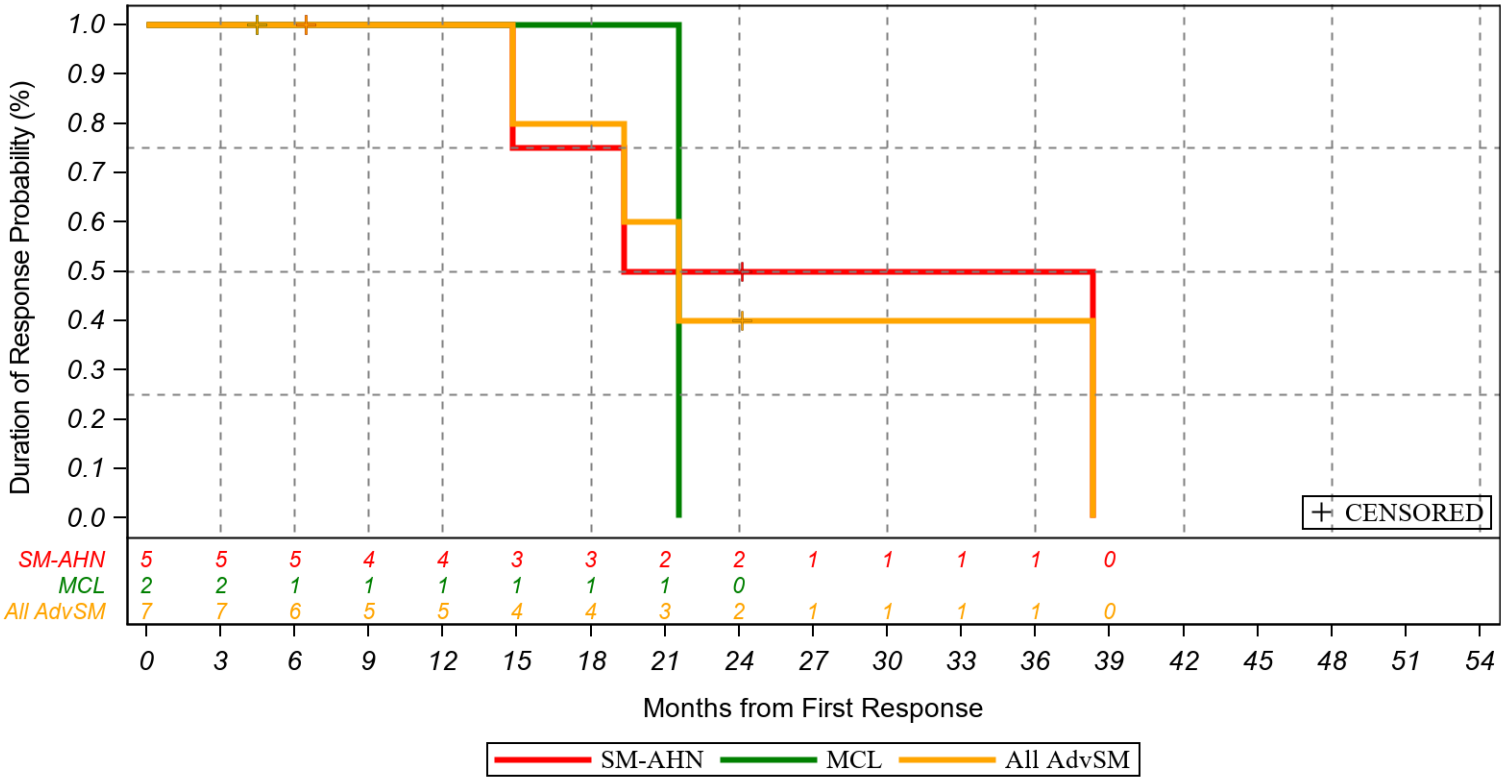

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: 200 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR+CI)

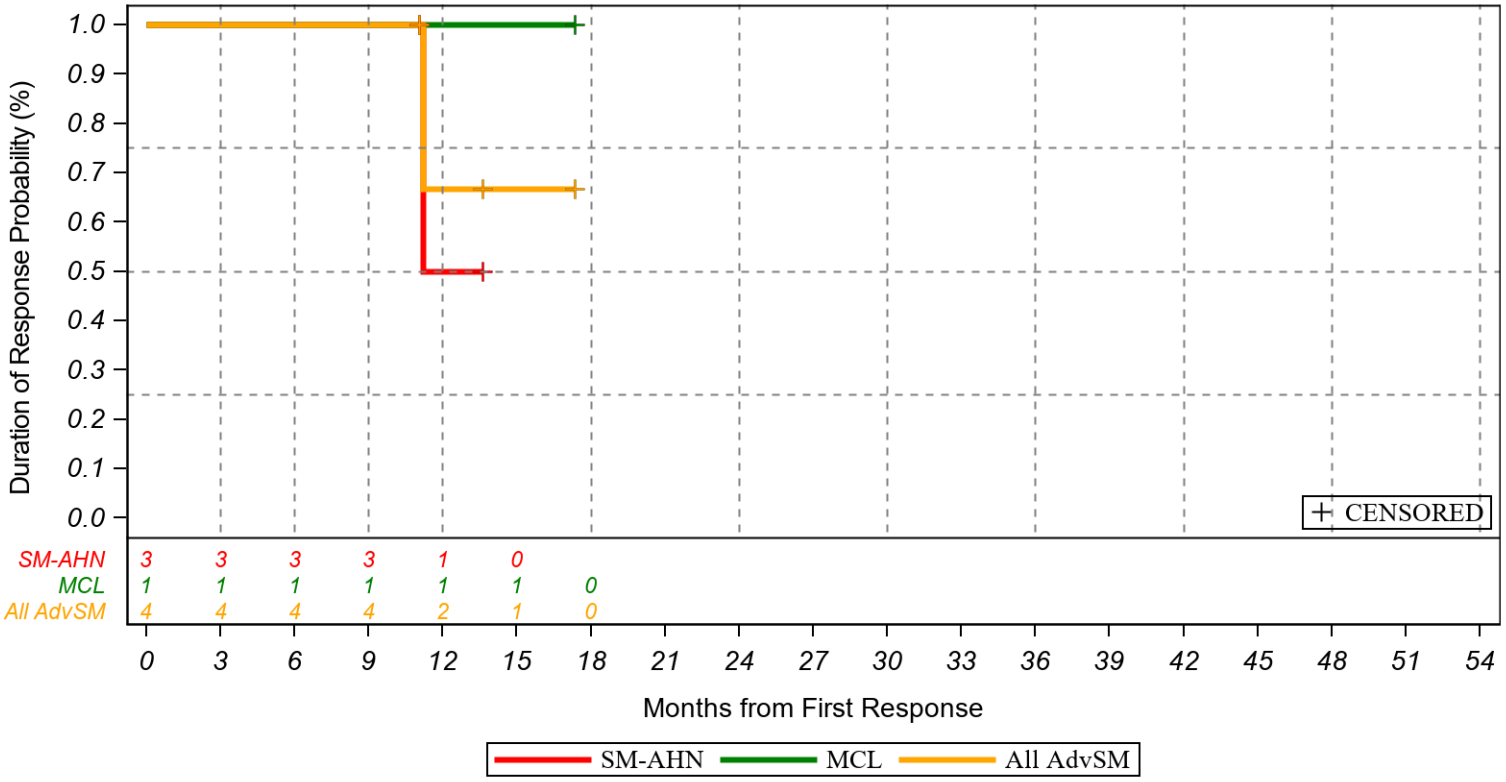

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: 200 mg
Prior Antineoplastic Therapy = Yes
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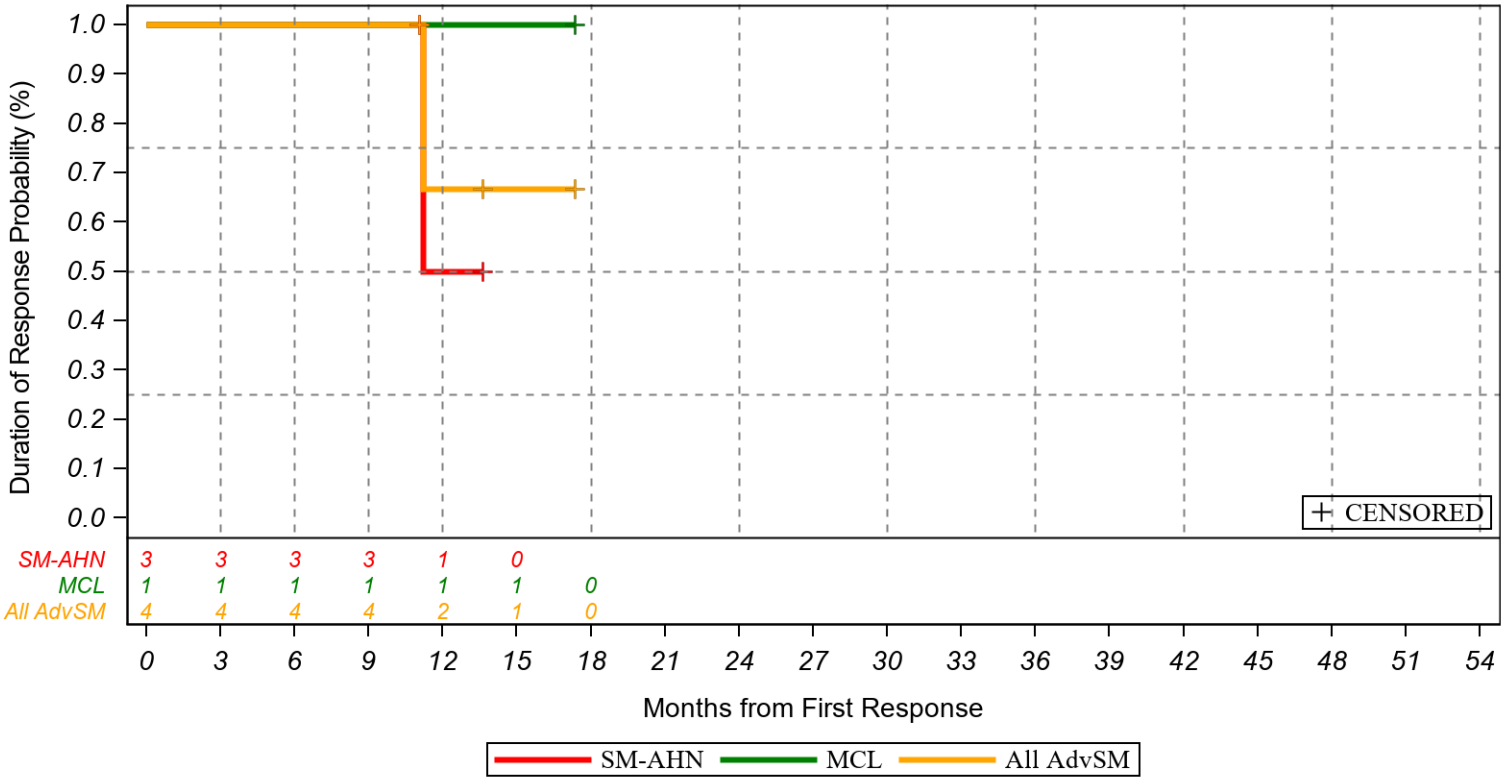

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: 200 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR+CI)

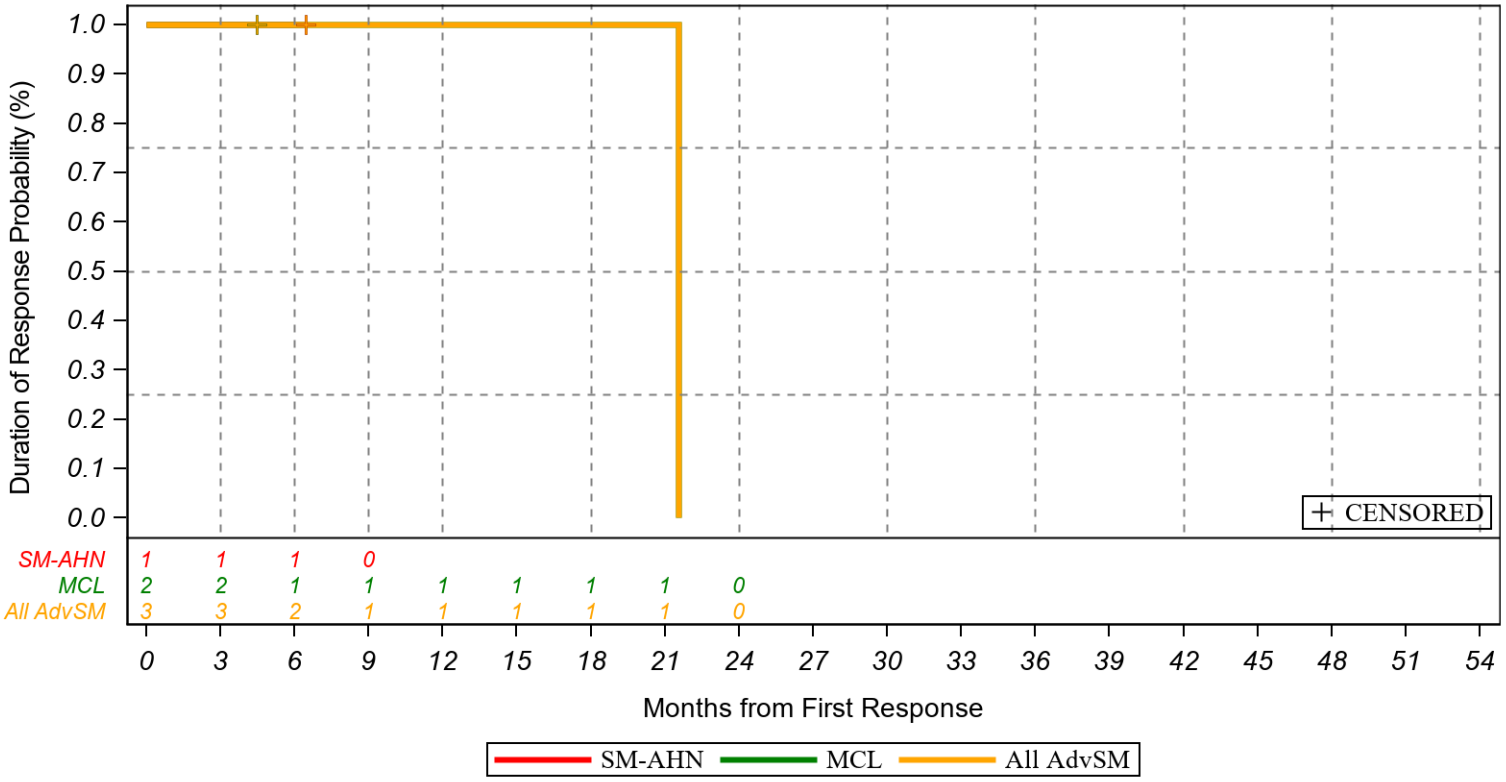

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: 200 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR)

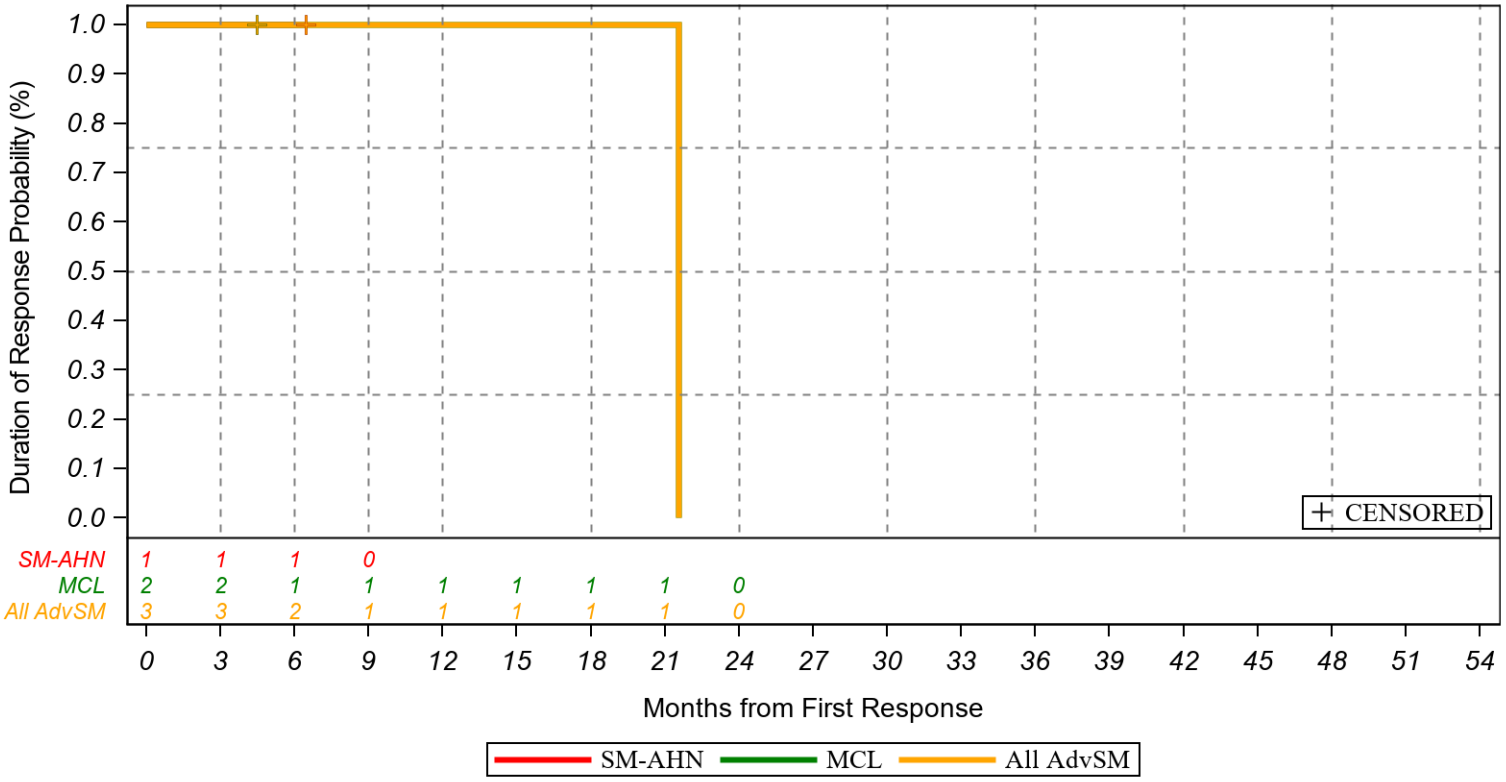

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR+CI)

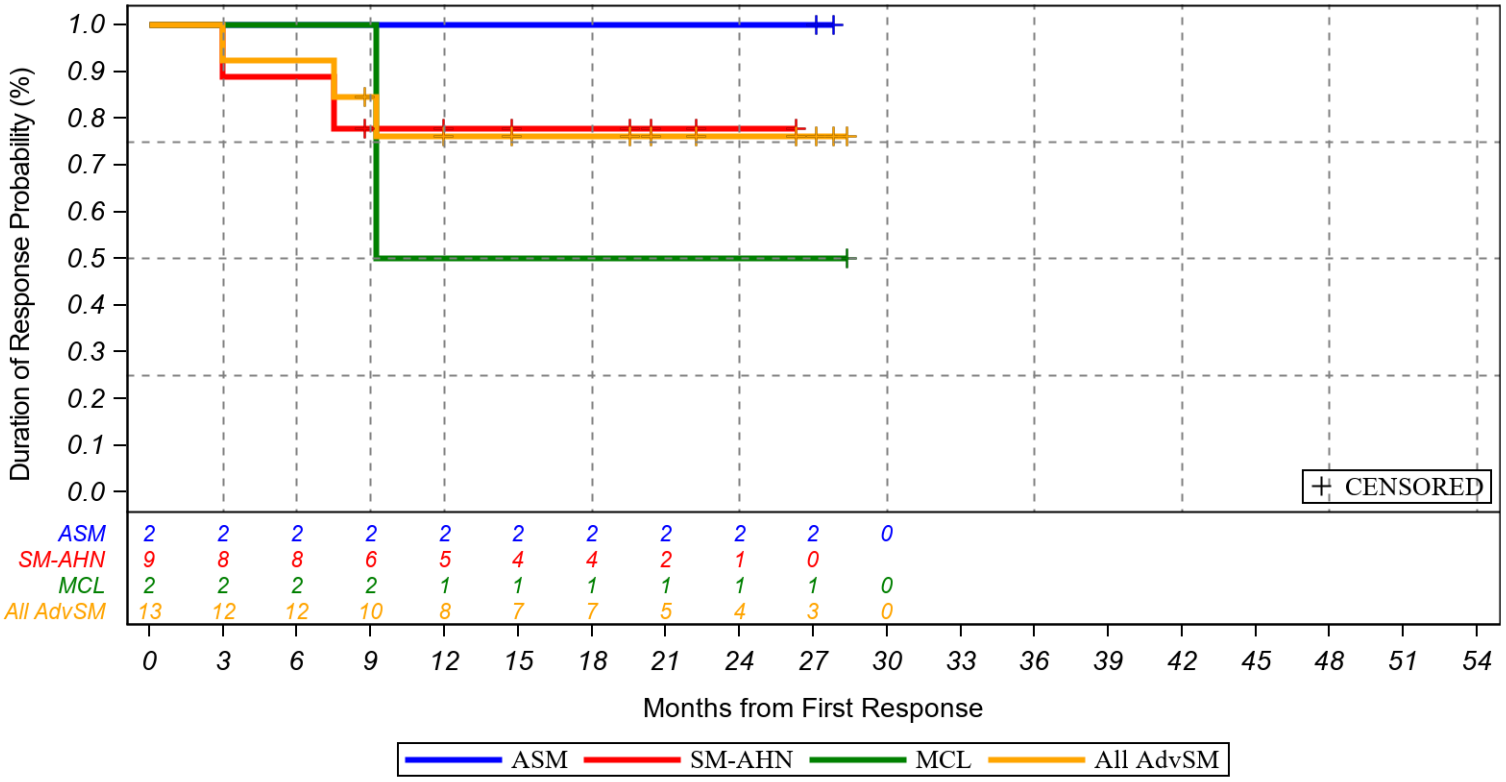

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR)

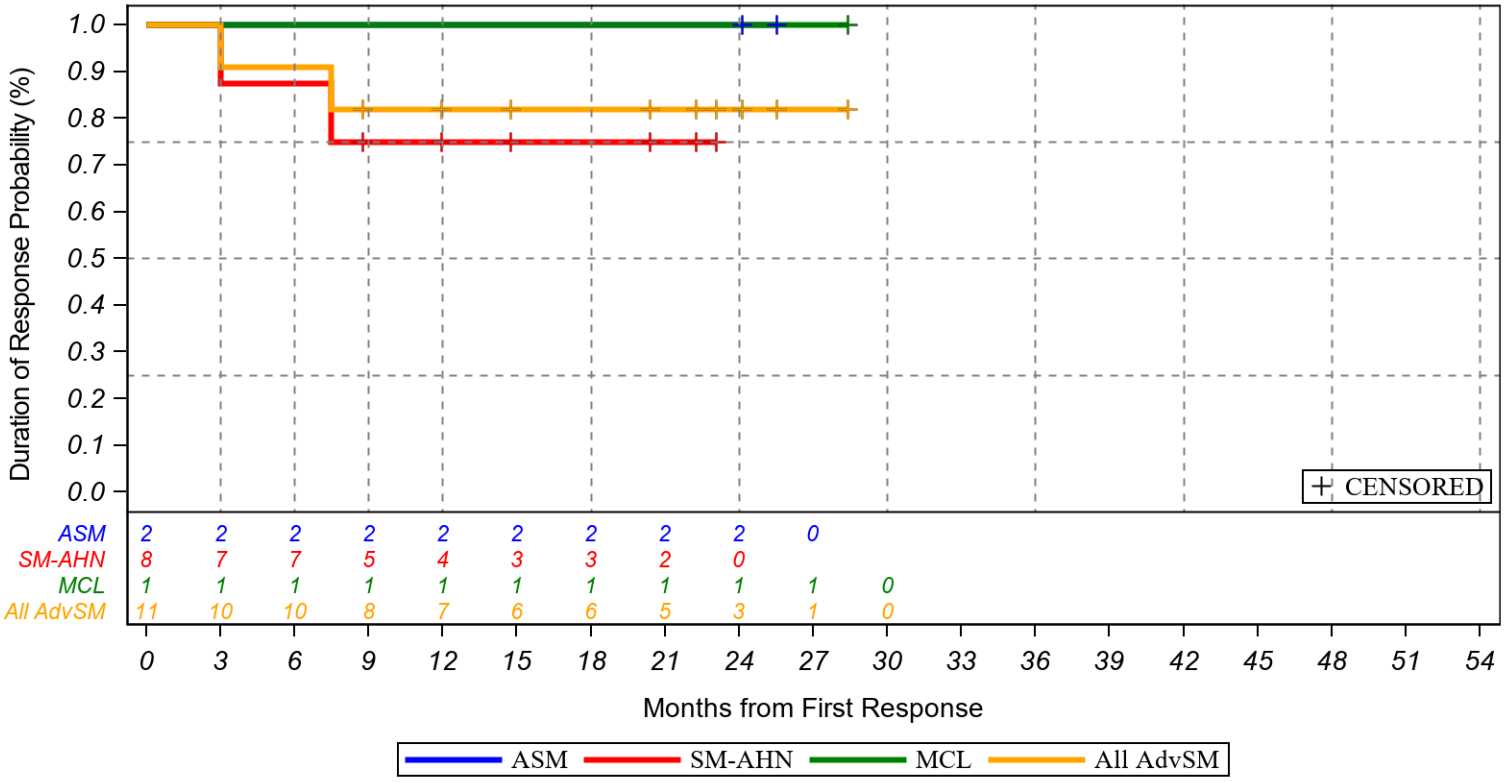

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR+CI)

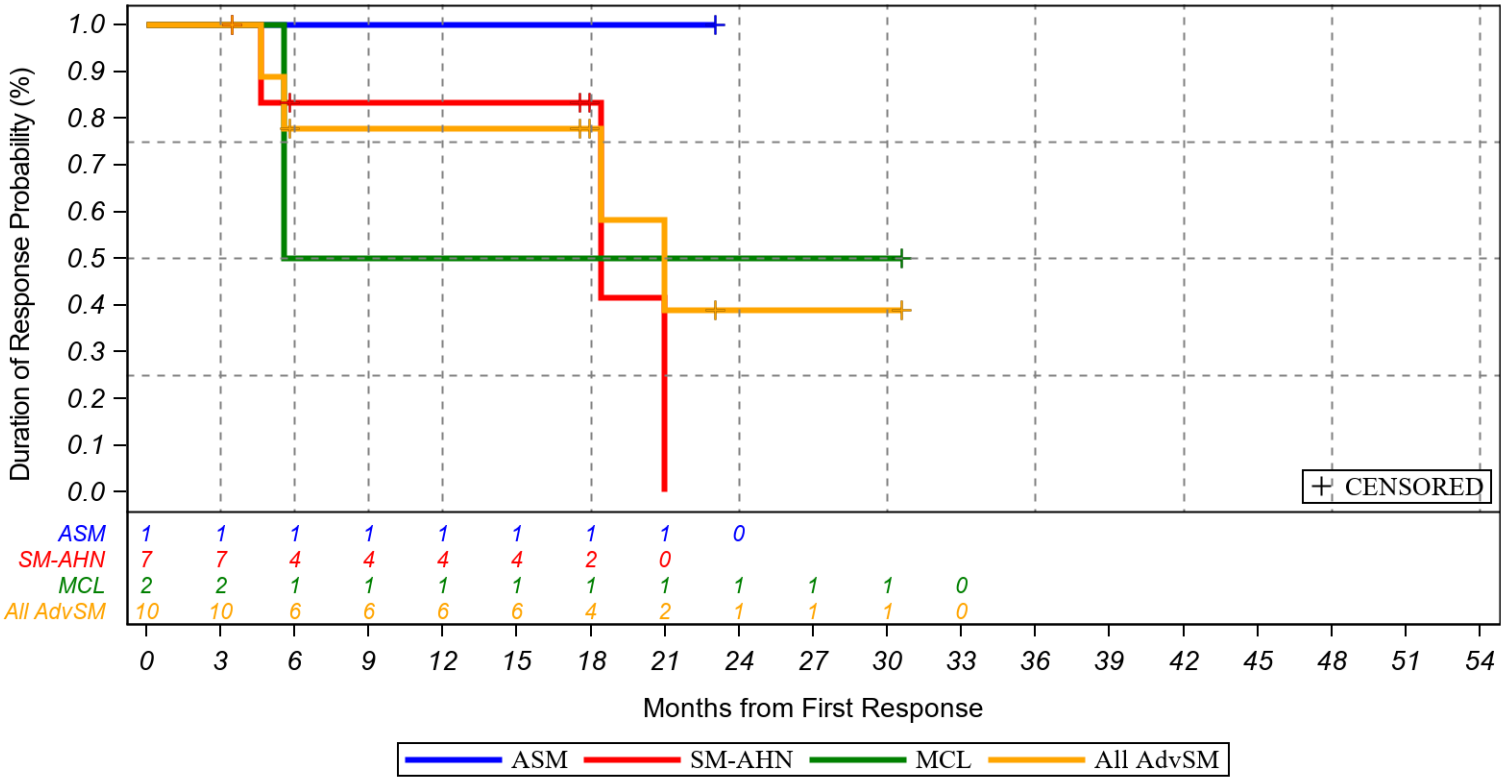

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR)

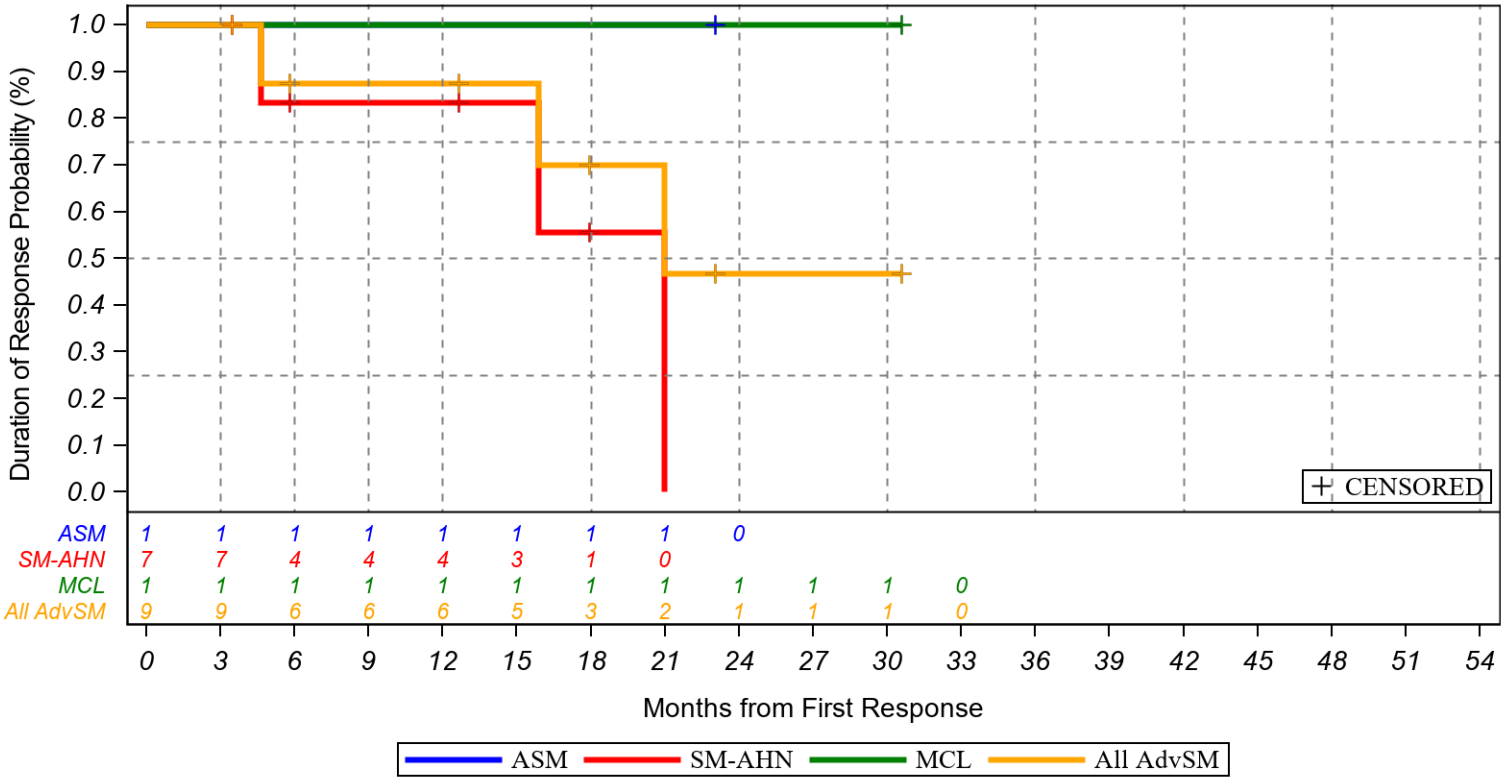

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: 200 mg and 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR+CI)

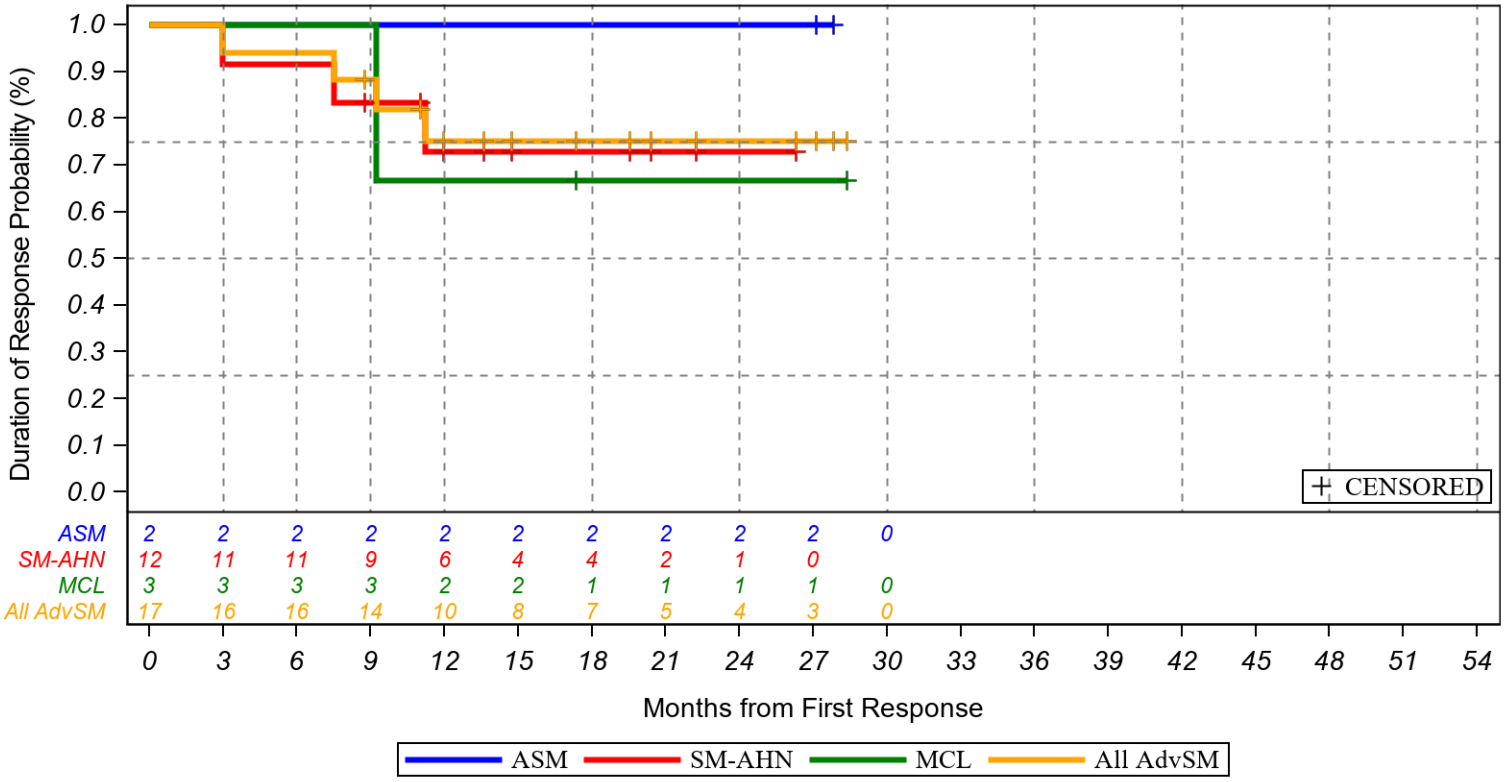

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: 200 mg and 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR)

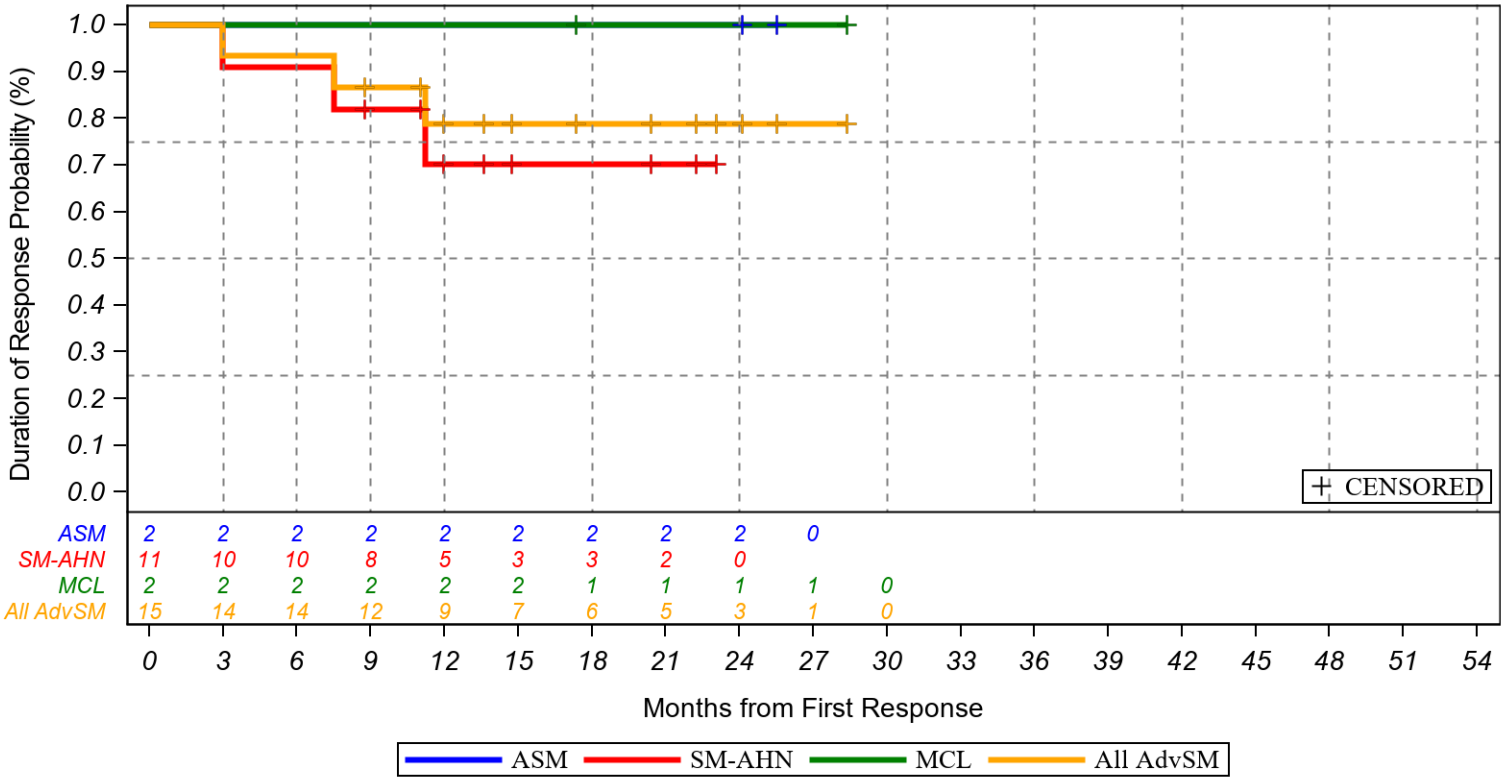

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: 200 mg and 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR+CI)

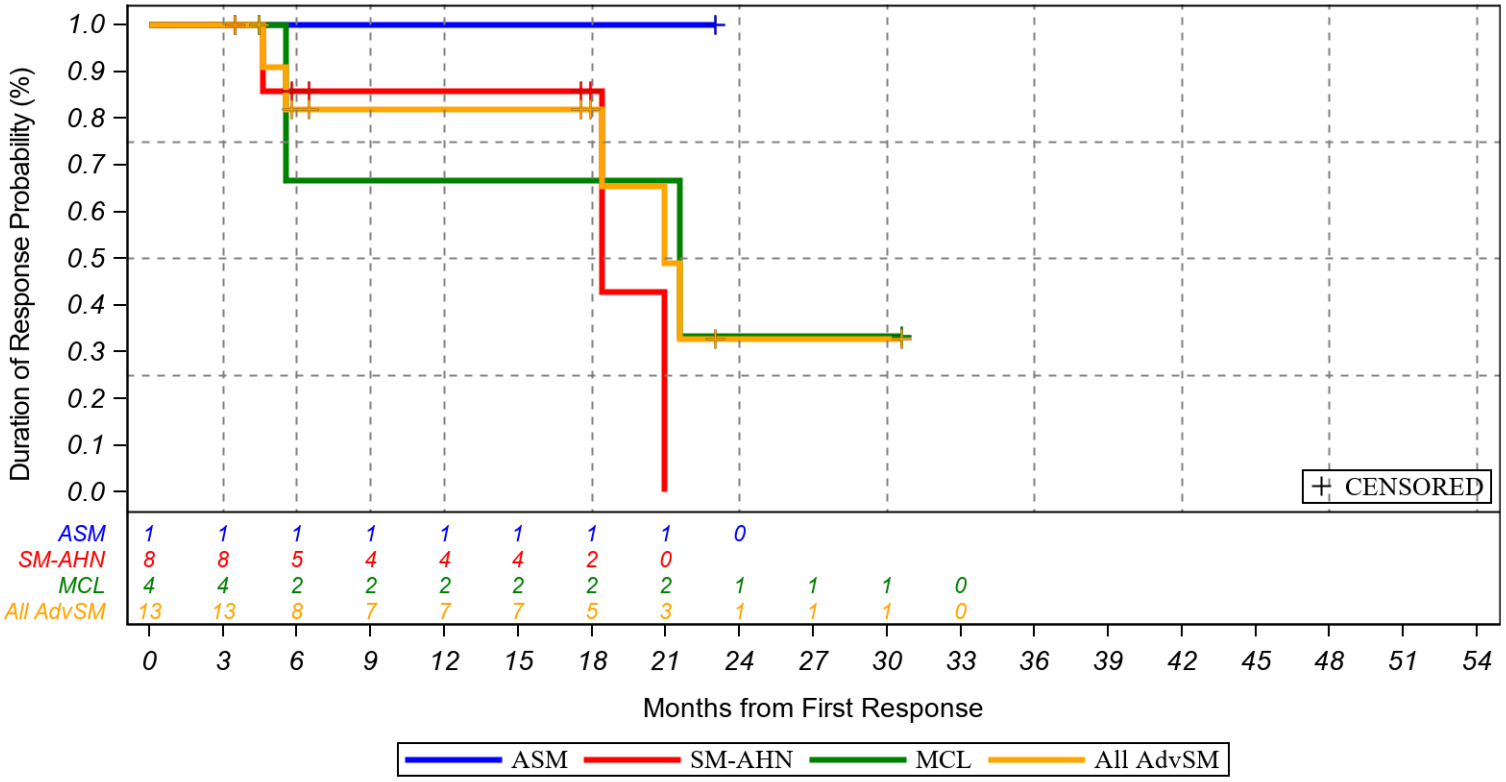

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: 200 mg and 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR)

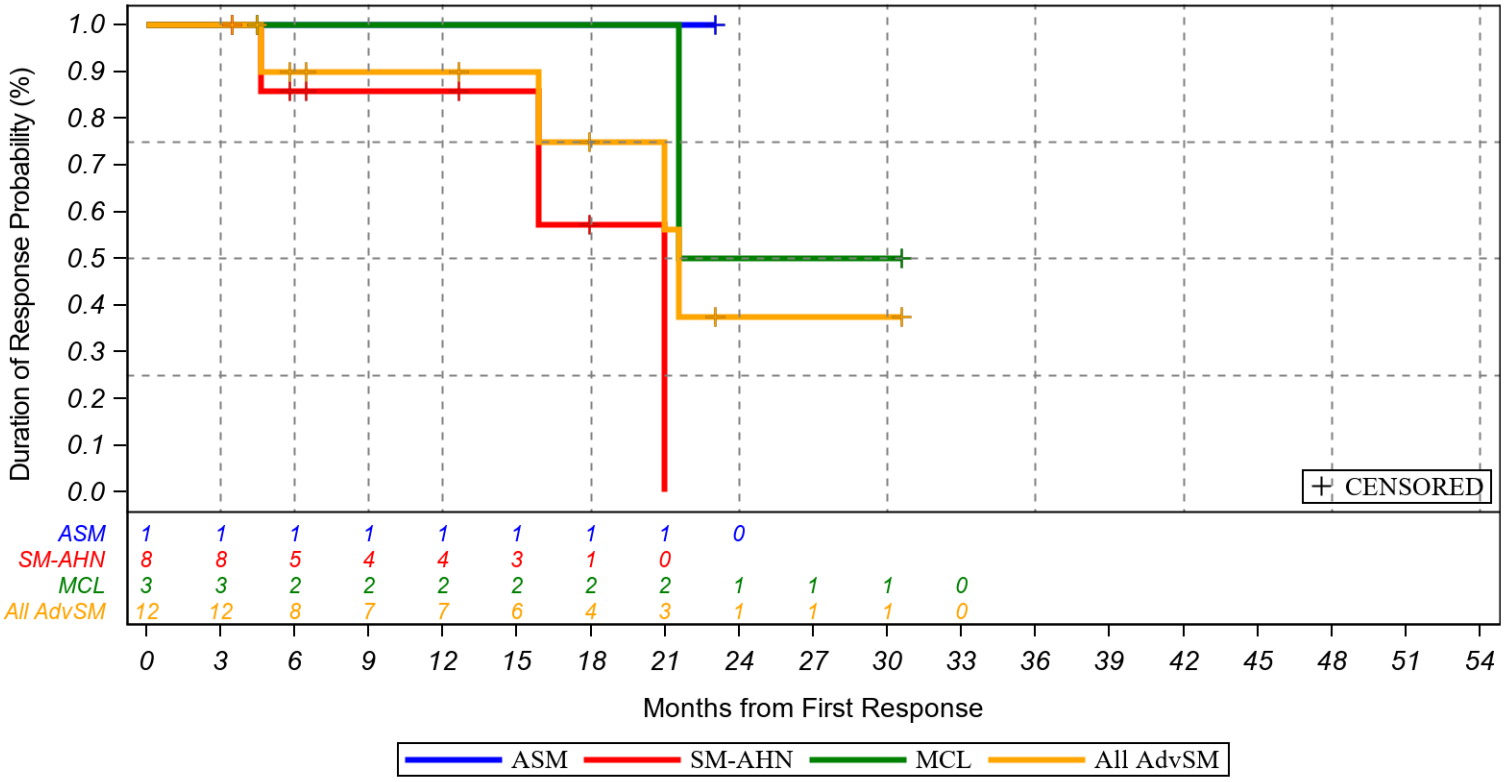

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: 400 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR+CI)

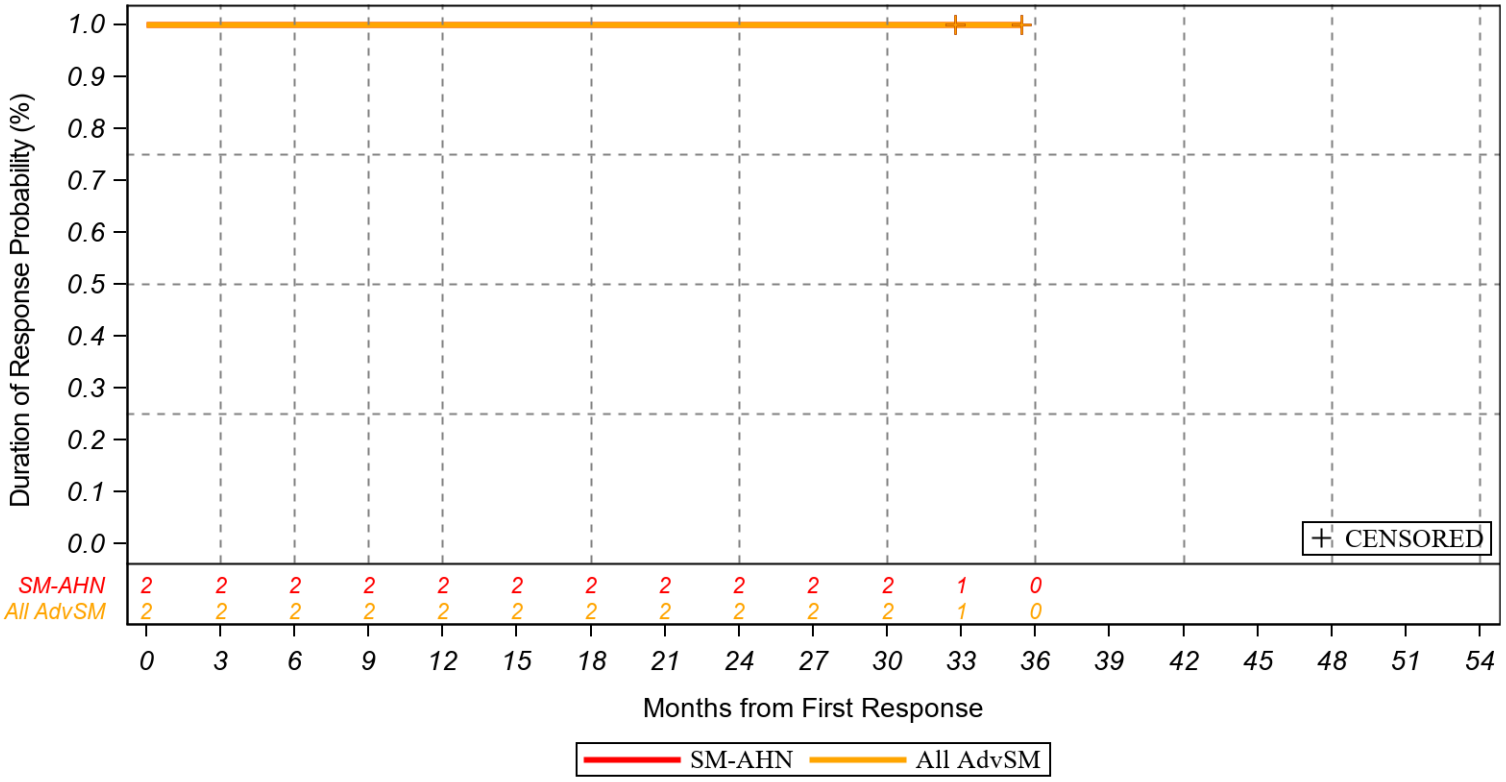

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: 400 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR)

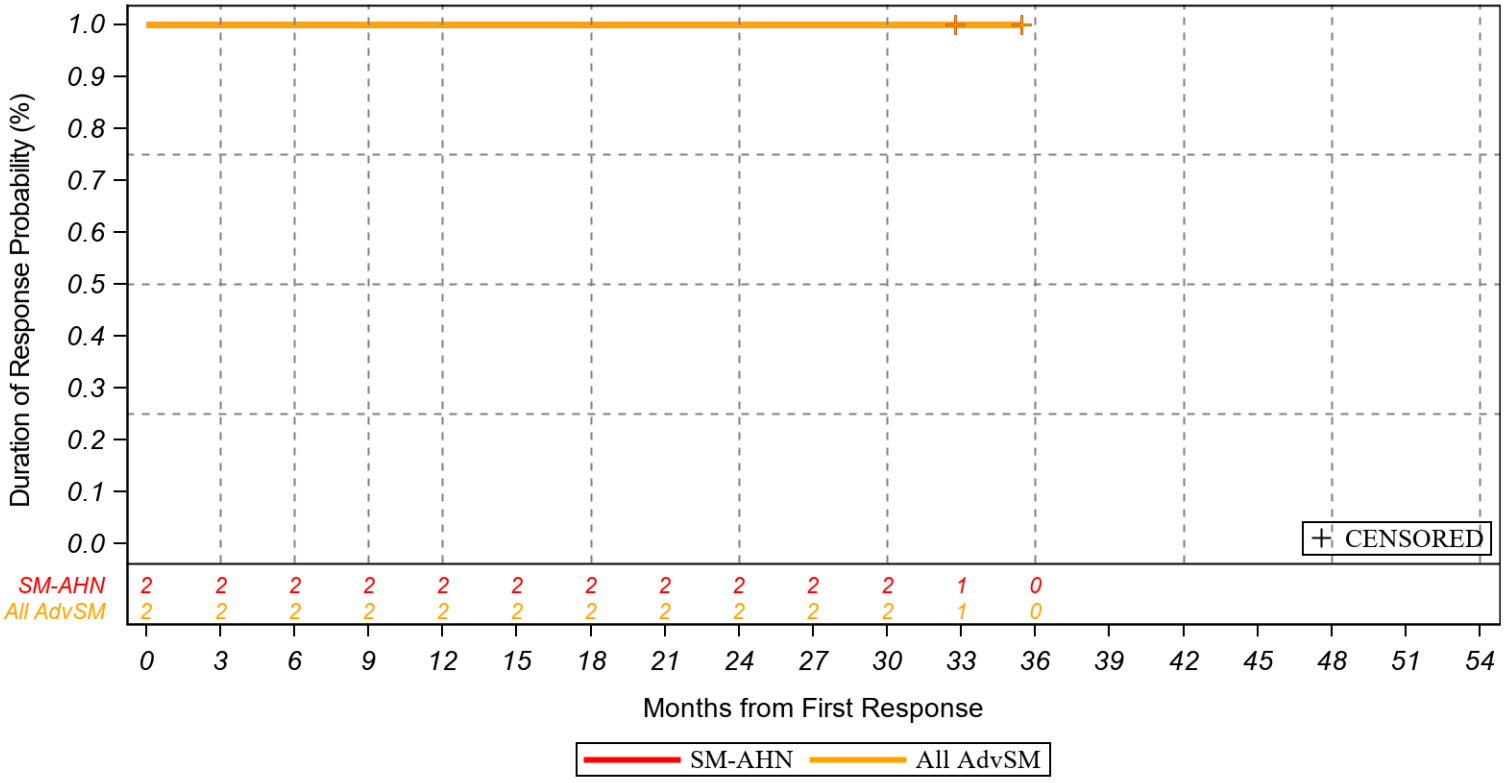

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: 400 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR+CI)

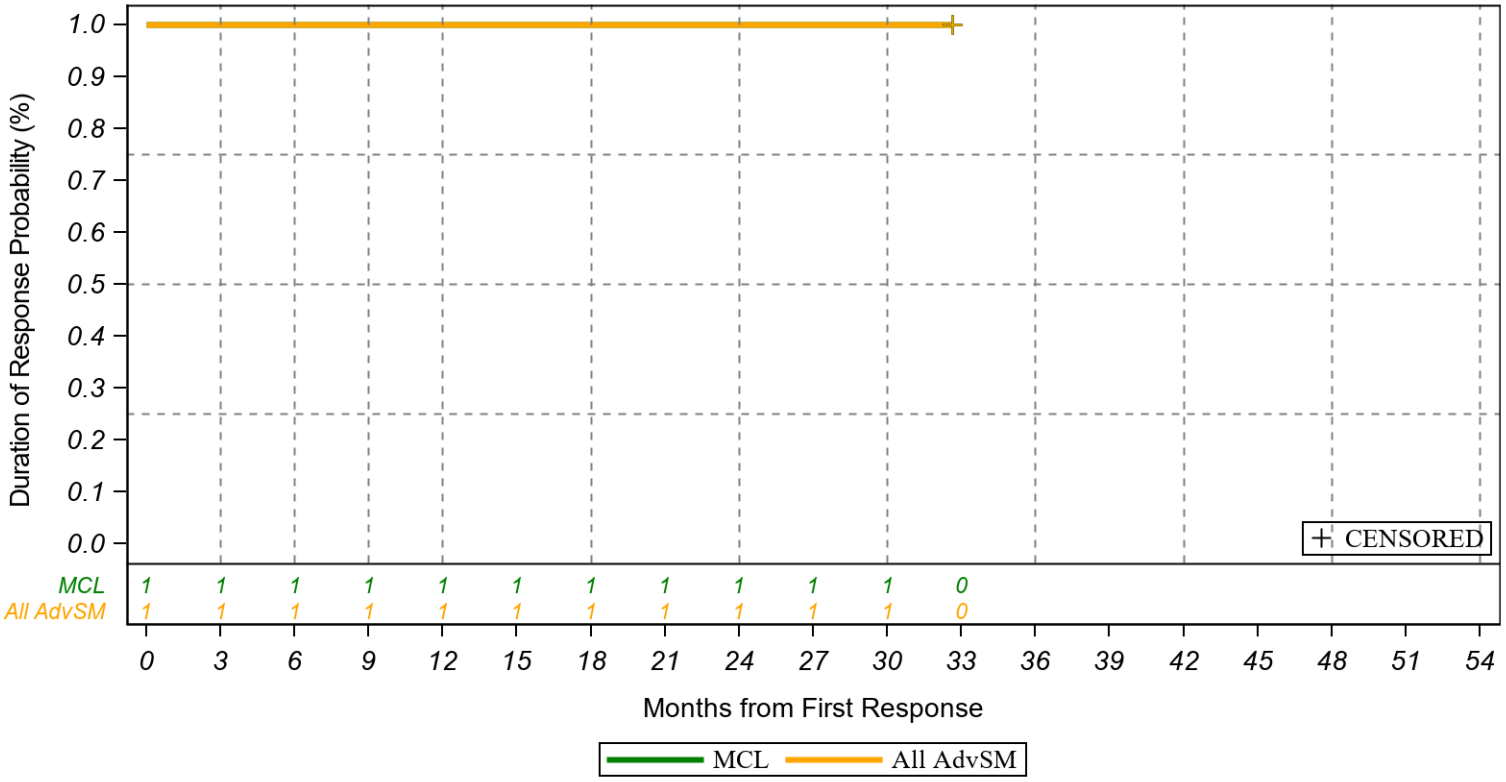

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: 400 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR)

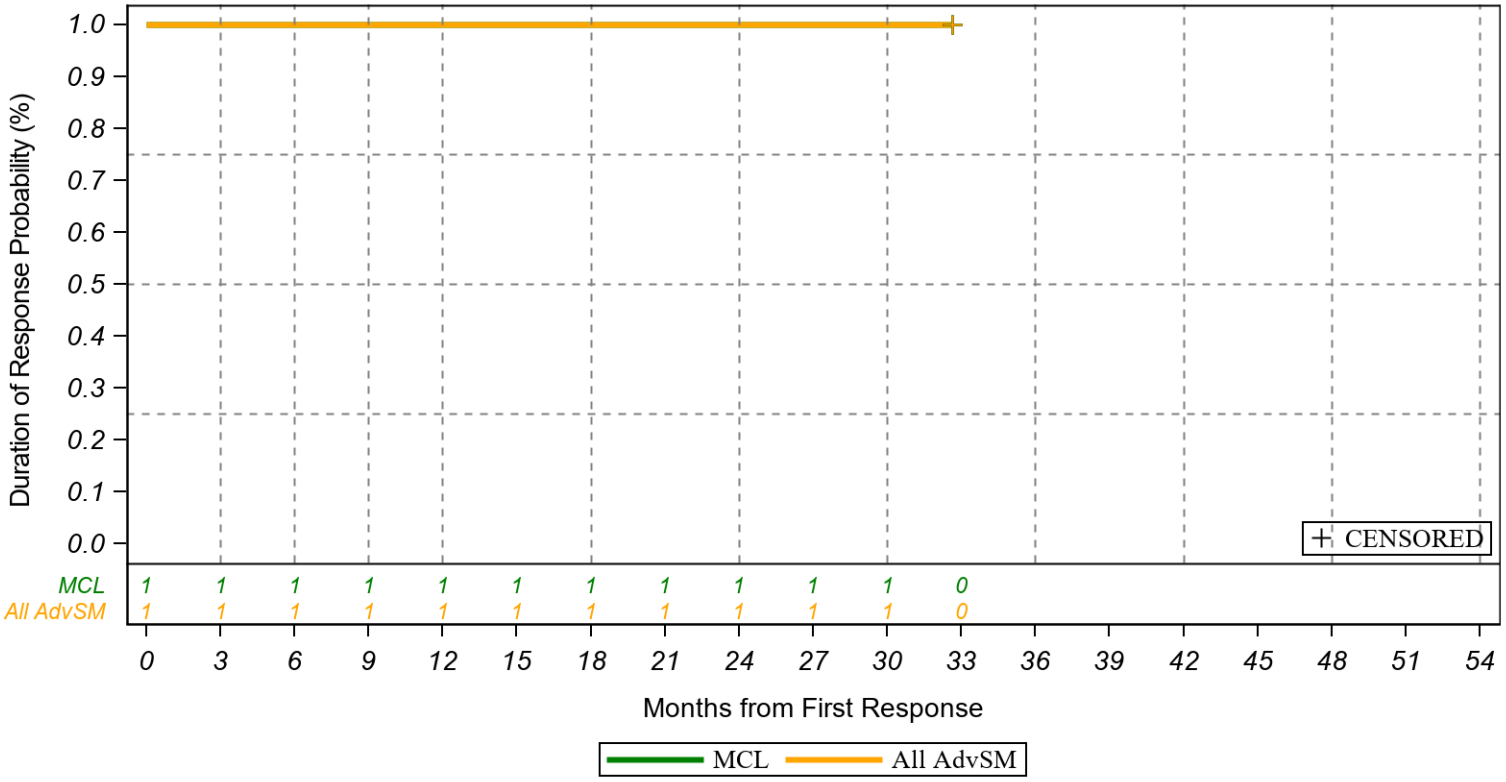

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2202
Starting Dose: Overall
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR+CI)

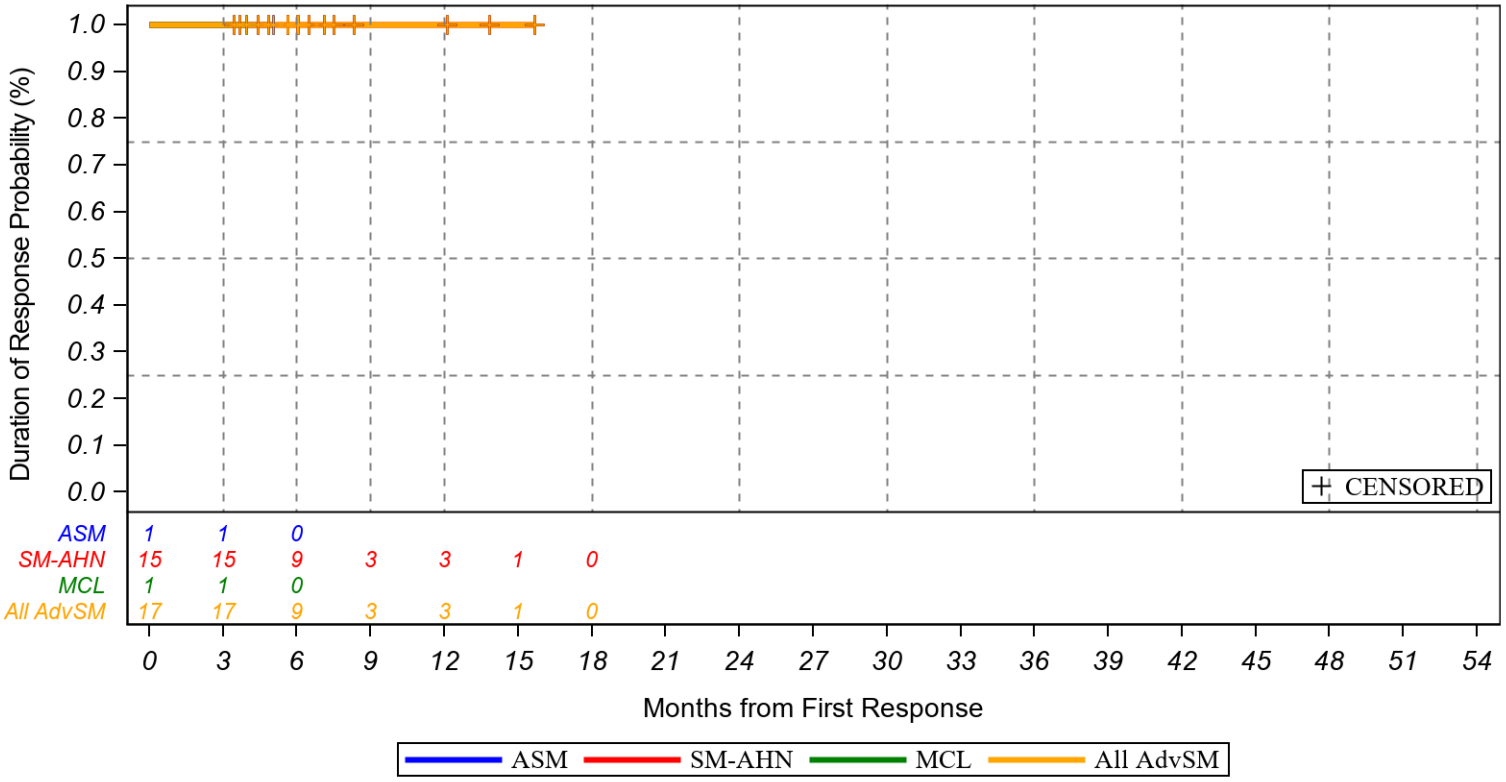

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2202
Starting Dose: Overall
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR)

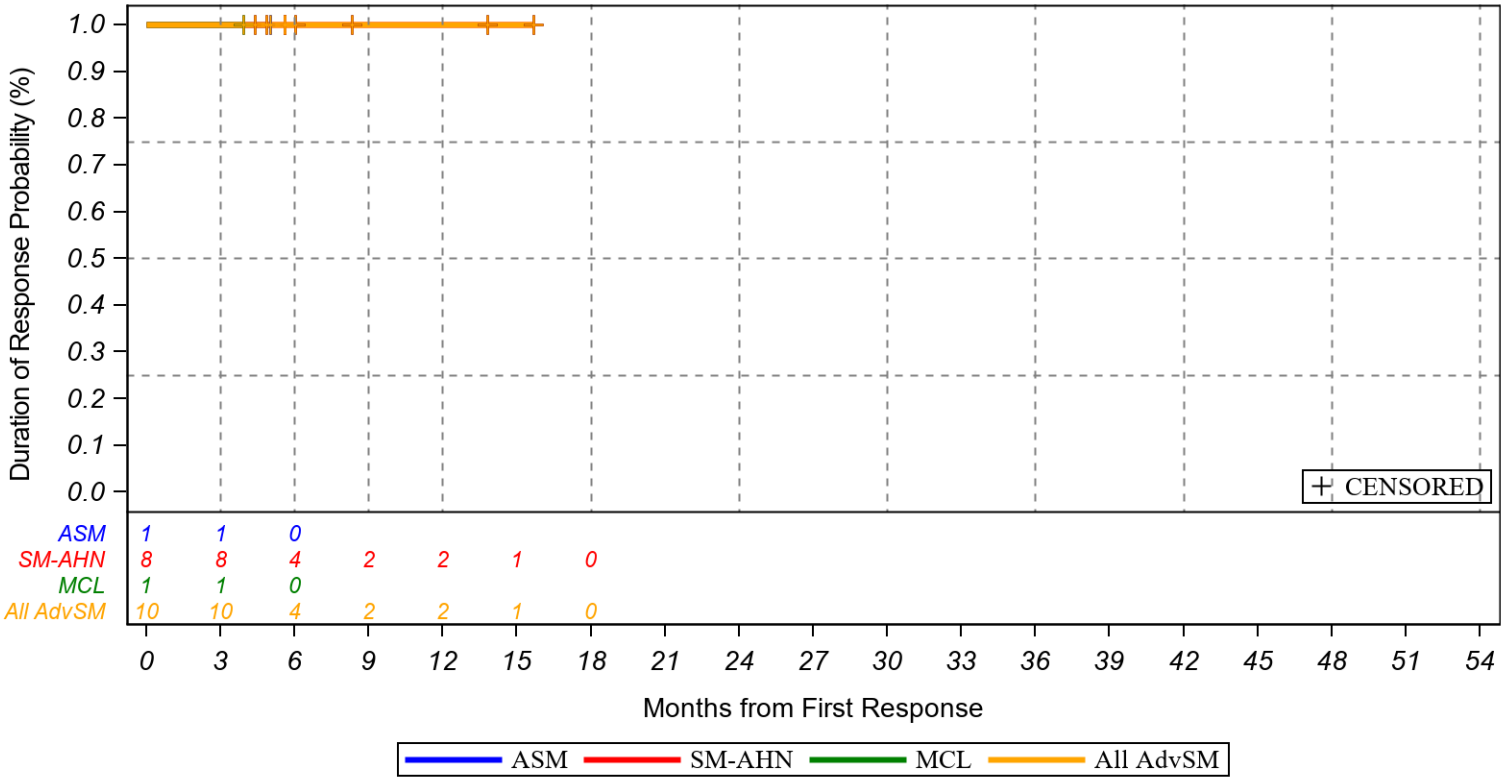

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2202
Starting Dose: Overall
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR+CI)

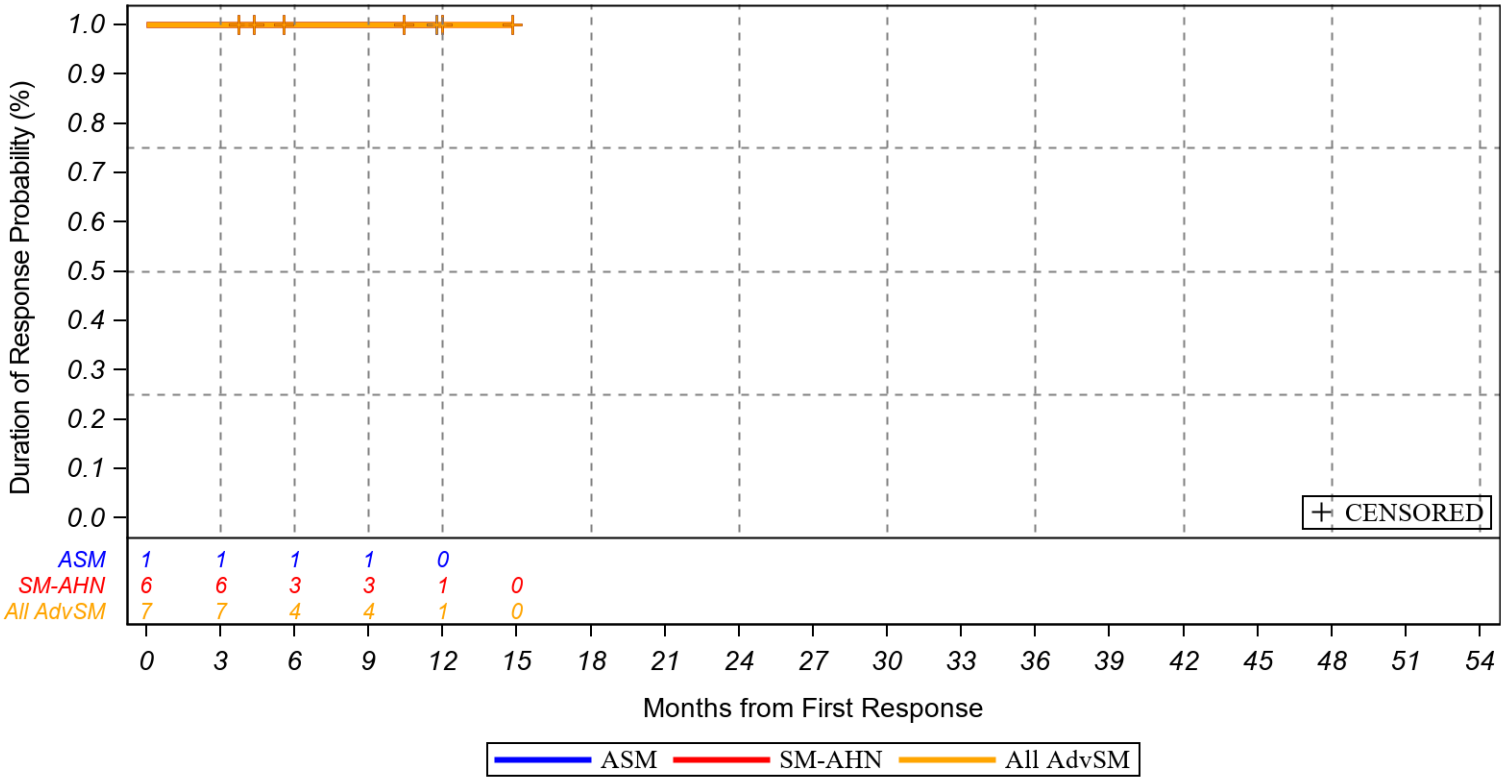

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2202
Starting Dose: Overall
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR)

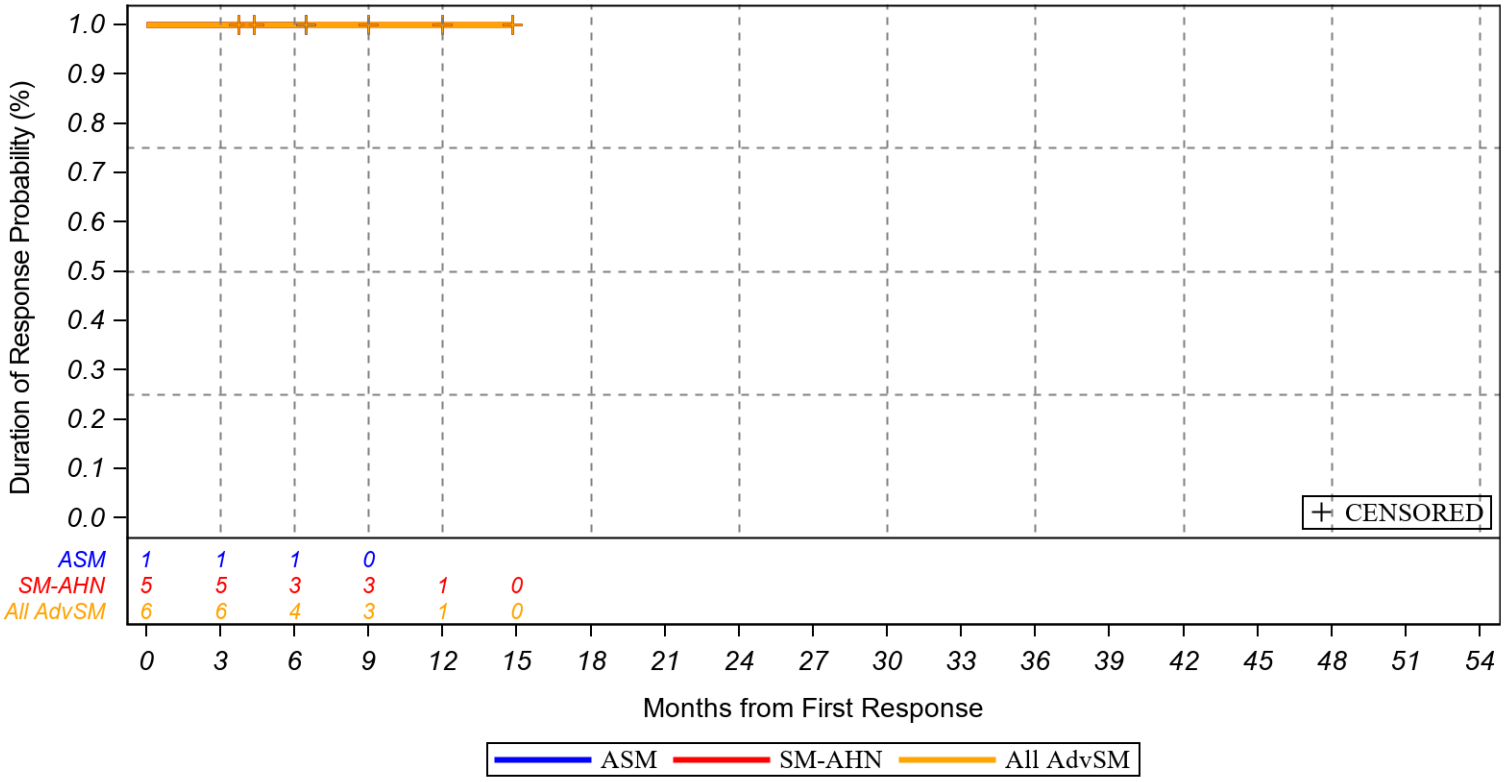

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2202
Starting Dose: 200 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR+CI)

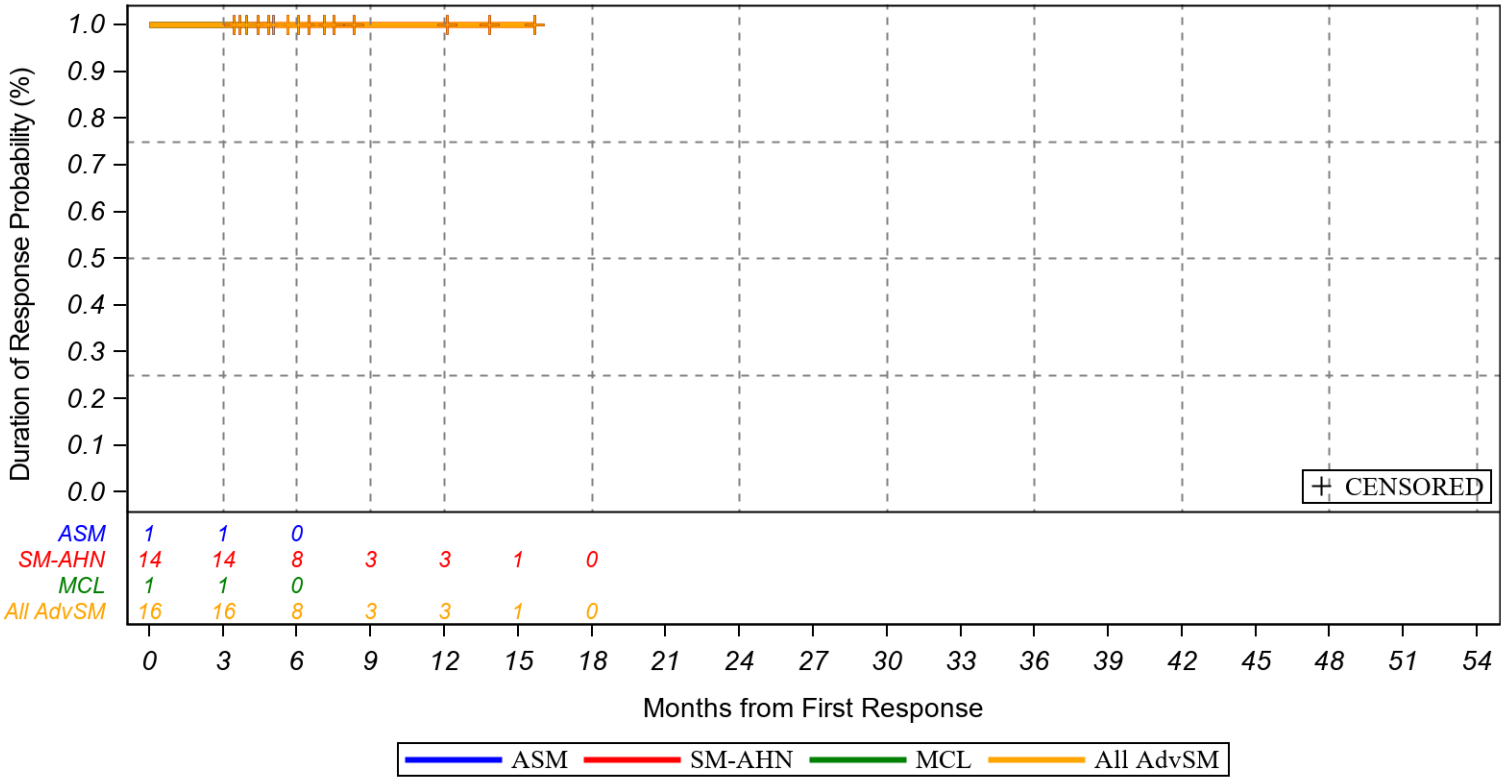

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2202
Starting Dose: 200 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR)

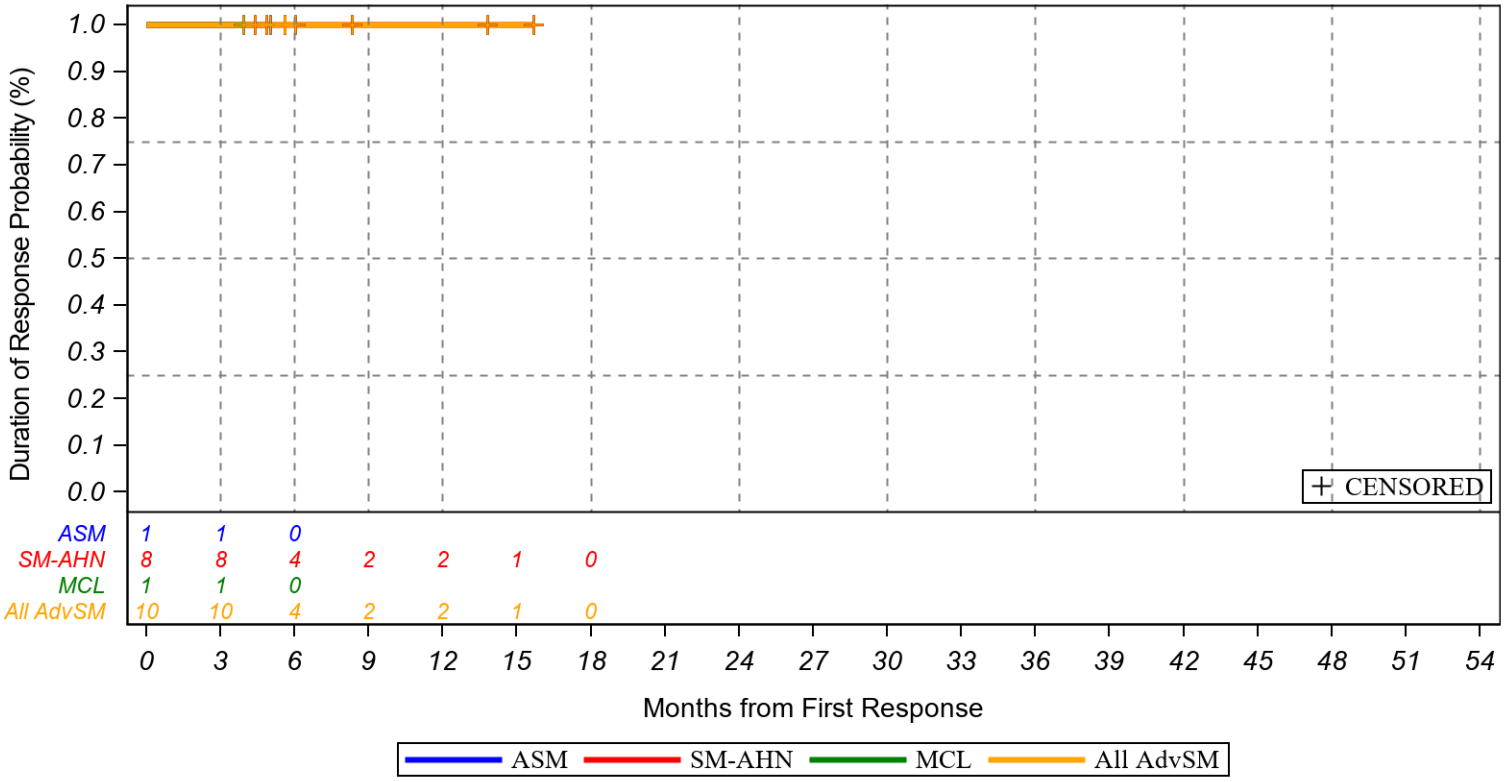

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2202
Starting Dose: 200 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR+CI)

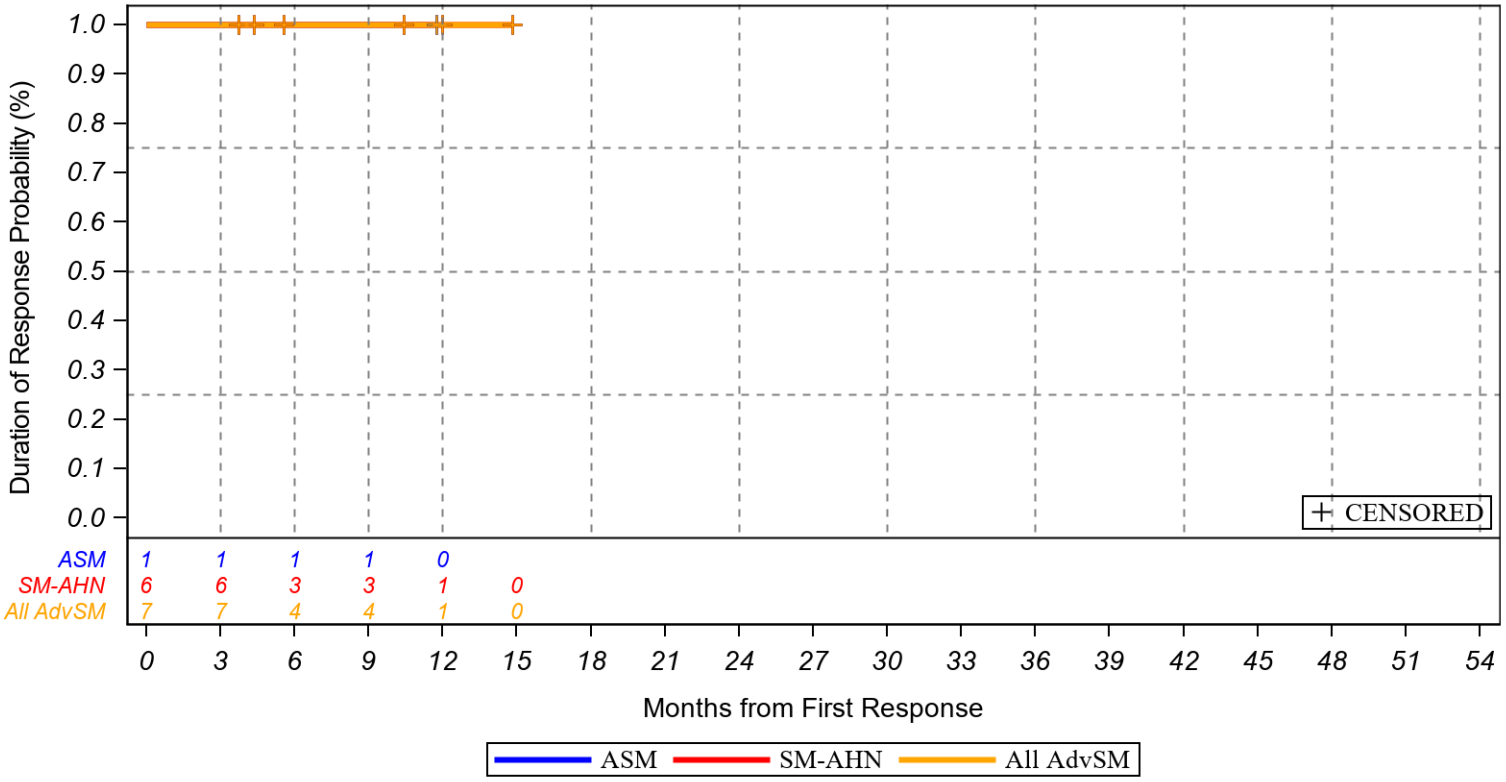

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2202
Starting Dose: 200 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR)

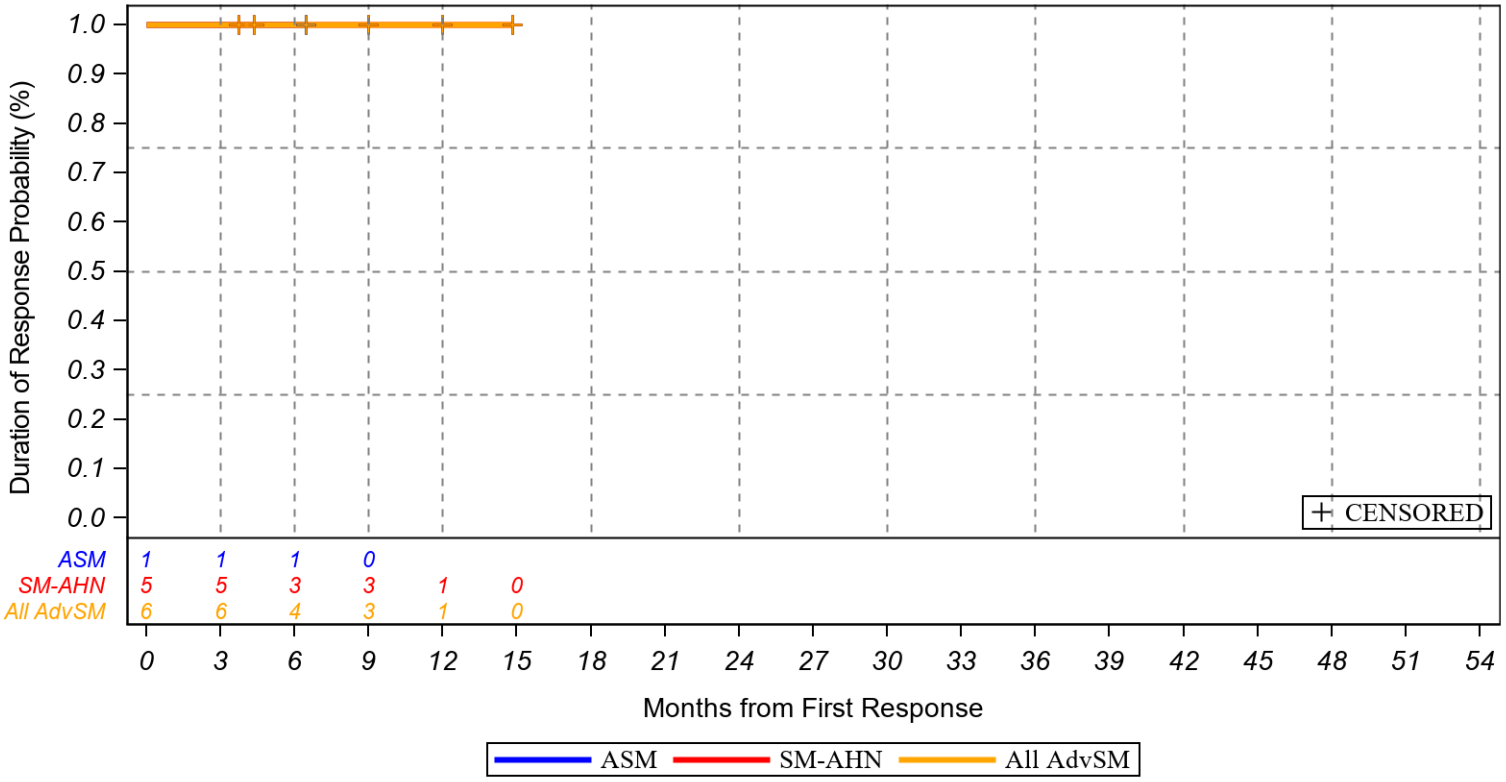

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR+CI)

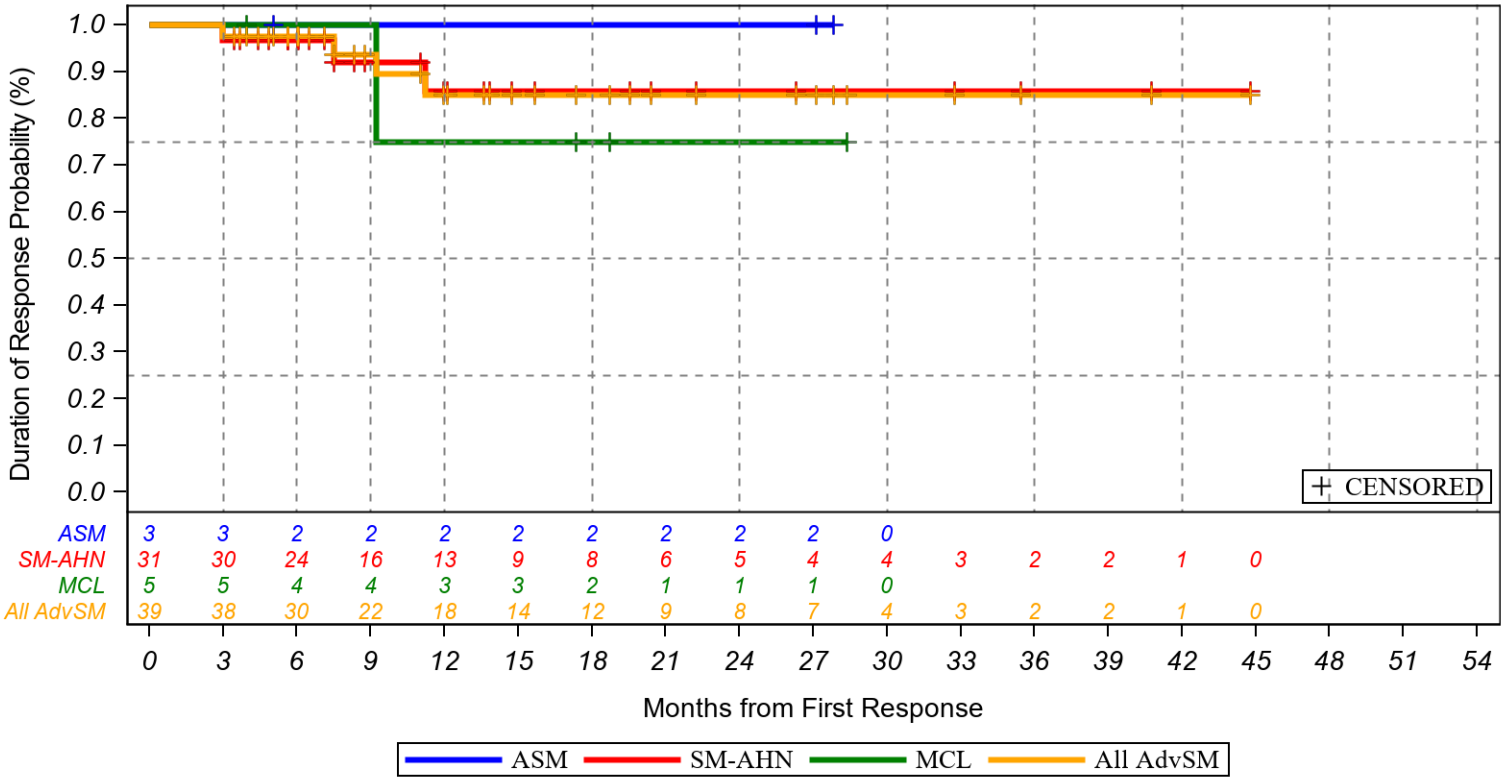

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR)

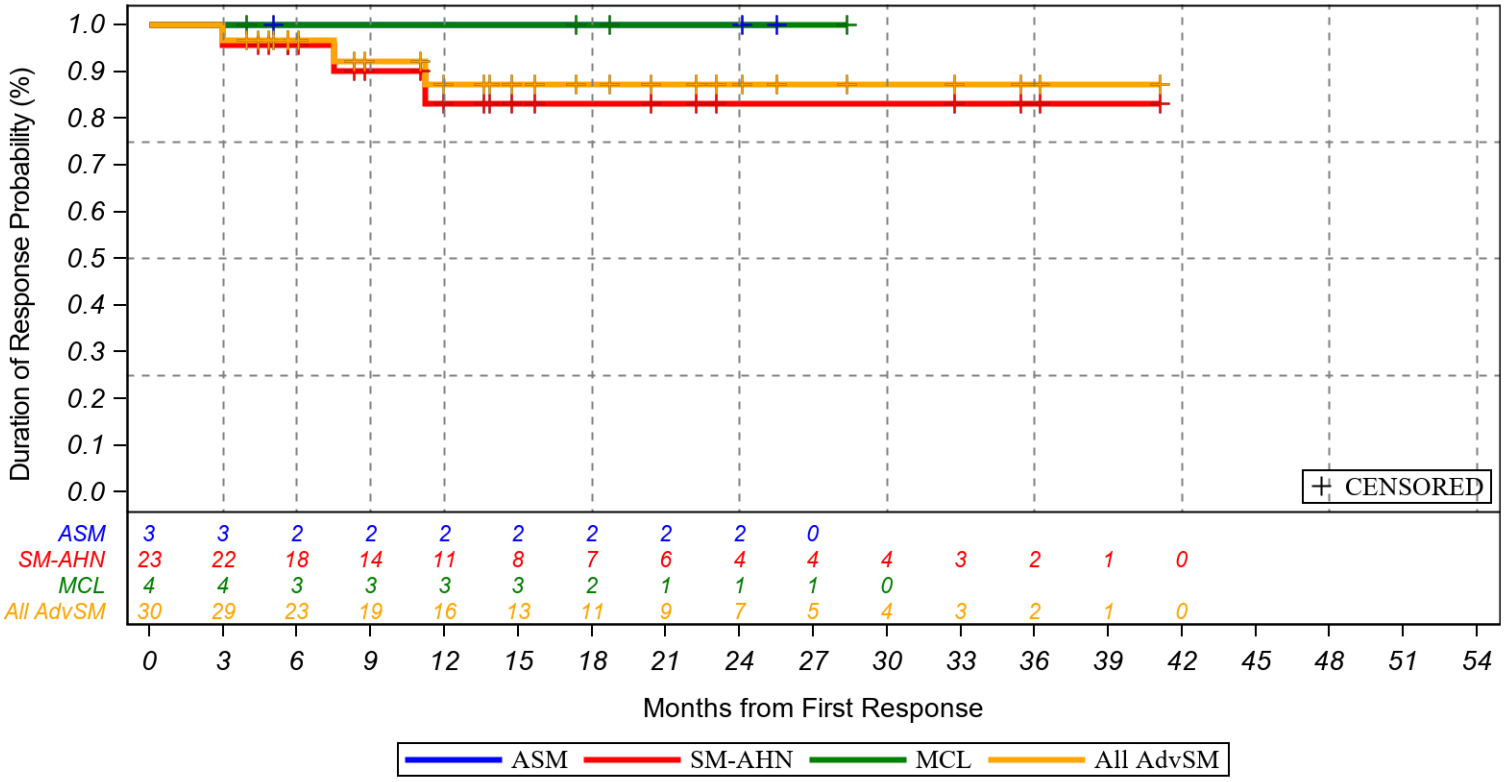

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall
Prior Antineoplastic Therapy = No
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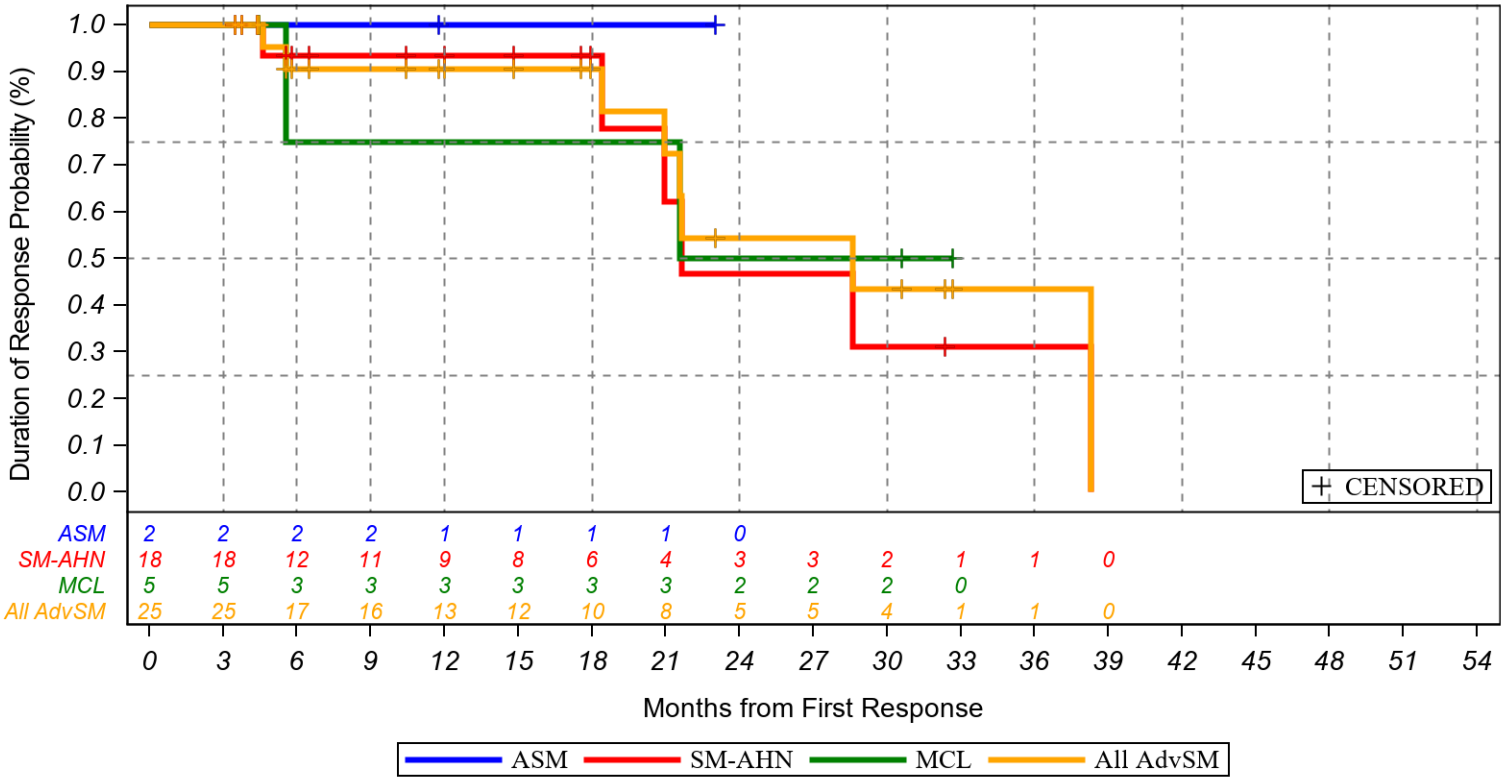

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR)

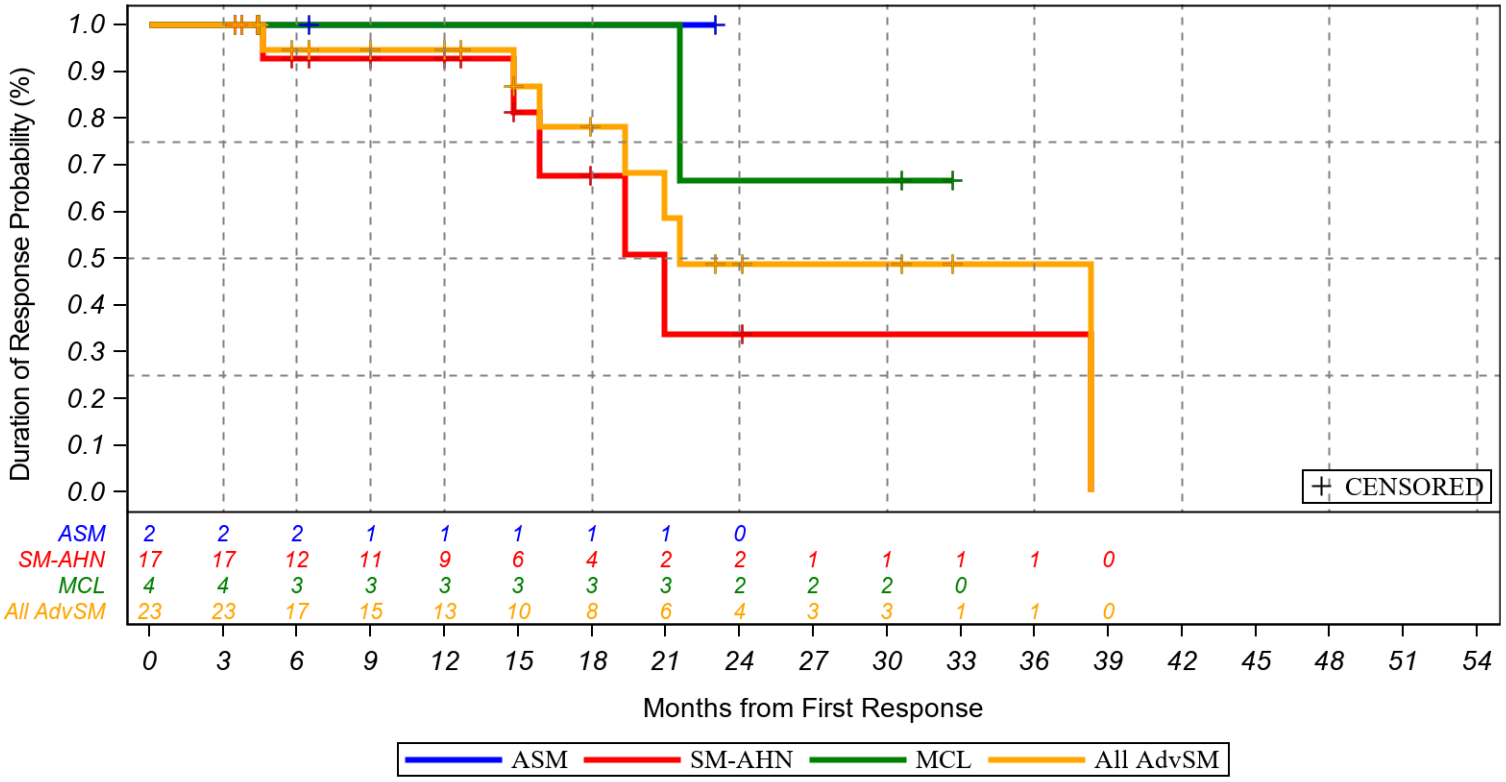

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR+CI)

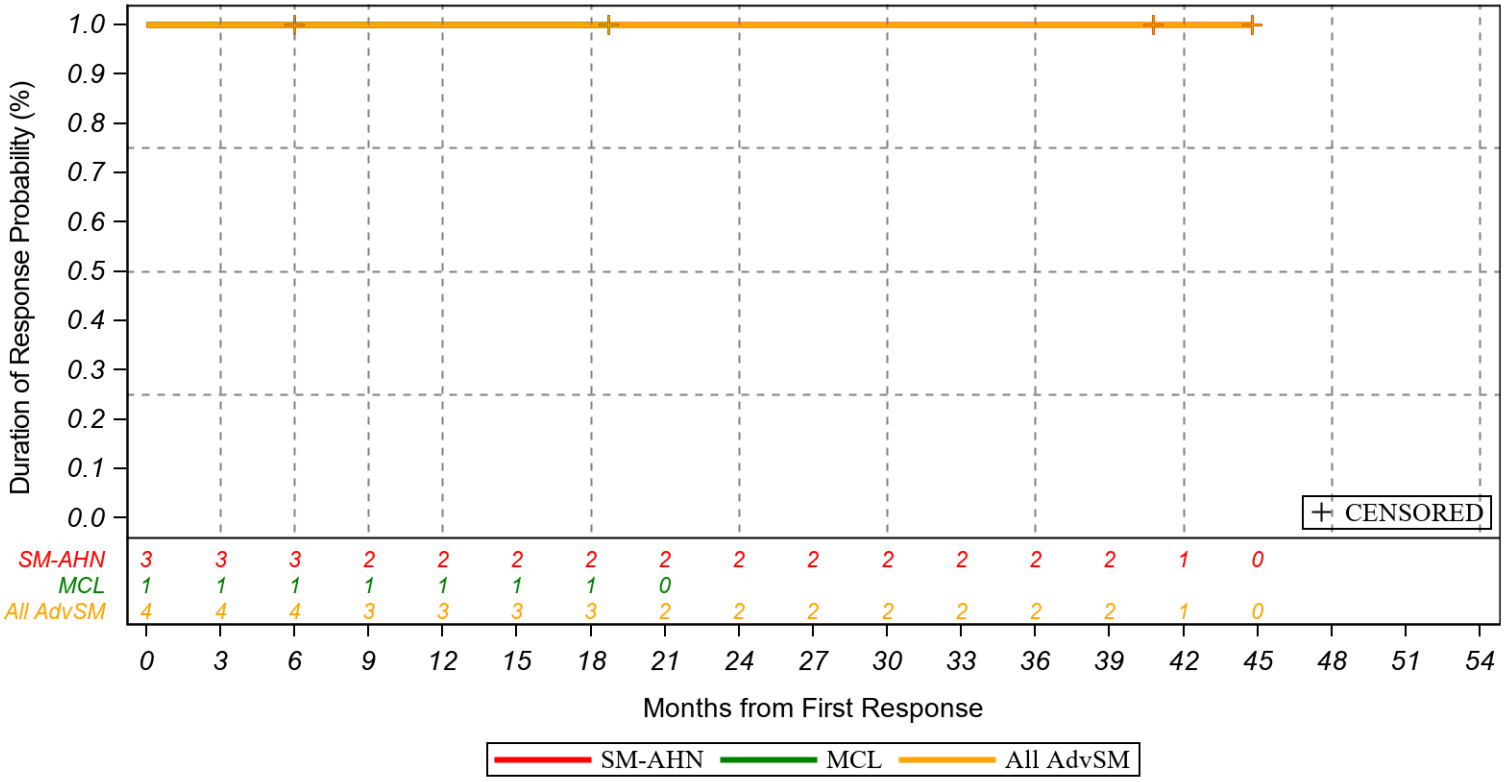

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR)

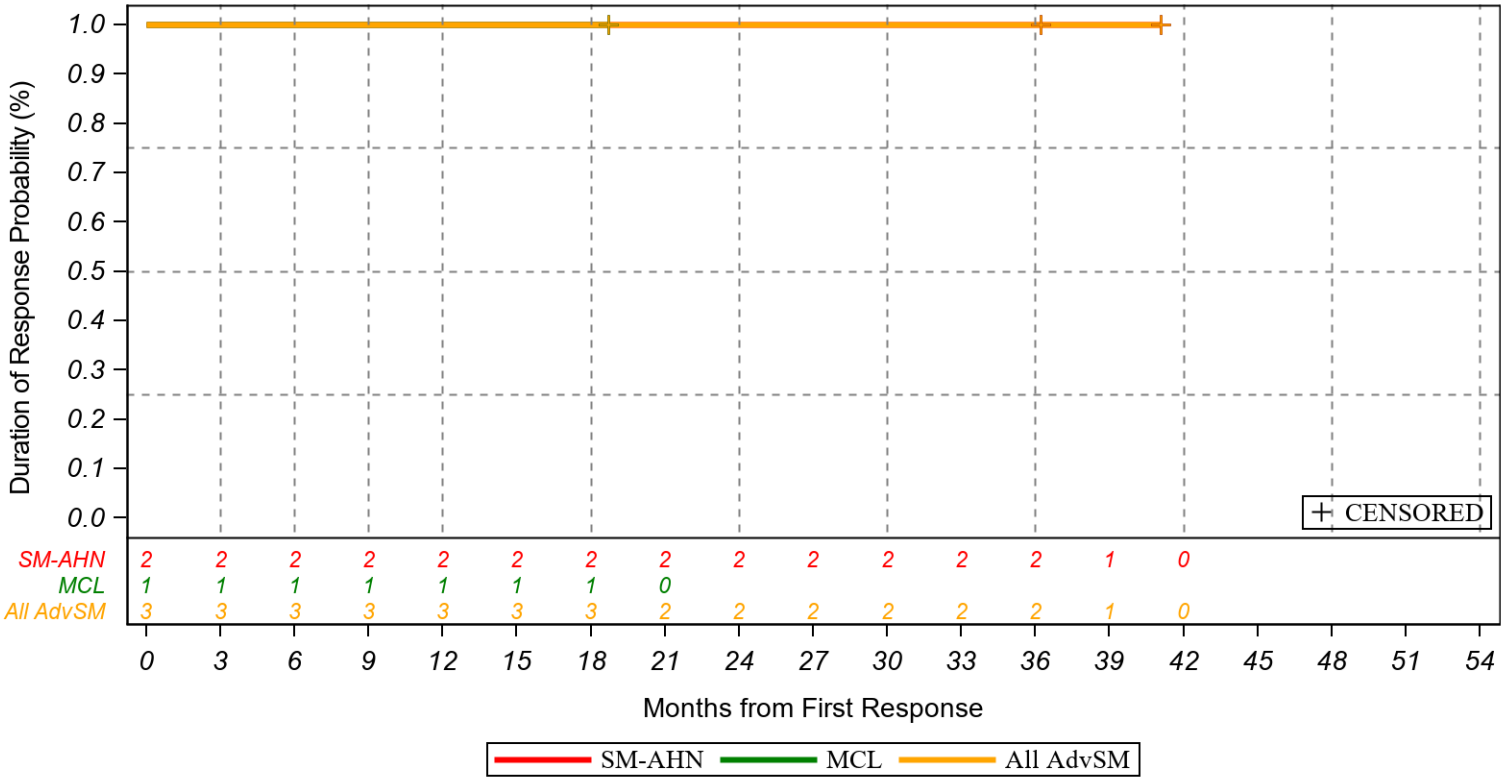

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR+CI)

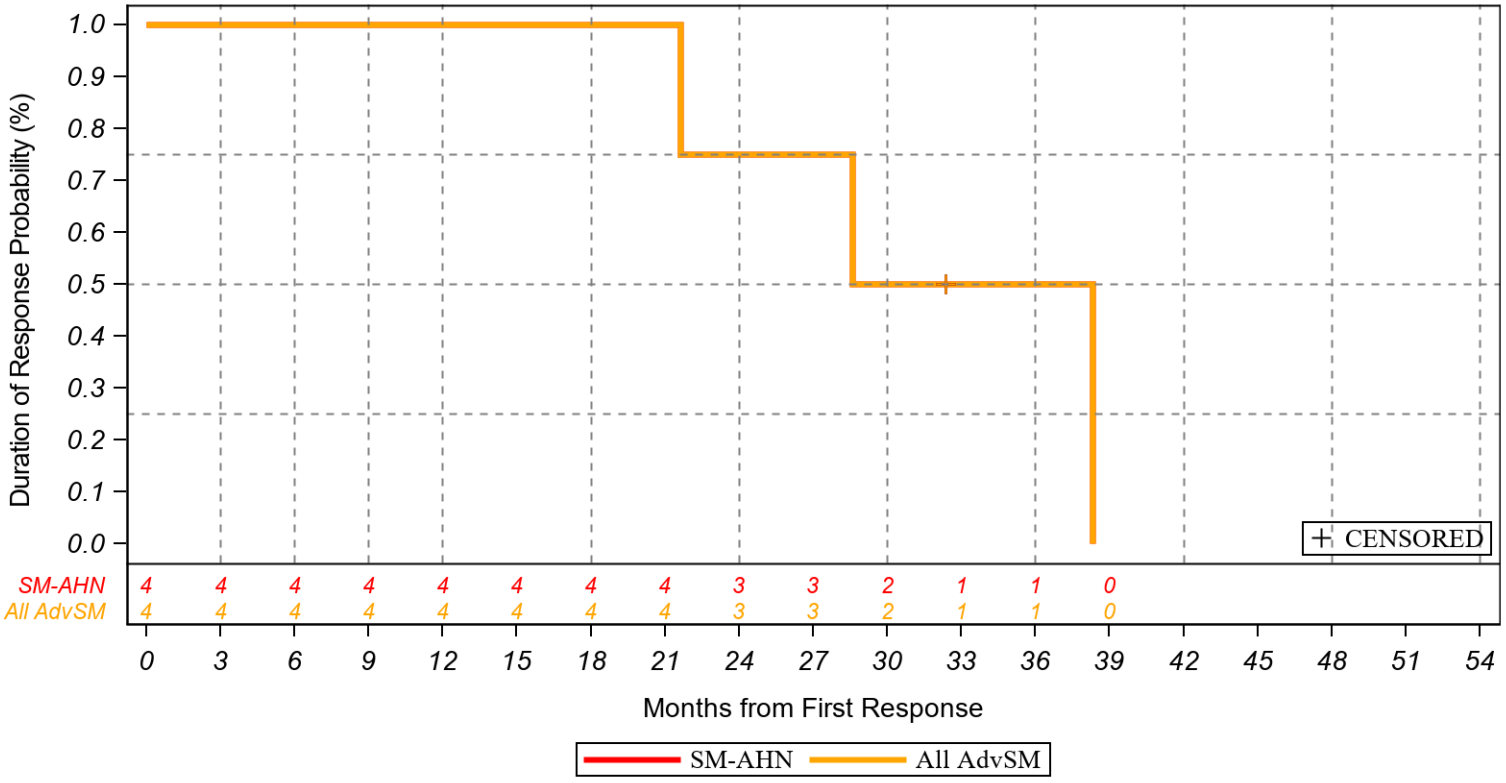

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg
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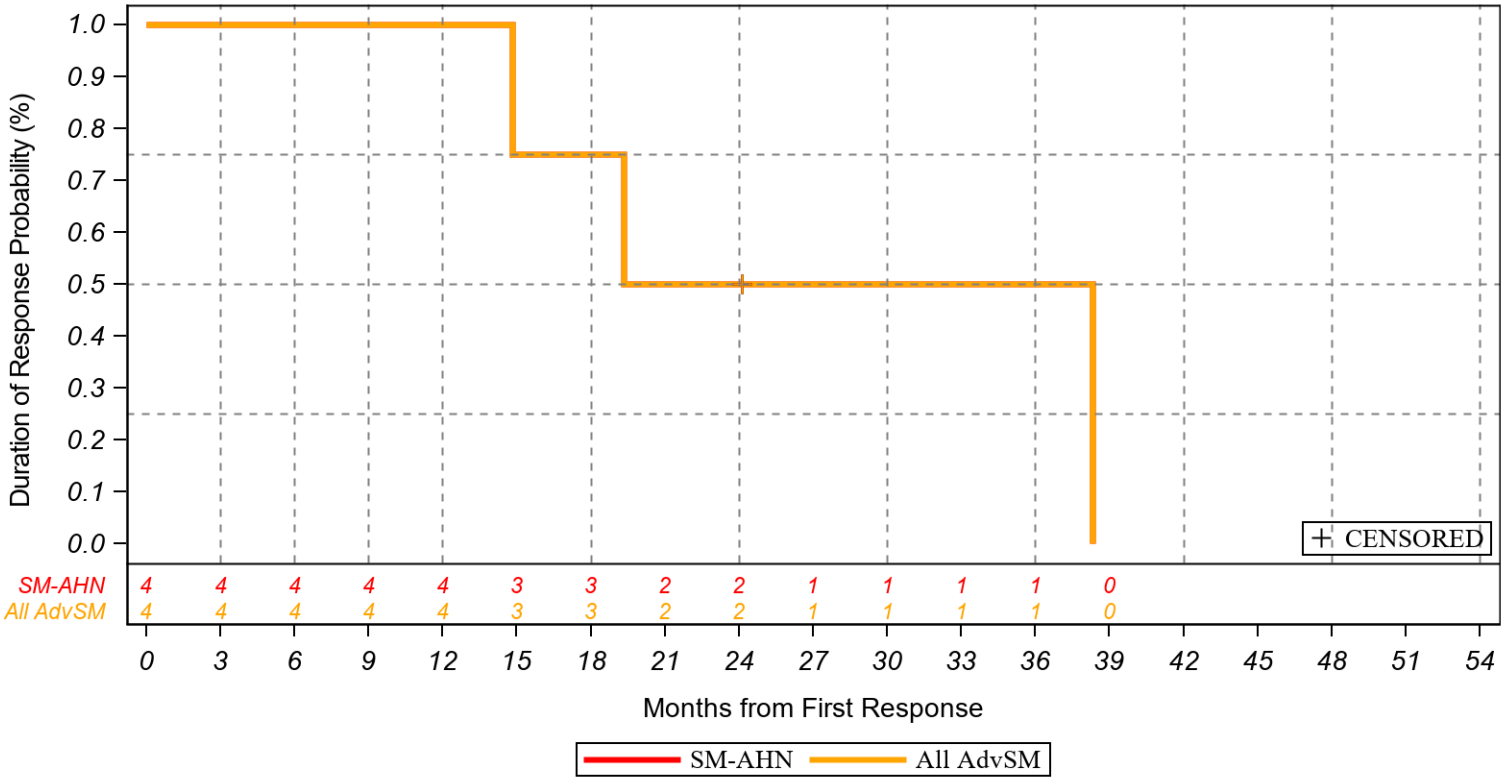

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR+CI)

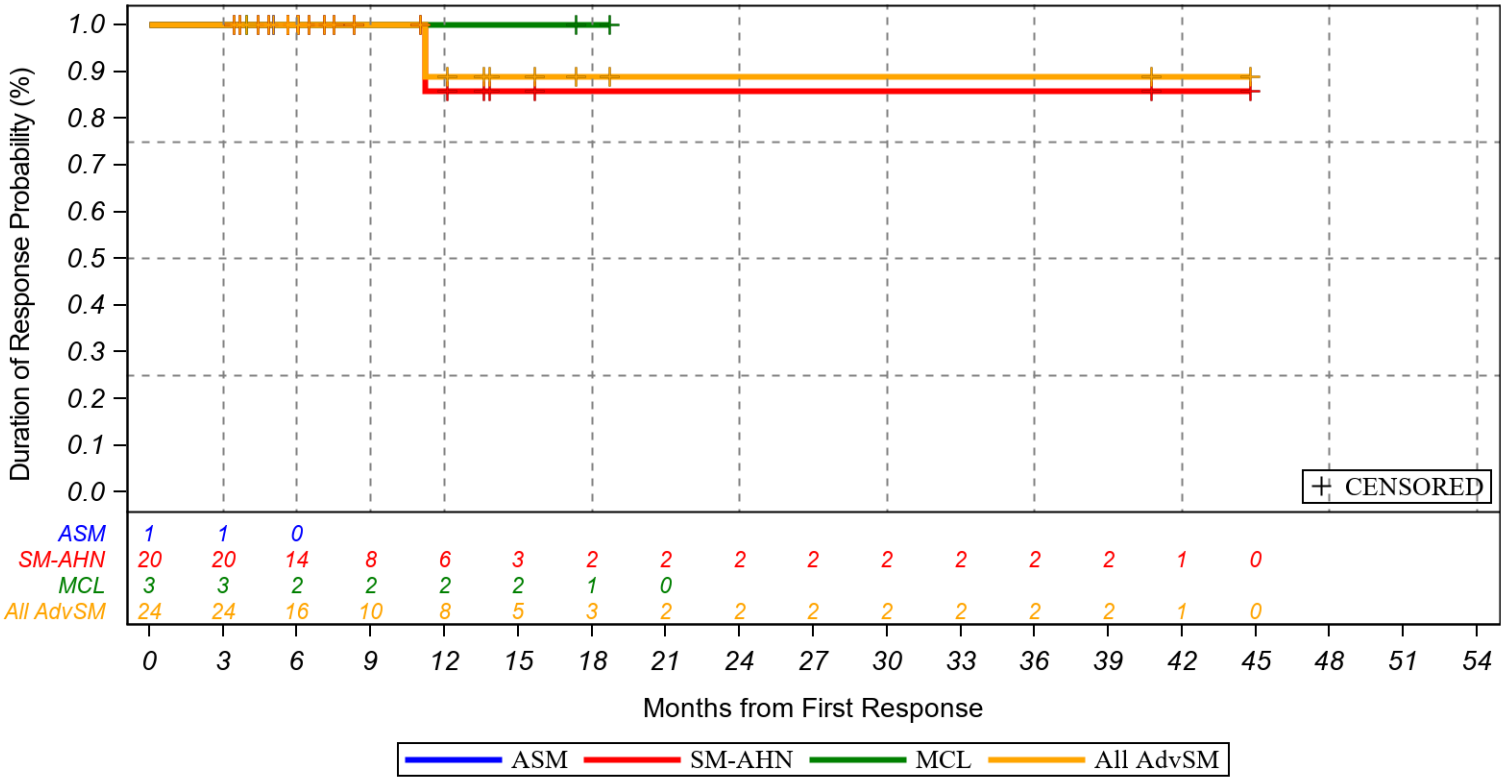

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR)

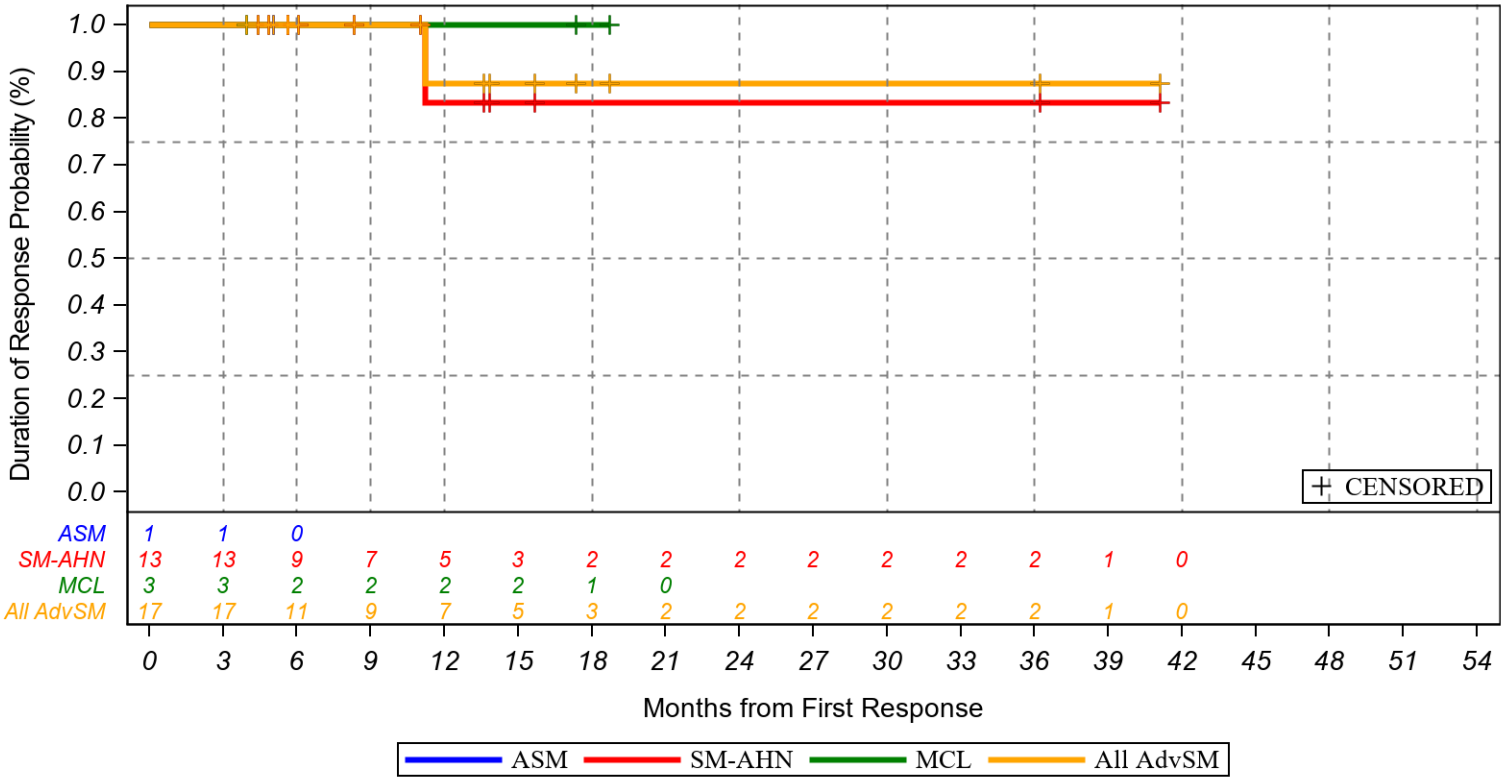

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR+CI)

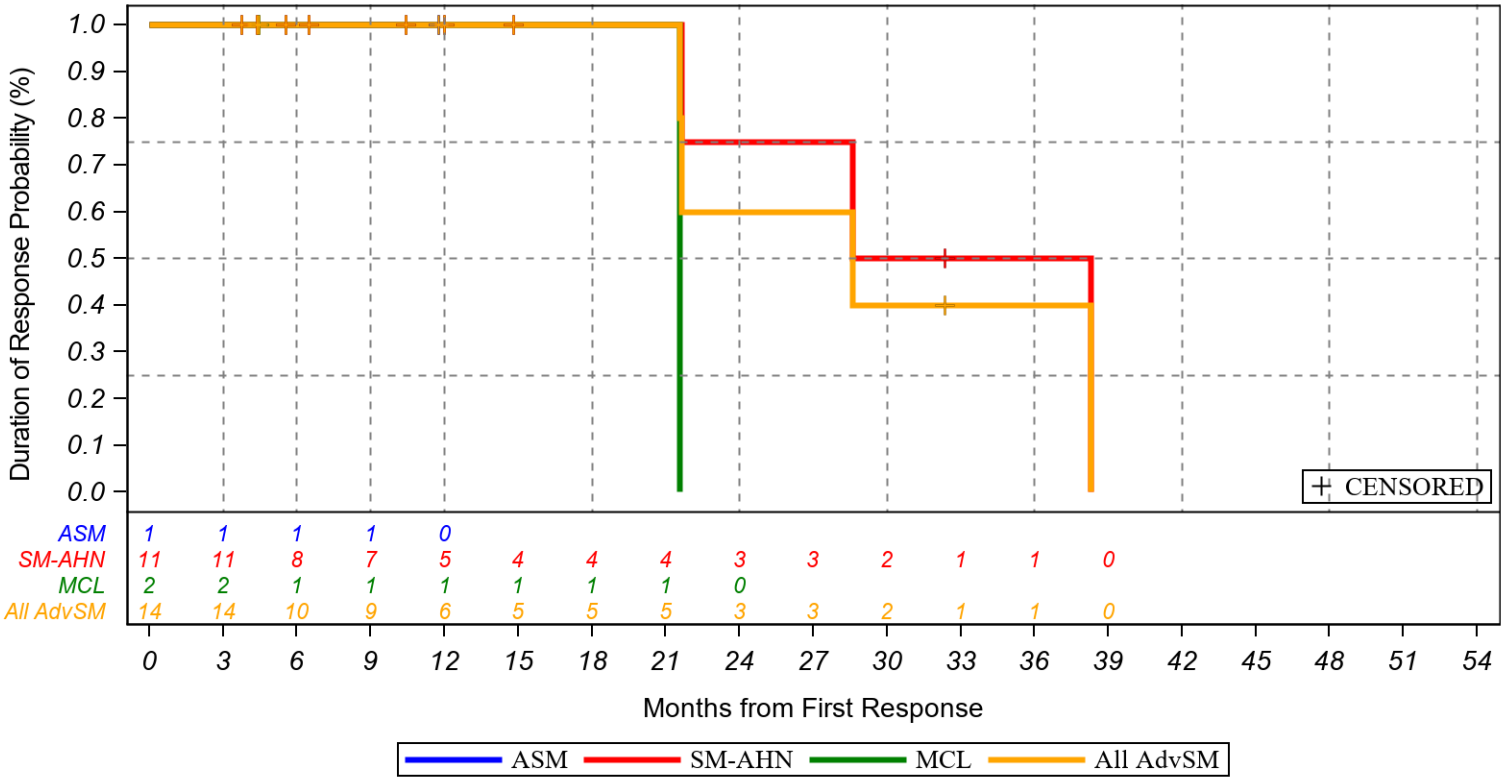

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR)

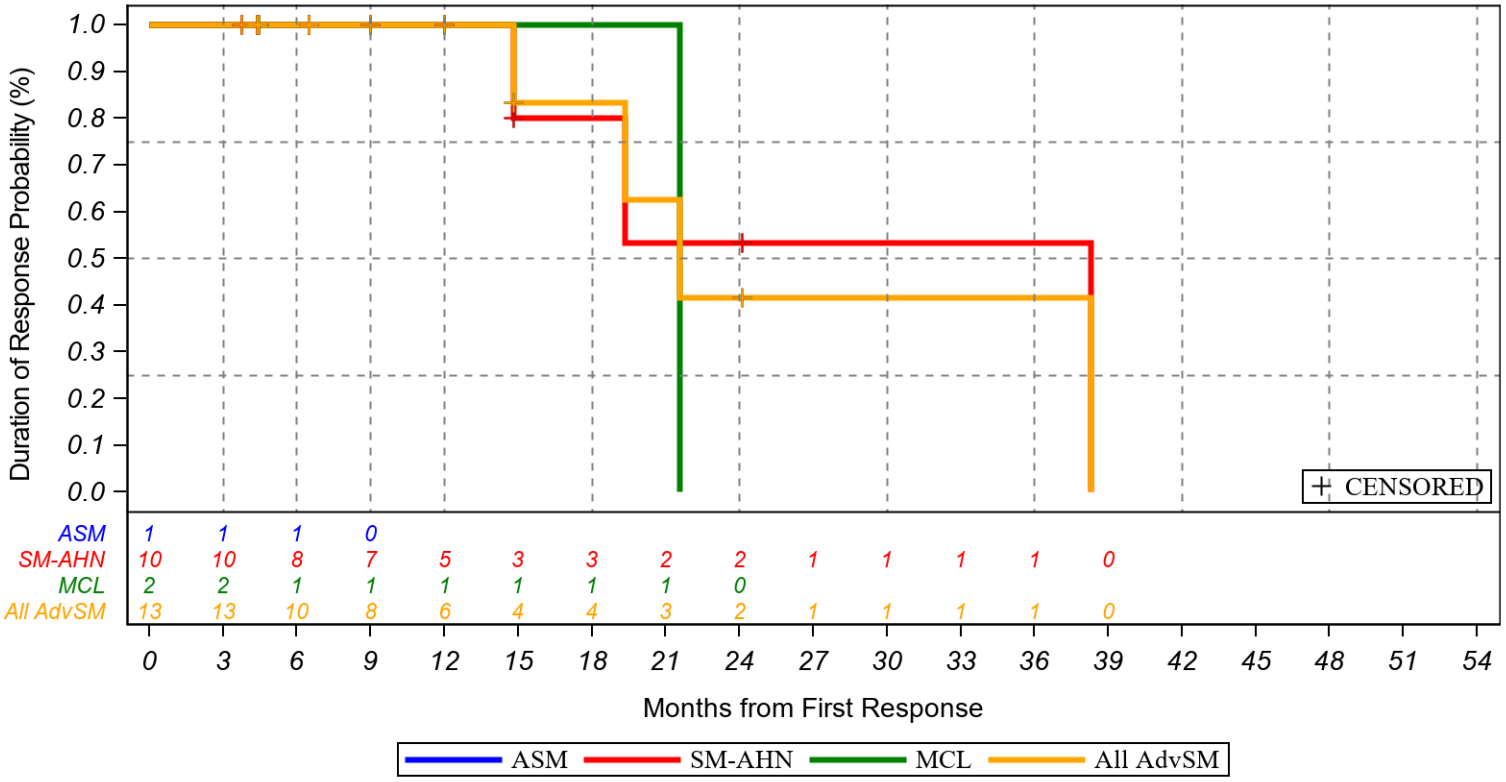

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR+CI)

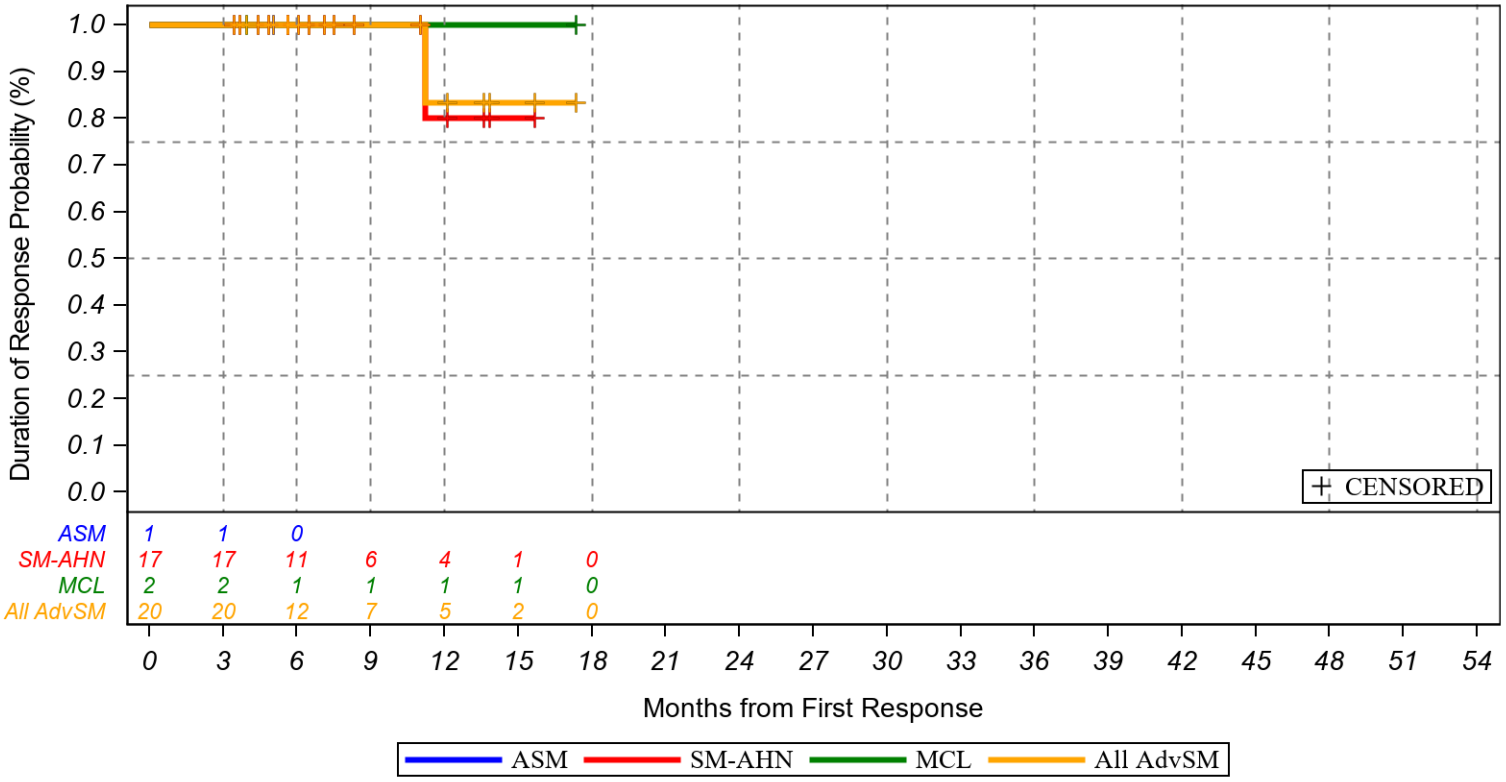

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR)

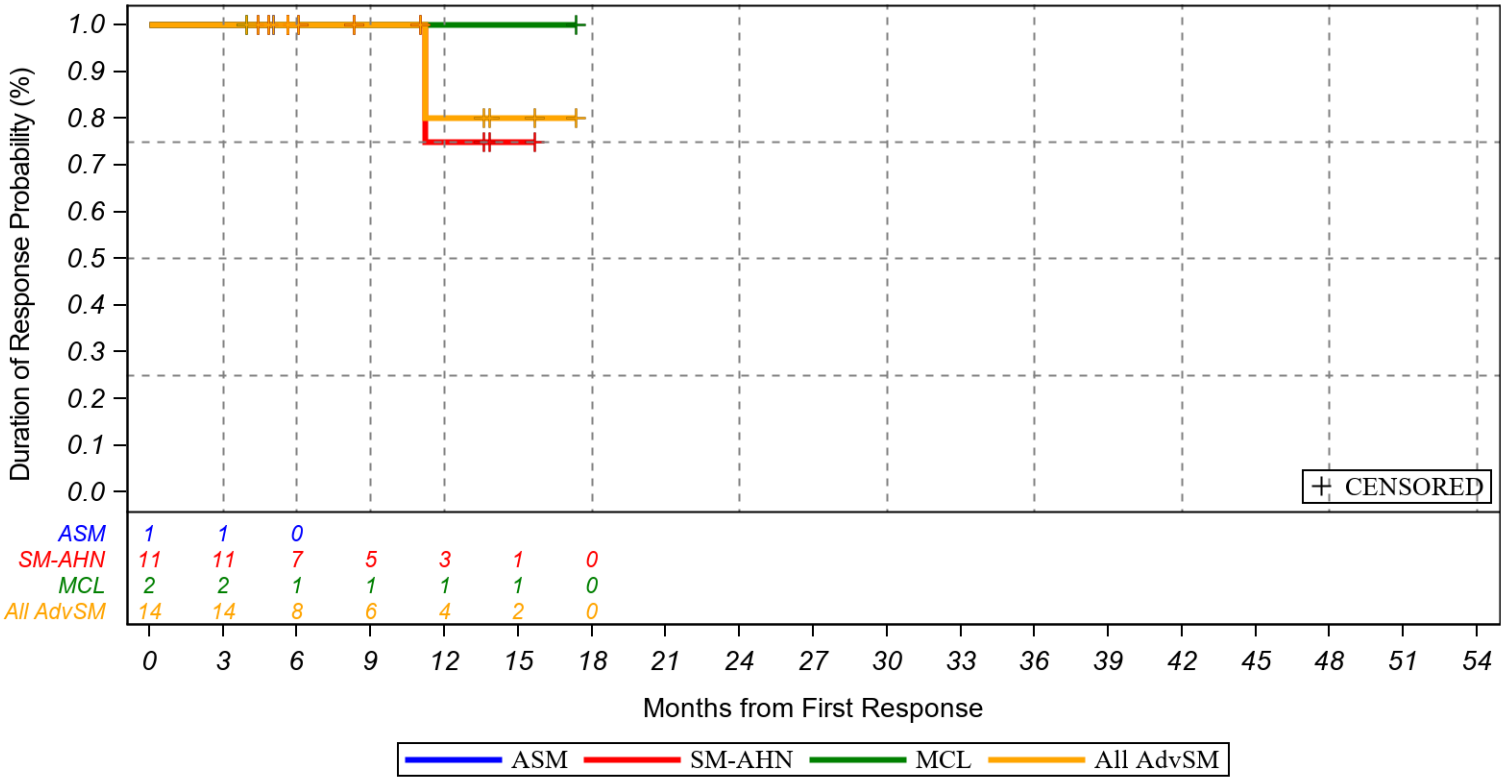

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR+CI)

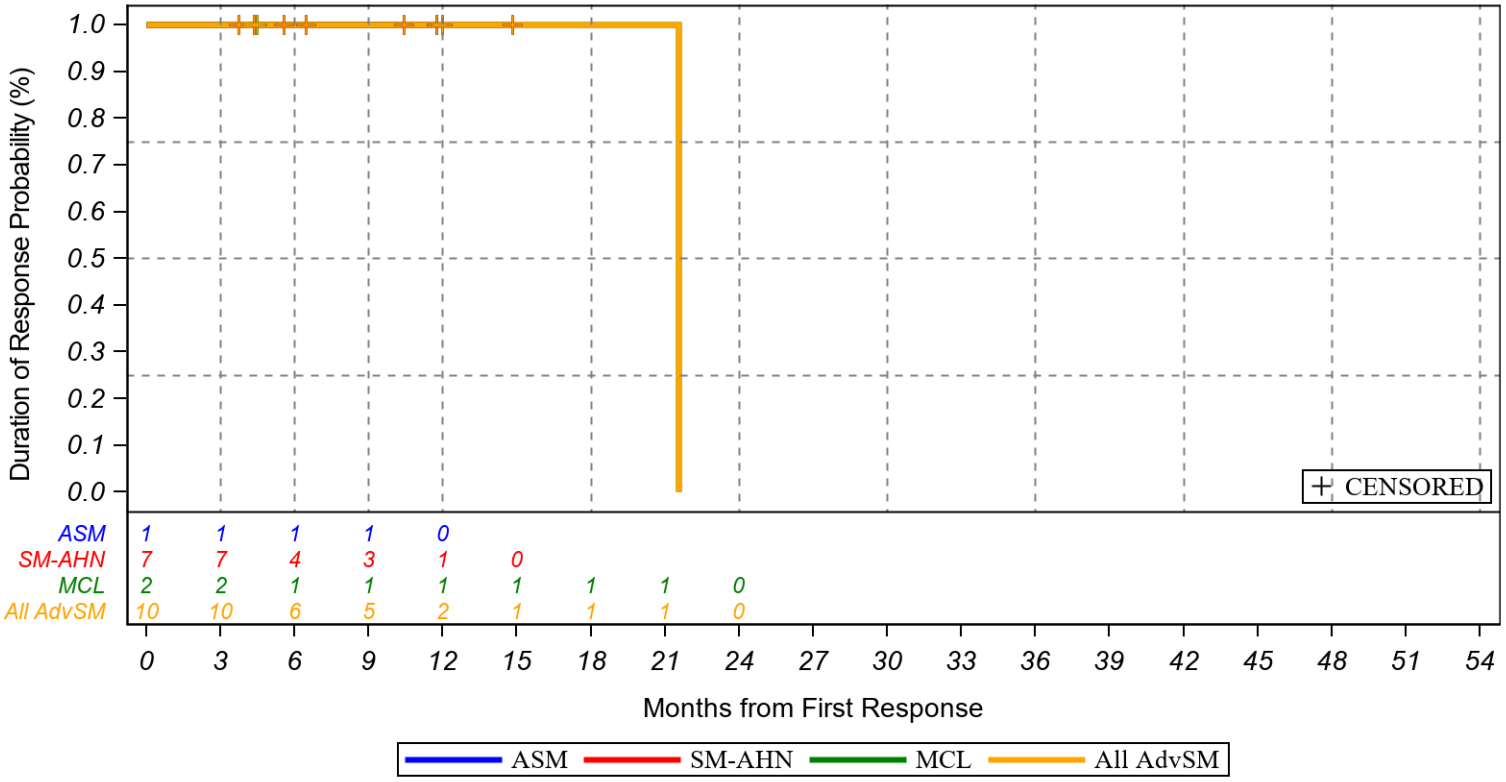

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR)

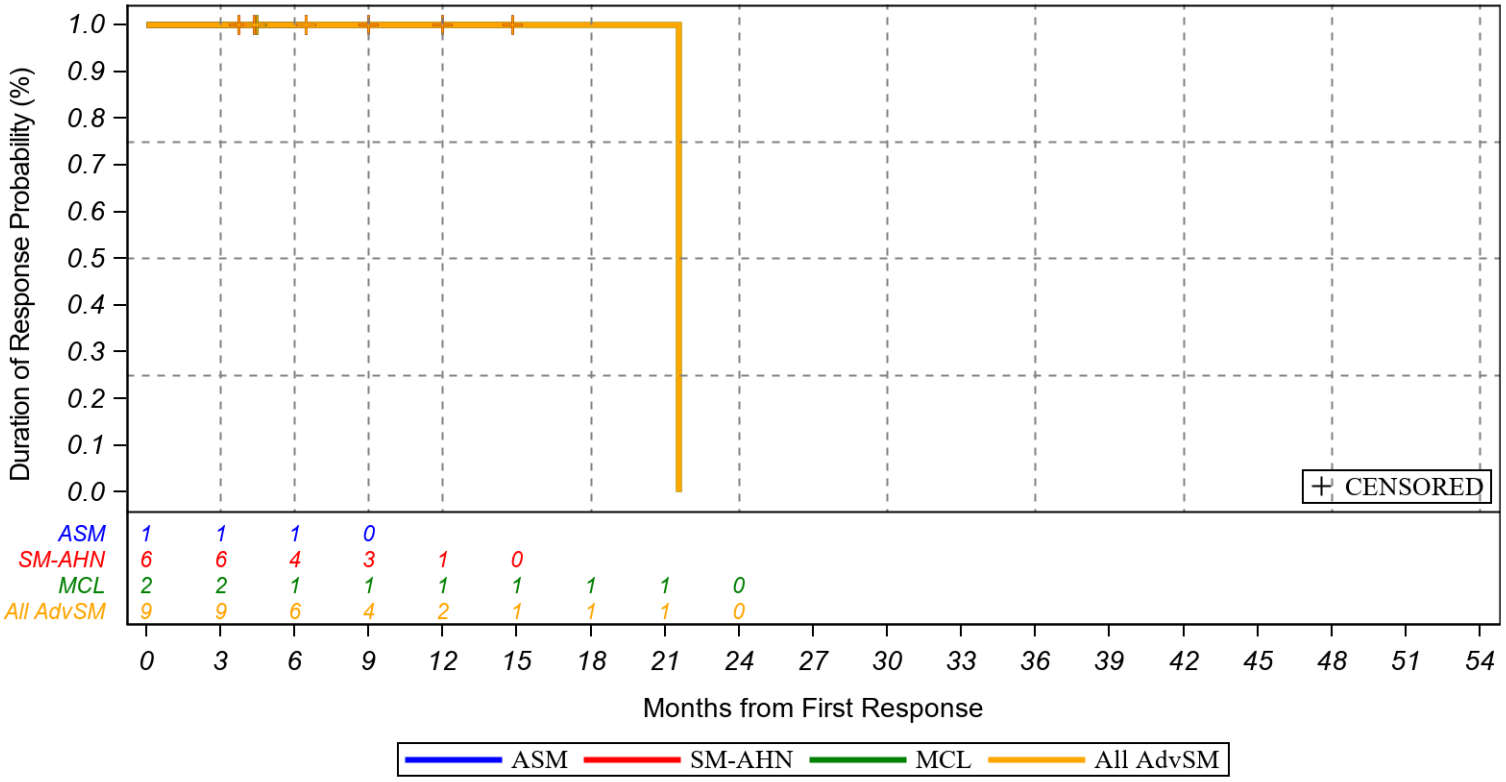

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR+CI)

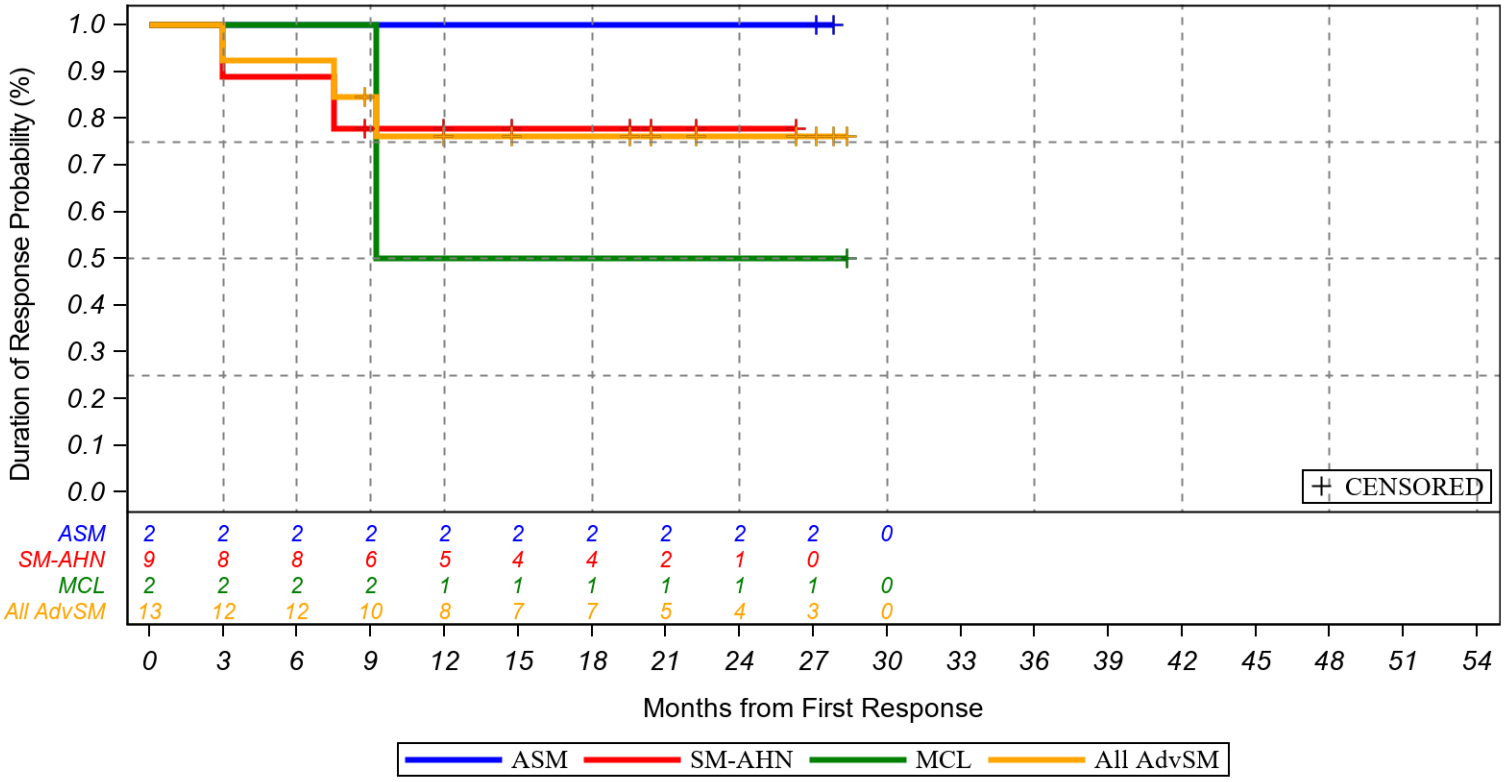
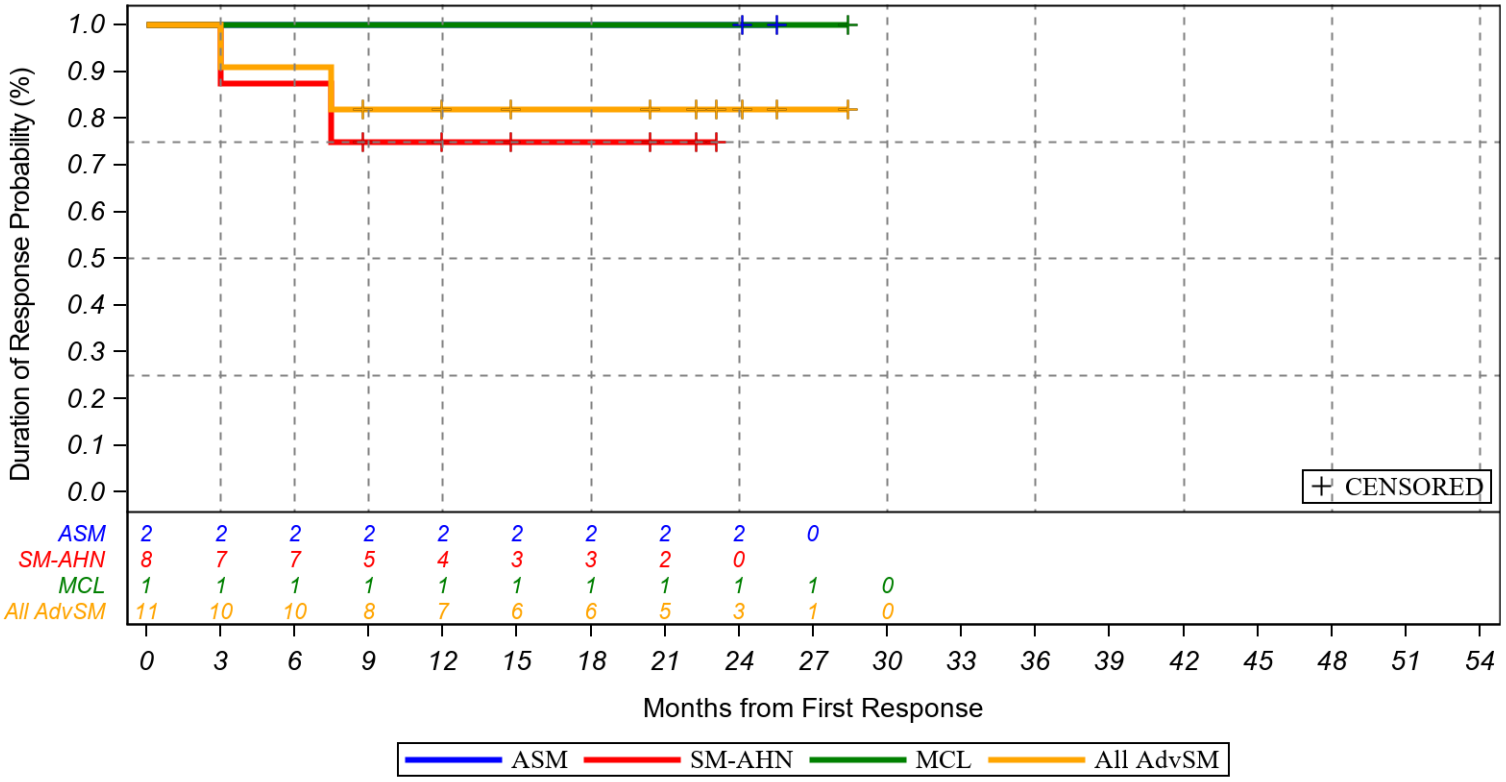


Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR)



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Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR+CI)

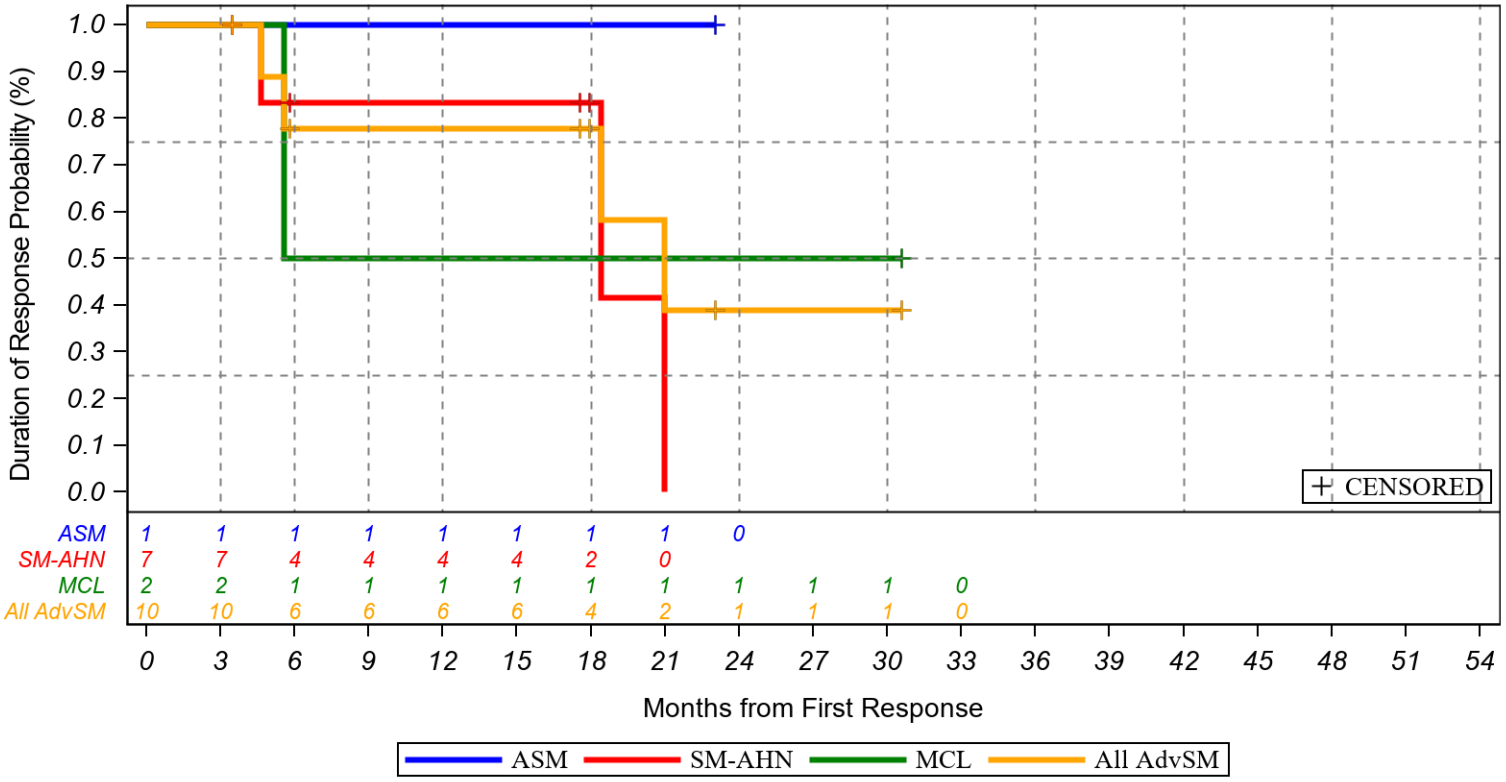

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR)

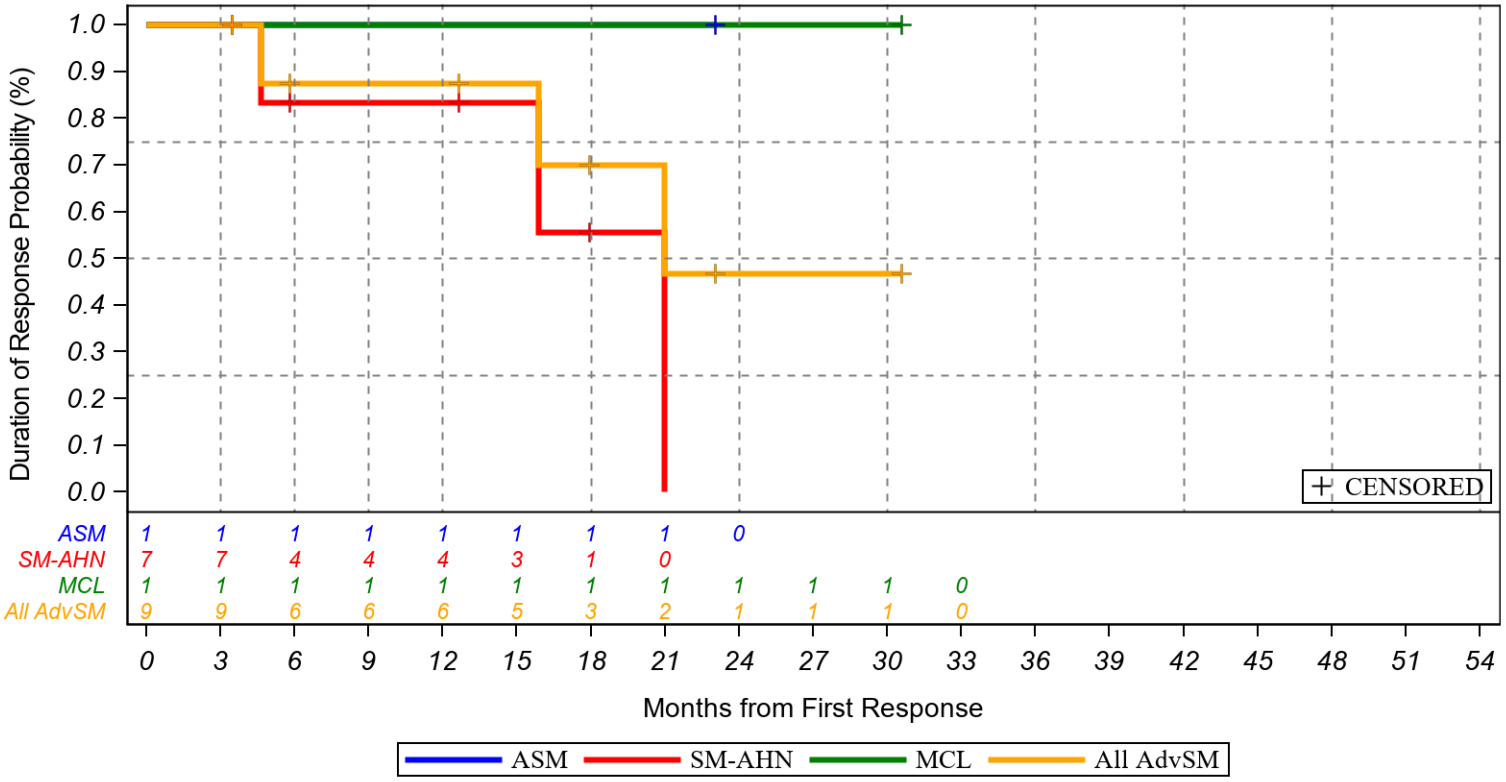

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR+CI)

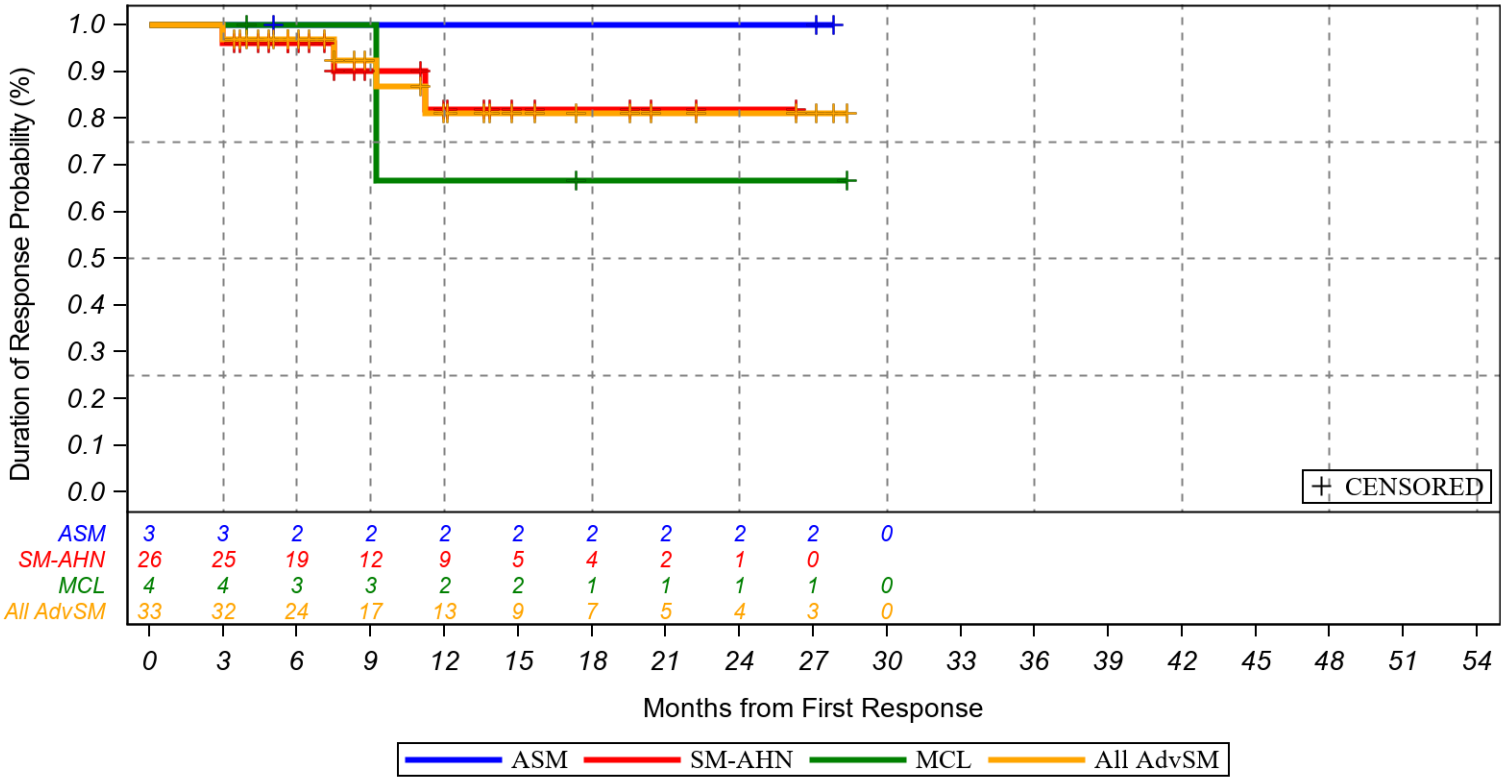

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR)

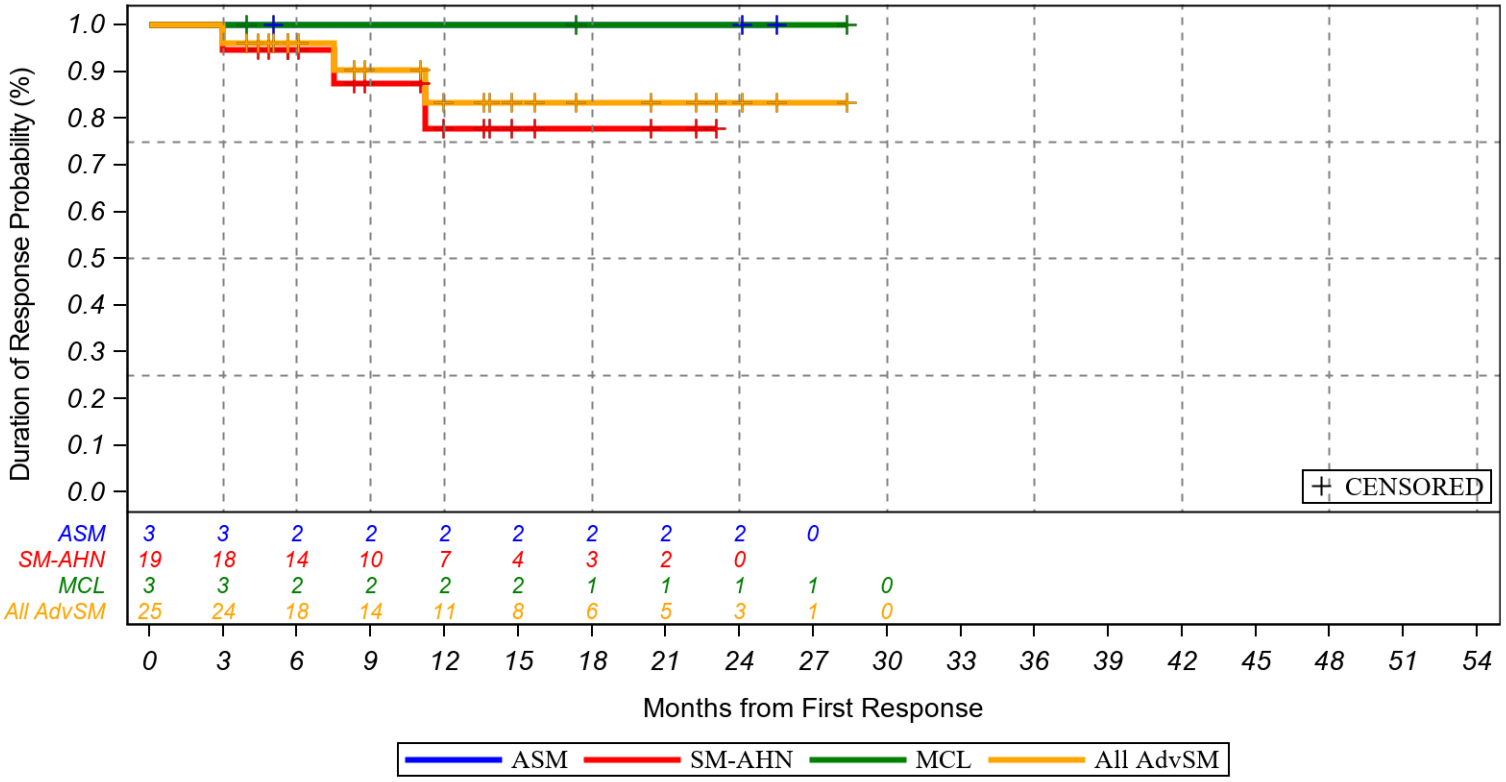

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR+CI)

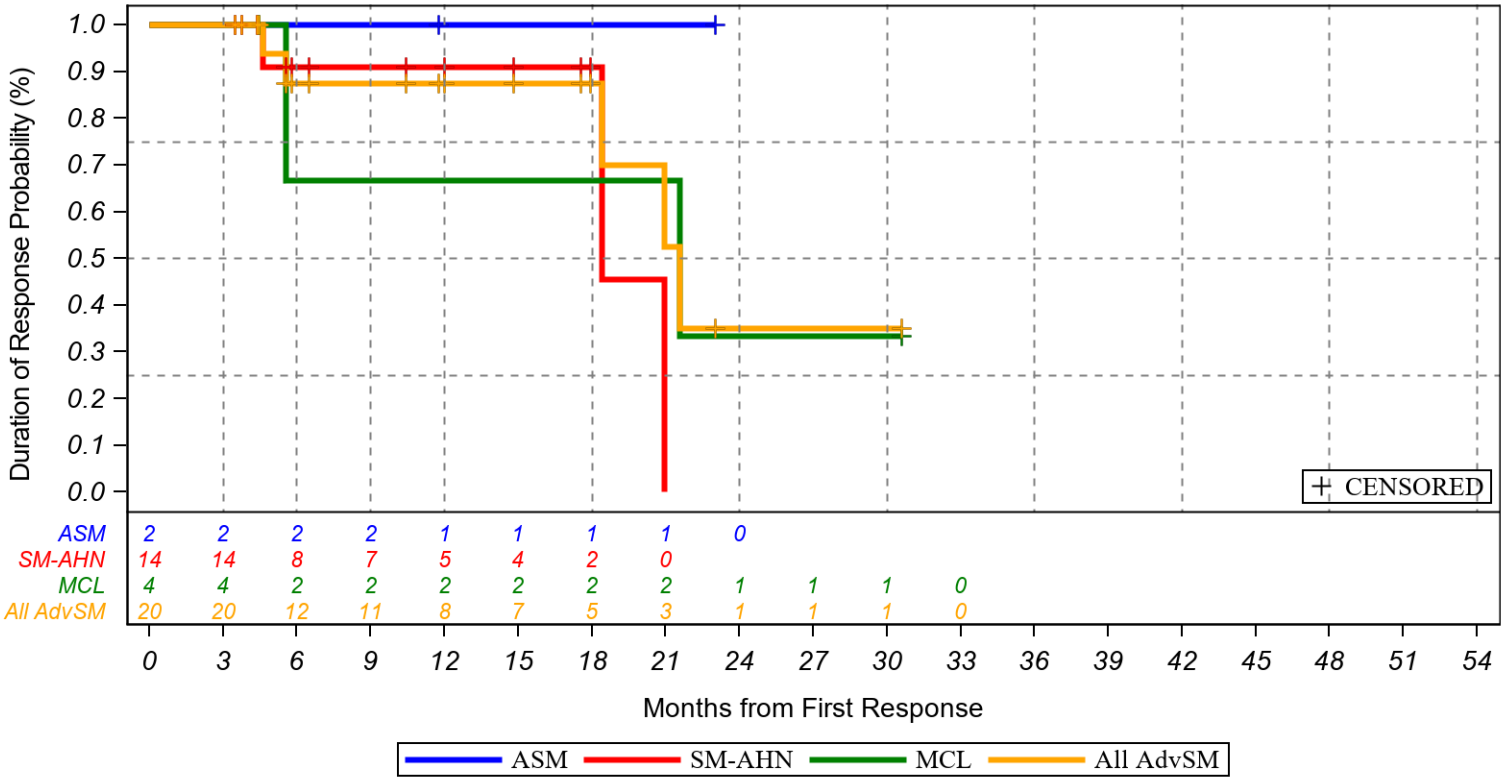

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR)

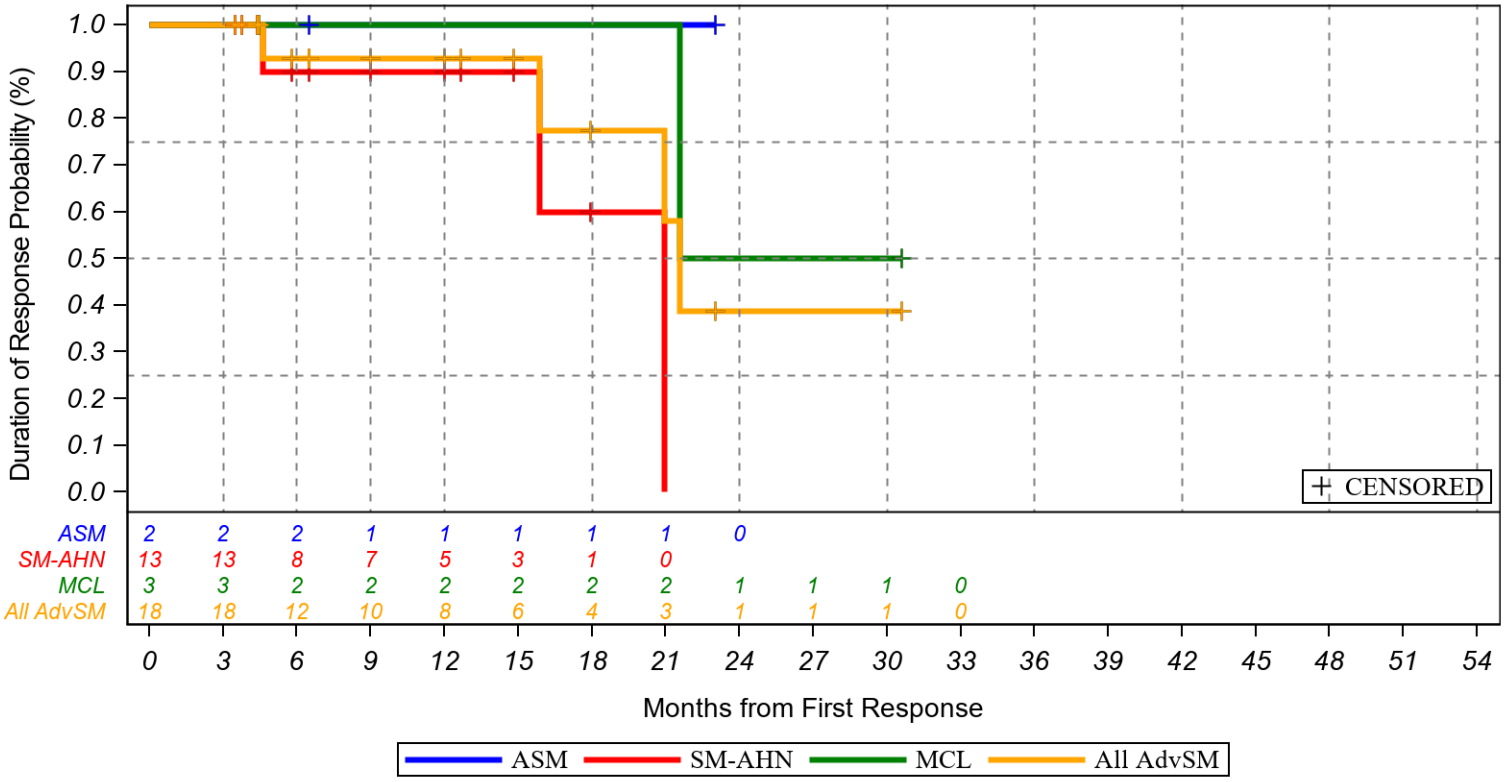

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR+CI)

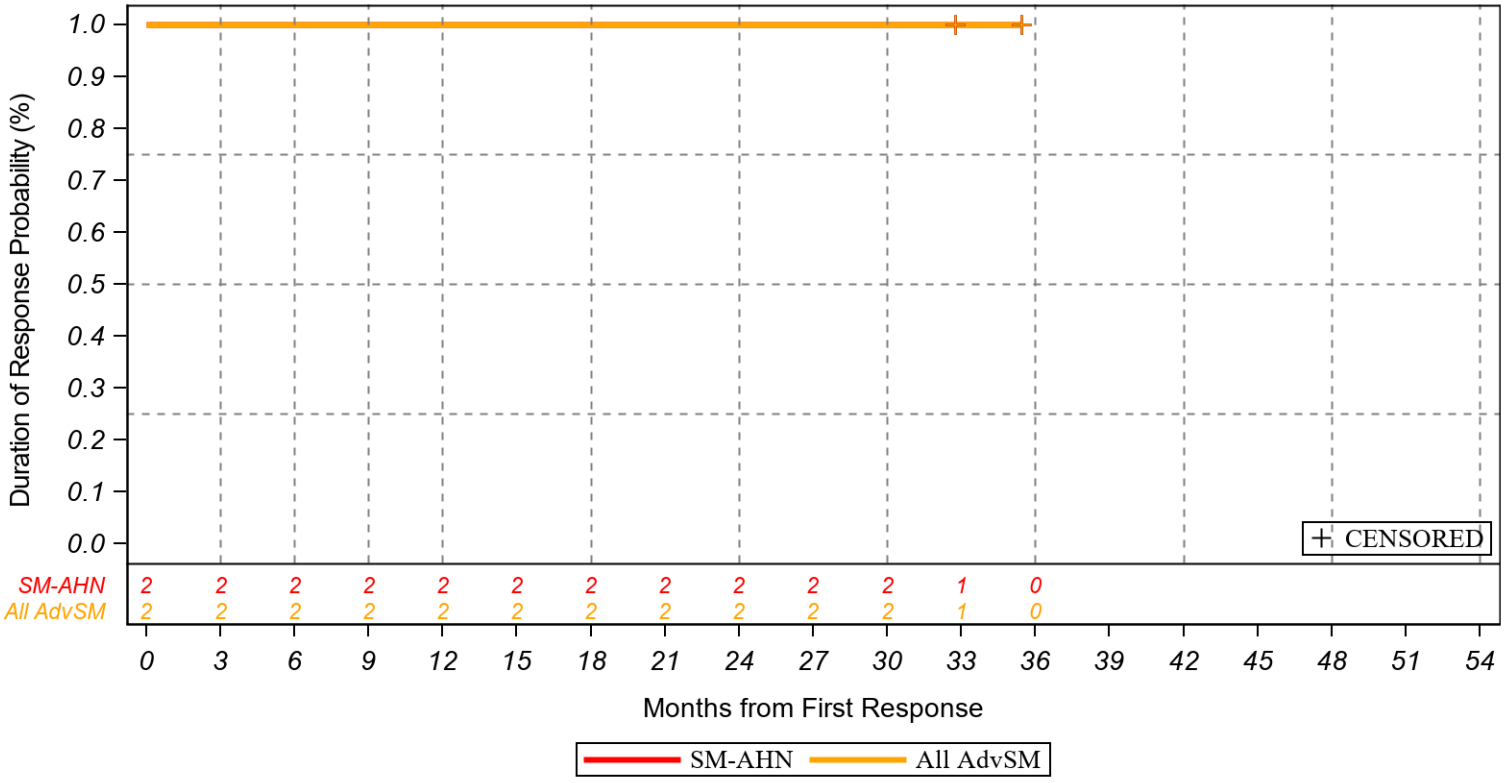

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR)

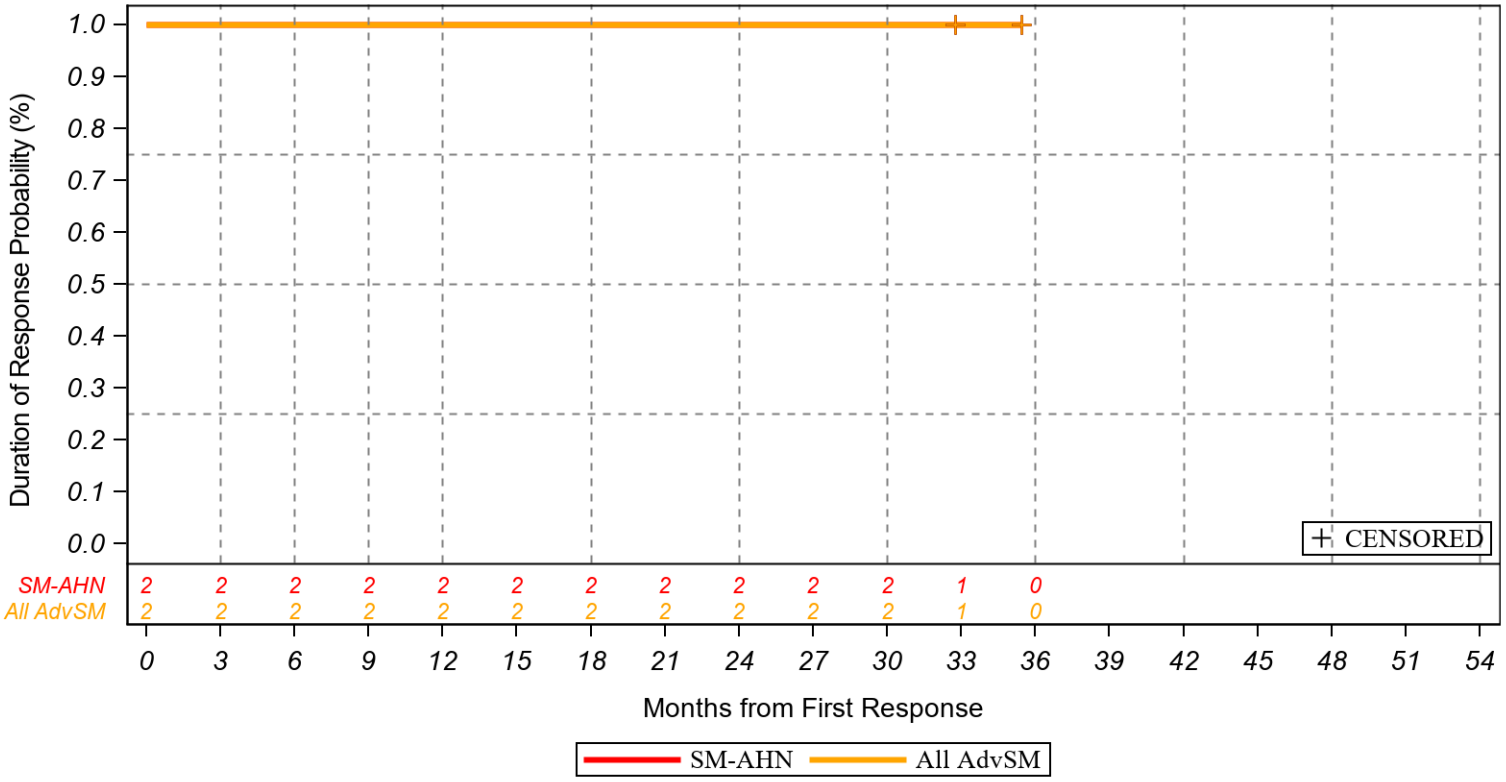

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR+CI)

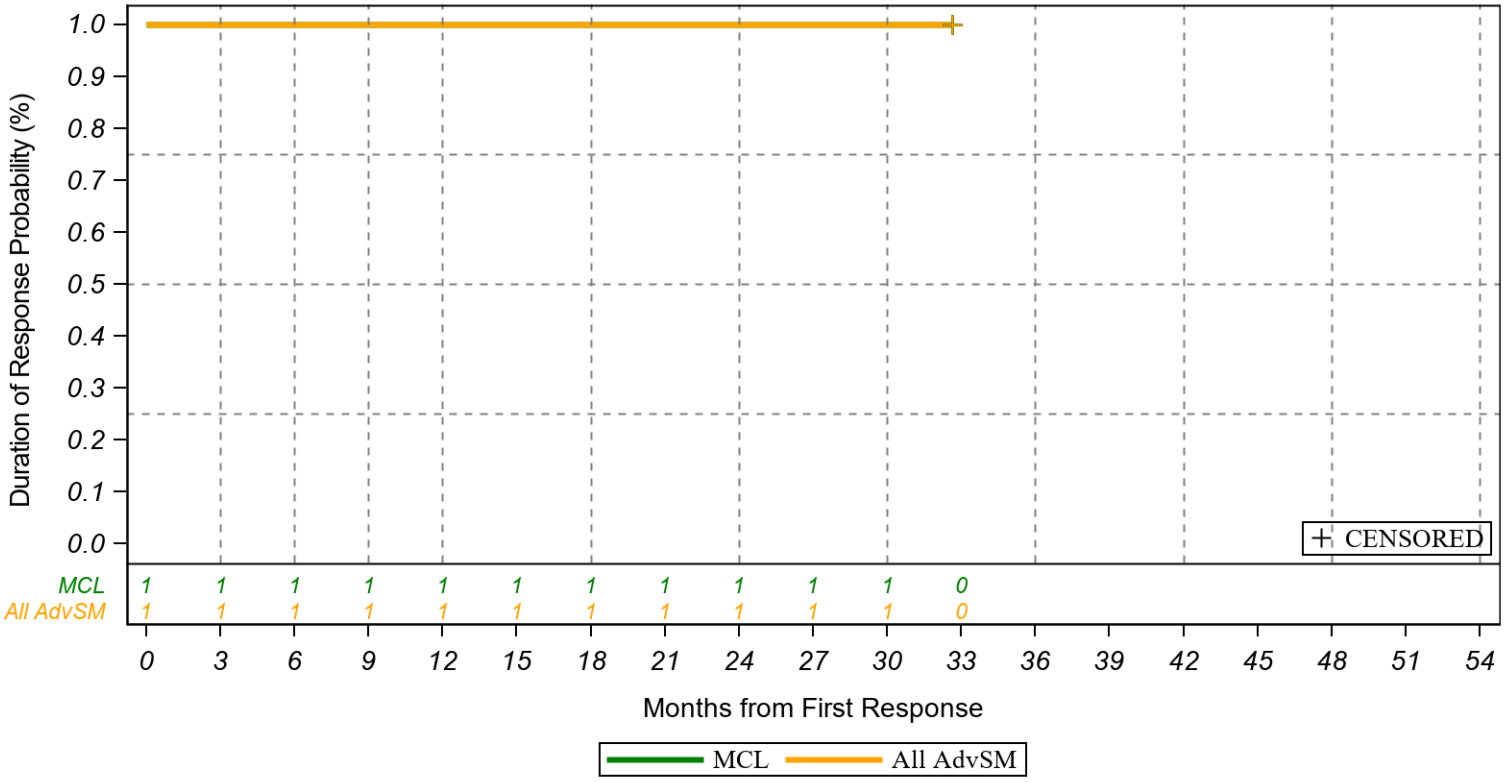

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR)

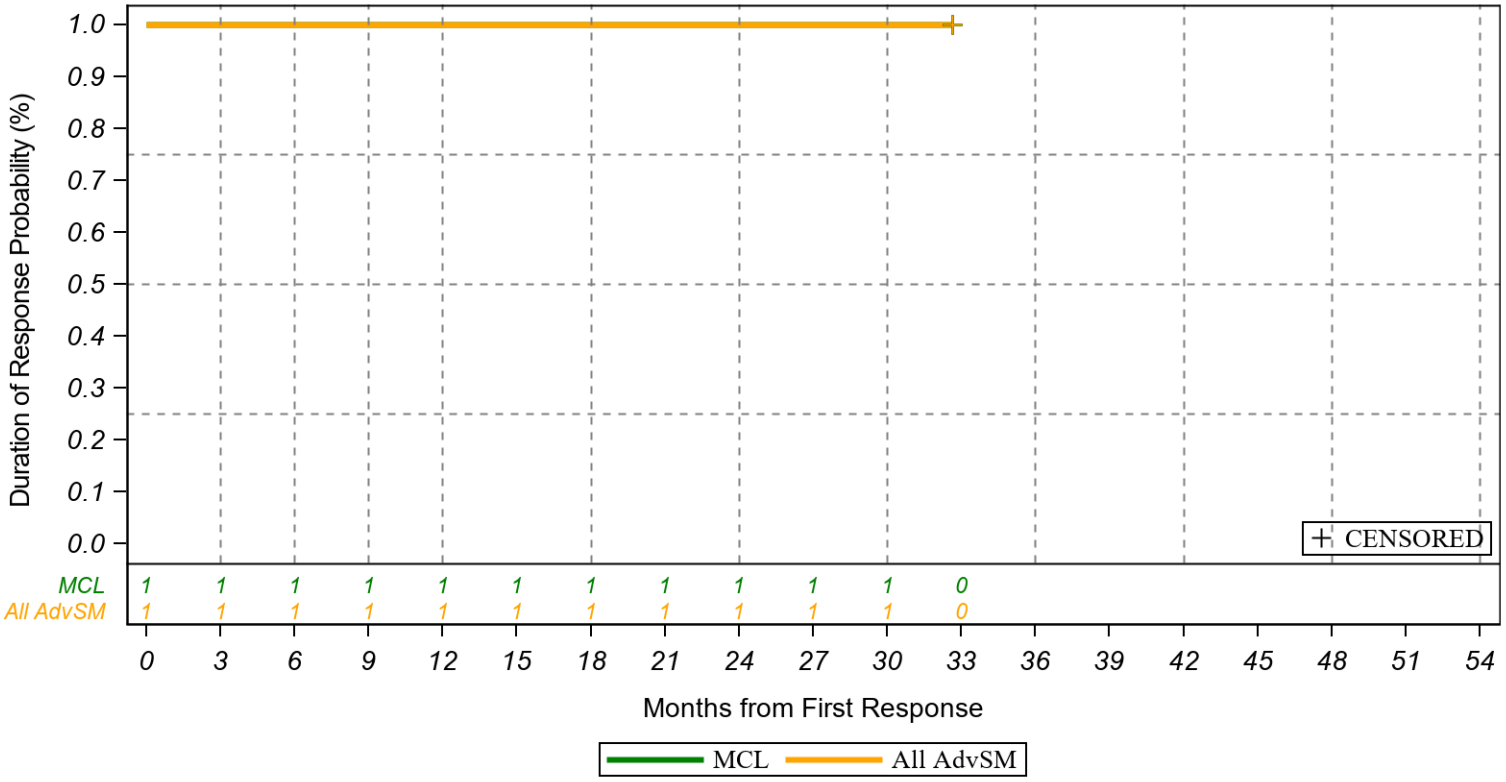

Table 35.2.2.2
Summary of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study 2101

All Doses

Duration of Response	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=15) n (%) (95% CIs)	MCL (N=4) n (%) (95% CIs)	All AdvSM (N=21) n (%) (95% CIs)
Events	0	2 (13.3)	0	2 (9.5)
Censors	2 (100.0)	13 (86.7)	4 (100.0)	19 (90.5)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (NE -NE)	NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	91.7 (76.0 -100.0)	100.0 (100.0 -100.0)	94.1 (82.9 -100.0)
12 Months (95% CIs)	100.0 (100.0 -100.0)	83.3 (62.2 -100.0)	100.0 (100.0 -100.0)	88.2 (72.9 -100.0)
18 Months (95% CIs)	100.0 (100.0 -100.0)	83.3 (62.2 -100.0)	100.0 (100.0 -100.0)	88.2 (72.9 -100.0)
24 Months (95% CIs)	100.0 (100.0 -100.0)	83.3 (62.2 -100.0)	100.0 (100.0 -100.0)	88.2 (72.9 -100.0)
30 Months (95% CIs)		83.3 (62.2 -100.0)	100.0 (100.0 -100.0)	88.2 (72.9 -100.0)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-dur-advsm.sas Date: 15:02/18OCT2021

Table 35.2.2.2
Summary of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study 2101

All Doses

Duration of CR+CRh+PR	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=13) n (%) (95% CIs)	MCL (N=3) n (%) (95% CIs)	All AdvSM (N=18) n (%) (95% CIs)
Events	0	1 (7.7)	0	1 (5.6)
Censors	2 (100.0)	12 (92.3)	3 (100.0)	17 (94.4)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (NE -NE)	NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	88.9 (68.4 -100.0)	100.0 (100.0 -100.0)	91.7 (76.0 -100.0)
12 Months (95% CIs)	100.0 (100.0 -100.0)	88.9 (68.4 -100.0)	100.0 (100.0 -100.0)	91.7 (76.0 -100.0)
18 Months (95% CIs)	100.0 (100.0 -100.0)	88.9 (68.4 -100.0)	100.0 (100.0 -100.0)	91.7 (76.0 -100.0)
24 Months (95% CIs)	100.0 (100.0 -100.0)	88.9 (68.4 -100.0)		91.7 (76.0 -100.0)
30 Months (95% CIs)		88.9 (68.4 -100.0)		91.7 (76.0 -100.0)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-dur-advsm.sas
Date: 15:02/18OCT2021

Table 35.2.2.2
Summary of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study 2101

Starting Dose: < 200 mg

Duration of Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=2) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=3) n (%) (95% CIs)
Events		0	0	0
Censors		2 (100.0)	1 (100.0)	3 (100.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE -NE)	NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles		NE, NE	NE, NE	NE, NE
3 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
12 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
18 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
24 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
30 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-dur-advsm.sas Date: 15:02/18OCT2021

Table 35.2.2.2
Summary of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study 2101

Starting Dose: < 200 mg

Duration of CR+CRh+PR	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=1) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=2) n (%) (95% CIs)
Events		0	0	0
Censors		1 (100.0)	1 (100.0)	2 (100.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE -NE)	NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles		NE, NE	NE, NE	NE, NE
3 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
9 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
12 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
18 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
24 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
30 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-dur-advsm.sas Date: 15:02/18OCT2021

Table 35.2.2.2
Summary of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study 2101

Starting Dose: < 300 mg

Duration of Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=5) n (%) (95% CIs)	MCL (N=3) n (%) (95% CIs)	All AdvSM (N=8) n (%) (95% CIs)
Events		1 (20.0)	0	1 (12.5)
Censors		4 (80.0)	3 (100.0)	7 (87.5)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (11.2 -NE)	NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles		NE, NE	NE, NE	NE, NE
3 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
12 Months (95% CIs)		75.0 (32.6 -100.0)	100.0 (100.0 -100.0)	83.3 (53.5 -100.0)
18 Months (95% CIs)		75.0 (32.6 -100.0)	100.0 (100.0 -100.0)	83.3 (53.5 -100.0)
24 Months (95% CIs)		75.0 (32.6 -100.0)	100.0 (100.0 -100.0)	83.3 (53.5 -100.0)
30 Months (95% CIs)		75.0 (32.6 -100.0)	100.0 (100.0 -100.0)	83.3 (53.5 -100.0)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-dur-advsm.sas
Date: 15:02/18OCT2021

Table 35.2.2.2
Summary of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study 2101

Starting Dose: < 300 mg

Duration of CR+CRh+PR	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=3) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=5) n (%) (95% CIs)
Events		0	0	0
Censors		3 (100.0)	2 (100.0)	5 (100.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE -NE)	NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles		NE, NE	NE, NE	NE, NE
3 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
12 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
18 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
24 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
30 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-dur-advsm.sas Date: 15:02/18OCT2021

Table 35.2.2.2
Summary of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study 2101

Starting Dose: 200 mg

Duration of Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=3) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=5) n (%) (95% CIs)
Events		1 (33.3)	0	1 (20.0)
Censors		2 (66.7)	2 (100.0)	4 (80.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (11.2 -NE)	NE (NE -NE)	NE (11.2 -NE)
25th, 75th percentiles		11.2, NE	NE, NE	11.2, NE
3 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
12 Months (95% CIs)		50.0 (0.0 -100.0)	100.0 (100.0 -100.0)	66.7 (13.3 -100.0)
18 Months (95% CIs)		50.0 (0.0 -100.0)		66.7 (13.3 -100.0)
24 Months (95% CIs)		50.0 (0.0 -100.0)		66.7 (13.3 -100.0)
30 Months (95% CIs)		50.0 (0.0 -100.0)		66.7 (13.3 -100.0)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-dur-advsm.sas Date: 15:02/18OCT2021

Table 35.2.2.2
Summary of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study 2101

Starting Dose: 200 mg

Duration of CR+CRh+PR	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=2) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=3) n (%) (95% CIs)
Events		0	0	0
Censors		2 (100.0)	1 (100.0)	3 (100.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE -NE)	NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles		NE, NE	NE, NE	NE, NE
3 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
12 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
18 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
24 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
30 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-dur-advsm.sas Date: 15:02/18OCT2021

Table 35.2.2.2
Summary of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study 2101

Starting Dose: 300 mg

Duration of Response	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=8) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=11) n (%) (95% CIs)
Events	0	1 (12.5)	0	1 (9.1)
Censors	2 (100.0)	7 (87.5)	1 (100.0)	10 (90.9)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (NE -NE)	NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	83.3 (53.5 -100.0)	100.0 (100.0 -100.0)	88.9 (68.4 -100.0)
12 Months (95% CIs)	100.0 (100.0 -100.0)	83.3 (53.5 -100.0)	100.0 (100.0 -100.0)	88.9 (68.4 -100.0)
18 Months (95% CIs)	100.0 (100.0 -100.0)	83.3 (53.5 -100.0)	100.0 (100.0 -100.0)	88.9 (68.4 -100.0)
24 Months (95% CIs)	100.0 (100.0 -100.0)	83.3 (53.5 -100.0)		88.9 (68.4 -100.0)
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-dur-advsm.sas Date: 15:02/18OCT2021

Table 35.2.2.2
Summary of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study 2101

Starting Dose: 300 mg

Duration of CR+CRh+PR	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=8) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=11) n (%) (95% CIs)
Events	0	1 (12.5)	0	1 (9.1)
Censors	2 (100.0)	7 (87.5)	1 (100.0)	10 (90.9)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (7.5 -NE)	NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	80.0 (44.9 -100.0)	100.0 (100.0 -100.0)	85.7 (59.8 -100.0)
12 Months (95% CIs)	100.0 (100.0 -100.0)	80.0 (44.9 -100.0)	100.0 (100.0 -100.0)	85.7 (59.8 -100.0)
18 Months (95% CIs)	100.0 (100.0 -100.0)	80.0 (44.9 -100.0)	100.0 (100.0 -100.0)	85.7 (59.8 -100.0)
24 Months (95% CIs)	100.0 (100.0 -100.0)	80.0 (44.9 -100.0)		85.7 (59.8 -100.0)
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-dur-advsm.sas Date: 15:02/18OCT2021

Table 35.2.2.2
Summary of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study 2101

Starting Dose: 200 mg and 300 mg

Duration of Response	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=11) n (%) (95% CIs)	MCL (N=3) n (%) (95% CIs)	All AdvSM (N=16) n (%) (95% CIs)
Events	0	2 (18.2)	0	2 (12.5)
Censors	2 (100.0)	9 (81.8)	3 (100.0)	14 (87.5)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (11.2 -NE)	NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	87.5 (64.6 -100.0)	100.0 (100.0 -100.0)	91.7 (76.0 -100.0)
12 Months (95% CIs)	100.0 (100.0 -100.0)	75.0 (45.0 -100.0)	100.0 (100.0 -100.0)	83.3 (62.2 -100.0)
18 Months (95% CIs)	100.0 (100.0 -100.0)	75.0 (45.0 -100.0)	100.0 (100.0 -100.0)	83.3 (62.2 -100.0)
24 Months (95% CIs)	100.0 (100.0 -100.0)	75.0 (45.0 -100.0)		83.3 (62.2 -100.0)
30 Months (95% CIs)		75.0 (45.0 -100.0)		83.3 (62.2 -100.0)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-dur-advsm.sas Date: 15:02/18OCT2021

Table 35.2.2.2
Summary of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study 2101

Starting Dose: 200 mg and 300 mg

Duration of CR+CRh+PR	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=10) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=14) n (%) (95% CIs)
Events	0	1 (10.0)	0	1 (7.1)
Censors	2 (100.0)	9 (90.0)	2 (100.0)	13 (92.9)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (NE -NE)	NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	83.3 (53.5 -100.0)	100.0 (100.0 -100.0)	88.9 (68.4 -100.0)
12 Months (95% CIs)	100.0 (100.0 -100.0)	83.3 (53.5 -100.0)	100.0 (100.0 -100.0)	88.9 (68.4 -100.0)
18 Months (95% CIs)	100.0 (100.0 -100.0)	83.3 (53.5 -100.0)	100.0 (100.0 -100.0)	88.9 (68.4 -100.0)
24 Months (95% CIs)	100.0 (100.0 -100.0)	83.3 (53.5 -100.0)		88.9 (68.4 -100.0)
30 Months (95% CIs)		83.3 (53.5 -100.0)		88.9 (68.4 -100.0)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-dur-advsm.sas
Date: 15:02/18OCT2021

Table 35.2.2.2
Summary of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study 2101

Starting Dose: 400 mg

Duration of Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=2) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=2) n (%) (95% CIs)
Events		0		0
Censors		2 (100.0)		2 (100.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE -NE)		NE (NE -NE)
25th, 75th percentiles		NE, NE		NE, NE
3 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
6 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
9 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
12 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
18 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
24 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
30 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-dur-advsm.sas Date: 15:02/18OCT2021

Table 35.2.2.2
Summary of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study 2101

Starting Dose: 400 mg

Duration of CR+CRh+PR	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=2) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=2) n (%) (95% CIs)
Events		0		0
Censors		2 (100.0)		2 (100.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE -NE)		NE (NE -NE)
25th, 75th percentiles		NE, NE		NE, NE
3 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
6 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
9 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
12 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
18 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
24 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-dur-advsm.sas Date: 15:02/18OCT2021

Table 35.2.2.2
Summary of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study 2202

All Doses

Duration of Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=12) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=13) n (%) (95% CIs)
Events		0	0	0
Censors		12 (100.0)	1 (100.0)	13 (100.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE -NE)	NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles		NE, NE	NE, NE	NE, NE
3 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
12 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
18 Months (95% CIs)				
24 Months (95% CIs)				
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-dur-advsm.sas Date: 15:02/18OCT2021

Table 35.2.2.2
Summary of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study 2202

All Doses

Duration of CR+CRh+PR	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=7) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=8) n (%) (95% CIs)
Events		0	0	0
Censors		7 (100.0)	1 (100.0)	8 (100.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE -NE)	NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles		NE, NE	NE, NE	NE, NE
3 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)			100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
12 Months (95% CIs)				
18 Months (95% CIs)				
24 Months (95% CIs)				
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-dur-advsm.sas Date: 15:02/18OCT2021

Table 35.2.2.2
Summary of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study 2202

Starting Dose: 200 mg

Duration of Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=11) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=12) n (%) (95% CIs)
Events		0	0	0
Censors		11 (100.0)	1 (100.0)	12 (100.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE -NE)	NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles		NE, NE	NE, NE	NE, NE
3 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
12 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
18 Months (95% CIs)				
24 Months (95% CIs)				
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-dur-advsm.sas Date: 15:02/18OCT2021

Table 35.2.2.2
Summary of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study 2202

Starting Dose: 200 mg

Duration of CR+CRh+PR	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=6) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=7) n (%) (95% CIs)
Events		0	0	0
Censors		6 (100.0)	1 (100.0)	7 (100.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE -NE)	NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles		NE, NE	NE, NE	NE, NE
3 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)			100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
12 Months (95% CIs)				
18 Months (95% CIs)				
24 Months (95% CIs)				
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-dur-advsm.sas Date: 15:02/18OCT2021

Table 35.2.2.2
Summary of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies 2101 and 2202

All Doses

Duration of Response	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=27) n (%) (95% CIs)	MCL (N=5) n (%) (95% CIs)	All AdvSM (N=34) n (%) (95% CIs)
Events	0	2 (7.4)	0	2 (5.9)
Censors	2 (100.0)	25 (92.6)	5 (100.0)	32 (94.1)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (NE -NE)	NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	92.3 (77.8 -100.0)	100.0 (100.0 -100.0)	94.7 (84.7 -100.0)
12 Months (95% CIs)	100.0 (100.0 -100.0)	84.6 (65.0 -100.0)	100.0 (100.0 -100.0)	89.2 (75.0 -100.0)
18 Months (95% CIs)	100.0 (100.0 -100.0)	84.6 (65.0 -100.0)	100.0 (100.0 -100.0)	89.2 (75.0 -100.0)
24 Months (95% CIs)	100.0 (100.0 -100.0)	84.6 (65.0 -100.0)	100.0 (100.0 -100.0)	89.2 (75.0 -100.0)
30 Months (95% CIs)		84.6 (65.0 -100.0)	100.0 (100.0 -100.0)	89.2 (75.0 -100.0)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-dur-advsm.sas
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Table 35.2.2.2
Summary of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies 2101 and 2202

All Doses

Duration of CR+CRh+PR	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=20) n (%) (95% CIs)	MCL (N=4) n (%) (95% CIs)	All AdvSM (N=26) n (%) (95% CIs)
Events	0	1 (5.0)	0	1 (3.8)
Censors	2 (100.0)	19 (95.0)	4 (100.0)	25 (96.2)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (NE -NE)	NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	88.9 (68.4 -100.0)	100.0 (100.0 -100.0)	92.3 (77.8 -100.0)
12 Months (95% CIs)	100.0 (100.0 -100.0)	88.9 (68.4 -100.0)	100.0 (100.0 -100.0)	92.3 (77.8 -100.0)
18 Months (95% CIs)	100.0 (100.0 -100.0)	88.9 (68.4 -100.0)	100.0 (100.0 -100.0)	92.3 (77.8 -100.0)
24 Months (95% CIs)	100.0 (100.0 -100.0)	88.9 (68.4 -100.0)		92.3 (77.8 -100.0)
30 Months (95% CIs)		88.9 (68.4 -100.0)		92.3 (77.8 -100.0)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-dur-advsm.sas Date: 15:02/18OCT2021

Table 35.2.2.2
Summary of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies 2101 and 2202

Starting Dose: < 200 mg

Duration of Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=3) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=4) n (%) (95% CIs)
Events		0	0	0
Censors		3 (100.0)	1 (100.0)	4 (100.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE -NE)	NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles		NE, NE	NE, NE	NE, NE
3 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
12 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
18 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
24 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
30 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-dur-advsm.sas
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Table 35.2.2.2
Summary of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies 2101 and 2202

Starting Dose: < 200 mg

Duration of CR+CRh+PR	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=2) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=3) n (%) (95% CIs)
Events		0	0	0
Censors		2 (100.0)	1 (100.0)	3 (100.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE -NE)	NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles		NE, NE	NE, NE	NE, NE
3 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
9 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
12 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
18 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
24 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
30 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-dur-advsm.sas Date: 15:02/18OCT2021

Table 35.2.2.2
Summary of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies 2101 and 2202

Starting Dose: < 300 mg

Duration of Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=17) n (%) (95% CIs)	MCL (N=4) n (%) (95% CIs)	All AdvSM (N=21) n (%) (95% CIs)
Events		1 (5.9)	0	1 (4.8)
Censors		16 (94.1)	4 (100.0)	20 (95.2)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (11.2 -NE)	NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles		NE, NE	NE, NE	NE, NE
3 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
12 Months (95% CIs)		80.0 (44.9 -100.0)	100.0 (100.0 -100.0)	85.7 (59.8 -100.0)
18 Months (95% CIs)		80.0 (44.9 -100.0)	100.0 (100.0 -100.0)	85.7 (59.8 -100.0)
24 Months (95% CIs)		80.0 (44.9 -100.0)	100.0 (100.0 -100.0)	85.7 (59.8 -100.0)
30 Months (95% CIs)		80.0 (44.9 -100.0)	100.0 (100.0 -100.0)	85.7 (59.8 -100.0)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-dur-advsm.sas Date: 15:02/18OCT2021

Table 35.2.2.2
Summary of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies 2101 and 2202

Starting Dose: < 300 mg

Duration of CR+CRh+PR	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=10) n (%) (95% CIs)	MCL (N=3) n (%) (95% CIs)	All AdvSM (N=13) n (%) (95% CIs)
Events		0	0	0
Censors		10 (100.0)	3 (100.0)	13 (100.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE -NE)	NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles		NE, NE	NE, NE	NE, NE
3 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
12 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
18 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
24 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
30 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-dur-advsm.sas
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Table 35.2.2.2
Summary of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies 2101 and 2202

Starting Dose: 200 mg

Duration of Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=14) n (%) (95% CIs)	MCL (N=3) n (%) (95% CIs)	All AdvSM (N=17) n (%) (95% CIs)
Events		1 (7.1)	0	1 (5.9)
Censors		13 (92.9)	3 (100.0)	16 (94.1)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (11.2 -NE)	NE (NE -NE)	NE (11.2 -NE)
25th, 75th percentiles		11.2, NE	NE, NE	NE, NE
3 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
12 Months (95% CIs)		66.7 (13.3 -100.0)	100.0 (100.0 -100.0)	75.0 (32.6 -100.0)
18 Months (95% CIs)		66.7 (13.3 -100.0)		75.0 (32.6 -100.0)
24 Months (95% CIs)		66.7 (13.3 -100.0)		75.0 (32.6 -100.0)
30 Months (95% CIs)		66.7 (13.3 -100.0)		75.0 (32.6 -100.0)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-dur-advsm.sas Date: 15:02/18OCT2021

Table 35.2.2.2
Summary of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies 2101 and 2202

Starting Dose: 200 mg

Duration of CR+CRh+PR	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=8) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=10) n (%) (95% CIs)
Events		0	0	0
Censors		8 (100.0)	2 (100.0)	10 (100.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE -NE)	NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles		NE, NE	NE, NE	NE, NE
3 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
12 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
18 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
24 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
30 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-dur-advsm.sas Date: 15:02/18OCT2021

Table 35.2.2.2
Summary of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies 2101 and 2202

Starting Dose: 300 mg

Duration of Response	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=8) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=11) n (%) (95% CIs)
Events	0	1 (12.5)	0	1 (9.1)
Censors	2 (100.0)	7 (87.5)	1 (100.0)	10 (90.9)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (NE -NE)	NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	83.3 (53.5 -100.0)	100.0 (100.0 -100.0)	88.9 (68.4 -100.0)
12 Months (95% CIs)	100.0 (100.0 -100.0)	83.3 (53.5 -100.0)	100.0 (100.0 -100.0)	88.9 (68.4 -100.0)
18 Months (95% CIs)	100.0 (100.0 -100.0)	83.3 (53.5 -100.0)	100.0 (100.0 -100.0)	88.9 (68.4 -100.0)
24 Months (95% CIs)	100.0 (100.0 -100.0)	83.3 (53.5 -100.0)		88.9 (68.4 -100.0)
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-dur-advsm.sas
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Table 35.2.2.2
Summary of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies 2101 and 2202

Starting Dose: 300 mg

Duration of CR+CRh+PR	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=8) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=11) n (%) (95% CIs)
Events	0	1 (12.5)	0	1 (9.1)
Censors	2 (100.0)	7 (87.5)	1 (100.0)	10 (90.9)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (7.5 -NE)	NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	80.0 (44.9 -100.0)	100.0 (100.0 -100.0)	85.7 (59.8 -100.0)
12 Months (95% CIs)	100.0 (100.0 -100.0)	80.0 (44.9 -100.0)	100.0 (100.0 -100.0)	85.7 (59.8 -100.0)
18 Months (95% CIs)	100.0 (100.0 -100.0)	80.0 (44.9 -100.0)	100.0 (100.0 -100.0)	85.7 (59.8 -100.0)
24 Months (95% CIs)	100.0 (100.0 -100.0)	80.0 (44.9 -100.0)		85.7 (59.8 -100.0)
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-dur-advsm.sas Date: 15:02/18OCT2021

Table 35.2.2.2
Summary of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies 2101 and 2202

Starting Dose: 200 mg and 300 mg

Duration of Response	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=22) n (%) (95% CIs)	MCL (N=4) n (%) (95% CIs)	All AdvSM (N=28) n (%) (95% CIs)
Events	0	2 (9.1)	0	2 (7.1)
Censors	2 (100.0)	20 (90.9)	4 (100.0)	26 (92.9)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (NE -NE)	NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	88.9 (68.4 -100.0)	100.0 (100.0 -100.0)	92.9 (79.4 -100.0)
12 Months (95% CIs)	100.0 (100.0 -100.0)	77.8 (50.6 -100.0)	100.0 (100.0 -100.0)	85.1 (66.0 -100.0)
18 Months (95% CIs)	100.0 (100.0 -100.0)	77.8 (50.6 -100.0)	100.0 (100.0 -100.0)	85.1 (66.0 -100.0)
24 Months (95% CIs)	100.0 (100.0 -100.0)	77.8 (50.6 -100.0)		85.1 (66.0 -100.0)
30 Months (95% CIs)		77.8 (50.6 -100.0)		85.1 (66.0 -100.0)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-dur-advsm.sas Date: 15:02/18OCT2021

Table 35.2.2.2
Summary of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies 2101 and 2202

Starting Dose: 200 mg and 300 mg

Duration of CR+CRh+PR	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=16) n (%) (95% CIs)	MCL (N=3) n (%) (95% CIs)	All AdvSM (N=21) n (%) (95% CIs)
Events	0	1 (6.3)	0	1 (4.8)
Censors	2 (100.0)	15 (93.8)	3 (100.0)	20 (95.2)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (NE -NE)	NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	83.3 (53.5 -100.0)	100.0 (100.0 -100.0)	90.0 (71.4 -100.0)
12 Months (95% CIs)	100.0 (100.0 -100.0)	83.3 (53.5 -100.0)	100.0 (100.0 -100.0)	90.0 (71.4 -100.0)
18 Months (95% CIs)	100.0 (100.0 -100.0)	83.3 (53.5 -100.0)	100.0 (100.0 -100.0)	90.0 (71.4 -100.0)
24 Months (95% CIs)	100.0 (100.0 -100.0)	83.3 (53.5 -100.0)		90.0 (71.4 -100.0)
30 Months (95% CIs)		83.3 (53.5 -100.0)		90.0 (71.4 -100.0)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-dur-advsm.sas
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Table 35.2.2.2
Summary of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies 2101 and 2202

Starting Dose: 400 mg

Duration of Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=2) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=2) n (%) (95% CIs)
Events		0		0
Censors		2 (100.0)		2 (100.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE -NE)		NE (NE -NE)
25th, 75th percentiles		NE, NE		NE, NE
3 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
6 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
9 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
12 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
18 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
24 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
30 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-dur-advsm.sas Date: 15:02/18OCT2021

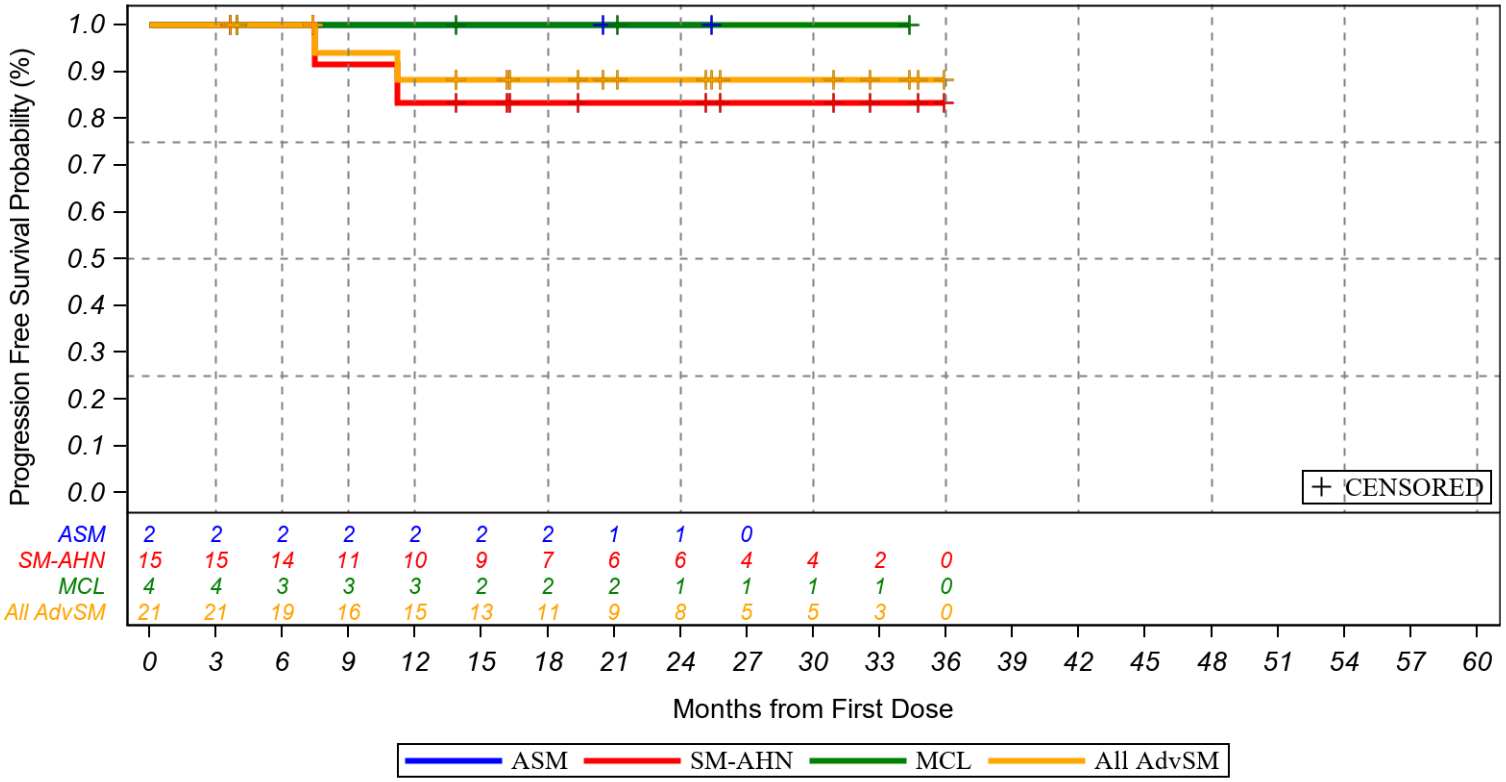
Table 35.2.2.2
Summary of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies 2101 and 2202

Starting Dose: 400 mg

Duration of CR+CRh+PR	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=2) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=2) n (%) (95% CIs)
Events		0		0
Censors		2 (100.0)		2 (100.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE -NE)		NE (NE -NE)
25th, 75th percentiles		NE, NE		NE, NE
3 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
6 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
9 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
12 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
18 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
24 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

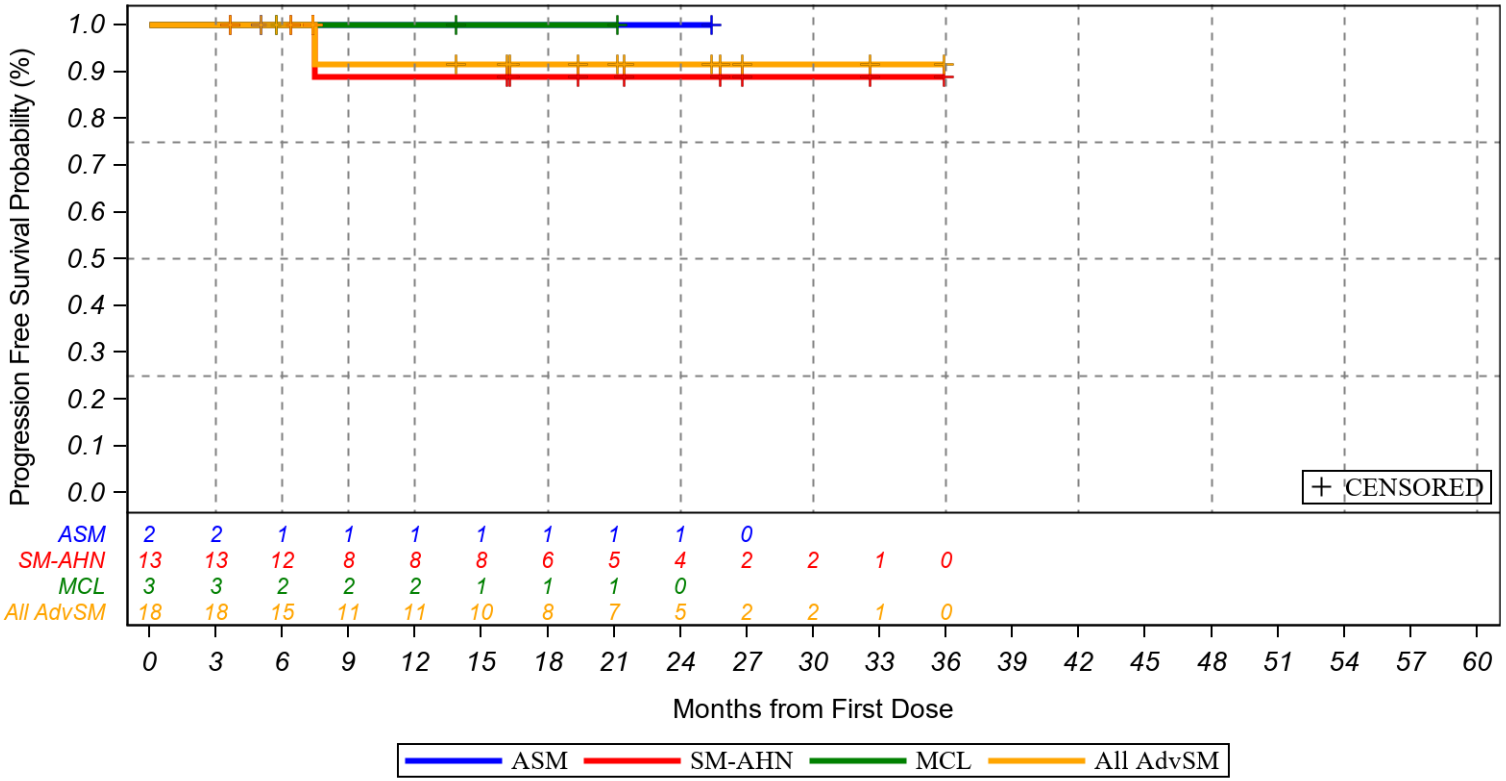
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-dur-advsm.sas Date: 15:02/18OCT2021

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: Overall, Duration of Response



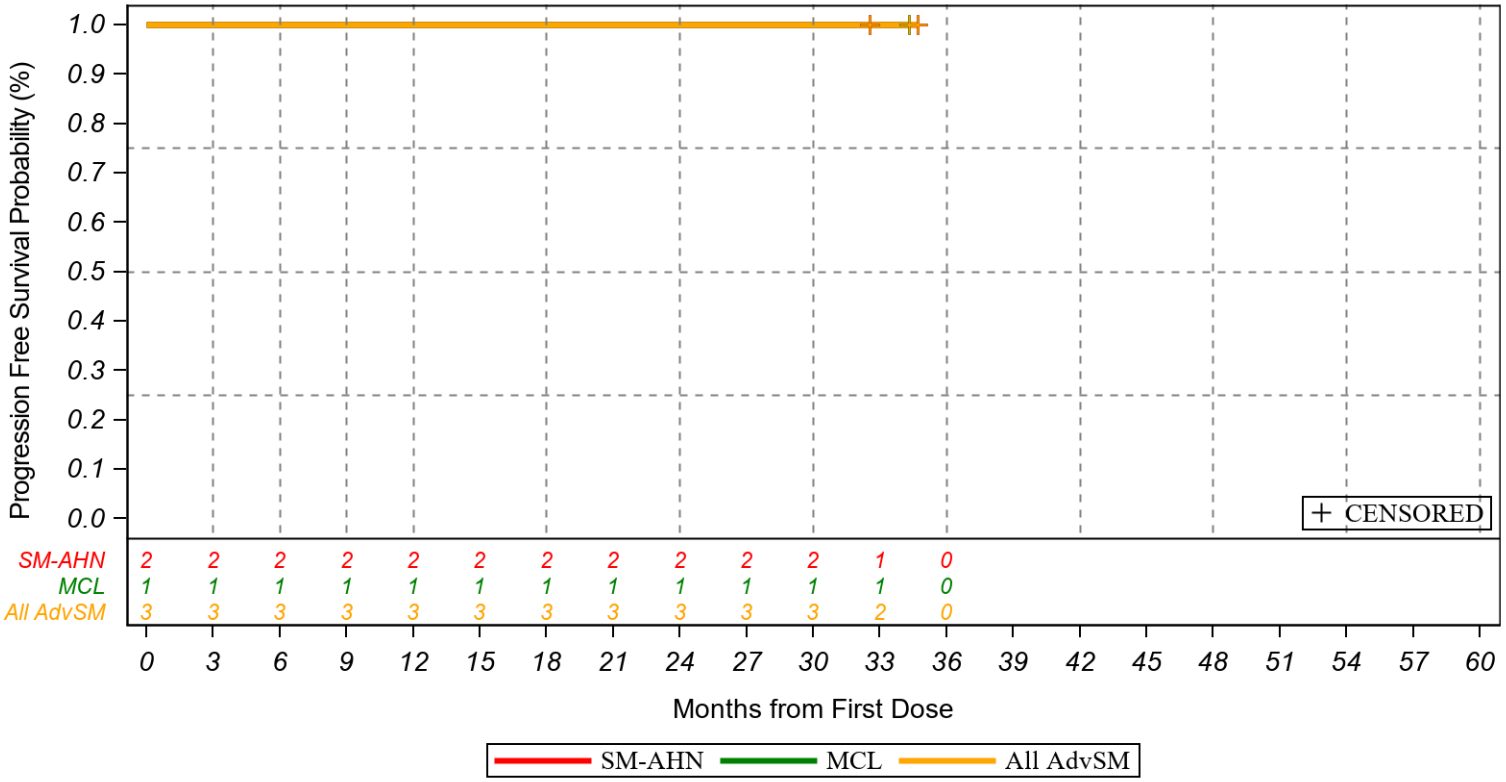
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/f-inv-dur-advsm.sas
Date: 10:28/18JAN2022

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: Overall, Duration of CR+CRh+PR



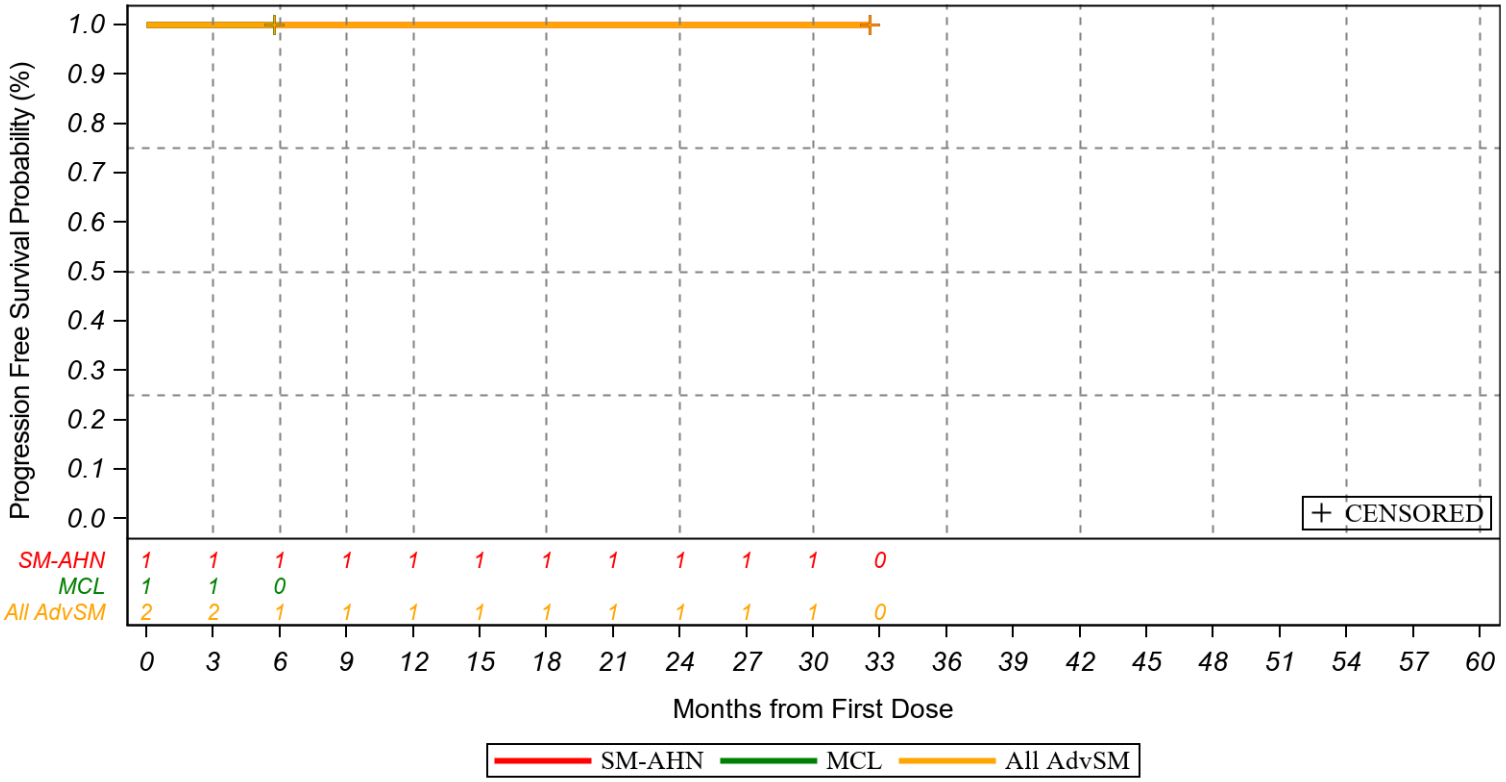
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/f-inv-dur-advsm.sas
Date: 10:28/18JAN2022

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: < 200 mg, Duration of Response



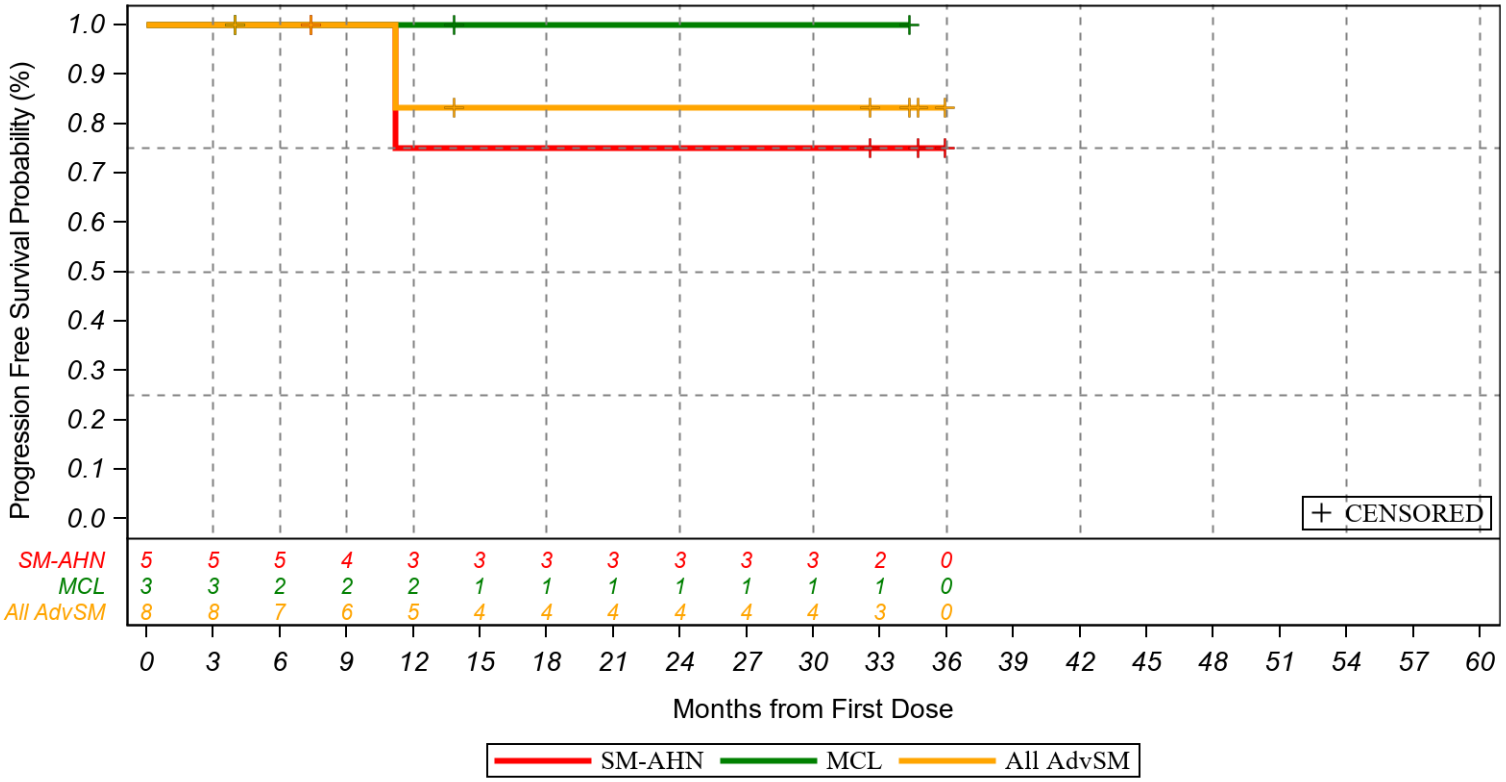
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/f-inv-dur-advsm.sas
Date: 10:28/18JAN2022

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: < 200 mg, Duration of CR+CRh+PR



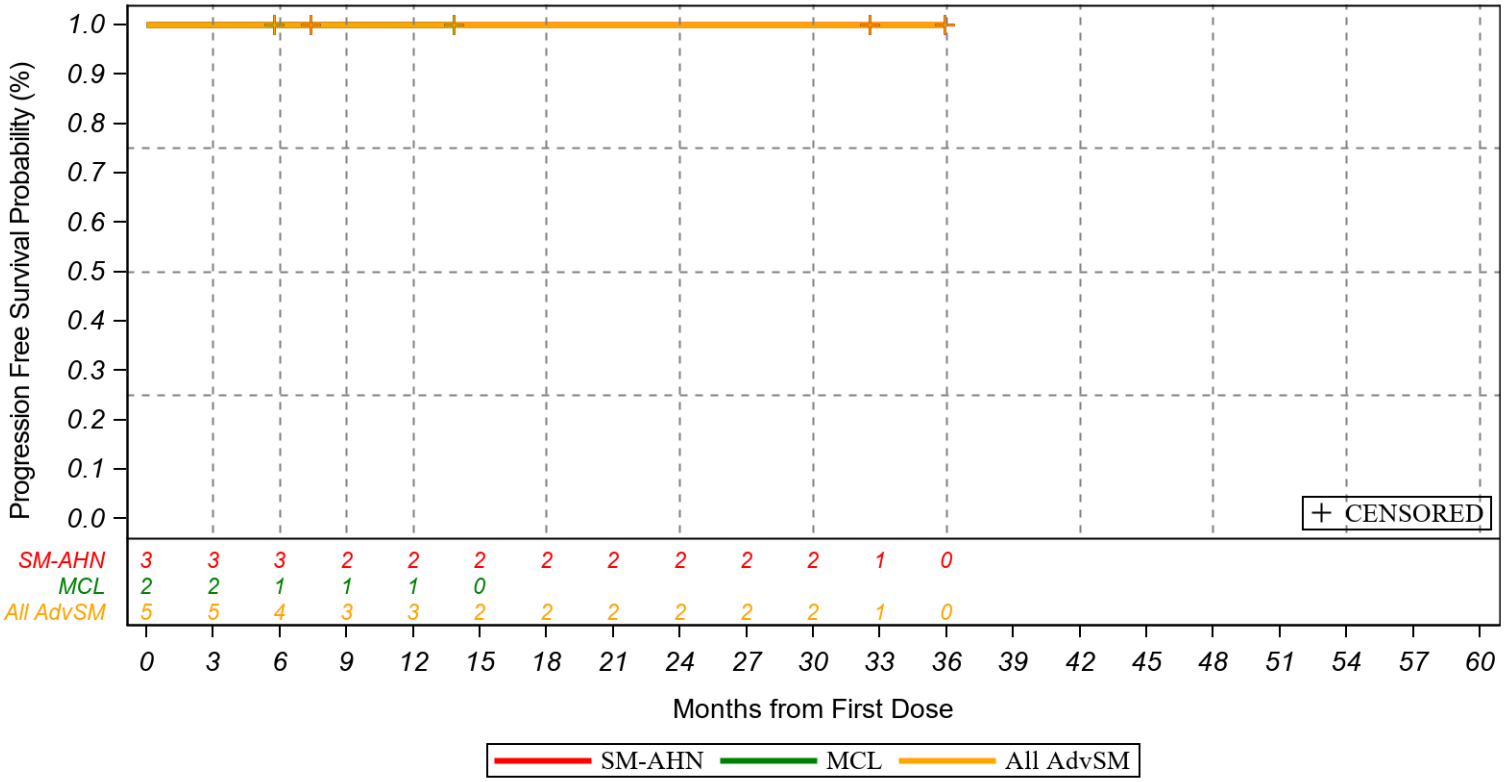
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/f-inv-dur-advsm.sas
Date: 10:28/18JAN2022

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: < 300 mg, Duration of Response



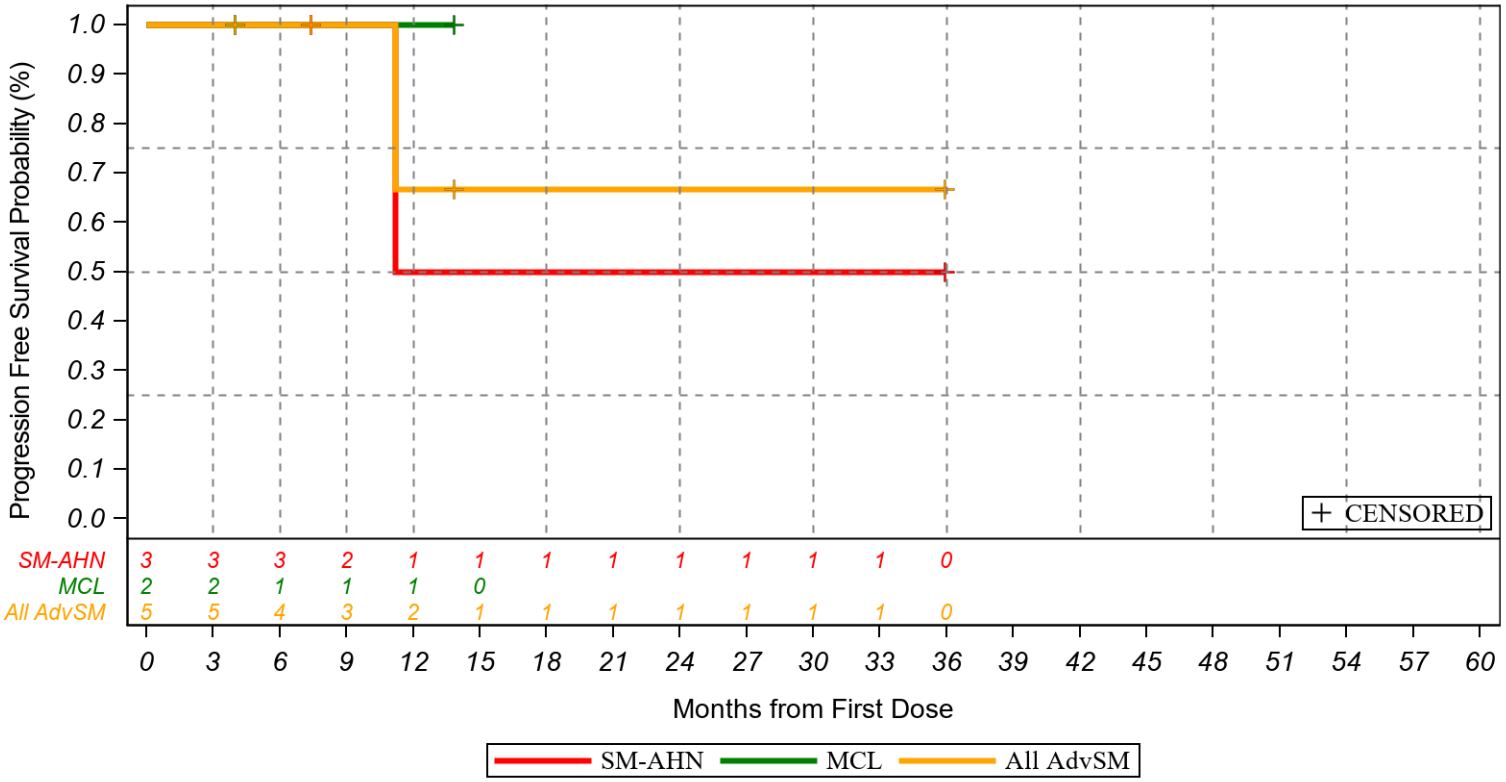
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/f-inv-dur-advsm.sas
Date: 10:28/18JAN2022

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: < 300 mg, Duration of CR+CRh+PR



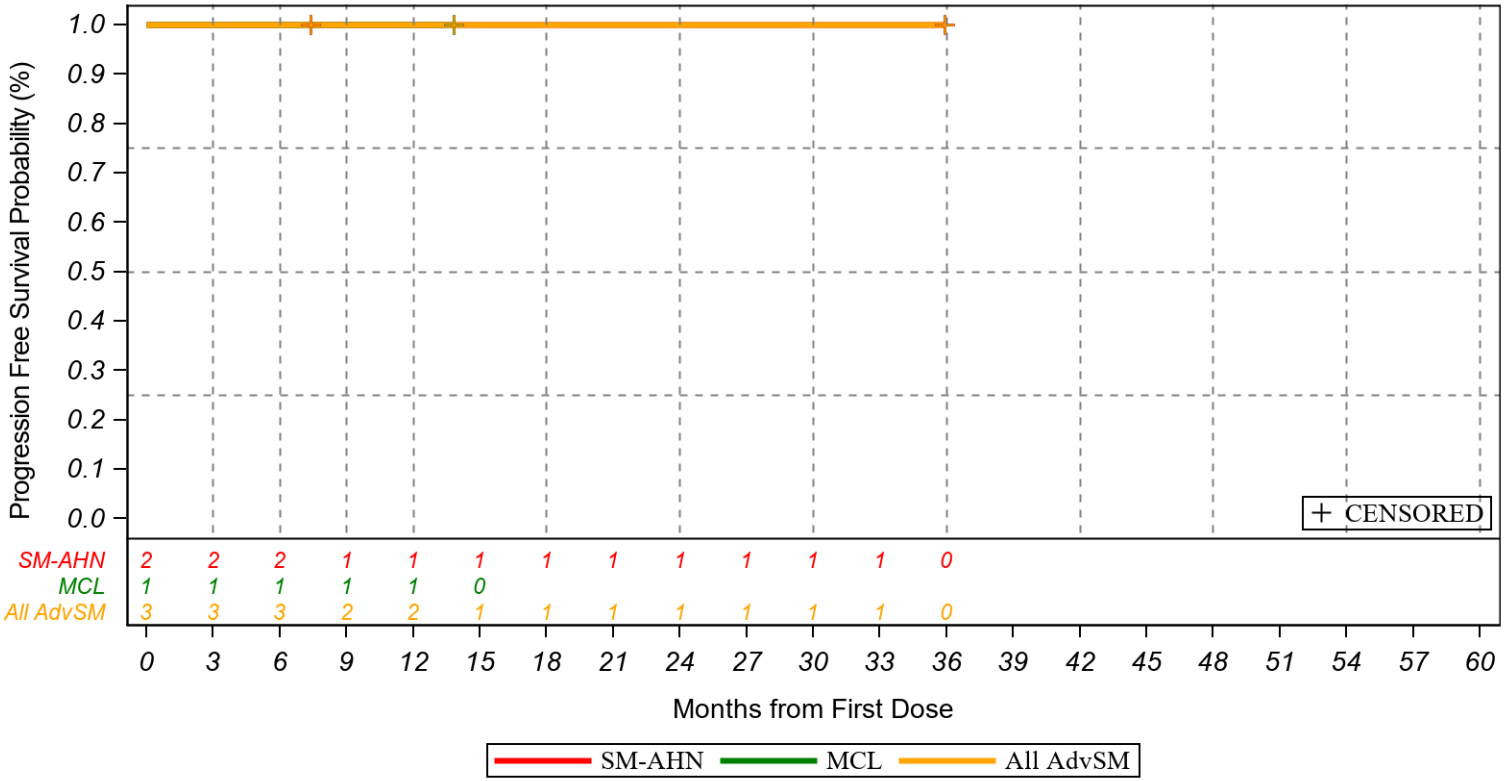
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/f-inv-dur-advsm.sas
Date: 10:28/18JAN2022

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: 200 mg, Duration of Response



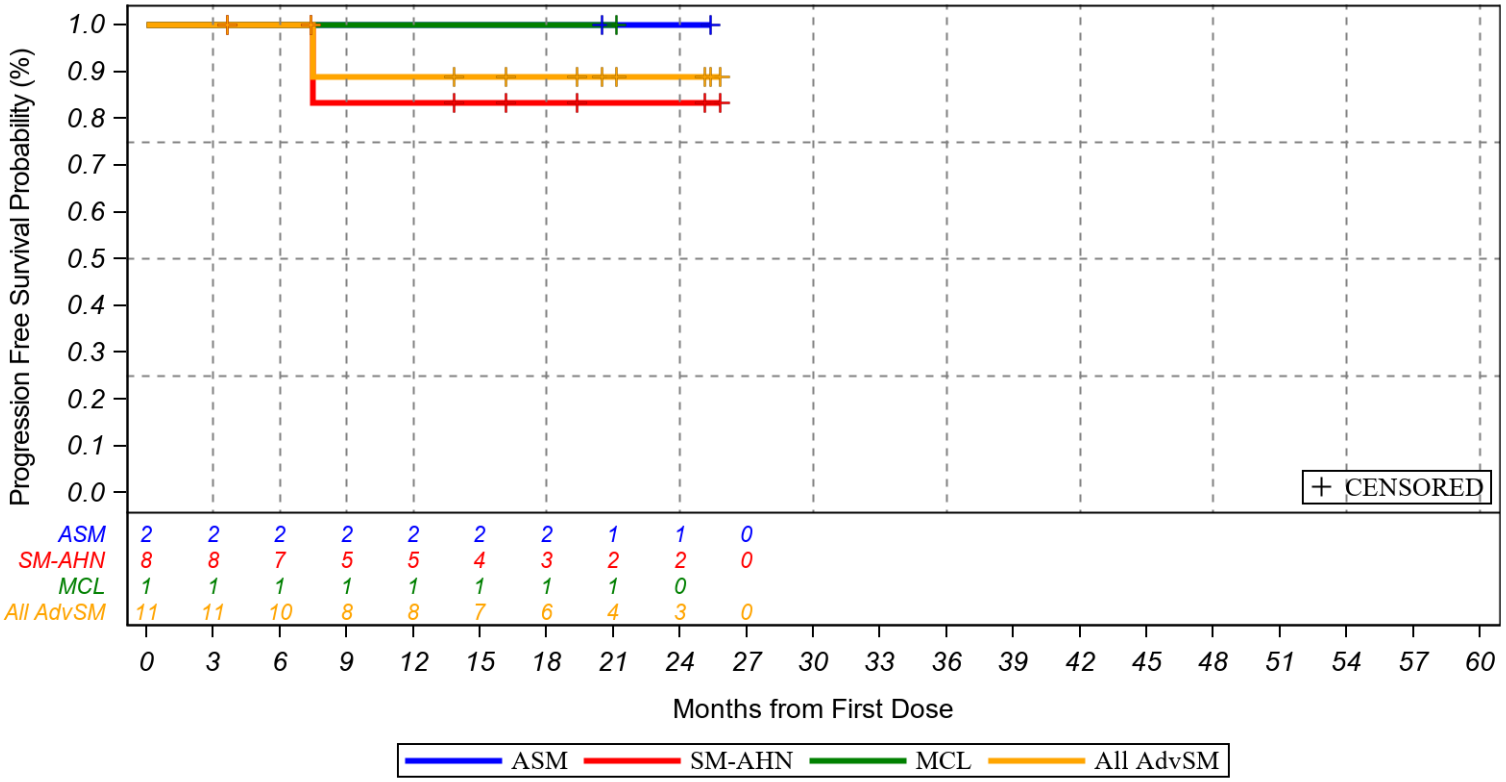
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/f-inv-dur-advsm.sas
Date: 10:28/18JAN2022

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: 200 mg, Duration of CR+CRh+PR



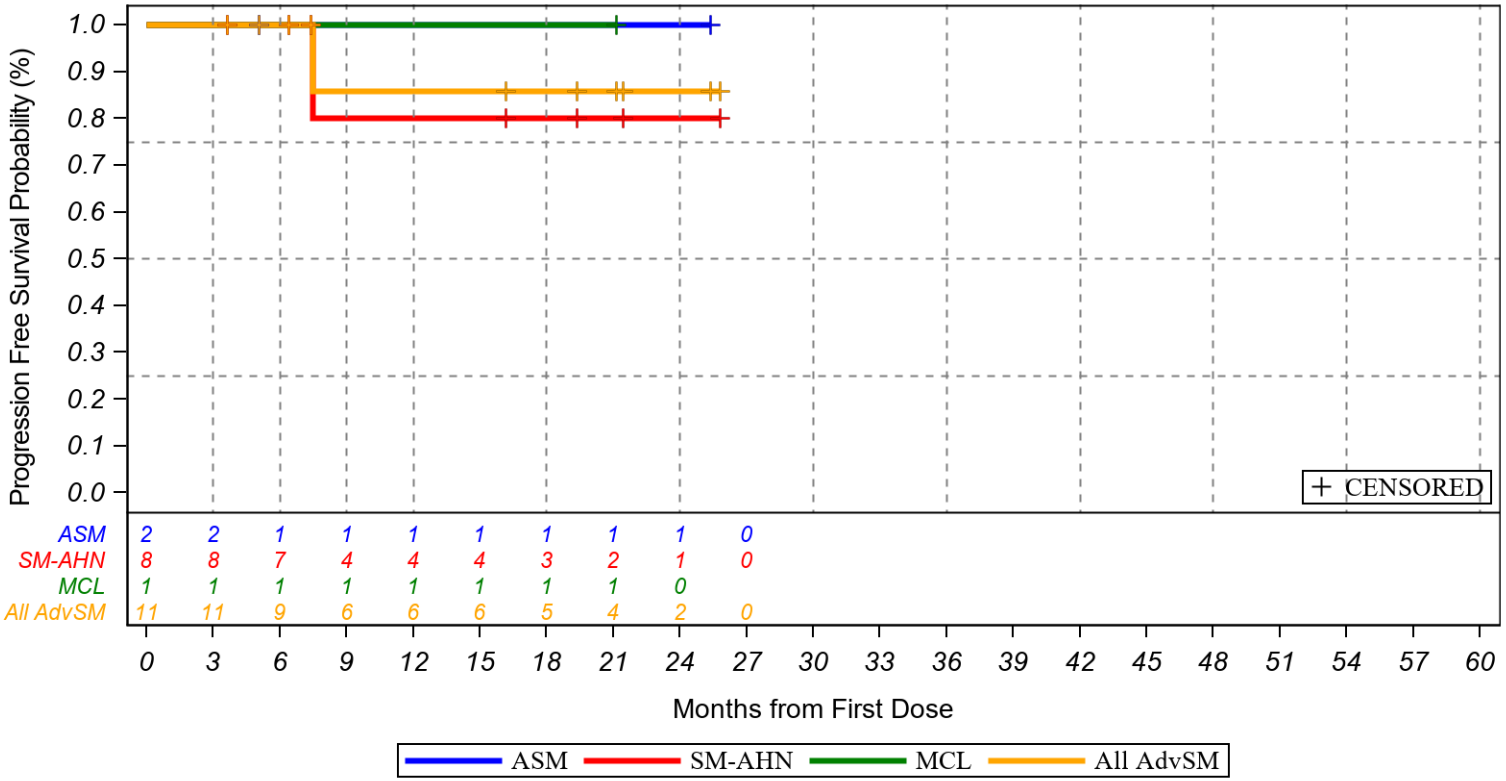
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/f-inv-dur-advsm.sas
Date: 10:28/18JAN2022

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: 300 mg, Duration of Response



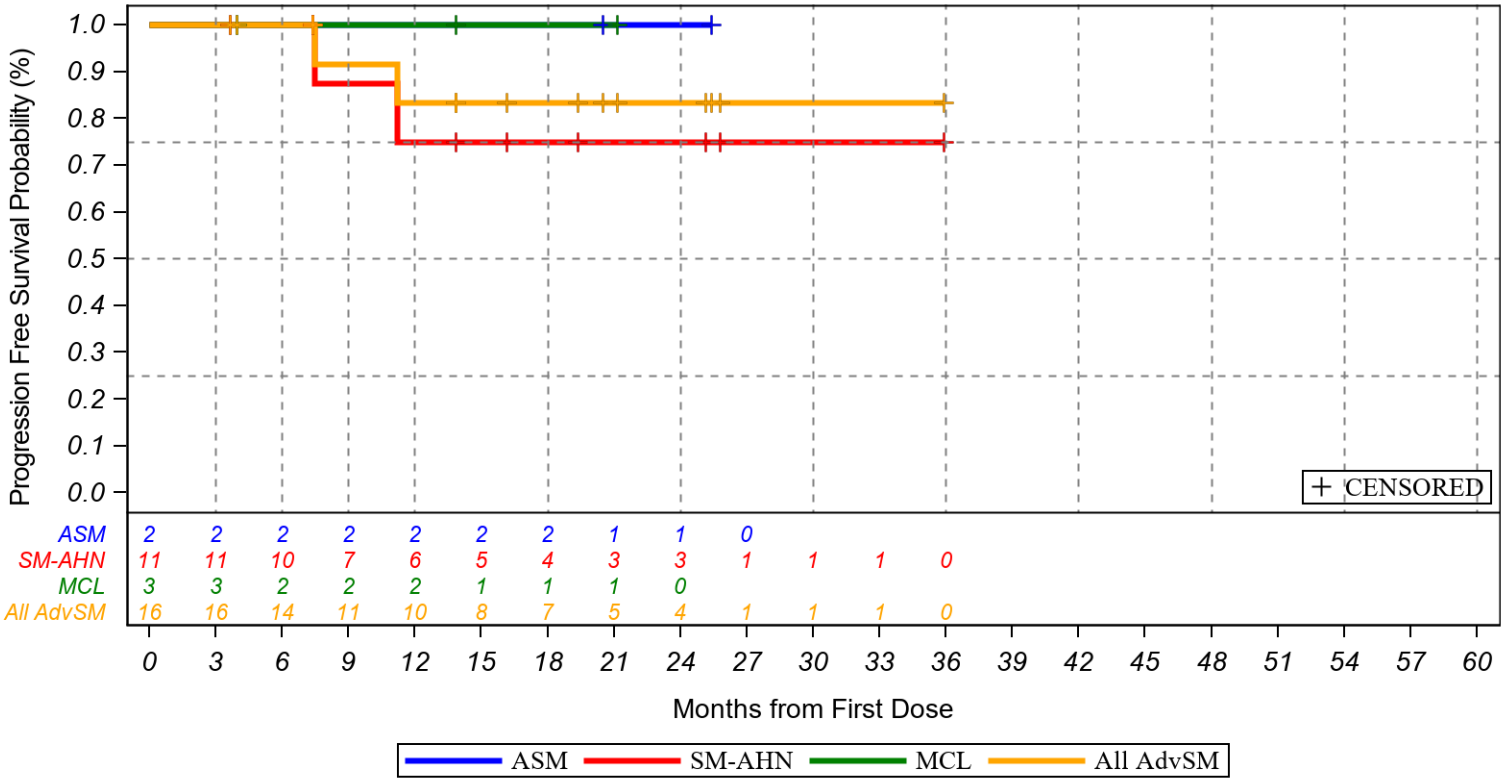
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/f-inv-dur-advsm.sas
Date: 10:28/18JAN2022

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: 300 mg, Duration of CR+CRh+PR



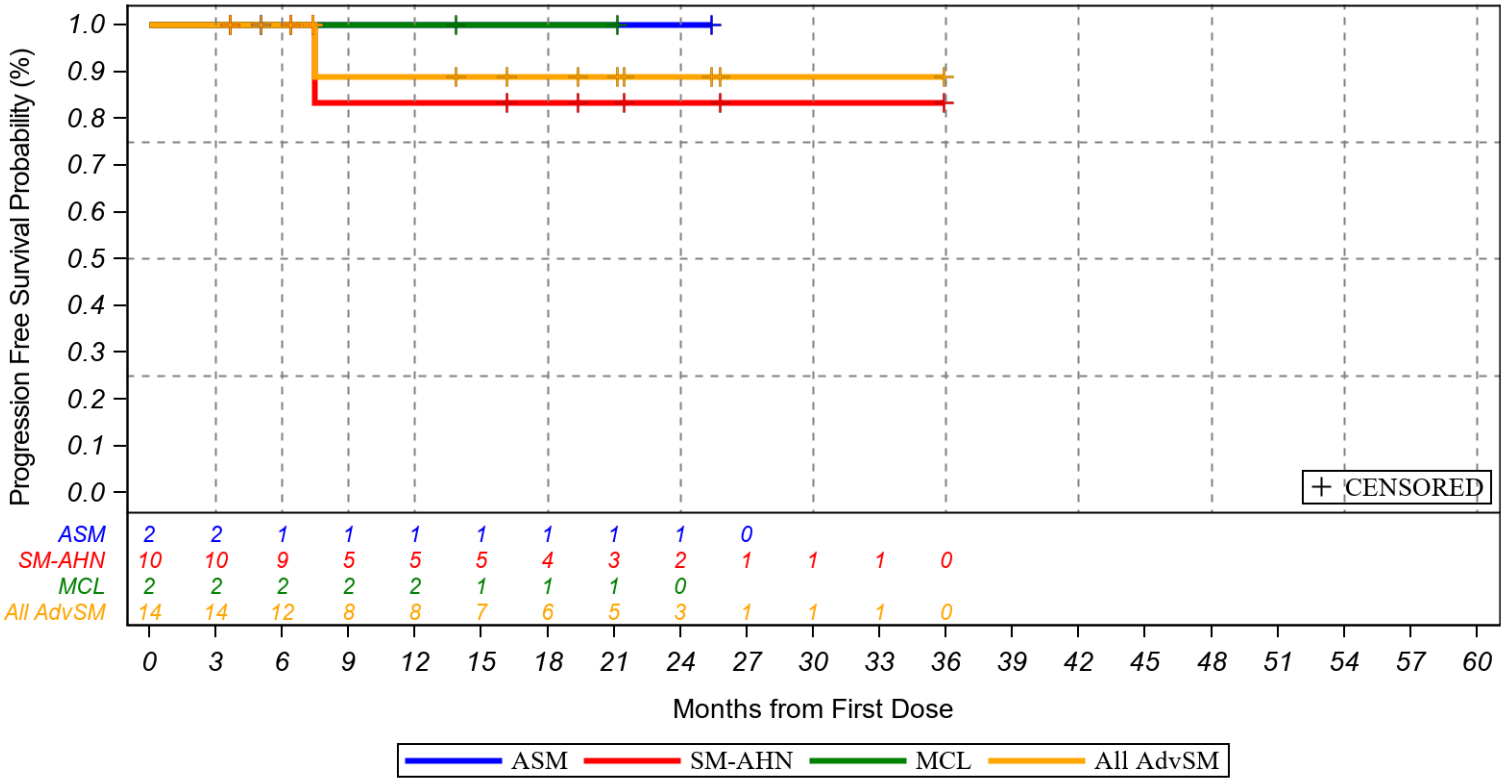
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/f-inv-dur-advsm.sas
Date: 10:28/18JAN2022

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: 200 mg and 300 mg, Duration of Response



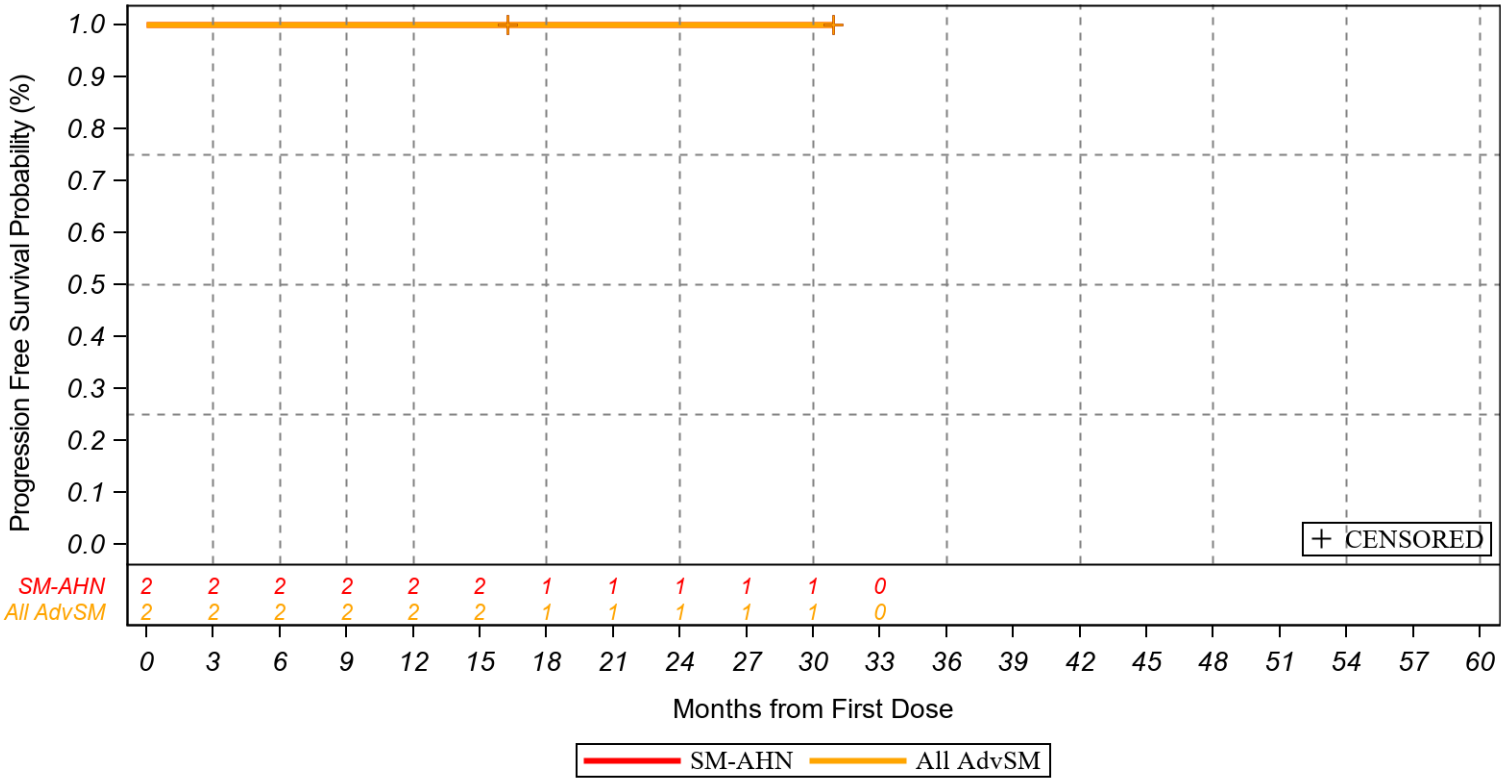
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/f-inv-dur-advsm.sas
Date: 10:28/18JAN2022

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: 200 mg and 300 mg, Duration of CR+CRh+PR



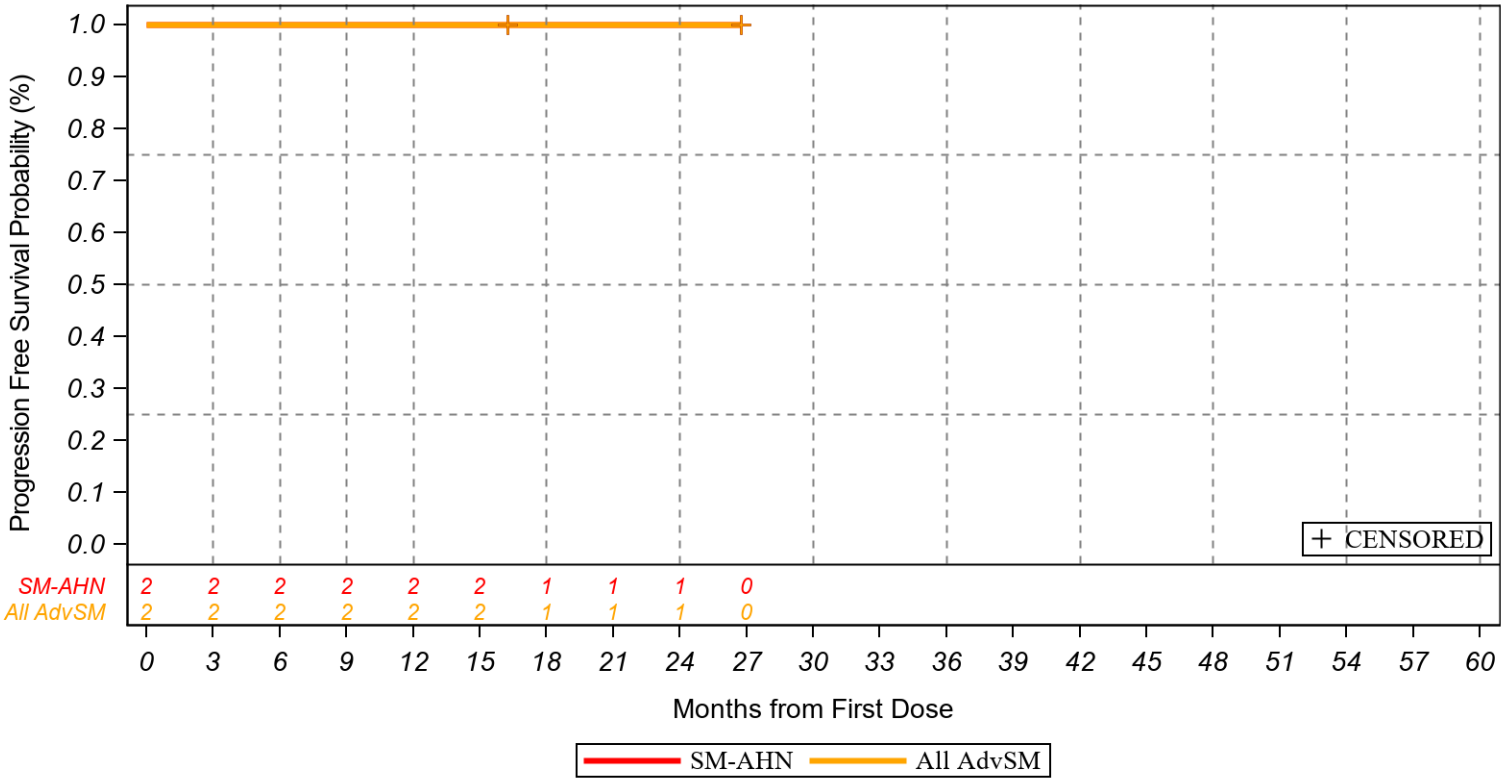
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/f-inv-dur-advsm.sas
Date: 10:28/18JAN2022

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: 400 mg, Duration of Response



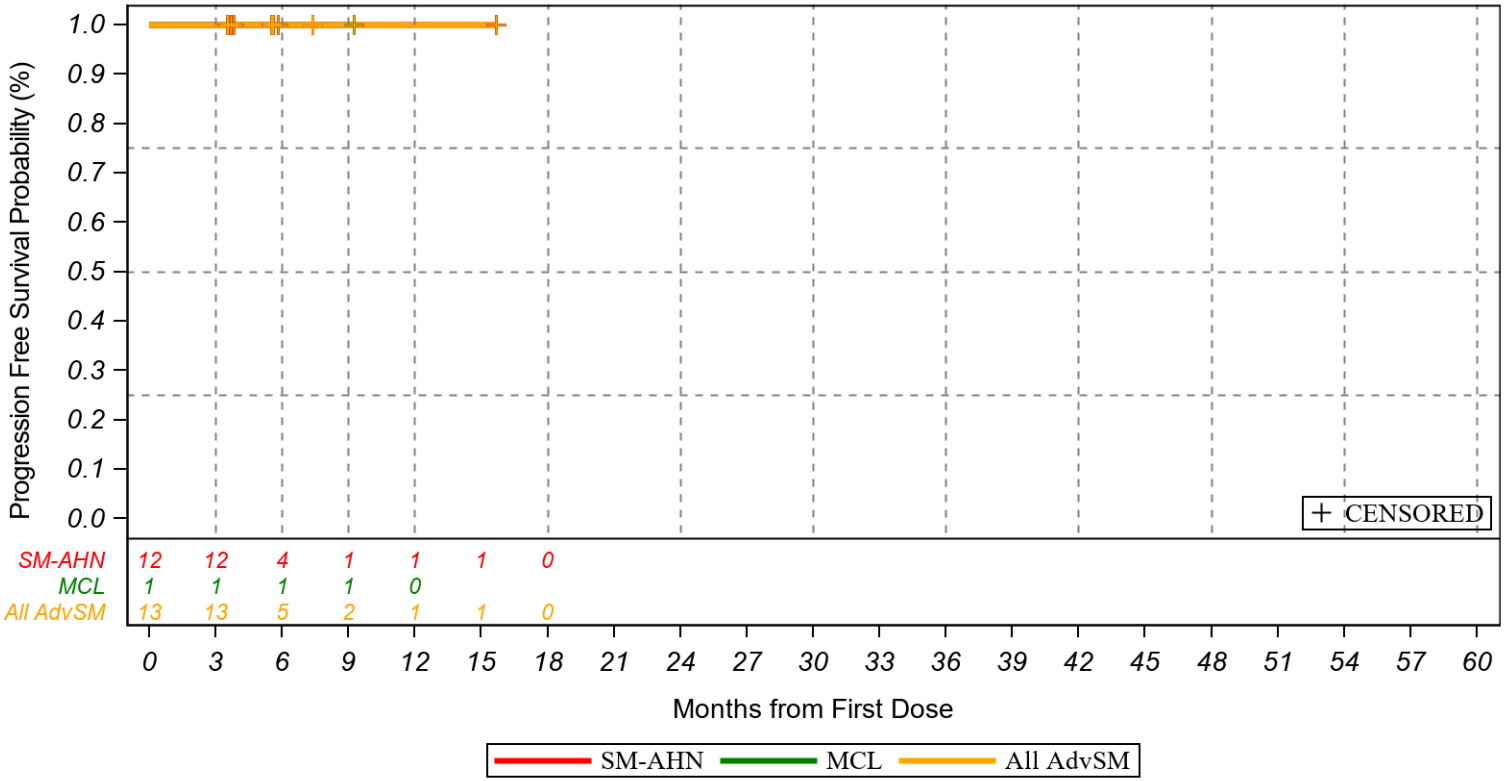
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/f-inv-dur-advsm.sas
Date: 10:28/18JAN2022

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: 400 mg, Duration of CR+CRh+PR



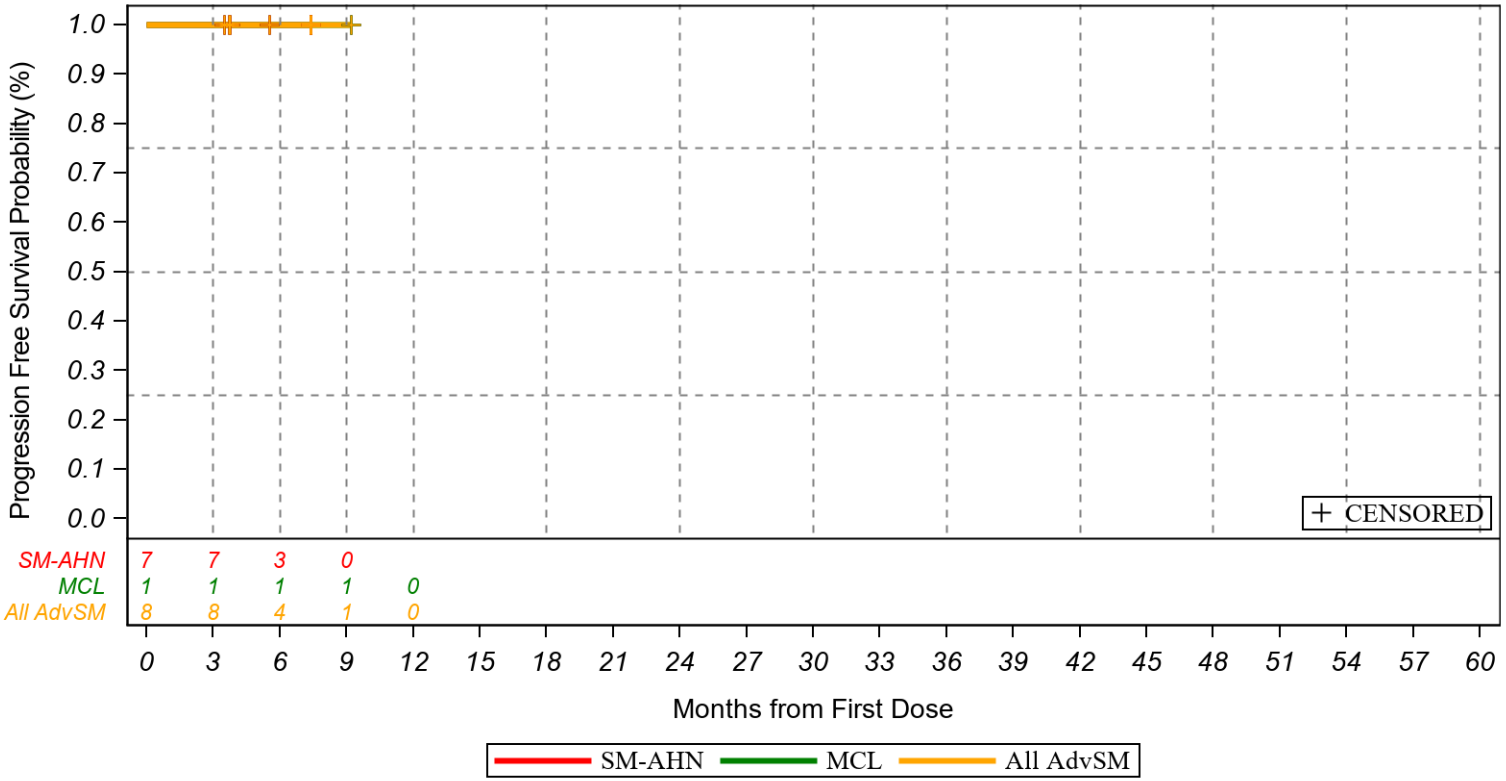
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/f-inv-dur-advsm.sas
Date: 10:28/18JAN2022

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study BLU-285-2202
Starting Dose: Overall, Duration of Response



Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/f-inv-dur-advsm.sas
Date: 10:28/18JAN2022

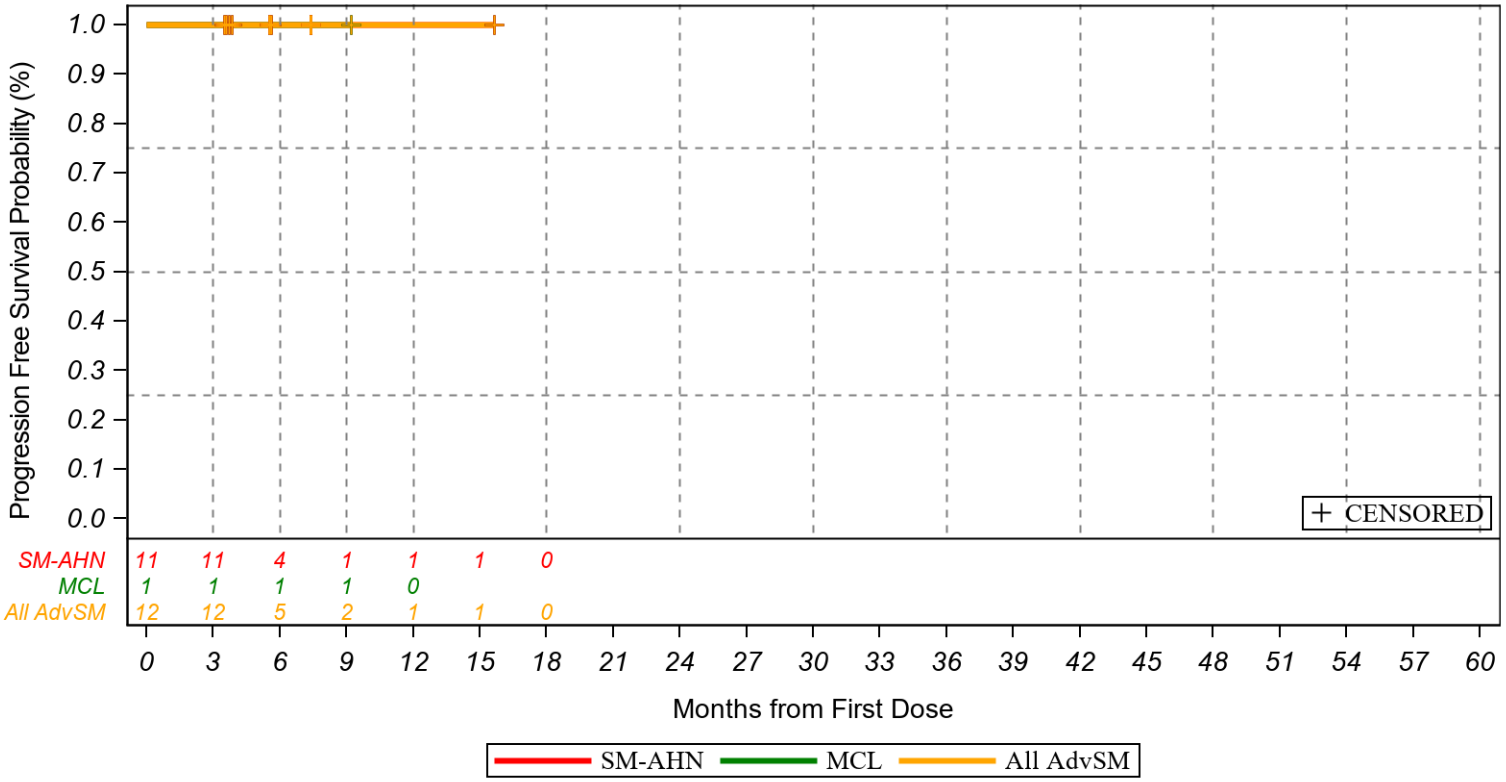
Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study BLU-285-2202
Starting Dose: Overall, Duration of CR+CRh+PR



Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

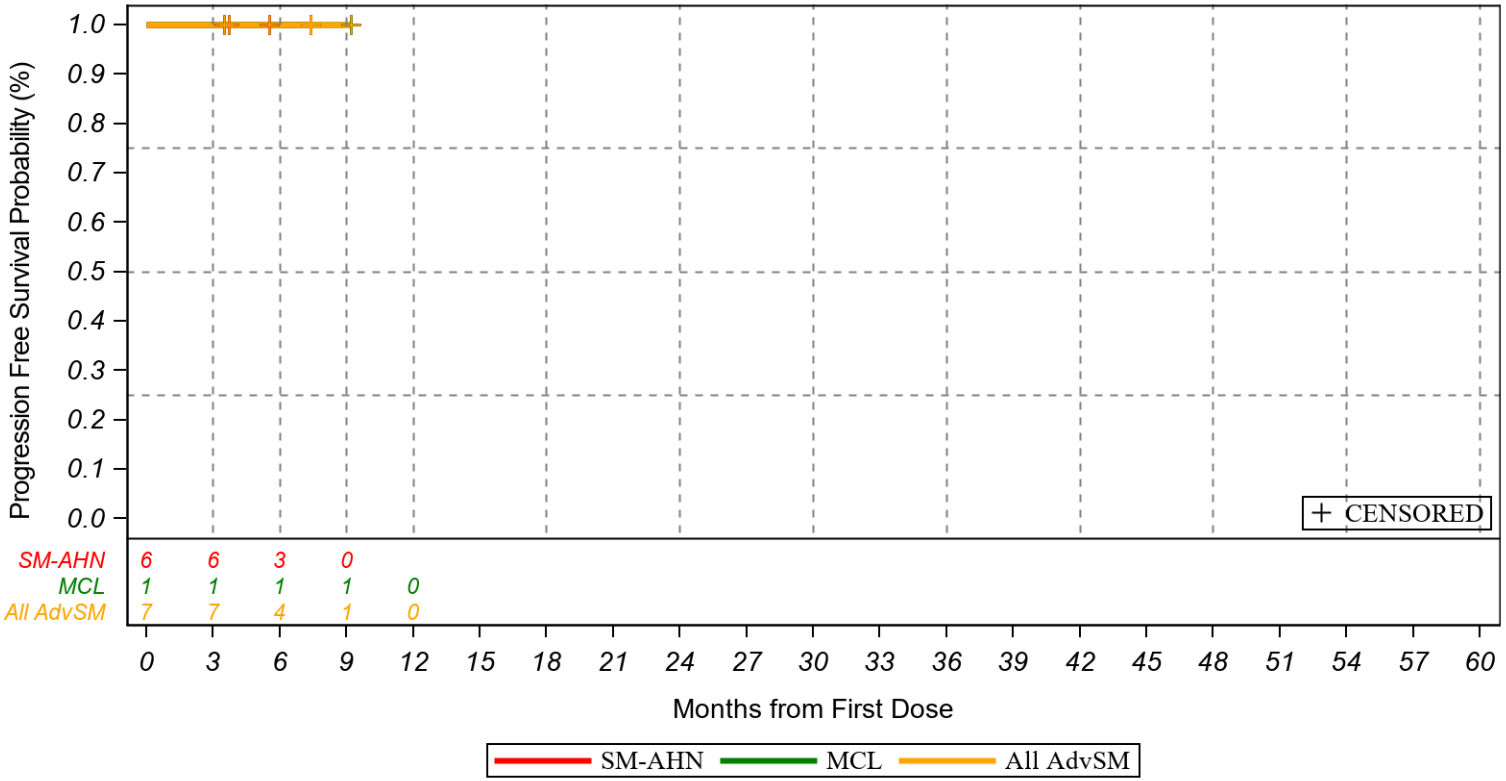
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/f-inv-dur-advsm.sas
Date: 10:28/18JAN2022

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study BLU-285-2202
Starting Dose: 200 mg, Duration of Response



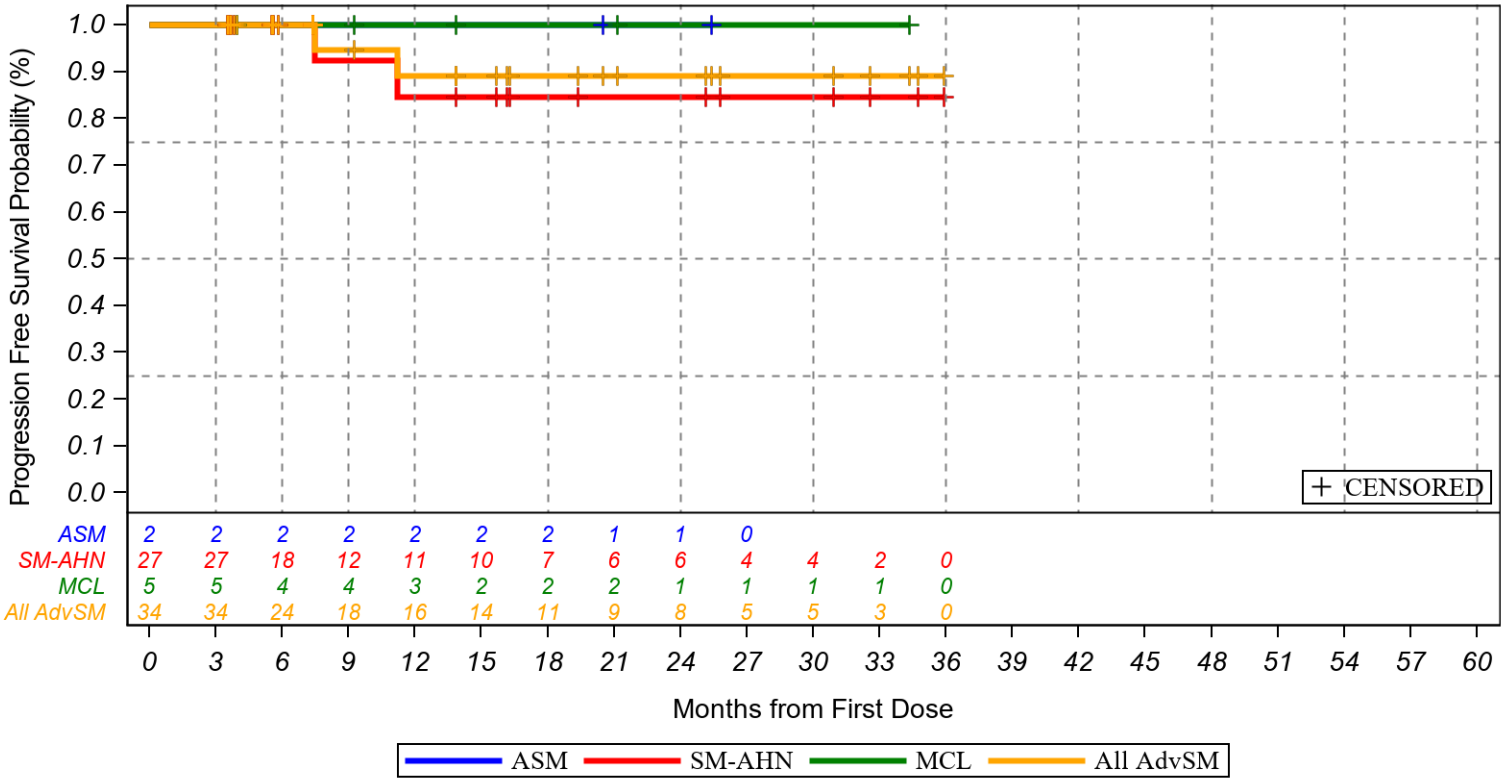
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/f-inv-dur-advsm.sas
Date: 10:28/18JAN2022

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study BLU-285-2202
Starting Dose: 200 mg, Duration of CR+CRh+PR



Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/f-inv-dur-advsm.sas
Date: 10:28/18JAN2022

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall, Duration of Response



Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/f-inv-dur-advsm.sas
Date: 10:28/18JAN2022

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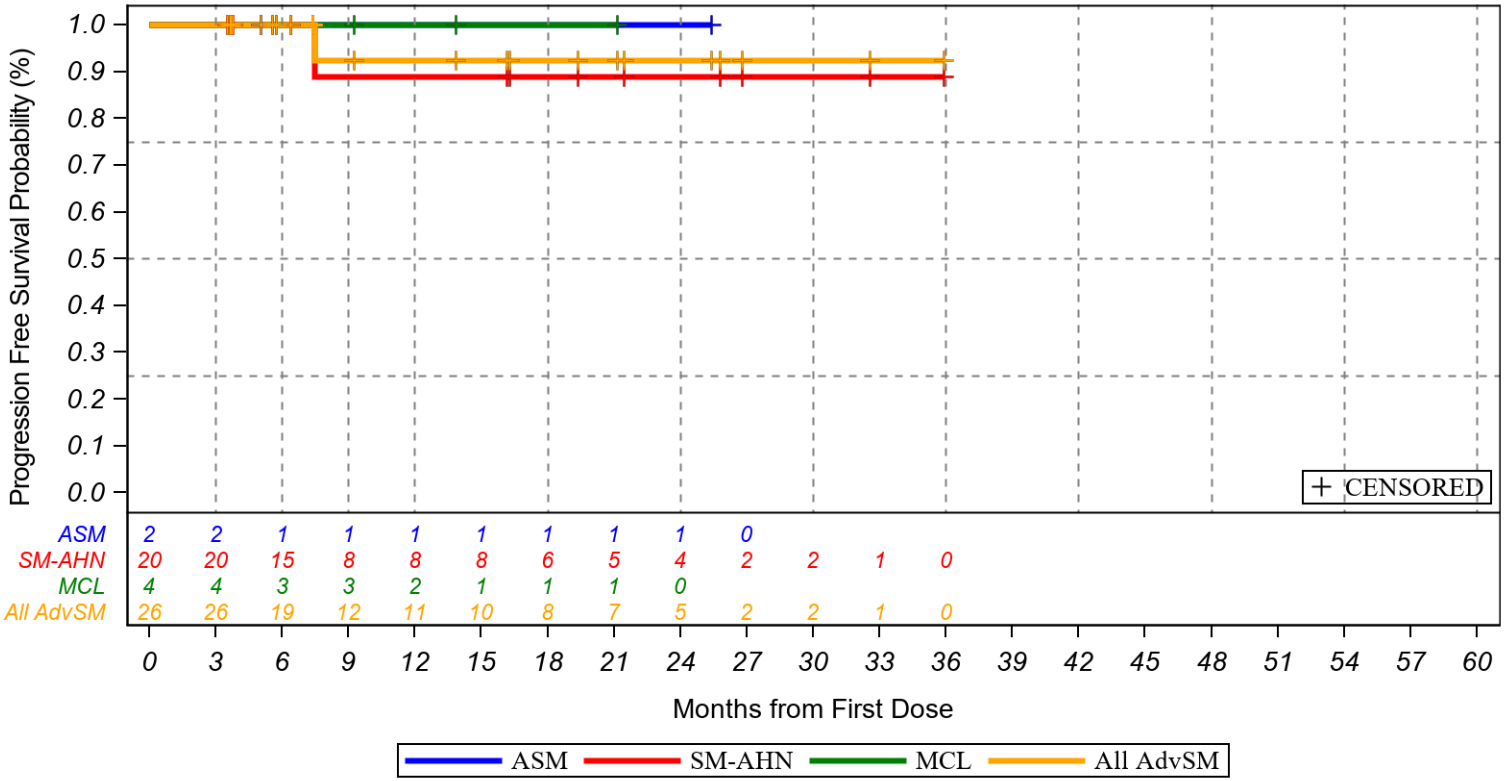
Avapritinib Systemic Mastocytosis Integrated Summary of Efficacy
BLU-285 SM Germany HTA Analysis
Cutoff date: 27may2020 (2101), 23jun2020 (2202)

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall, Duration of CR+CRh+PR



Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/f-inv-dur-advsm.sas
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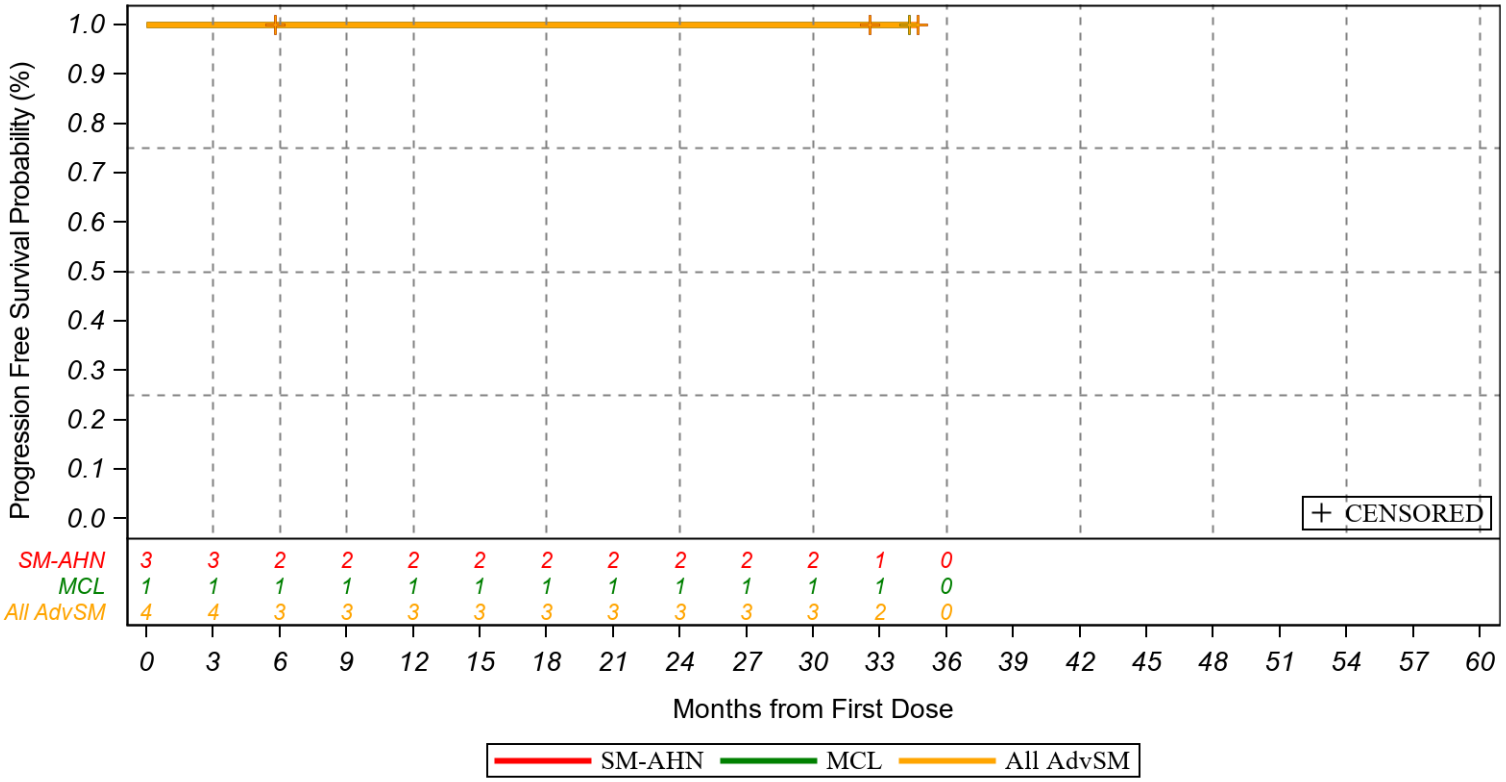
Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg, Duration of Response



Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/f-inv-dur-advsm.sas
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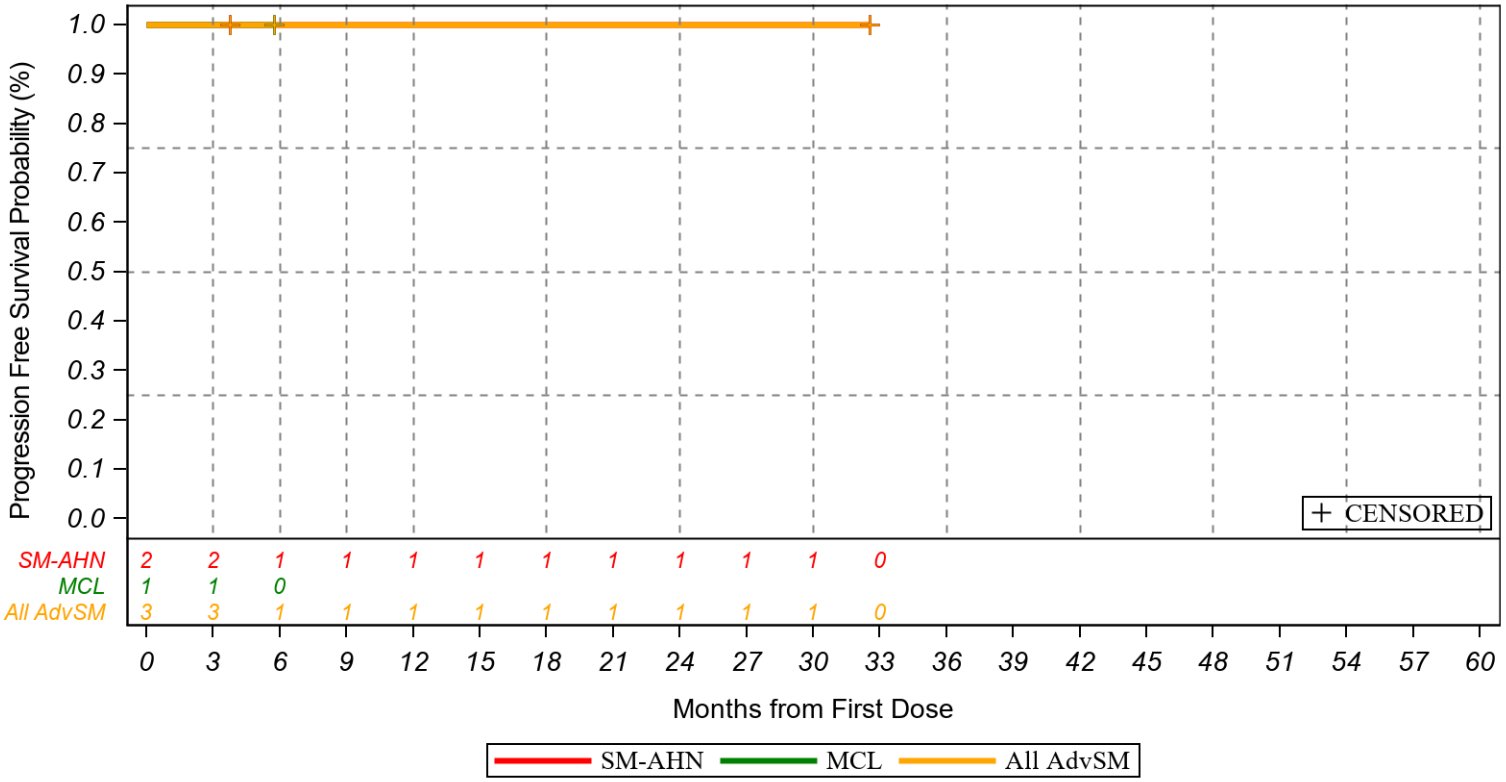
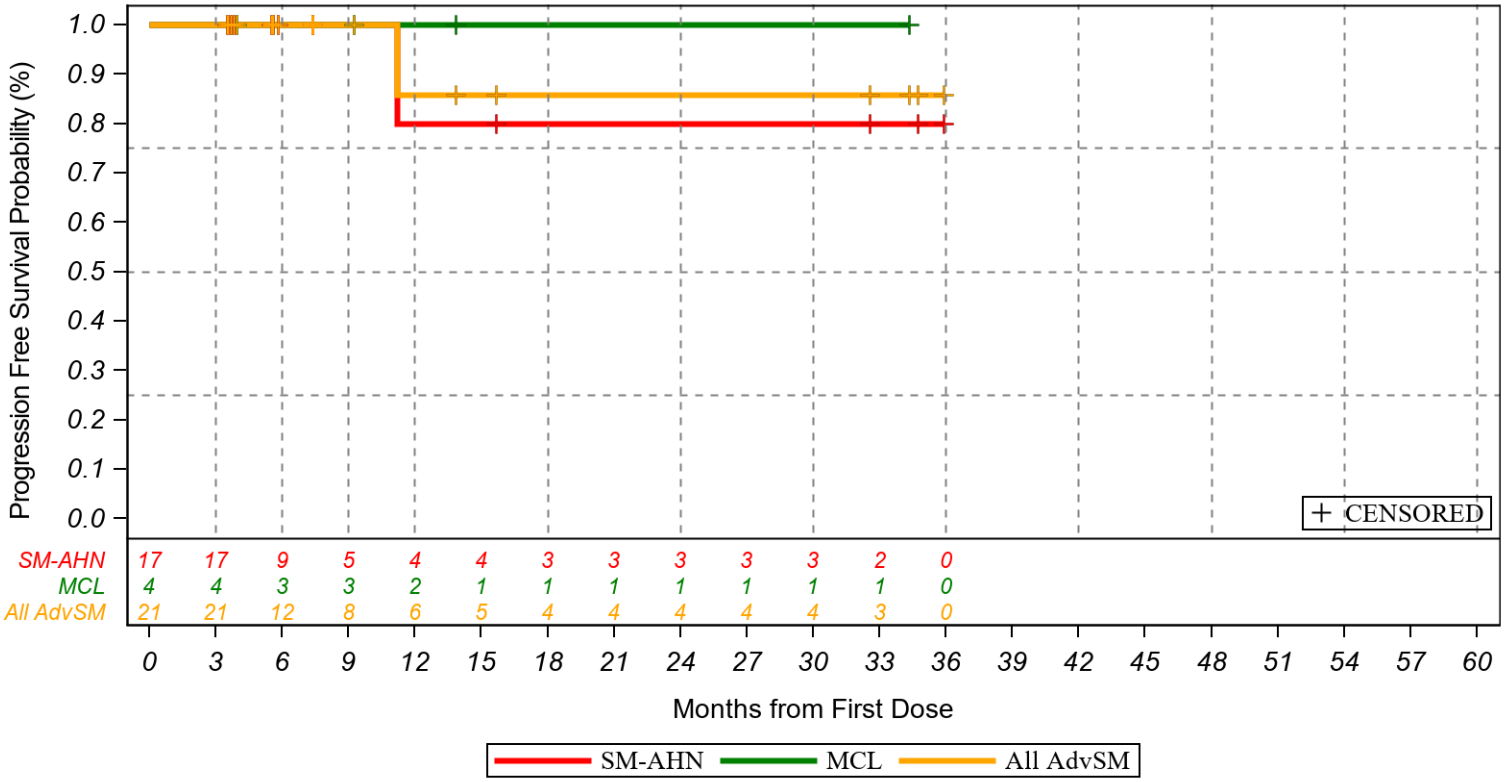
BLU-285 SM Germany HTA Analysis
Cutoff date: 27may2020 (2101), 23jun2020 (2202)

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg, Duration of CR+CRh+PR



Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/f-inv-dur-advsm.sas
Date: 10:28/18JAN2022

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg, Duration of Response



Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/f-inv-dur-advsm.sas
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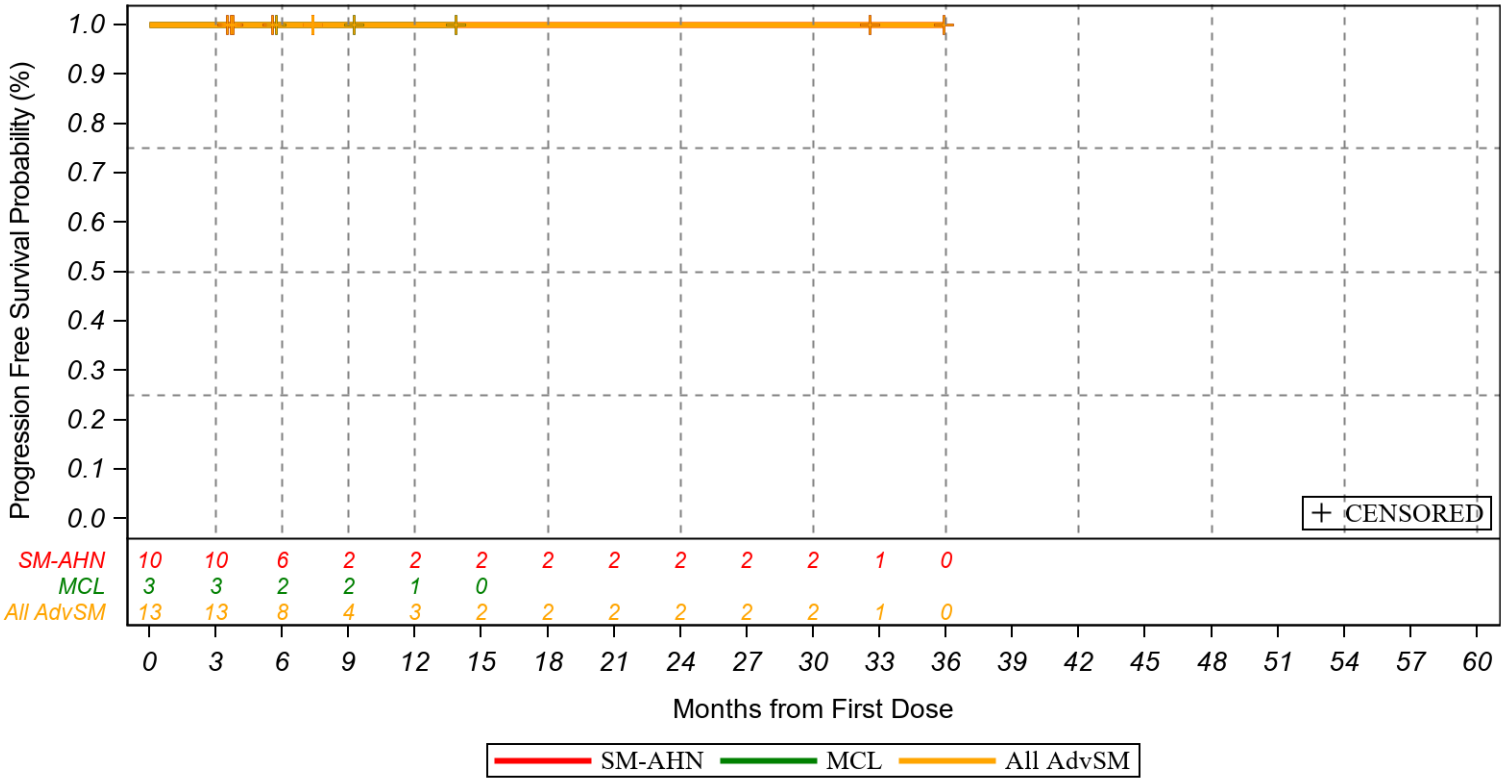
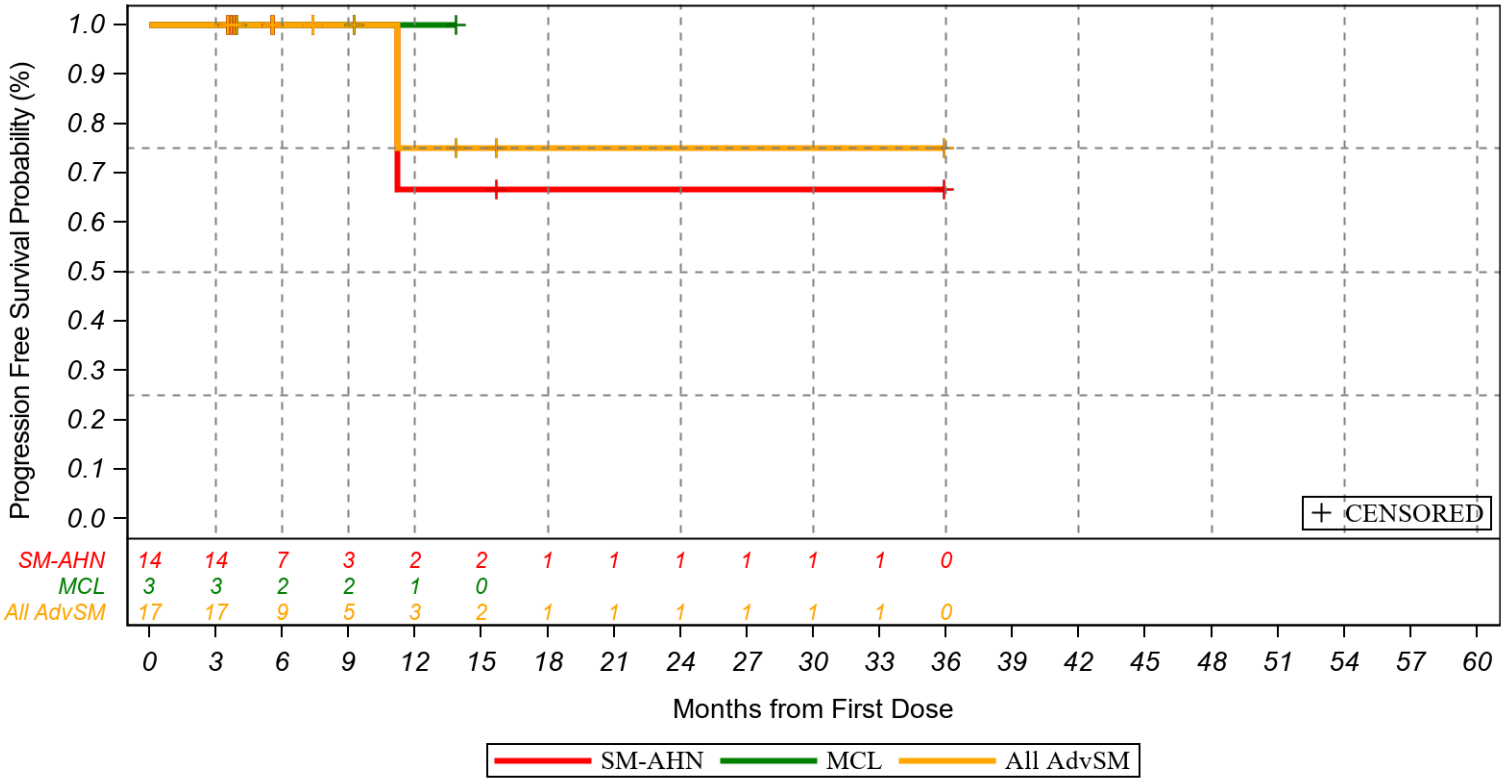
Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg, Duration of CR+CRh+PR



Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/f-inv-dur-advsm.sas
Date: 10:28/18JAN2022

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg, Duration of Response



Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/f-inv-dur-advsm.sas
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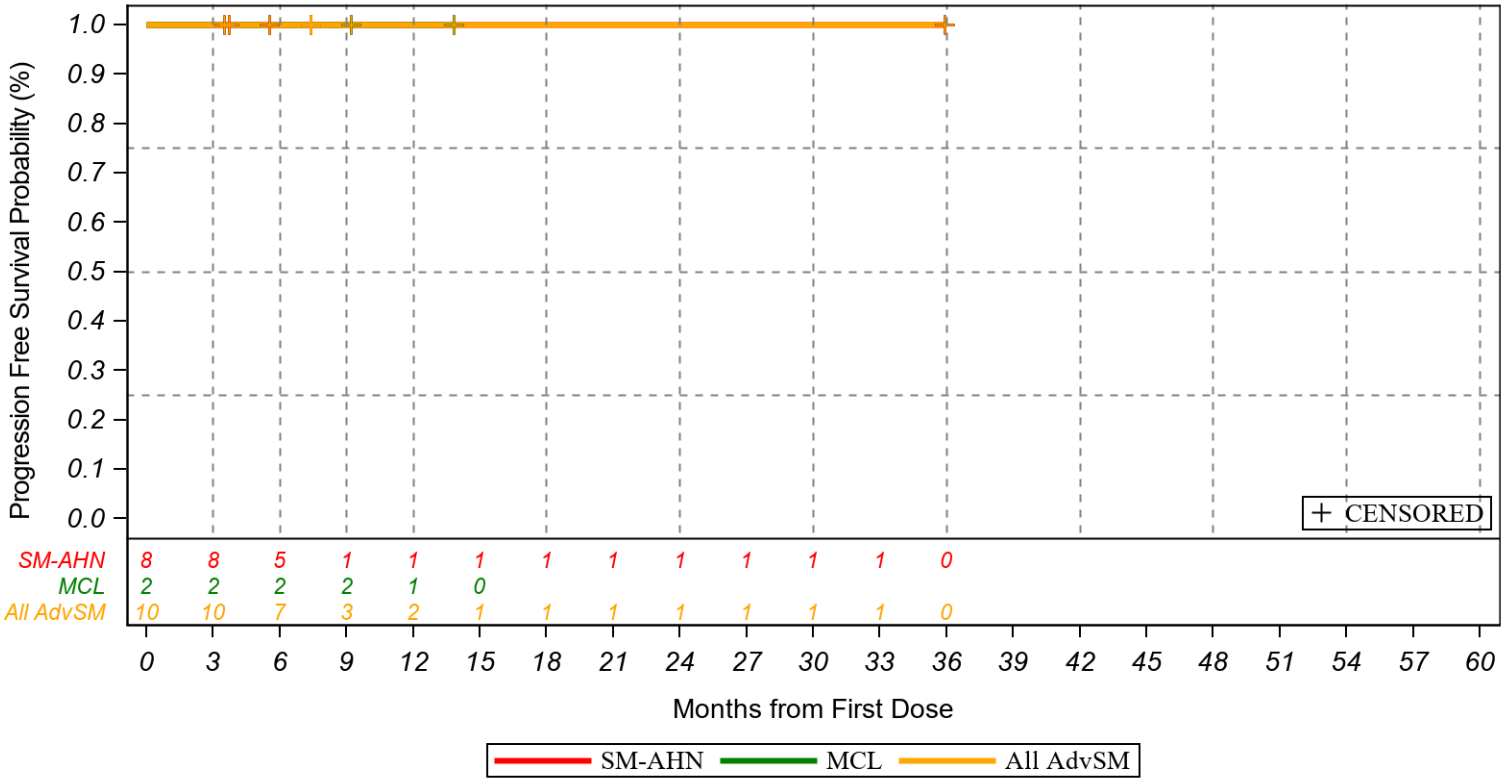
Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg, Duration of CR+CRh+PR



Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/f-inv-dur-advsm.sas
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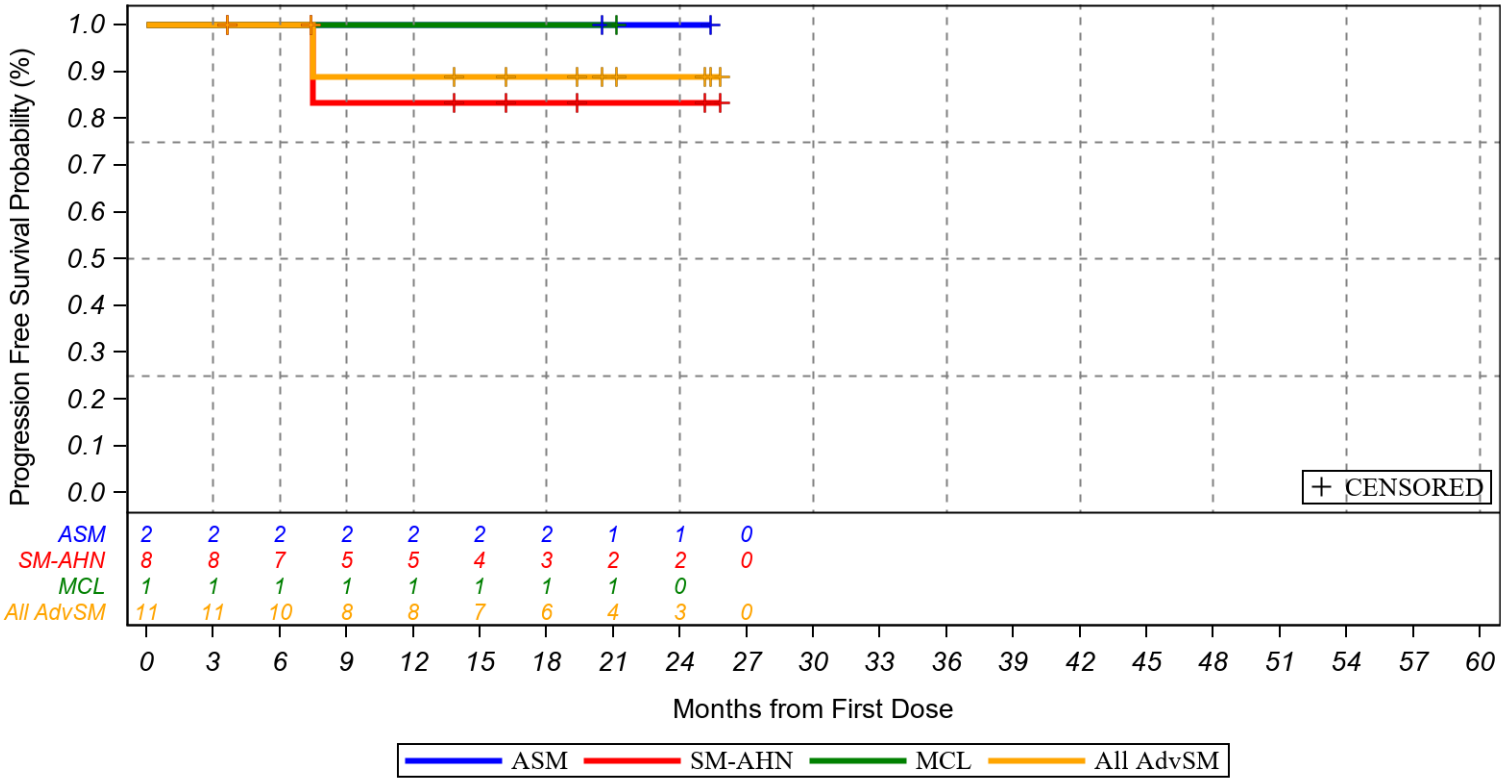
Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg, Duration of Response



Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/f-inv-dur-advsm.sas
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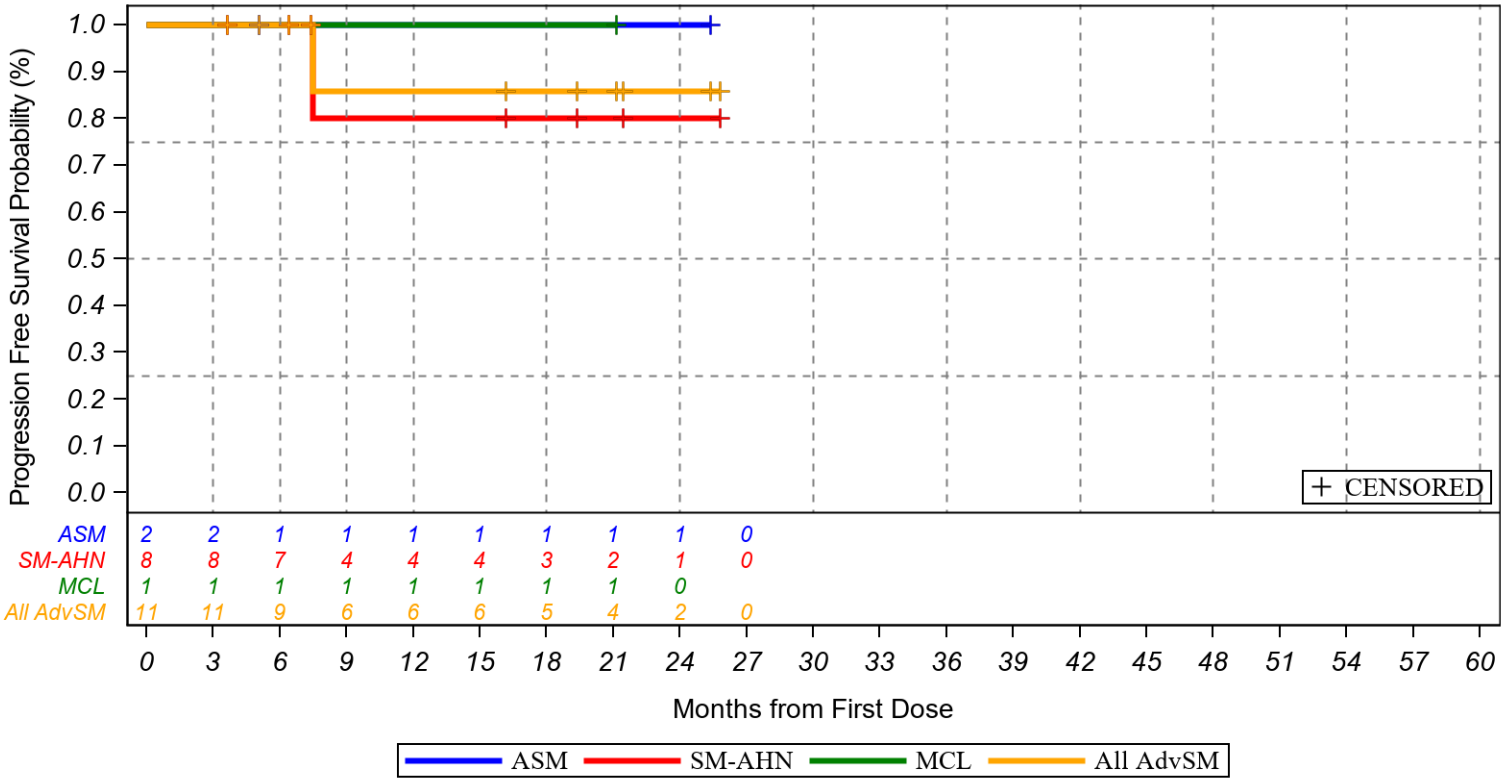
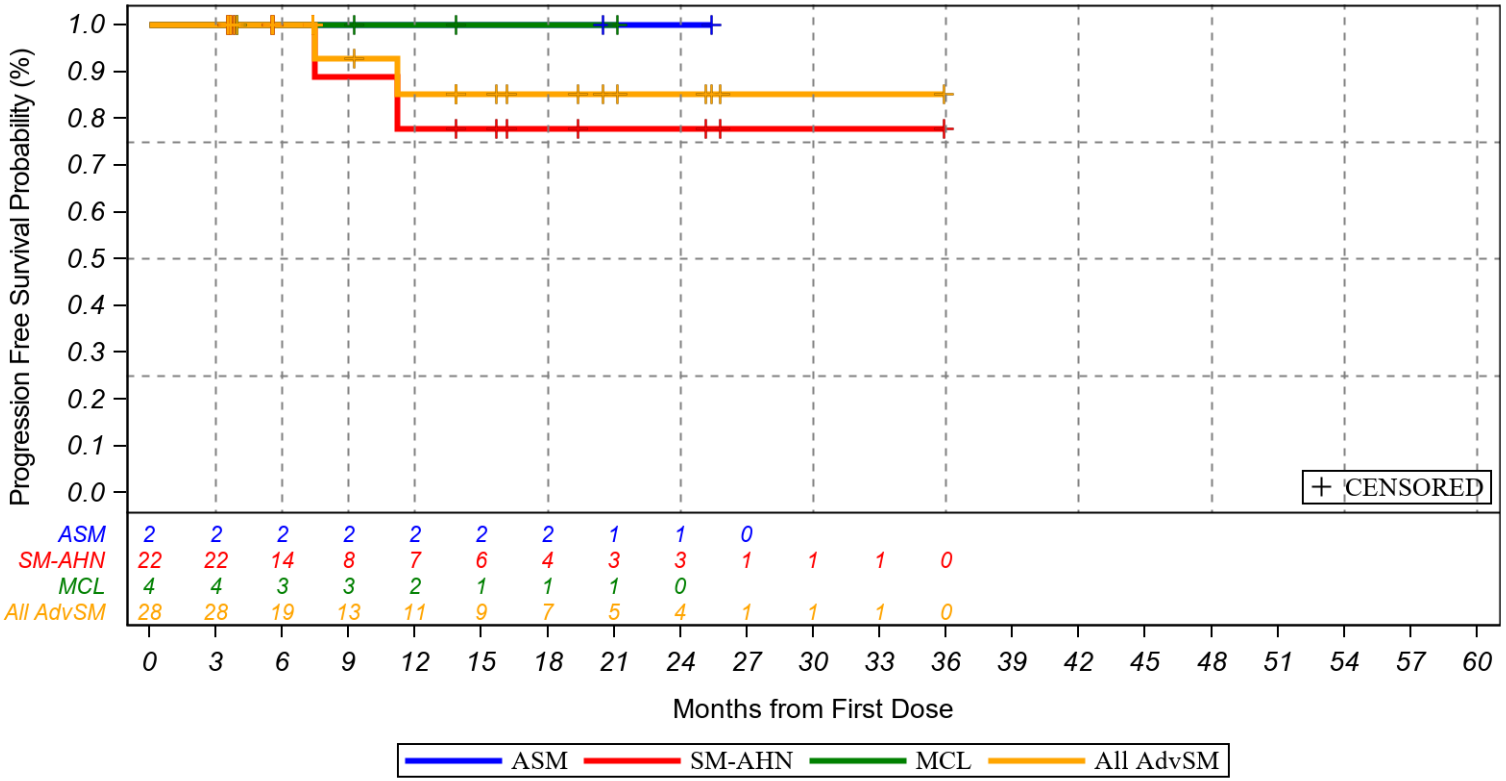
Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg, Duration of CR+CRh+PR



Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/f-inv-dur-advsm.sas
Date: 10:28/18JAN2022

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg, Duration of Response



Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/f-inv-dur-advsm.sas
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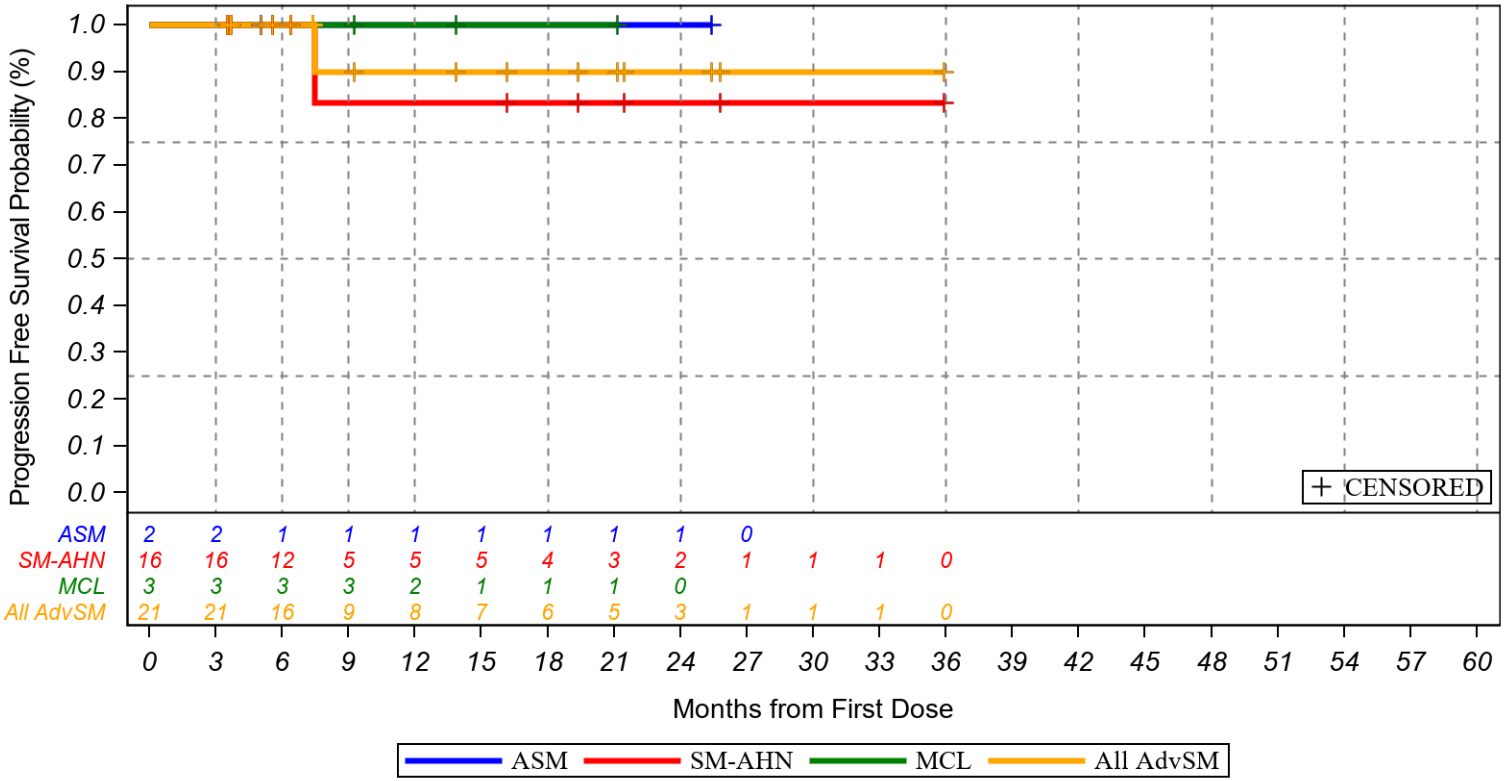
Cutoff date: 27may2020 (2101), 23jun2020 (2202)

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg, Duration of CR+CRh+PR



Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/f-inv-dur-advsm.sas
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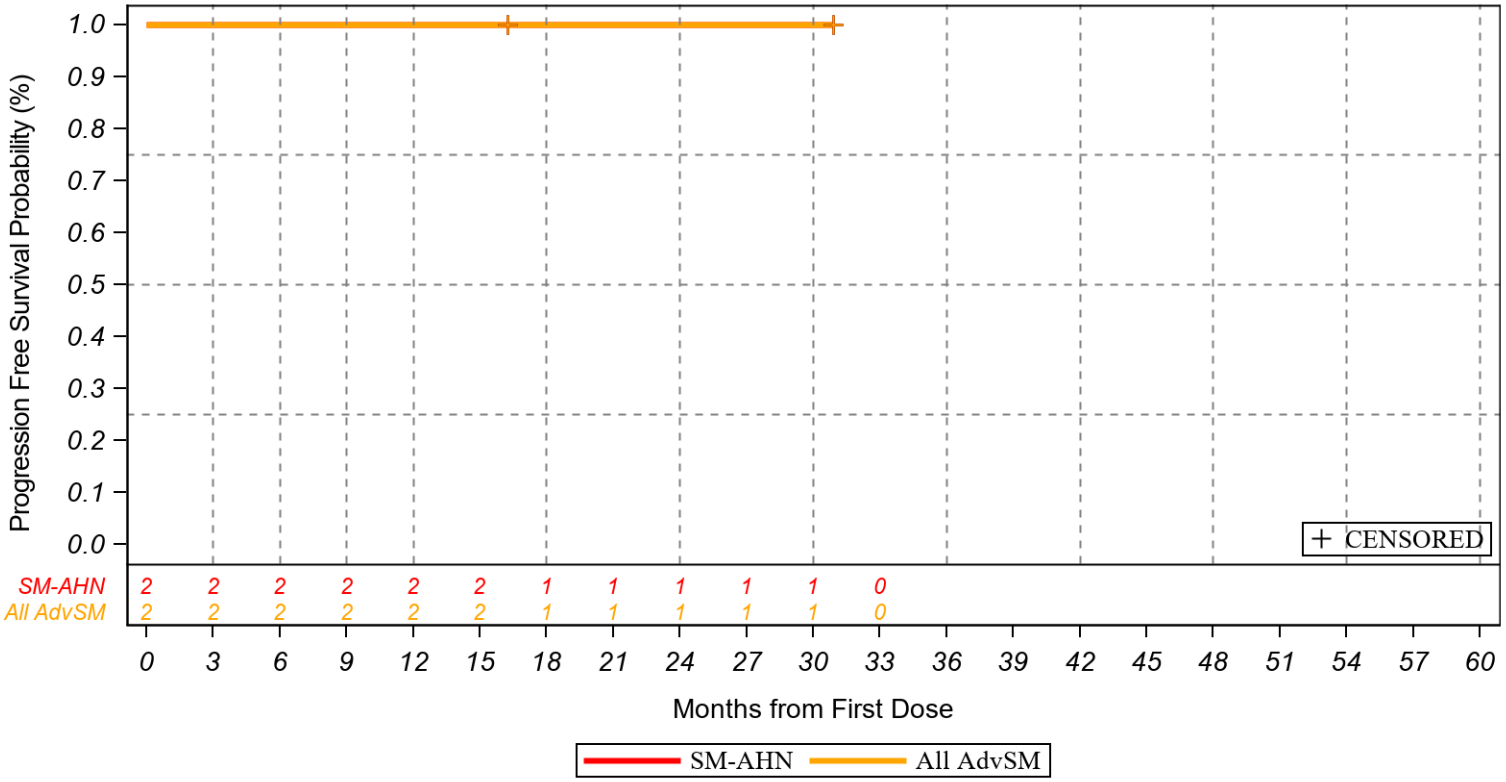
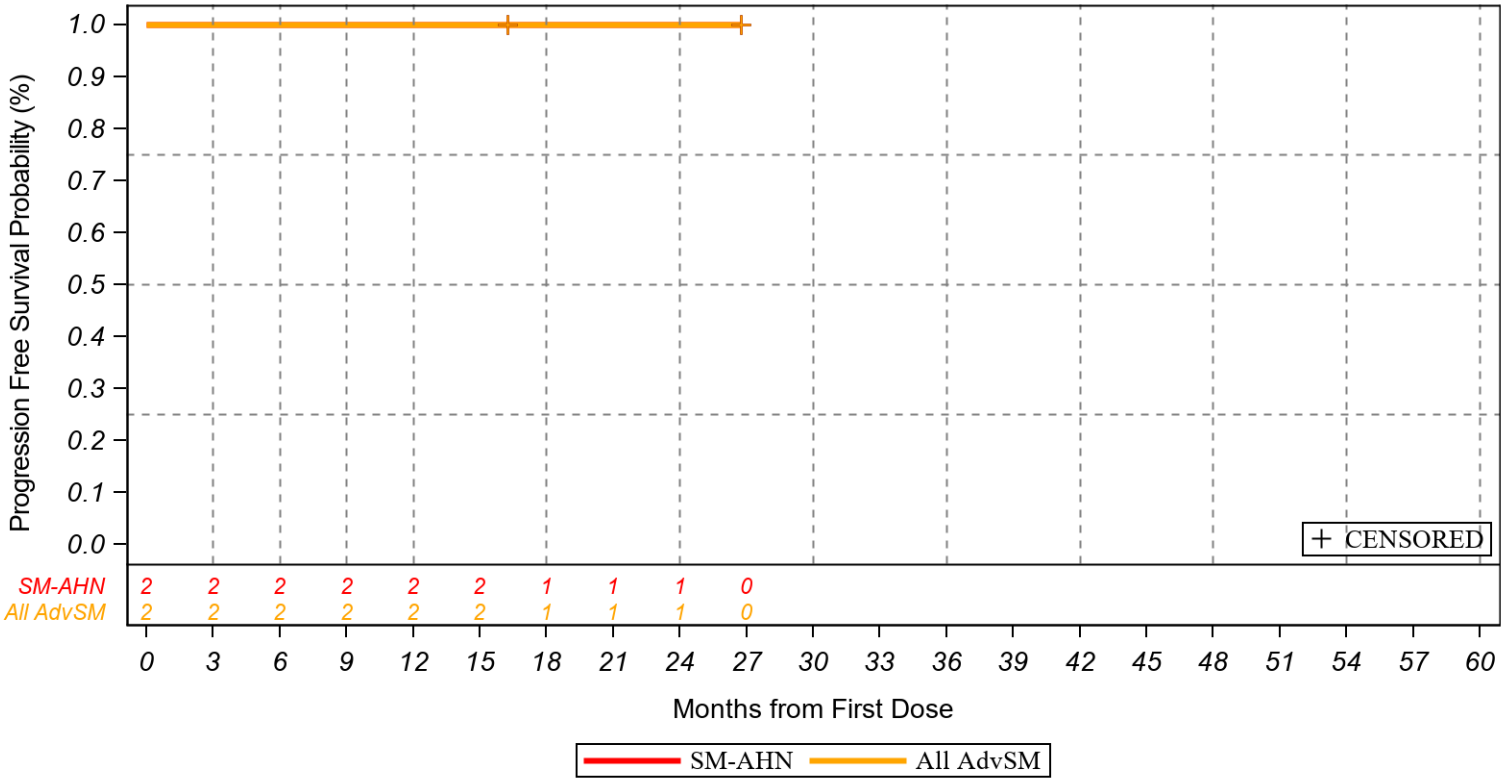
Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg, Duration of Response



Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/f-inv-dur-advsm.sas
Date: 10:28/18JAN2022

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg, Duration of CR+CRh+PR



Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/f-inv-dur-advsm.sas
Date: 10:28/18JAN2022

Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Overall & Prior antineoplastic therapy = Yes

Duration of Response	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=12) n (%) (95% CIs)	MCL (N=5) n (%) (95% CIs)	All AdvSM (N=19) n (%) (95% CIs)
Events	0	2 (16.7)	1 (20.0)	3 (15.8)
Censors	2 (100)	10 (83.3)	4 (80.0)	16 (84.2)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)	NE (3.7 - NE)	NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	91.7 (76.0-100.0)	80.0 (44.9-100.0)	89.5 (75.7-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	82.5 (60.4-100.0)	80.0 (44.9-100.0)	83.5 (66.4-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	82.5 (60.4-100.0)	80.0 (44.9-100.0)	83.5 (66.4-100.0)
18 Months (95% CIs)	100.0 (100.0-100.0)	82.5 (60.4-100.0)	80.0 (44.9-100.0)	83.5 (66.4-100.0)
24 Months (95% CIs)	100.0 (100.0-100.0)	82.5 (60.4-100.0)	80.0 (44.9-100.0)	83.5 (66.4-100.0)
30 Months (95% CIs)		82.5 (60.4-100.0)		83.5 (66.4-100.0)
36 Months (95% CIs)		82.5 (60.4-100.0)		83.5 (66.4-100.0)
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-dur-rac-tpy.saDate: 21:06/02NOV2020

Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Overall & Prior antineoplastic therapy = Yes

Duration of CR+PR	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=12) n (%) (95% CIs)	MCL (N=4) n (%) (95% CIs)	All AdvSM (N=18) n (%) (95% CIs)
Events	0	2 (16.7)	0	2 (11.1)
Censors	2 (100)	10 (83.3)	4 (100)	16 (88.9)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	91.7 (76.0-100.0)	100.0 (100.0-100.0)	94.4 (83.9-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	82.5 (60.4-100.0)	100.0 (100.0-100.0)	88.1 (72.7-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	82.5 (60.4-100.0)	100.0 (100.0-100.0)	88.1 (72.7-100.0)
18 Months (95% CIs)	100.0 (100.0-100.0)	82.5 (60.4-100.0)	100.0 (100.0-100.0)	88.1 (72.7-100.0)
24 Months (95% CIs)	100.0 (100.0-100.0)	82.5 (60.4-100.0)	100.0 (100.0-100.0)	88.1 (72.7-100.0)
30 Months (95% CIs)		82.5 (60.4-100.0)		88.1 (72.7-100.0)
36 Months (95% CIs)		82.5 (60.4-100.0)		88.1 (72.7-100.0)
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-dur-rac-tpy.saDate: 21:06/02NOV2020

Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Overall & Prior antineoplastic therapy = No

Duration of Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=10) n (%) (95% CIs)	MCL (N=5) n (%) (95% CIs)	All AdvSM (N=16) n (%) (95% CIs)
Events	0	5 (50.0)	1 (20.0)	6 (37.5)
Censors	1 (100)	5 (50.0)	4 (80.0)	10 (62.5)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	23.1 (18.4 - NE)	NE (5.6 - NE)	28.6 (18.4 - NE)
25th, 75th percentiles	NE, NE	18.4, 28.6	NE, NE	18.4, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	90.0 (71.4-100.0)	75.0 (32.6-100.0)	86.7 (69.5-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	90.0 (71.4-100.0)	75.0 (32.6-100.0)	86.7 (69.5-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	90.0 (71.4-100.0)	75.0 (32.6-100.0)	86.7 (69.5-100.0)
18 Months (95% CIs)	100.0 (100.0-100.0)	80.0 (55.2-100.0)	75.0 (32.6-100.0)	80.0 (59.8-100.0)
24 Months (95% CIs)		44.4 (3.1- 85.8)	75.0 (32.6-100.0)	57.6 (26.1- 89.1)
30 Months (95% CIs)		22.2 (0.0- 59.3)	75.0 (32.6-100.0)	38.4 (1.2- 75.6)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-dur-rac-tpy.saDate: 21:06/02NOV2020

Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Overall & Prior antineoplastic therapy = No

Duration of CR+PR	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=9) n (%) (95% CIs)	MCL (N=4) n (%) (95% CIs)	All AdvSM (N=14) n (%) (95% CIs)
Events	0	4 (44.4)	0	4 (28.6)
Censors	1 (100)	5 (55.6)	4 (100)	10 (71.4)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	20.8 (14.8 - NE)	NE (NE - NE)	NE (17.7 - NE)
25th, 75th percentiles	NE, NE	17.7, NE	NE, NE	17.7, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	88.9 (68.4-100.0)	100.0 (100.0-100.0)	92.3 (77.8-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	88.9 (68.4-100.0)	100.0 (100.0-100.0)	92.3 (77.8-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	88.9 (68.4-100.0)	100.0 (100.0-100.0)	92.3 (77.8-100.0)
18 Months (95% CIs)	100.0 (100.0-100.0)	57.1 (18.2- 96.1)	100.0 (100.0-100.0)	73.4 (47.1- 99.7)
24 Months (95% CIs)		38.1 (0.0- 78.1)	100.0 (100.0-100.0)	62.9 (33.4- 92.4)
30 Months (95% CIs)			100.0 (100.0-100.0)	62.9 (33.4- 92.4)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: <200 mg & Prior antineoplastic therapy = Yes

Duration of Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=1) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=2) n (%) (95% CIs)
Events		0	0	0
Censors		1 (100)	1 (100)	2 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles		NE, NE	NE, NE	NE, NE
3 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
18 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
24 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
30 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
36 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: <200 mg & Prior antineoplastic therapy = Yes

Duration of CR+PR	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=1) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=2) n (%) (95% CIs)
Events		0	0	0
Censors		1 (100)	1 (100)	2 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles		NE, NE	NE, NE	NE, NE
3 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
18 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
24 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
30 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
36 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-dur-rac-tpy.saDate: 21:06/02NOV2020

Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: <200 mg & Prior antineoplastic therapy = No

Duration of Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=3) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=3) n (%) (95% CIs)
Events		2 (66.7)		2 (66.7)
Censors		1 (33.3)		1 (33.3)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		28.6 (23.1 - NE)		28.6 (23.1 - NE)
25th, 75th percentiles		23.1, NE		23.1, NE
3 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
18 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
24 Months (95% CIs)		66.7 (13.3-100.0)		66.7 (13.3-100.0)
30 Months (95% CIs)		33.3 (0.0- 86.7)		33.3 (0.0- 86.7)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: <200 mg & Prior antineoplastic therapy = No

Duration of CR+PR	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=3) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=3) n (%) (95% CIs)
Events		2 (66.7)		2 (66.7)
Censors		1 (33.3)		1 (33.3)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		20.8 (14.8 - NE)		20.8 (14.8 - NE)
25th, 75th percentiles		14.8, NE		14.8, NE
3 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
18 Months (95% CIs)		66.7 (13.3-100.0)		66.7 (13.3-100.0)
24 Months (95% CIs)		33.3 (0.0- 86.7)		33.3 (0.0- 86.7)
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: <300 mg & Prior antineoplastic therapy = Yes

Duration of Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=2) n (%) (95% CIs)	MCL (N=3) n (%) (95% CIs)	All AdvSM (N=5) n (%) (95% CIs)
Events		0	0	0
Censors		2 (100)	3 (100)	5 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles		NE, NE	NE, NE	NE, NE
3 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
18 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
24 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
30 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
36 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: <300 mg & Prior antineoplastic therapy = Yes

Duration of CR+PR	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=2) n (%) (95% CIs)	MCL (N=3) n (%) (95% CIs)	All AdvSM (N=5) n (%) (95% CIs)
Events		0	0	0
Censors		2 (100)	3 (100)	5 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles		NE, NE	NE, NE	NE, NE
3 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
18 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
24 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
30 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
36 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: <300 mg & Prior antineoplastic therapy = No

Duration of Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=3) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=5) n (%) (95% CIs)
Events		2 (66.7)	0	2 (40.0)
Censors		1 (33.3)	2 (100)	3 (60.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		28.6 (23.1 - NE)	NE (NE - NE)	28.6 (23.1 - NE)
25th, 75th percentiles		23.1, NE	NE, NE	23.1, NE
3 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
18 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
24 Months (95% CIs)		66.7 (13.3-100.0)		66.7 (13.3-100.0)
30 Months (95% CIs)		33.3 (0.0- 86.7)		33.3 (0.0- 86.7)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: <300 mg & Prior antineoplastic therapy = No

Duration of CR+PR	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=3) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=5) n (%) (95% CIs)
Events		2 (66.7)	0	2 (40.0)
Censors		1 (33.3)	2 (100)	3 (60.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		20.8 (14.8 - NE)	NE (NE - NE)	NE (14.8 - NE)
25th, 75th percentiles		14.8, NE	NE, NE	17.8, NE
3 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
18 Months (95% CIs)		66.7 (13.3-100.0)	100.0 (100.0-100.0)	75.0 (32.6-100.0)
24 Months (95% CIs)		33.3 (0.0- 86.7)		50.0 (1.0- 99.0)
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: 200 mg & Prior antineoplastic therapy = Yes

Duration of Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=1) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=3) n (%) (95% CIs)
Events		0	0	0
Censors		1 (100)	2 (100)	3 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles		NE, NE	NE, NE	NE, NE
3 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
18 Months (95% CIs)				
24 Months (95% CIs)				
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: 200 mg & Prior antineoplastic therapy = Yes

Duration of CR+PR	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=1) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=3) n (%) (95% CIs)
Events		0	0	0
Censors		1 (100)	2 (100)	3 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles		NE, NE	NE, NE	NE, NE
3 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
18 Months (95% CIs)				
24 Months (95% CIs)				
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: 200 mg & Prior antineoplastic therapy = No

Duration of Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=0) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=2) n (%) (95% CIs)
Events			0	0
Censors			2 (100)	2 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)			NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles			NE, NE	NE, NE
3 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
18 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
24 Months (95% CIs)				
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: 200 mg & Prior antineoplastic therapy = No

Duration of CR+PR	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=0) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=2) n (%) (95% CIs)
Events			0	0
Censors			2 (100)	2 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)			NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles			NE, NE	NE, NE
3 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
18 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
24 Months (95% CIs)				
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: 300 mg & Prior antineoplastic therapy = Yes

Duration of Response	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=7) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=11) n (%) (95% CIs)
Events	0	1 (14.3)	1 (50.0)	2 (18.2)
Censors	2 (100)	6 (85.7)	1 (50.0)	9 (81.8)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)	NE (3.7 - NE)	NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE	3.7, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	50.0 (0.0-100.0)	90.9 (73.9-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	85.7 (59.8-100.0)	50.0 (0.0-100.0)	81.8 (59.0-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	85.7 (59.8-100.0)	50.0 (0.0-100.0)	81.8 (59.0-100.0)
18 Months (95% CIs)	100.0 (100.0-100.0)	85.7 (59.8-100.0)	50.0 (0.0-100.0)	81.8 (59.0-100.0)
24 Months (95% CIs)	100.0 (100.0-100.0)	85.7 (59.8-100.0)	50.0 (0.0-100.0)	81.8 (59.0-100.0)
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: 300 mg & Prior antineoplastic therapy = Yes

Duration of CR+PR	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=7) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=10) n (%) (95% CIs)
Events	0	1 (14.3)	0	1 (10.0)
Censors	2 (100)	6 (85.7)	1 (100)	9 (90.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	85.7 (59.8-100.0)	100.0 (100.0-100.0)	90.0 (71.4-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	85.7 (59.8-100.0)	100.0 (100.0-100.0)	90.0 (71.4-100.0)
18 Months (95% CIs)	100.0 (100.0-100.0)	85.7 (59.8-100.0)	100.0 (100.0-100.0)	90.0 (71.4-100.0)
24 Months (95% CIs)	100.0 (100.0-100.0)		100.0 (100.0-100.0)	90.0 (71.4-100.0)
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: 300 mg & Prior antineoplastic therapy = No

Duration of Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=7) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=10) n (%) (95% CIs)
Events	0	3 (42.9)	1 (50.0)	4 (40.0)
Censors	1 (100)	4 (57.1)	1 (50.0)	6 (60.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	18.4 (13.3 - NE)	NE (5.6 - NE)	NE (13.3 - NE)
25th, 75th percentiles	NE, NE	13.3, NE	5.6, NE	13.3, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	85.7 (59.8-100.0)	50.0 (0.0-100.0)	80.0 (55.2-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	85.7 (59.8-100.0)	50.0 (0.0-100.0)	80.0 (55.2-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	85.7 (59.8-100.0)	50.0 (0.0-100.0)	80.0 (55.2-100.0)
18 Months (95% CIs)	100.0 (100.0-100.0)	71.4 (38.0-100.0)	50.0 (0.0-100.0)	70.0 (41.6- 98.4)
24 Months (95% CIs)			50.0 (0.0-100.0)	56.0 (22.6- 89.4)
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: 300 mg & Prior antineoplastic therapy = No

Duration of CR+PR	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=6) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=8) n (%) (95% CIs)
Events	0	2 (33.3)	0	2 (25.0)
Censors	1 (100)	4 (66.7)	1 (100)	6 (75.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	17.7 (17.7 - NE)	NE (NE - NE)	NE (17.7 - NE)
25th, 75th percentiles	NE, NE	17.7, NE	NE, NE	17.7, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	83.3 (53.5-100.0)	100.0 (100.0-100.0)	87.5 (64.6-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	83.3 (53.5-100.0)	100.0 (100.0-100.0)	87.5 (64.6-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	83.3 (53.5-100.0)	100.0 (100.0-100.0)	87.5 (64.6-100.0)
18 Months (95% CIs)	100.0 (100.0-100.0)	41.7 (0.0-100.0)	100.0 (100.0-100.0)	65.6 (24.7-100.0)
24 Months (95% CIs)			100.0 (100.0-100.0)	65.6 (24.7-100.0)
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg & Prior antineoplastic therapy = Yes

Duration of Response	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=8) n (%) (95% CIs)	MCL (N=4) n (%) (95% CIs)	All AdvSM (N=14) n (%) (95% CIs)
Events	0	1 (12.5)	1 (25.0)	2 (14.3)
Censors	2 (100)	7 (87.5)	3 (75.0)	12 (85.7)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)	NE (3.7 - NE)	NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	75.0 (32.6-100.0)	92.9 (79.4-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	87.5 (64.6-100.0)	75.0 (32.6-100.0)	85.1 (66.0-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	87.5 (64.6-100.0)	75.0 (32.6-100.0)	85.1 (66.0-100.0)
18 Months (95% CIs)	100.0 (100.0-100.0)	87.5 (64.6-100.0)	75.0 (32.6-100.0)	85.1 (66.0-100.0)
24 Months (95% CIs)	100.0 (100.0-100.0)	87.5 (64.6-100.0)	75.0 (32.6-100.0)	85.1 (66.0-100.0)
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-dur-rac-tpy.saDate: 21:06/02NOV2020

Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg & Prior antineoplastic therapy = Yes

Duration of CR+PR	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=8) n (%) (95% CIs)	MCL (N=3) n (%) (95% CIs)	All AdvSM (N=13) n (%) (95% CIs)
Events	0	1 (12.5)	0	1 (7.7)
Censors	2 (100)	7 (87.5)	3 (100)	12 (92.3)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	87.5 (64.6-100.0)	100.0 (100.0-100.0)	91.7 (76.0-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	87.5 (64.6-100.0)	100.0 (100.0-100.0)	91.7 (76.0-100.0)
18 Months (95% CIs)	100.0 (100.0-100.0)	87.5 (64.6-100.0)	100.0 (100.0-100.0)	91.7 (76.0-100.0)
24 Months (95% CIs)	100.0 (100.0-100.0)		100.0 (100.0-100.0)	91.7 (76.0-100.0)
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-dur-rac-tpy.saDate: 21:06/02NOV2020

Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg & Prior antineoplastic therapy = No

Duration of Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=7) n (%) (95% CIs)	MCL (N=4) n (%) (95% CIs)	All AdvSM (N=12) n (%) (95% CIs)
Events	0	3 (42.9)	1 (25.0)	4 (33.3)
Censors	1 (100)	4 (57.1)	3 (75.0)	8 (66.7)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	18.4 (13.3 - NE)	NE (5.6 - NE)	NE (13.3 - NE)
25th, 75th percentiles	NE, NE	13.3, NE	5.6, NE	13.3, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	85.7 (59.8-100.0)	66.7 (13.3-100.0)	81.8 (59.0-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	85.7 (59.8-100.0)	66.7 (13.3-100.0)	81.8 (59.0-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	85.7 (59.8-100.0)	66.7 (13.3-100.0)	81.8 (59.0-100.0)
18 Months (95% CIs)	100.0 (100.0-100.0)	71.4 (38.0-100.0)	66.7 (13.3-100.0)	72.7 (46.4- 99.0)
24 Months (95% CIs)			66.7 (13.3-100.0)	60.6 (29.8- 91.5)
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-dur-rac-tpy.saDate: 21:06/02NOV2020

Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg & Prior antineoplastic therapy = No

Duration of CR+PR	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=6) n (%) (95% CIs)	MCL (N=3) n (%) (95% CIs)	All AdvSM (N=10) n (%) (95% CIs)
Events	0	2 (33.3)	0	2 (20.0)
Censors	1 (100)	4 (66.7)	3 (100)	8 (80.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	17.7 (17.7 - NE)	NE (NE - NE)	NE (17.7 - NE)
25th, 75th percentiles	NE, NE	17.7, NE	NE, NE	17.7, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	83.3 (53.5-100.0)	100.0 (100.0-100.0)	88.9 (68.4-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	83.3 (53.5-100.0)	100.0 (100.0-100.0)	88.9 (68.4-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	83.3 (53.5-100.0)	100.0 (100.0-100.0)	88.9 (68.4-100.0)
18 Months (95% CIs)	100.0 (100.0-100.0)	41.7 (0.0-100.0)	100.0 (100.0-100.0)	71.1 (35.9-100.0)
24 Months (95% CIs)			100.0 (100.0-100.0)	71.1 (35.9-100.0)
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-dur-rac-tpy.saDate: 21:06/02NOV2020

Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: 400 mg & Prior antineoplastic therapy = Yes

Duration of Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=3) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=3) n (%) (95% CIs)
Events		1 (33.3)		1 (33.3)
Censors		2 (66.7)		2 (66.7)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (3.7 - NE)		NE (3.7 - NE)
25th, 75th percentiles		3.7, NE		3.7, NE
3 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
6 Months (95% CIs)		66.7 (13.3-100.0)		66.7 (13.3-100.0)
9 Months (95% CIs)		66.7 (13.3-100.0)		66.7 (13.3-100.0)
12 Months (95% CIs)		66.7 (13.3-100.0)		66.7 (13.3-100.0)
18 Months (95% CIs)		66.7 (13.3-100.0)		66.7 (13.3-100.0)
24 Months (95% CIs)		66.7 (13.3-100.0)		66.7 (13.3-100.0)
30 Months (95% CIs)		66.7 (13.3-100.0)		66.7 (13.3-100.0)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: 400 mg & Prior antineoplastic therapy = Yes

Duration of CR+PR	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=3) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=3) n (%) (95% CIs)
Events		1 (33.3)		1 (33.3)
Censors		2 (66.7)		2 (66.7)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (3.7 - NE)		NE (3.7 - NE)
25th, 75th percentiles		3.7, NE		3.7, NE
3 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
6 Months (95% CIs)		66.7 (13.3-100.0)		66.7 (13.3-100.0)
9 Months (95% CIs)		66.7 (13.3-100.0)		66.7 (13.3-100.0)
12 Months (95% CIs)		66.7 (13.3-100.0)		66.7 (13.3-100.0)
18 Months (95% CIs)		66.7 (13.3-100.0)		66.7 (13.3-100.0)
24 Months (95% CIs)		66.7 (13.3-100.0)		66.7 (13.3-100.0)
30 Months (95% CIs)		66.7 (13.3-100.0)		66.7 (13.3-100.0)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: 400 mg & Prior antineoplastic therapy = No

Duration of Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=0) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=1) n (%) (95% CIs)
Events			0	0
Censors			1 (100)	1 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)			NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles			NE, NE	NE, NE
3 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
18 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
24 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
30 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101

Starting Dose: 400 mg & Prior antineoplastic therapy = No

Duration of CR+PR	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=0) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=1) n (%) (95% CIs)
Events			0	0
Censors			1 (100)	1 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)			NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles			NE, NE	NE, NE
3 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
18 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
24 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
30 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202

Overall & Prior antineoplastic therapy = Yes

Duration of Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=12) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=15) n (%) (95% CIs)
Events	0	0	0	0
Censors	1 (100)	12 (100)	2 (100)	15 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
18 Months (95% CIs)				
24 Months (95% CIs)				
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202

Overall & Prior antineoplastic therapy = Yes

Duration of CR+PR	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=6) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=8) n (%) (95% CIs)
Events	0	0	0	0
Censors	1 (100)	6 (100)	1 (100)	8 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
18 Months (95% CIs)				
24 Months (95% CIs)				
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202

Overall & Prior antineoplastic therapy = No

Duration of Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=3) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=4) n (%) (95% CIs)
Events	0	0		0
Censors	1 (100)	3 (100)		4 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)		NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE		NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)		100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)		100.0 (100.0-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)		100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
18 Months (95% CIs)				
24 Months (95% CIs)				
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202

Overall & Prior antineoplastic therapy = No

Duration of CR+PR	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=3) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=4) n (%) (95% CIs)
Events	0	0		0
Censors	1 (100)	3 (100)		4 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)		NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE		NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)		100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)		100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
12 Months (95% CIs)				
18 Months (95% CIs)				
24 Months (95% CIs)				
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202

Starting Dose: 200 mg & Prior antineoplastic therapy = Yes

Duration of Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=11) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=14) n (%) (95% CIs)
Events	0	0	0	0
Censors	1 (100)	11 (100)	2 (100)	14 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
18 Months (95% CIs)				
24 Months (95% CIs)				
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202

Starting Dose: 200 mg & Prior antineoplastic therapy = Yes

Duration of CR+PR	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=5) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=7) n (%) (95% CIs)
Events	0	0	0	0
Censors	1 (100)	5 (100)	1 (100)	7 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
18 Months (95% CIs)				
24 Months (95% CIs)				
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202

Starting Dose: 200 mg & Prior antineoplastic therapy = No

Duration of Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=3) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=4) n (%) (95% CIs)
Events	0	0		0
Censors	1 (100)	3 (100)		4 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)		NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE		NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)		100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)		100.0 (100.0-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)		100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
18 Months (95% CIs)				
24 Months (95% CIs)				
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202

Starting Dose: 200 mg & Prior antineoplastic therapy = No

Duration of CR+PR	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=3) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=4) n (%) (95% CIs)
Events	0	0		0
Censors	1 (100)	3 (100)		4 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)		NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE		NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)		100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)		100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
12 Months (95% CIs)				
18 Months (95% CIs)				
24 Months (95% CIs)				
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-dur-rac-tpy.saDate: 21:06/02NOV2020

Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Overall & Prior antineoplastic therapy = Yes

Duration of Response	ASM (N=3) n (%) (95% CIs)	SM-AHN (N=24) n (%) (95% CIs)	MCL (N=7) n (%) (95% CIs)	All AdvSM (N=34) n (%) (95% CIs)
Events	0	2 (8.3)	1 (14.3)	3 (8.8)
Censors	3 (100)	22 (91.7)	6 (85.7)	31 (91.2)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	95.7 (87.3-100.0)	83.3 (53.5-100.0)	93.8 (85.4-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	89.3 (74.9-100.0)	83.3 (53.5-100.0)	89.1 (77.1-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	89.3 (74.9-100.0)	83.3 (53.5-100.0)	89.1 (77.1-100.0)
18 Months (95% CIs)	100.0 (100.0-100.0)	89.3 (74.9-100.0)	83.3 (53.5-100.0)	89.1 (77.1-100.0)
24 Months (95% CIs)	100.0 (100.0-100.0)	89.3 (74.9-100.0)	83.3 (53.5-100.0)	89.1 (77.1-100.0)
30 Months (95% CIs)		89.3 (74.9-100.0)		89.1 (77.1-100.0)
36 Months (95% CIs)		89.3 (74.9-100.0)		89.1 (77.1-100.0)
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Overall & Prior antineoplastic therapy = Yes

Duration of CR+PR	ASM (N=3) n (%) (95% CIs)	SM-AHN (N=18) n (%) (95% CIs)	MCL (N=5) n (%) (95% CIs)	All AdvSM (N=26) n (%) (95% CIs)
Events	0	2 (11.1)	0	2 (7.7)
Censors	3 (100)	16 (88.9)	5 (100)	24 (92.3)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	94.4 (83.9-100.0)	100.0 (100.0-100.0)	96.2 (88.8-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	87.2 (70.4-100.0)	100.0 (100.0-100.0)	90.8 (78.5-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	87.2 (70.4-100.0)	100.0 (100.0-100.0)	90.8 (78.5-100.0)
18 Months (95% CIs)	100.0 (100.0-100.0)	87.2 (70.4-100.0)	100.0 (100.0-100.0)	90.8 (78.5-100.0)
24 Months (95% CIs)	100.0 (100.0-100.0)	87.2 (70.4-100.0)	100.0 (100.0-100.0)	90.8 (78.5-100.0)
30 Months (95% CIs)		87.2 (70.4-100.0)		90.8 (78.5-100.0)
36 Months (95% CIs)		87.2 (70.4-100.0)		90.8 (78.5-100.0)
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Overall & Prior antineoplastic therapy = No

Duration of Response	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=13) n (%) (95% CIs)	MCL (N=5) n (%) (95% CIs)	All AdvSM (N=20) n (%) (95% CIs)
Events	0	5 (38.5)	1 (20.0)	6 (30.0)
Censors	2 (100)	8 (61.5)	4 (80.0)	14 (70.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	23.1 (18.4 - NE)	NE (5.6 - NE)	28.6 (23.1 - NE)
25th, 75th percentiles	NE, NE	18.4, 28.6	NE, NE	18.4, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	91.7 (76.0-100.0)	75.0 (32.6-100.0)	88.9 (74.4-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	91.7 (76.0-100.0)	75.0 (32.6-100.0)	88.9 (74.4-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	91.7 (76.0-100.0)	75.0 (32.6-100.0)	88.9 (74.4-100.0)
18 Months (95% CIs)	100.0 (100.0-100.0)	82.5 (60.4-100.0)	75.0 (32.6-100.0)	82.5 (64.5-100.0)
24 Months (95% CIs)		45.8 (3.8- 87.8)	75.0 (32.6-100.0)	59.4 (27.8- 91.0)
30 Months (95% CIs)		22.9 (0.0- 61.0)	75.0 (32.6-100.0)	39.6 (1.6- 77.7)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Overall & Prior antineoplastic therapy = No

Duration of CR+PR	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=12) n (%) (95% CIs)	MCL (N=4) n (%) (95% CIs)	All AdvSM (N=18) n (%) (95% CIs)
Events	0	4 (33.3)	0	4 (22.2)
Censors	2 (100)	8 (66.7)	4 (100)	14 (77.8)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	20.8 (17.7 - NE)	NE (NE - NE)	NE (17.7 - NE)
25th, 75th percentiles	NE, NE	17.7, NE	NE, NE	17.7, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	90.9 (73.9-100.0)	100.0 (100.0-100.0)	93.8 (81.9-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	90.9 (73.9-100.0)	100.0 (100.0-100.0)	93.8 (81.9-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	90.9 (73.9-100.0)	100.0 (100.0-100.0)	93.8 (81.9-100.0)
18 Months (95% CIs)	100.0 (100.0-100.0)	58.4 (19.4- 97.5)	100.0 (100.0-100.0)	74.6 (48.8-100.0)
24 Months (95% CIs)		39.0 (0.0- 79.6)	100.0 (100.0-100.0)	63.9 (34.6- 93.3)
30 Months (95% CIs)			100.0 (100.0-100.0)	63.9 (34.6- 93.3)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg & Prior antineoplastic therapy = Yes

Duration of Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=2) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=3) n (%) (95% CIs)
Events		0	0	0
Censors		2 (100)	1 (100)	3 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles		NE, NE	NE, NE	NE, NE
3 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
18 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
24 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
30 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
36 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg & Prior antineoplastic therapy = Yes

Duration of CR+PR	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=2) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=3) n (%) (95% CIs)
Events		0	0	0
Censors		2 (100)	1 (100)	3 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles		NE, NE	NE, NE	NE, NE
3 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
18 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
24 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
30 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
36 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg & Prior antineoplastic therapy = No

Duration of Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=3) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=3) n (%) (95% CIs)
Events		2 (66.7)		2 (66.7)
Censors		1 (33.3)		1 (33.3)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		28.6 (23.1 - NE)		28.6 (23.1 - NE)
25th, 75th percentiles		23.1, NE		23.1, NE
3 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
18 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
24 Months (95% CIs)		66.7 (13.3-100.0)		66.7 (13.3-100.0)
30 Months (95% CIs)		33.3 (0.0- 86.7)		33.3 (0.0- 86.7)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg & Prior antineoplastic therapy = No

Duration of CR+PR	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=3) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=3) n (%) (95% CIs)
Events		2 (66.7)		2 (66.7)
Censors		1 (33.3)		1 (33.3)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		20.8 (14.8 - NE)		20.8 (14.8 - NE)
25th, 75th percentiles		14.8, NE		14.8, NE
3 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
18 Months (95% CIs)		66.7 (13.3-100.0)		66.7 (13.3-100.0)
24 Months (95% CIs)		33.3 (0.0- 86.7)		33.3 (0.0- 86.7)
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg & Prior antineoplastic therapy = Yes

Duration of Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=14) n (%) (95% CIs)	MCL (N=5) n (%) (95% CIs)	All AdvSM (N=20) n (%) (95% CIs)
Events	0	0	0	0
Censors	1 (100)	14 (100)	5 (100)	20 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
18 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
24 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
30 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
36 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-dur-rac-tpy.saDate: 21:06/02NOV2020

Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg & Prior antineoplastic therapy = Yes

Duration of CR+PR	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=8) n (%) (95% CIs)	MCL (N=4) n (%) (95% CIs)	All AdvSM (N=13) n (%) (95% CIs)
Events	0	0	0	0
Censors	1 (100)	8 (100)	4 (100)	13 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
18 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
24 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
30 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
36 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg & Prior antineoplastic therapy = No

Duration of Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=6) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=9) n (%) (95% CIs)
Events	0	2 (33.3)	0	2 (22.2)
Censors	1 (100)	4 (66.7)	2 (100)	7 (77.8)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	28.6 (23.1 - NE)	NE (NE - NE)	28.6 (23.1 - NE)
25th, 75th percentiles	NE, NE	23.1, NE	NE, NE	23.1, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
18 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
24 Months (95% CIs)		66.7 (13.3-100.0)		66.7 (13.3-100.0)
30 Months (95% CIs)		33.3 (0.0- 86.7)		33.3 (0.0- 86.7)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-dur-rac-tpy.saDate: 21:06/02NOV2020

Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg & Prior antineoplastic therapy = No

Duration of CR+PR	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=6) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=9) n (%) (95% CIs)
Events	0	2 (33.3)	0	2 (22.2)
Censors	1 (100)	4 (66.7)	2 (100)	7 (77.8)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	20.8 (14.8 - NE)	NE (NE - NE)	NE (14.8 - NE)
25th, 75th percentiles	NE, NE	14.8, NE	NE, NE	17.8, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
18 Months (95% CIs)		66.7 (13.3-100.0)	100.0 (100.0-100.0)	75.0 (32.6-100.0)
24 Months (95% CIs)		33.3 (0.0- 86.7)		50.0 (1.0- 99.0)
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-dur-rac-tpy.saDate: 21:06/02NOV2020

Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg & Prior antineoplastic therapy = Yes

Duration of Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=12) n (%) (95% CIs)	MCL (N=4) n (%) (95% CIs)	All AdvSM (N=17) n (%) (95% CIs)
Events	0	0	0	0
Censors	1 (100)	12 (100)	4 (100)	17 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
18 Months (95% CIs)				
24 Months (95% CIs)				
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg & Prior antineoplastic therapy = Yes

Duration of CR+PR	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=6) n (%) (95% CIs)	MCL (N=3) n (%) (95% CIs)	All AdvSM (N=10) n (%) (95% CIs)
Events	0	0	0	0
Censors	1 (100)	6 (100)	3 (100)	10 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
18 Months (95% CIs)				
24 Months (95% CIs)				
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg & Prior antineoplastic therapy = No

Duration of Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=3) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=6) n (%) (95% CIs)
Events	0	0	0	0
Censors	1 (100)	3 (100)	2 (100)	6 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
18 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
24 Months (95% CIs)				
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg & Prior antineoplastic therapy = No

Duration of CR+PR	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=3) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=6) n (%) (95% CIs)
Events	0	0	0	0
Censors	1 (100)	3 (100)	2 (100)	6 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)		100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
18 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
24 Months (95% CIs)				
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg & Prior antineoplastic therapy = Yes

Duration of Response	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=7) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=11) n (%) (95% CIs)
Events	0	1 (14.3)	1 (50.0)	2 (18.2)
Censors	2 (100)	6 (85.7)	1 (50.0)	9 (81.8)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)	NE (3.7 - NE)	NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE	3.7, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	50.0 (0.0-100.0)	90.9 (73.9-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	85.7 (59.8-100.0)	50.0 (0.0-100.0)	81.8 (59.0-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	85.7 (59.8-100.0)	50.0 (0.0-100.0)	81.8 (59.0-100.0)
18 Months (95% CIs)	100.0 (100.0-100.0)	85.7 (59.8-100.0)	50.0 (0.0-100.0)	81.8 (59.0-100.0)
24 Months (95% CIs)	100.0 (100.0-100.0)	85.7 (59.8-100.0)	50.0 (0.0-100.0)	81.8 (59.0-100.0)
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg & Prior antineoplastic therapy = Yes

Duration of CR+PR	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=7) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=10) n (%) (95% CIs)
Events	0	1 (14.3)	0	1 (10.0)
Censors	2 (100)	6 (85.7)	1 (100)	9 (90.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	85.7 (59.8-100.0)	100.0 (100.0-100.0)	90.0 (71.4-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	85.7 (59.8-100.0)	100.0 (100.0-100.0)	90.0 (71.4-100.0)
18 Months (95% CIs)	100.0 (100.0-100.0)	85.7 (59.8-100.0)	100.0 (100.0-100.0)	90.0 (71.4-100.0)
24 Months (95% CIs)	100.0 (100.0-100.0)		100.0 (100.0-100.0)	90.0 (71.4-100.0)
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg & Prior antineoplastic therapy = No

Duration of Response	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=7) n (%) (95% CIs)	MCL (N=2) n (%) (95% CIs)	All AdvSM (N=10) n (%) (95% CIs)
Events	0	3 (42.9)	1 (50.0)	4 (40.0)
Censors	1 (100)	4 (57.1)	1 (50.0)	6 (60.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	18.4 (13.3 - NE)	NE (5.6 - NE)	NE (13.3 - NE)
25th, 75th percentiles	NE, NE	13.3, NE	5.6, NE	13.3, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	85.7 (59.8-100.0)	50.0 (0.0-100.0)	80.0 (55.2-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	85.7 (59.8-100.0)	50.0 (0.0-100.0)	80.0 (55.2-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	85.7 (59.8-100.0)	50.0 (0.0-100.0)	80.0 (55.2-100.0)
18 Months (95% CIs)	100.0 (100.0-100.0)	71.4 (38.0-100.0)	50.0 (0.0-100.0)	70.0 (41.6- 98.4)
24 Months (95% CIs)			50.0 (0.0-100.0)	56.0 (22.6- 89.4)
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg & Prior antineoplastic therapy = No

Duration of CR+PR	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=6) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=8) n (%) (95% CIs)
Events	0	2 (33.3)	0	2 (25.0)
Censors	1 (100)	4 (66.7)	1 (100)	6 (75.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	17.7 (17.7 - NE)	NE (NE - NE)	NE (17.7 - NE)
25th, 75th percentiles	NE, NE	17.7, NE	NE, NE	17.7, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	83.3 (53.5-100.0)	100.0 (100.0-100.0)	87.5 (64.6-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	83.3 (53.5-100.0)	100.0 (100.0-100.0)	87.5 (64.6-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	83.3 (53.5-100.0)	100.0 (100.0-100.0)	87.5 (64.6-100.0)
18 Months (95% CIs)	100.0 (100.0-100.0)	41.7 (0.0-100.0)	100.0 (100.0-100.0)	65.6 (24.7-100.0)
24 Months (95% CIs)			100.0 (100.0-100.0)	65.6 (24.7-100.0)
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg & Prior antineoplastic therapy = Yes

Duration of Response	ASM (N=3) n (%) (95% CIs)	SM-AHN (N=19) n (%) (95% CIs)	MCL (N=6) n (%) (95% CIs)	All AdvSM (N=28) n (%) (95% CIs)
Events	0	1 (5.3)	1 (16.7)	2 (7.1)
Censors	3 (100)	18 (94.7)	5 (83.3)	26 (92.9)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)	NE (3.7 - NE)	NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	80.0 (44.9-100.0)	96.2 (88.8-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	92.3 (77.8-100.0)	80.0 (44.9-100.0)	90.5 (77.7-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	92.3 (77.8-100.0)	80.0 (44.9-100.0)	90.5 (77.7-100.0)
18 Months (95% CIs)	100.0 (100.0-100.0)	92.3 (77.8-100.0)	80.0 (44.9-100.0)	90.5 (77.7-100.0)
24 Months (95% CIs)	100.0 (100.0-100.0)	92.3 (77.8-100.0)	80.0 (44.9-100.0)	90.5 (77.7-100.0)
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-dur-rac-tpy.saDate: 21:06/02NOV2020

Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg & Prior antineoplastic therapy = Yes

Duration of CR+PR	ASM (N=3) n (%) (95% CIs)	SM-AHN (N=13) n (%) (95% CIs)	MCL (N=4) n (%) (95% CIs)	All AdvSM (N=20) n (%) (95% CIs)
Events	0	1 (7.7)	0	1 (5.0)
Censors	3 (100)	12 (92.3)	4 (100)	19 (95.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles	NE, NE	NE, NE	NE, NE	NE, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	90.9 (73.9-100.0)	100.0 (100.0-100.0)	93.3 (80.7-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	90.9 (73.9-100.0)	100.0 (100.0-100.0)	93.3 (80.7-100.0)
18 Months (95% CIs)	100.0 (100.0-100.0)	90.9 (73.9-100.0)	100.0 (100.0-100.0)	93.3 (80.7-100.0)
24 Months (95% CIs)	100.0 (100.0-100.0)		100.0 (100.0-100.0)	93.3 (80.7-100.0)
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-dur-rac-tpy.saDate: 21:06/02NOV2020

Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg & Prior antineoplastic therapy = No

Duration of Response	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=10) n (%) (95% CIs)	MCL (N=4) n (%) (95% CIs)	All AdvSM (N=16) n (%) (95% CIs)
Events	0	3 (30.0)	1 (25.0)	4 (25.0)
Censors	2 (100)	7 (70.0)	3 (75.0)	12 (75.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	NE (13.3 - NE)	NE (5.6 - NE)	NE (18.4 - NE)
25th, 75th percentiles	NE, NE	18.4, NE	5.6, NE	18.4, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	88.9 (68.4-100.0)	66.7 (13.3-100.0)	85.7 (67.4-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	88.9 (68.4-100.0)	66.7 (13.3-100.0)	85.7 (67.4-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	88.9 (68.4-100.0)	66.7 (13.3-100.0)	85.7 (67.4-100.0)
18 Months (95% CIs)	100.0 (100.0-100.0)	76.2 (47.2-100.0)	66.7 (13.3-100.0)	77.1 (54.2-100.0)
24 Months (95% CIs)			66.7 (13.3-100.0)	64.3 (34.4- 94.2)
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-dur-rac-tpy.saDate: 21:06/02NOV2020

Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg & Prior antineoplastic therapy = No

Duration of CR+PR	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=9) n (%) (95% CIs)	MCL (N=3) n (%) (95% CIs)	All AdvSM (N=14) n (%) (95% CIs)
Events	0	2 (22.2)	0	2 (14.3)
Censors	2 (100)	7 (77.8)	3 (100)	12 (85.7)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE - NE)	17.7 (17.7 - NE)	NE (NE - NE)	NE (17.7 - NE)
25th, 75th percentiles	NE, NE	17.7, NE	NE, NE	17.7, NE
3 Months (95% CIs)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)	100.0 (100.0-100.0)	87.5 (64.6-100.0)	100.0 (100.0-100.0)	91.7 (76.0-100.0)
9 Months (95% CIs)	100.0 (100.0-100.0)	87.5 (64.6-100.0)	100.0 (100.0-100.0)	91.7 (76.0-100.0)
12 Months (95% CIs)	100.0 (100.0-100.0)	87.5 (64.6-100.0)	100.0 (100.0-100.0)	91.7 (76.0-100.0)
18 Months (95% CIs)	100.0 (100.0-100.0)	43.8 (0.0-100.0)	100.0 (100.0-100.0)	73.3 (38.8-100.0)
24 Months (95% CIs)			100.0 (100.0-100.0)	73.3 (38.8-100.0)
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-dur-rac-tpy.saDate: 21:06/02NOV2020

Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg & Prior antineoplastic therapy = Yes

Duration of Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=3) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=3) n (%) (95% CIs)
Events		1 (33.3)		1 (33.3)
Censors		2 (66.7)		2 (66.7)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (3.7 - NE)		NE (3.7 - NE)
25th, 75th percentiles		3.7, NE		3.7, NE
3 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
6 Months (95% CIs)		66.7 (13.3-100.0)		66.7 (13.3-100.0)
9 Months (95% CIs)		66.7 (13.3-100.0)		66.7 (13.3-100.0)
12 Months (95% CIs)		66.7 (13.3-100.0)		66.7 (13.3-100.0)
18 Months (95% CIs)		66.7 (13.3-100.0)		66.7 (13.3-100.0)
24 Months (95% CIs)		66.7 (13.3-100.0)		66.7 (13.3-100.0)
30 Months (95% CIs)		66.7 (13.3-100.0)		66.7 (13.3-100.0)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg & Prior antineoplastic therapy = Yes

Duration of CR+PR	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=3) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=3) n (%) (95% CIs)
Events		1 (33.3)		1 (33.3)
Censors		2 (66.7)		2 (66.7)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (3.7 - NE)		NE (3.7 - NE)
25th, 75th percentiles		3.7, NE		3.7, NE
3 Months (95% CIs)		100.0 (100.0-100.0)		100.0 (100.0-100.0)
6 Months (95% CIs)		66.7 (13.3-100.0)		66.7 (13.3-100.0)
9 Months (95% CIs)		66.7 (13.3-100.0)		66.7 (13.3-100.0)
12 Months (95% CIs)		66.7 (13.3-100.0)		66.7 (13.3-100.0)
18 Months (95% CIs)		66.7 (13.3-100.0)		66.7 (13.3-100.0)
24 Months (95% CIs)		66.7 (13.3-100.0)		66.7 (13.3-100.0)
30 Months (95% CIs)		66.7 (13.3-100.0)		66.7 (13.3-100.0)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-dur-rac-tpy.saDate: 21:06/02NOV2020

Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg & Prior antineoplastic therapy = No

Duration of Response	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=0) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=1) n (%) (95% CIs)
Events			0	0
Censors			1 (100)	1 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)			NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles			NE, NE	NE, NE
3 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
18 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
24 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
30 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Table 14.2.2.7b
Summary of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg & Prior antineoplastic therapy = No

Duration of CR+PR	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=0) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=1) n (%) (95% CIs)
Events			0	0
Censors			1 (100)	1 (100)
Kaplan-Meier Estimates				
Median (months) (95% CIs)			NE (NE - NE)	NE (NE - NE)
25th, 75th percentiles			NE, NE	NE, NE
3 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
6 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
9 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
12 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
18 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
24 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
30 Months (95% CIs)			100.0 (100.0-100.0)	100.0 (100.0-100.0)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				

Abbreviations: CIs=Confidence intervals, CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, LoR=Loss of response, PD=Progressive disease, PR=Partial remission

Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: Overall
Prior Antineoplastic Therapy = Yes
Responders (CR+PR+CI)

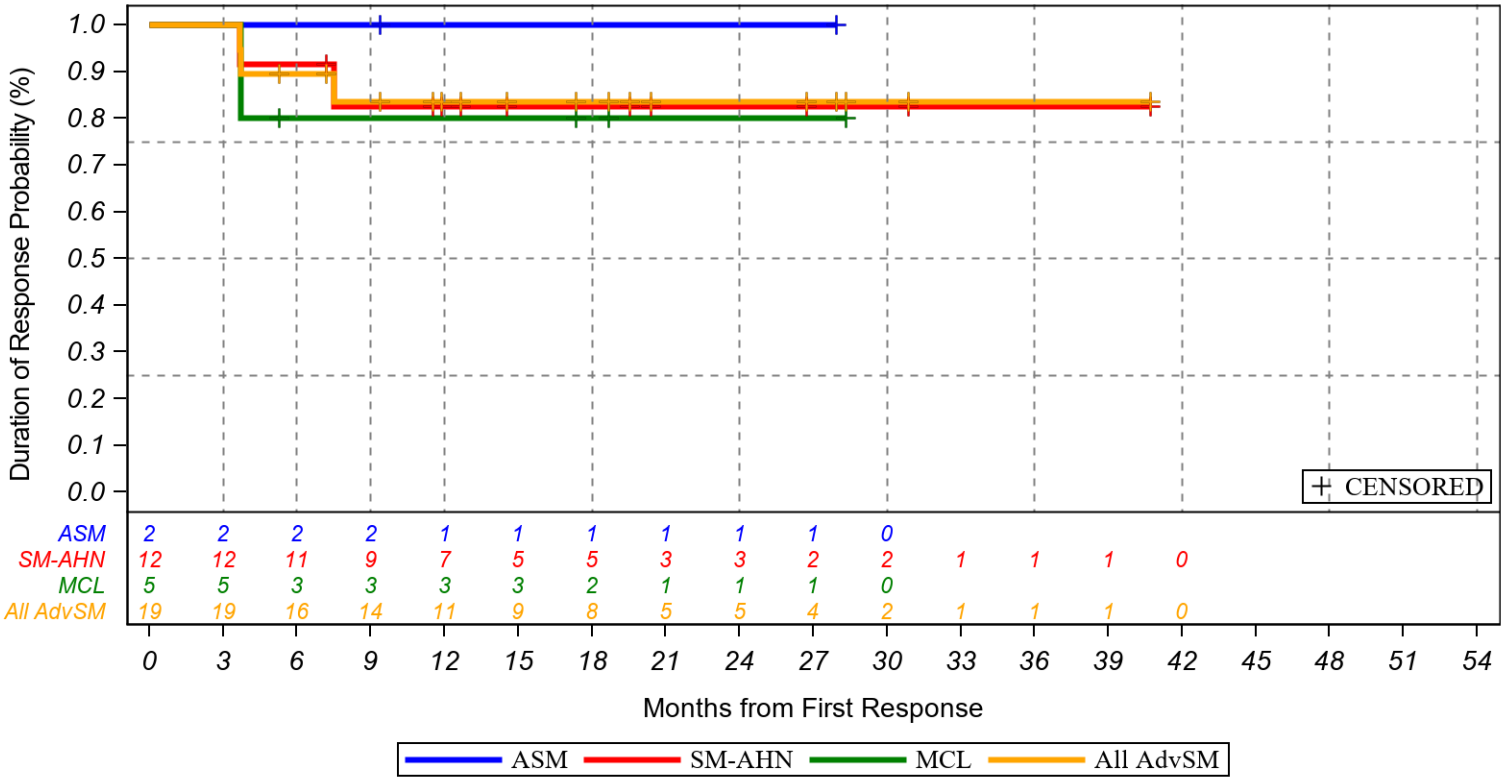

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: Overall
Prior Antineoplastic Therapy = Yes
Responders (CR+PR)

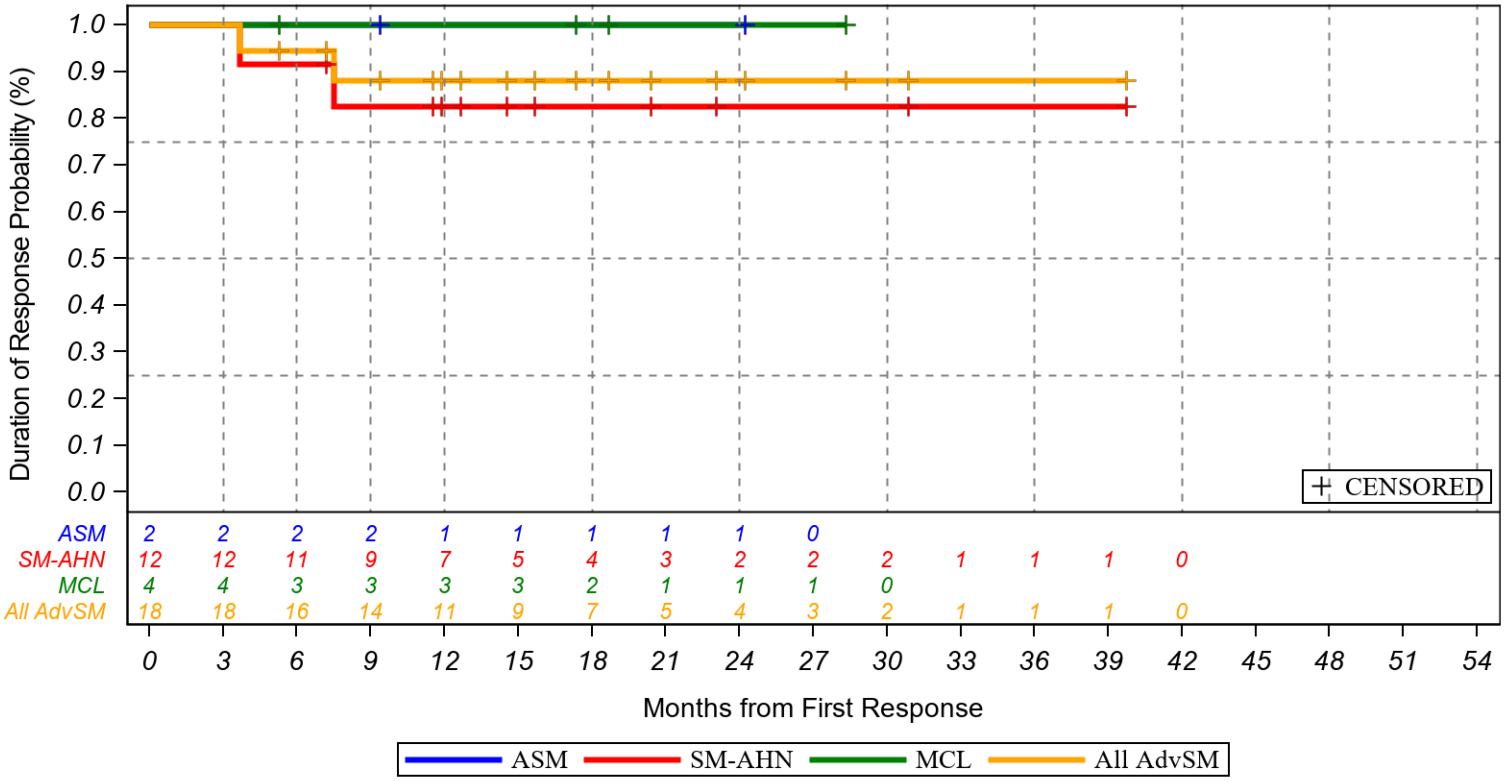

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: Overall
Prior Antineoplastic Therapy = No
Responders (CR+PR+CI)

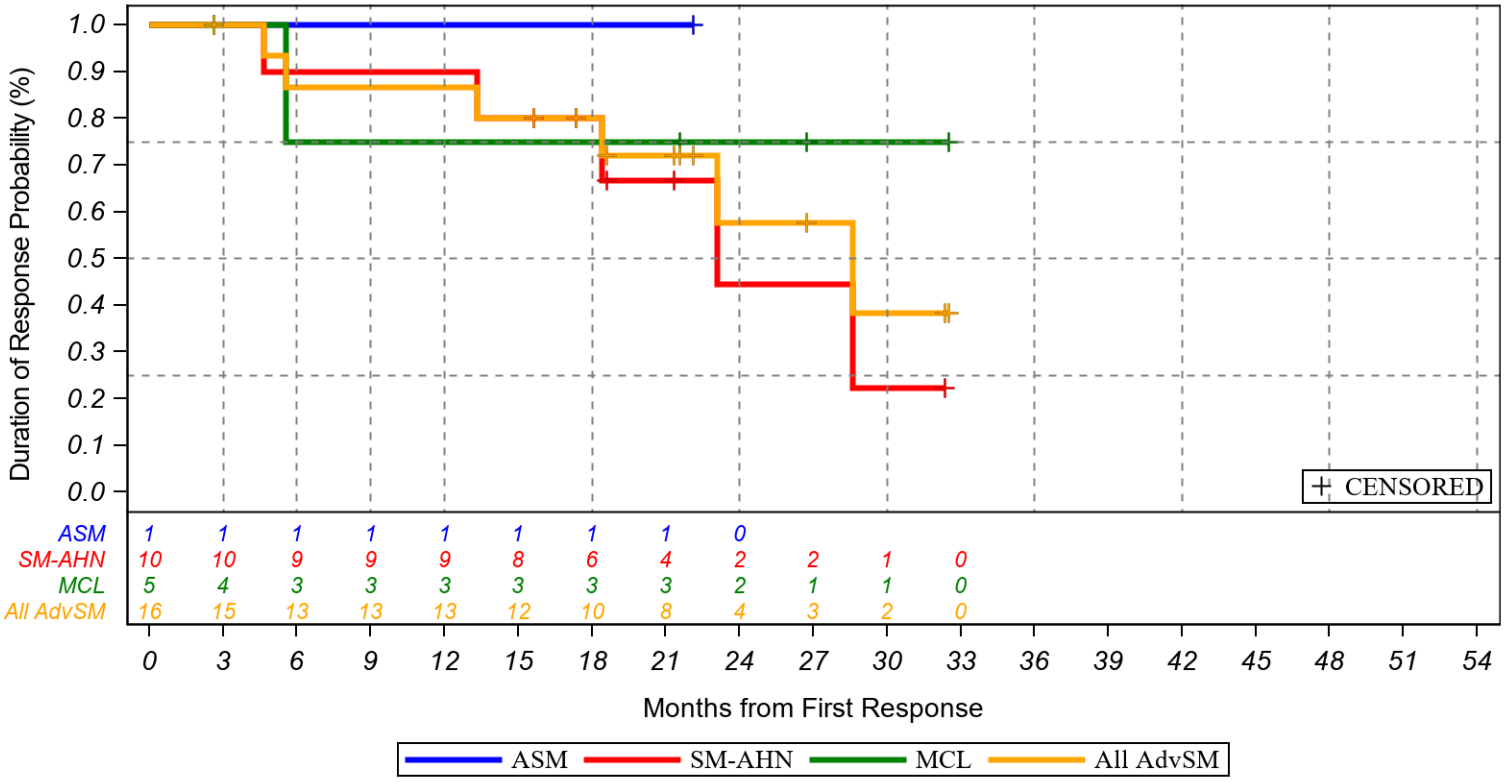

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: Overall
Prior Antineoplastic Therapy = No
Responders (CR+PR)

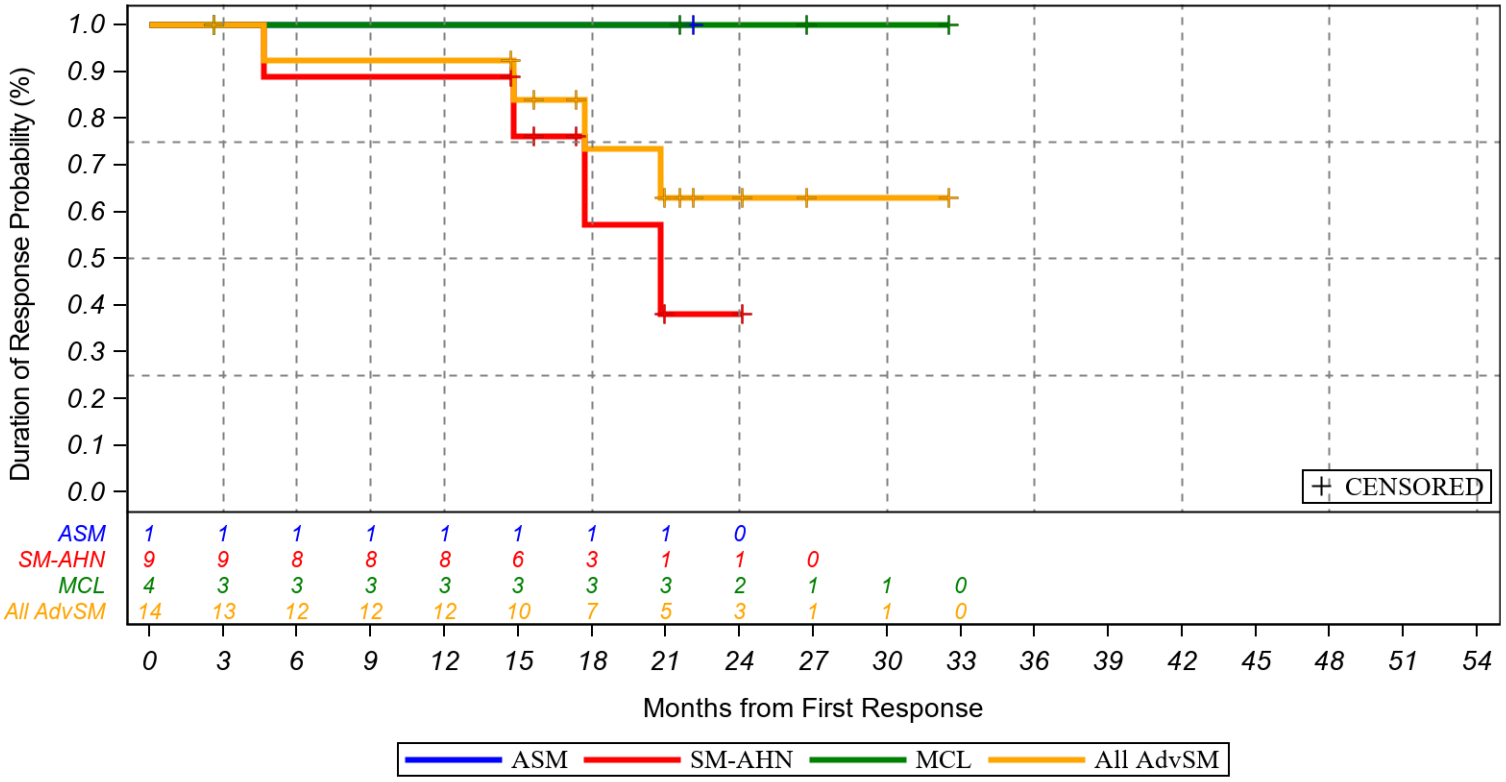

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: < 200 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR+CI)

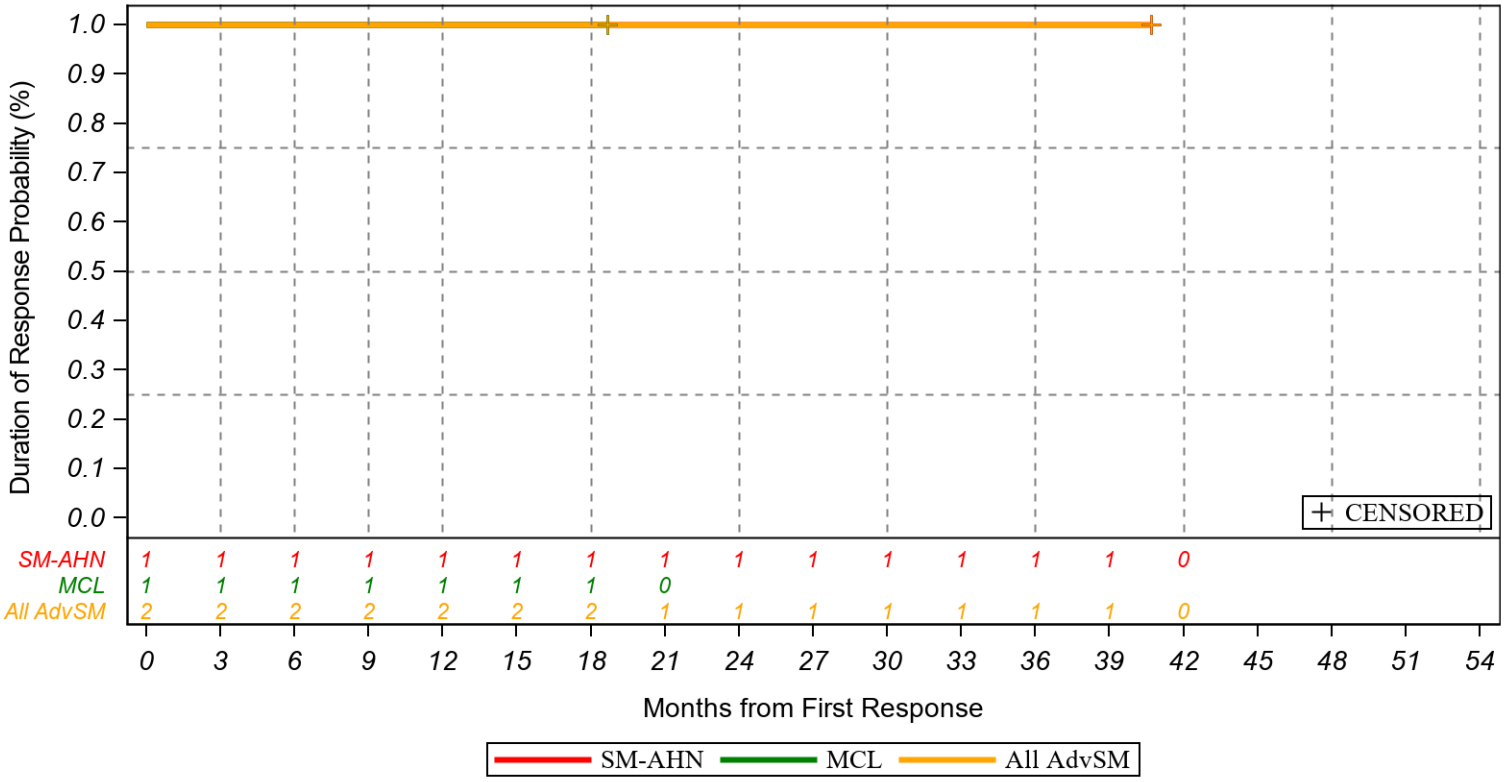

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: < 200 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR)

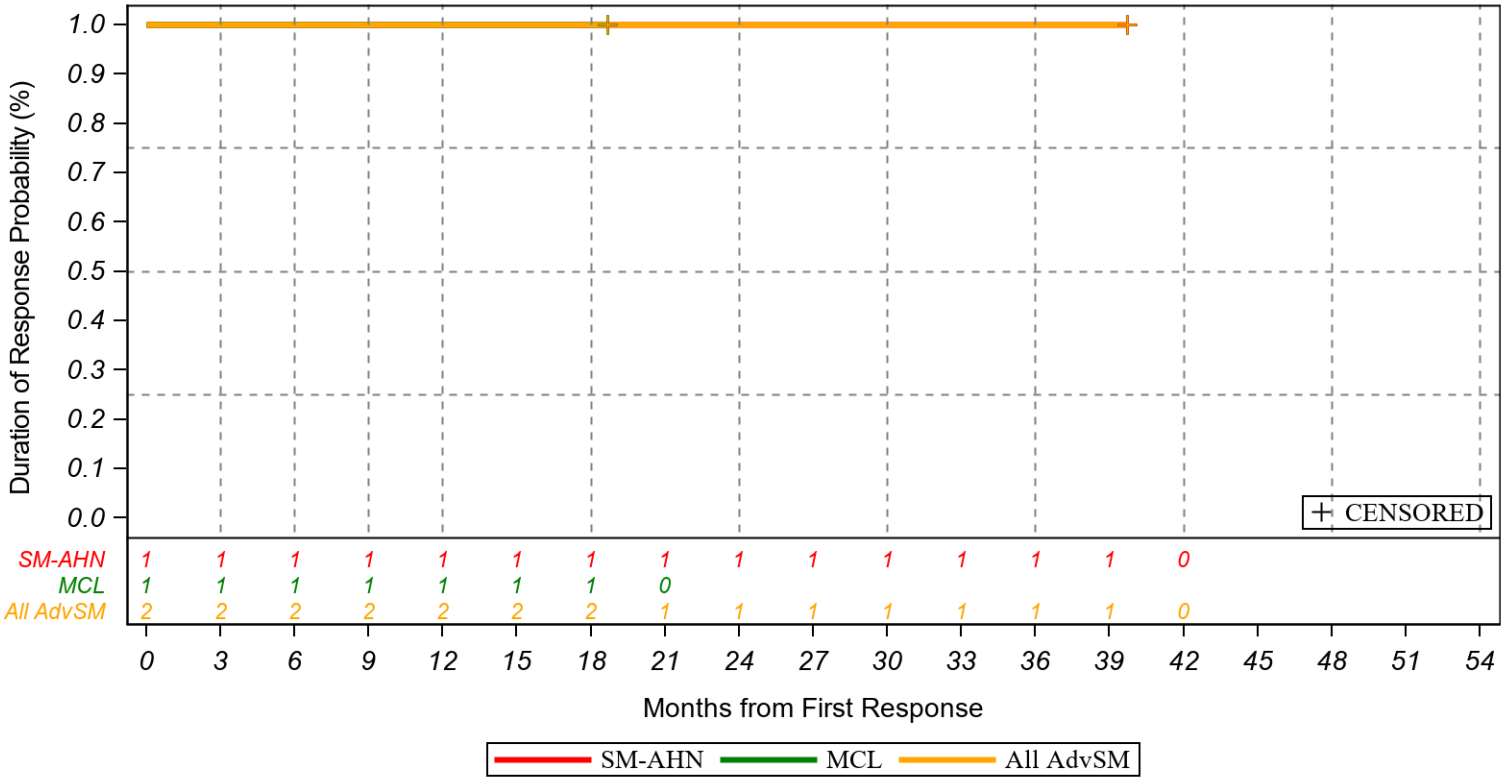

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: < 200 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR+CI)

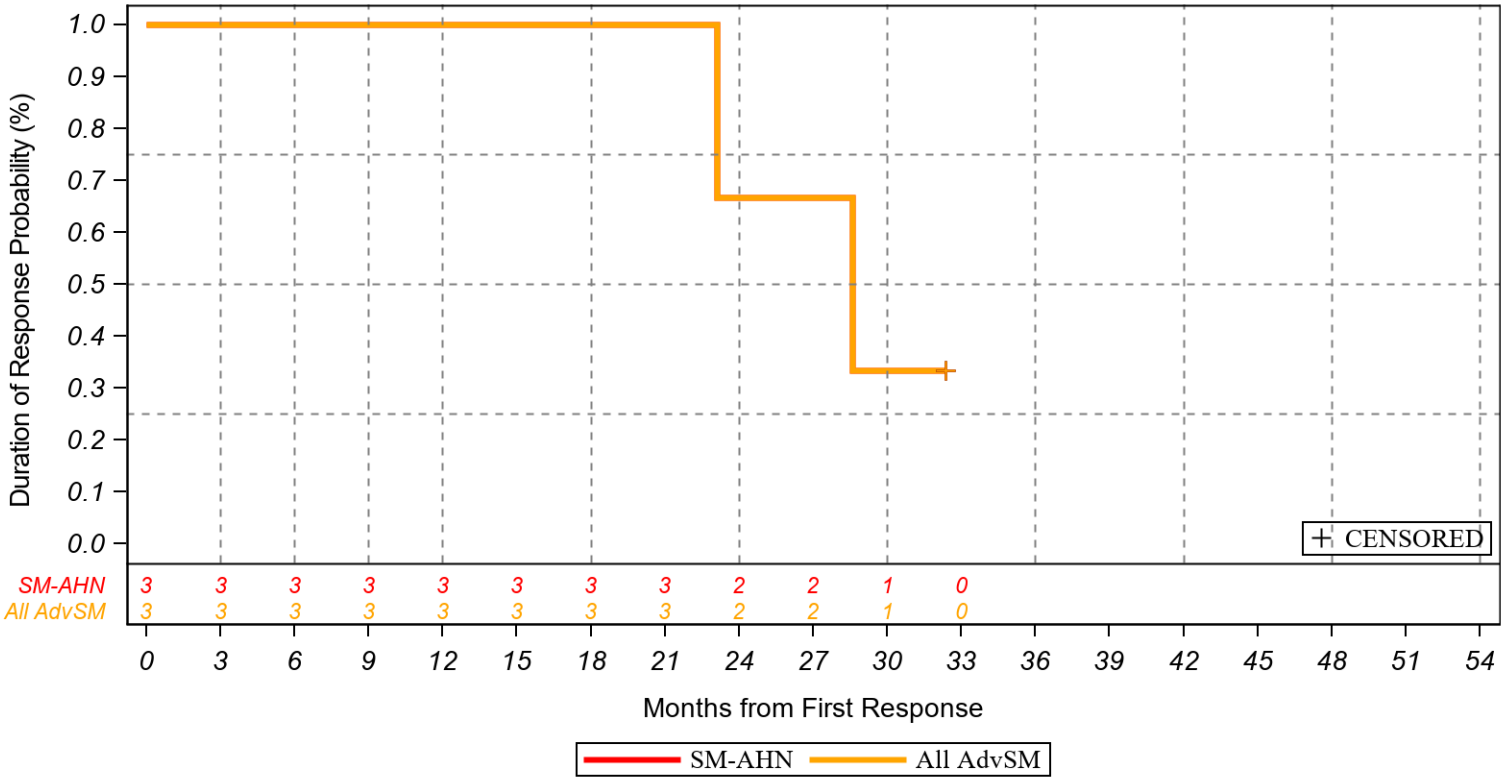

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: < 200 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR)

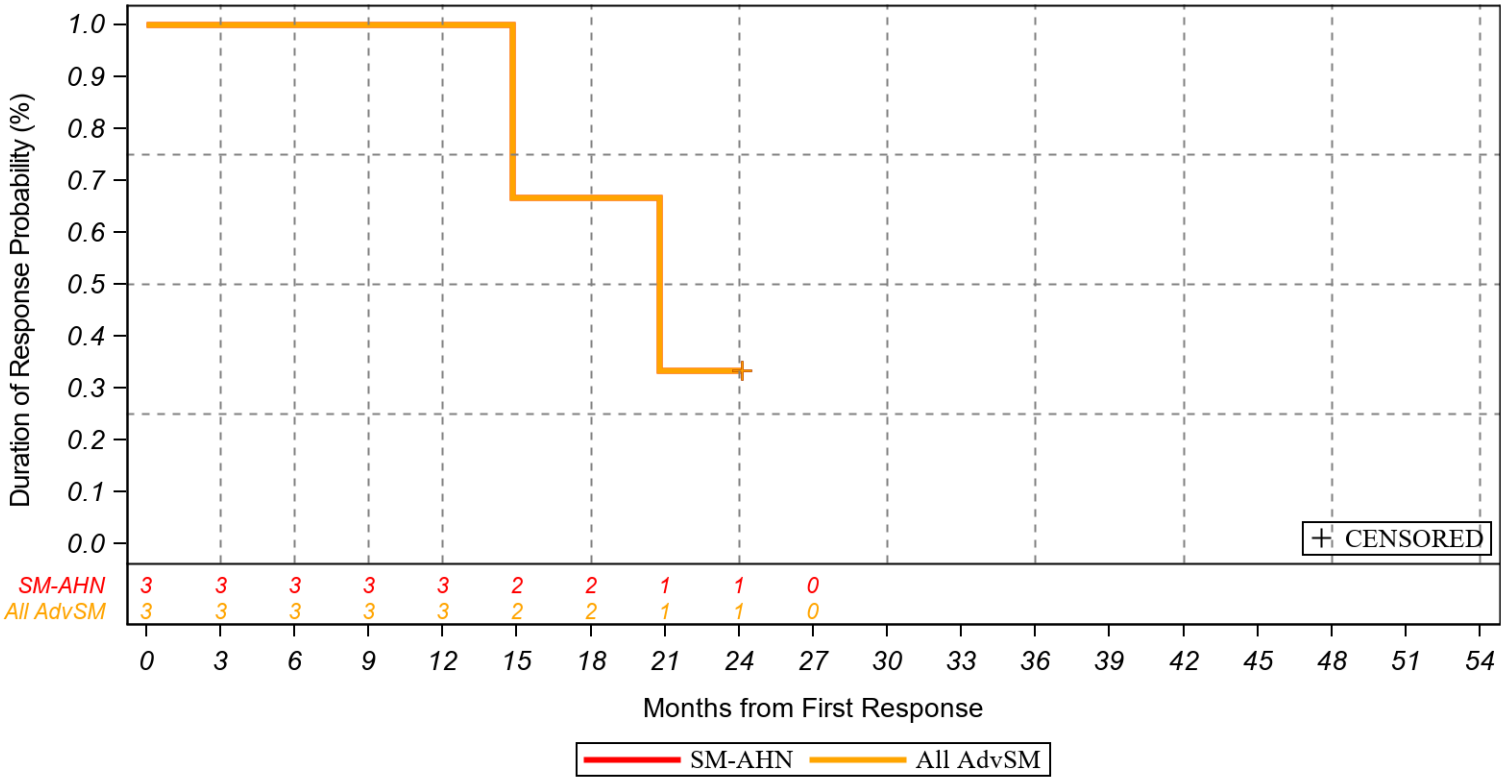

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: < 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR+CI)

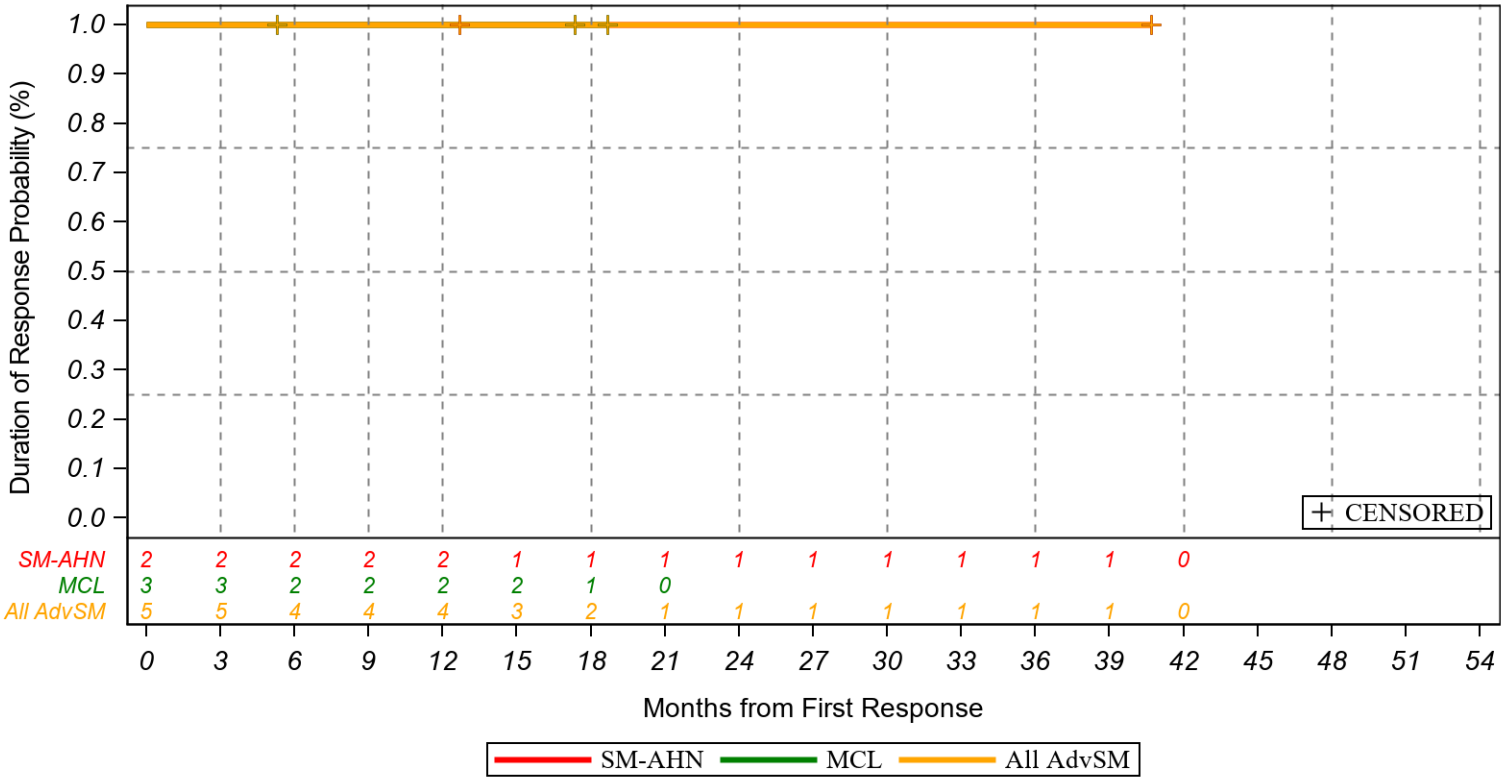

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: < 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR)

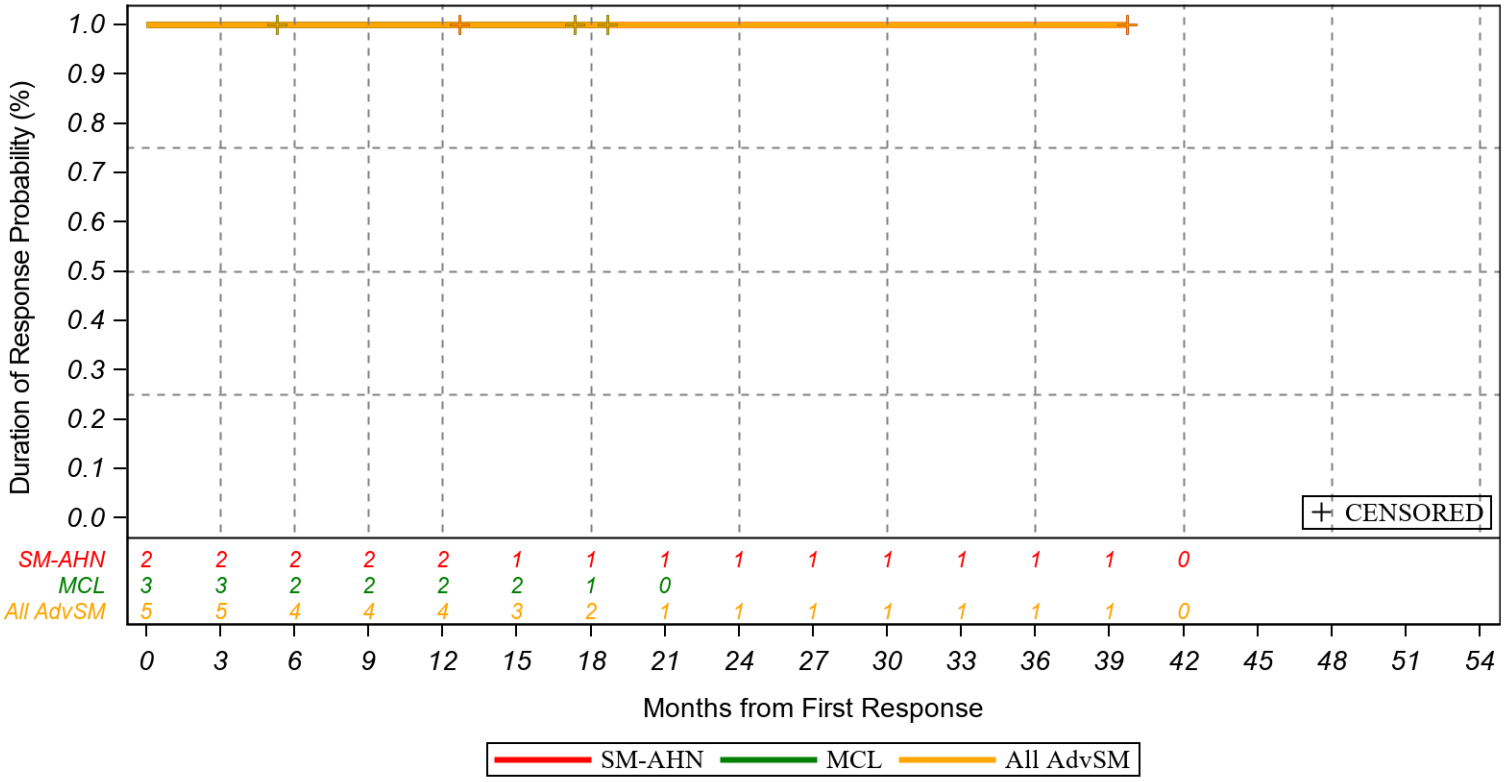

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: < 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR+CI)

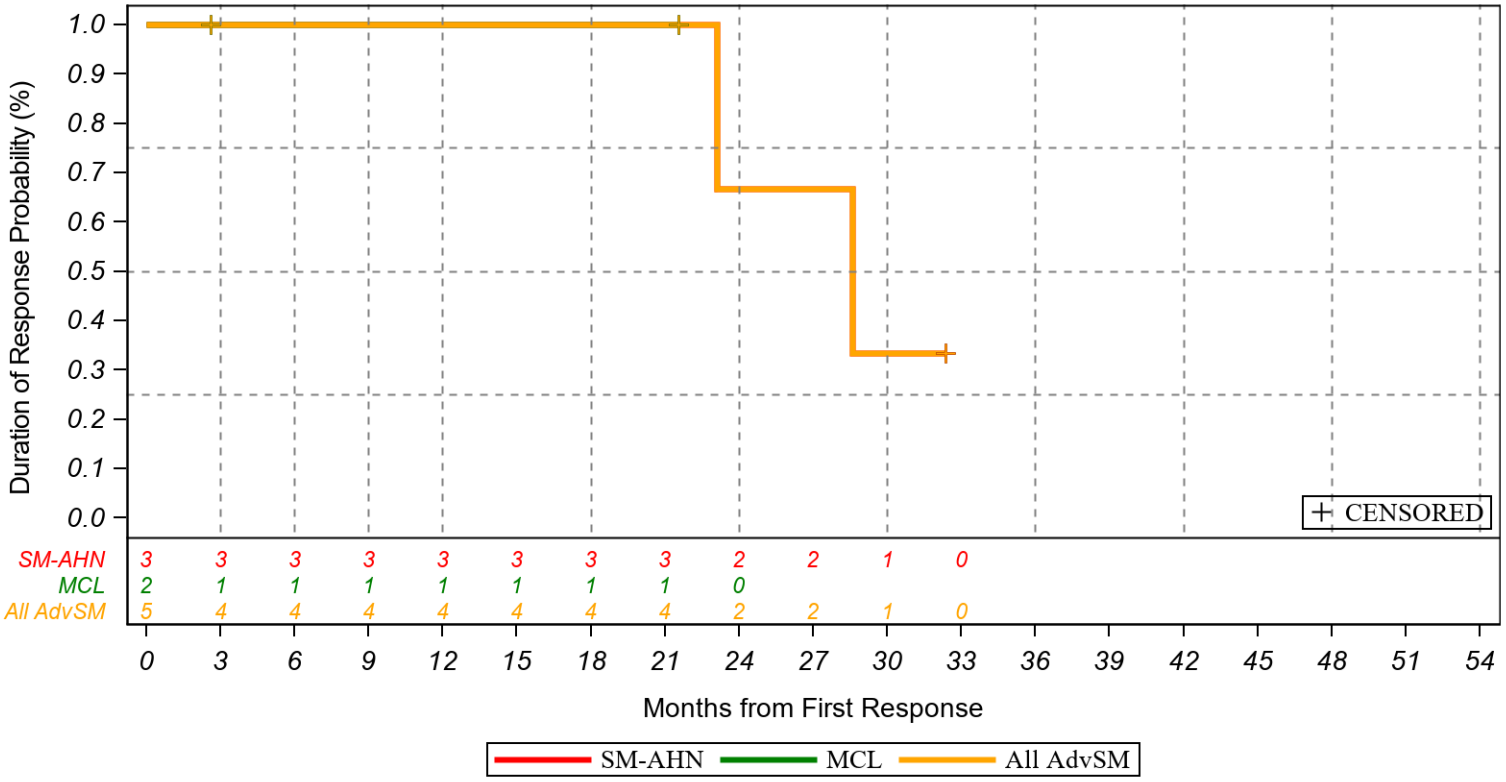

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: < 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR)

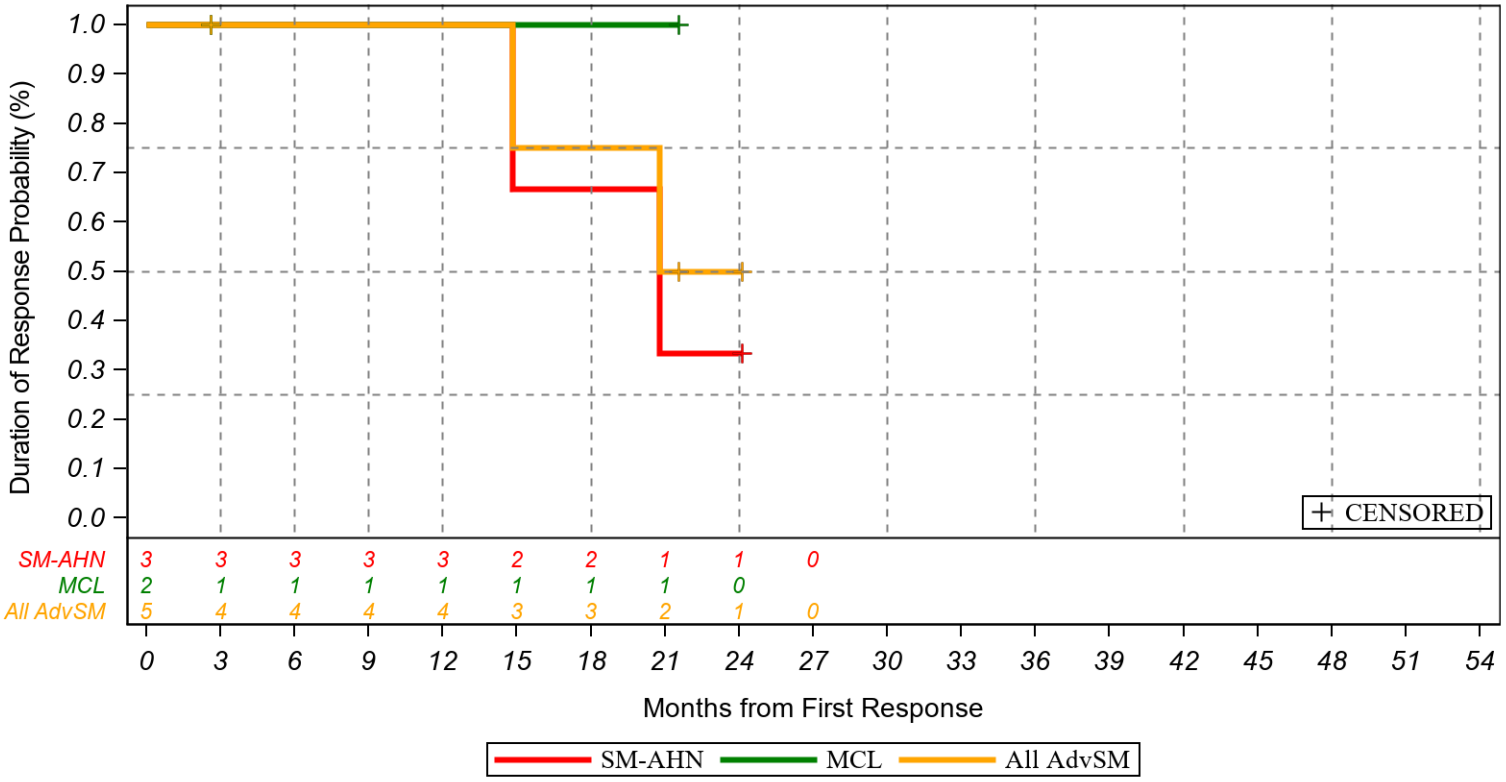

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: 200 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR+CI)

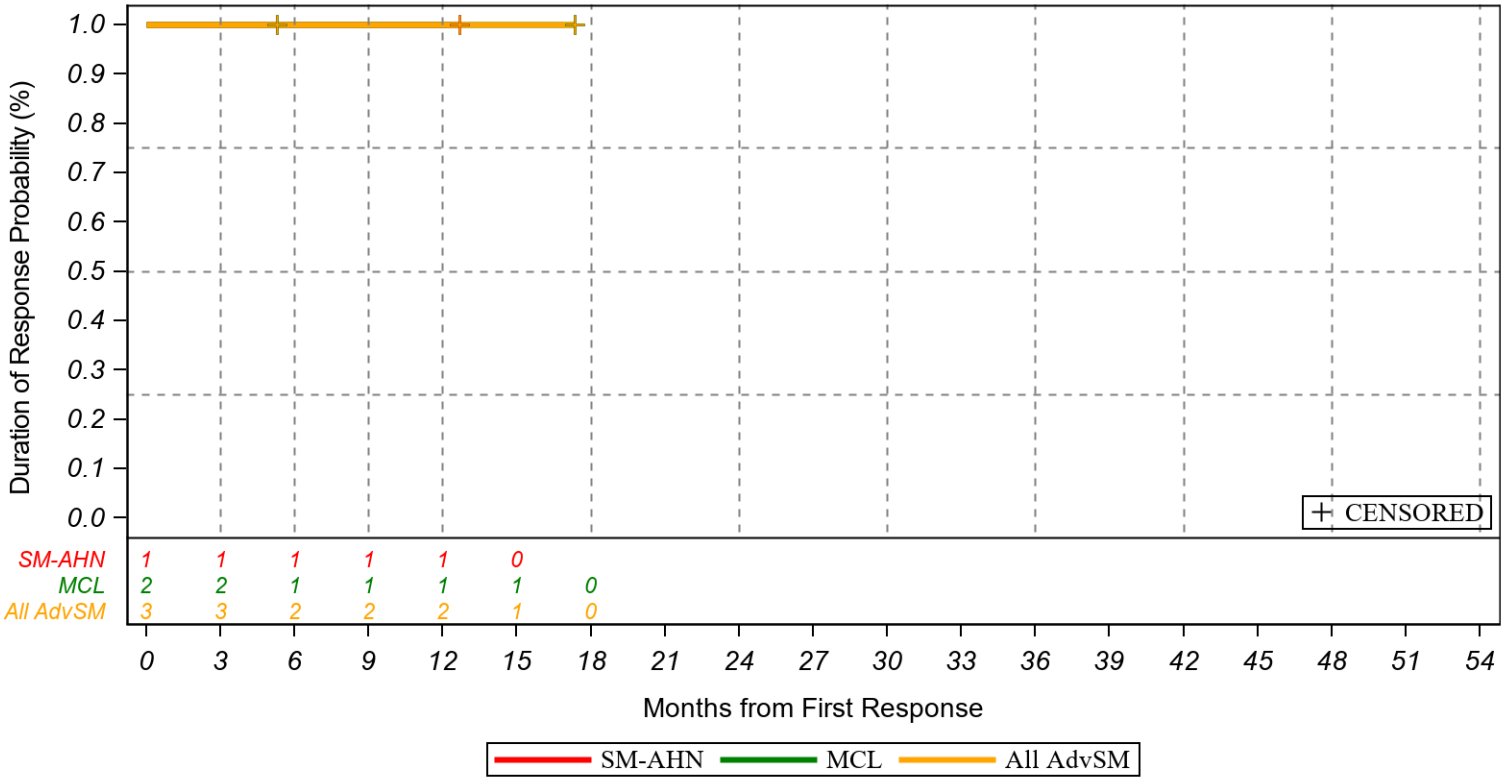

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: 200 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR)

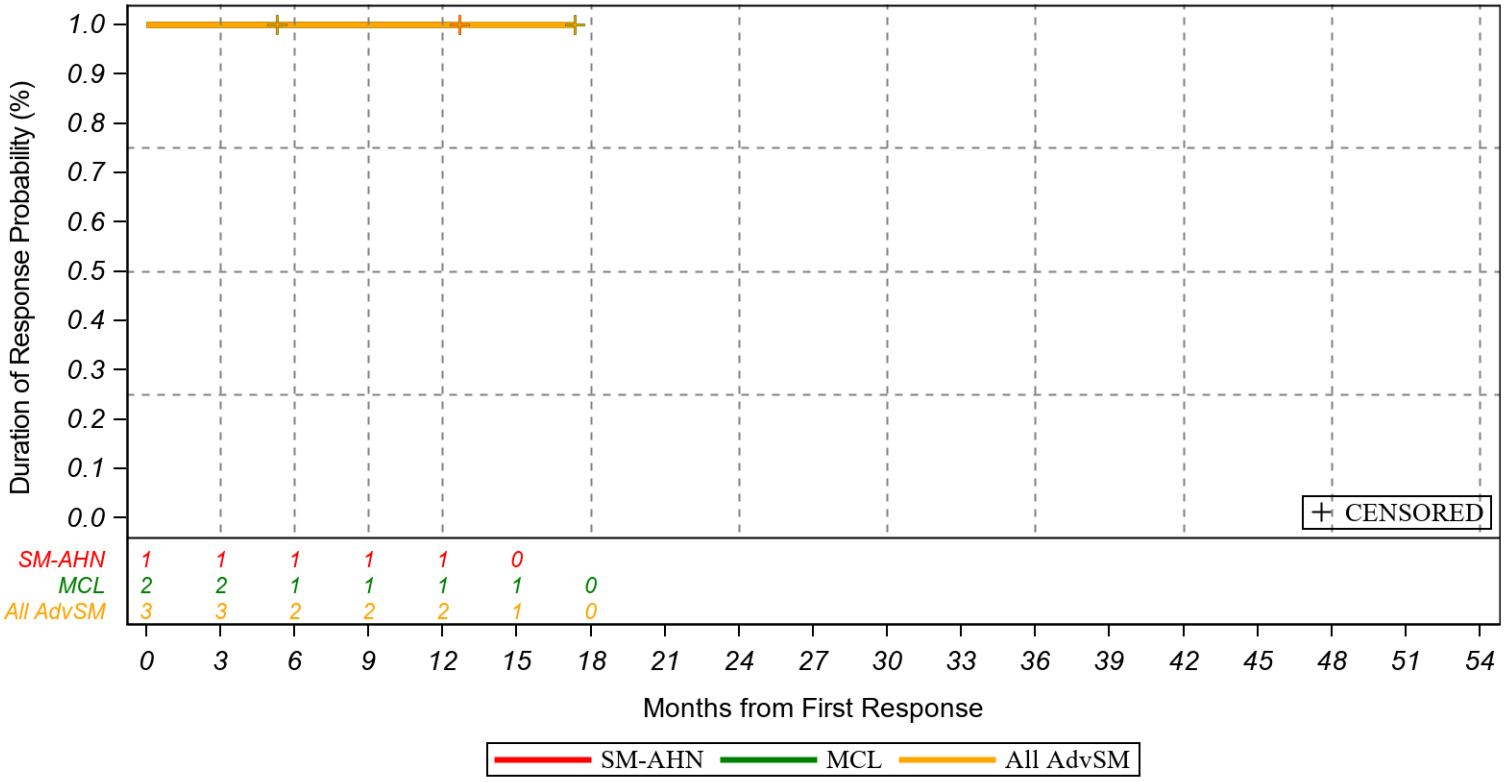

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: 200 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR+CI)

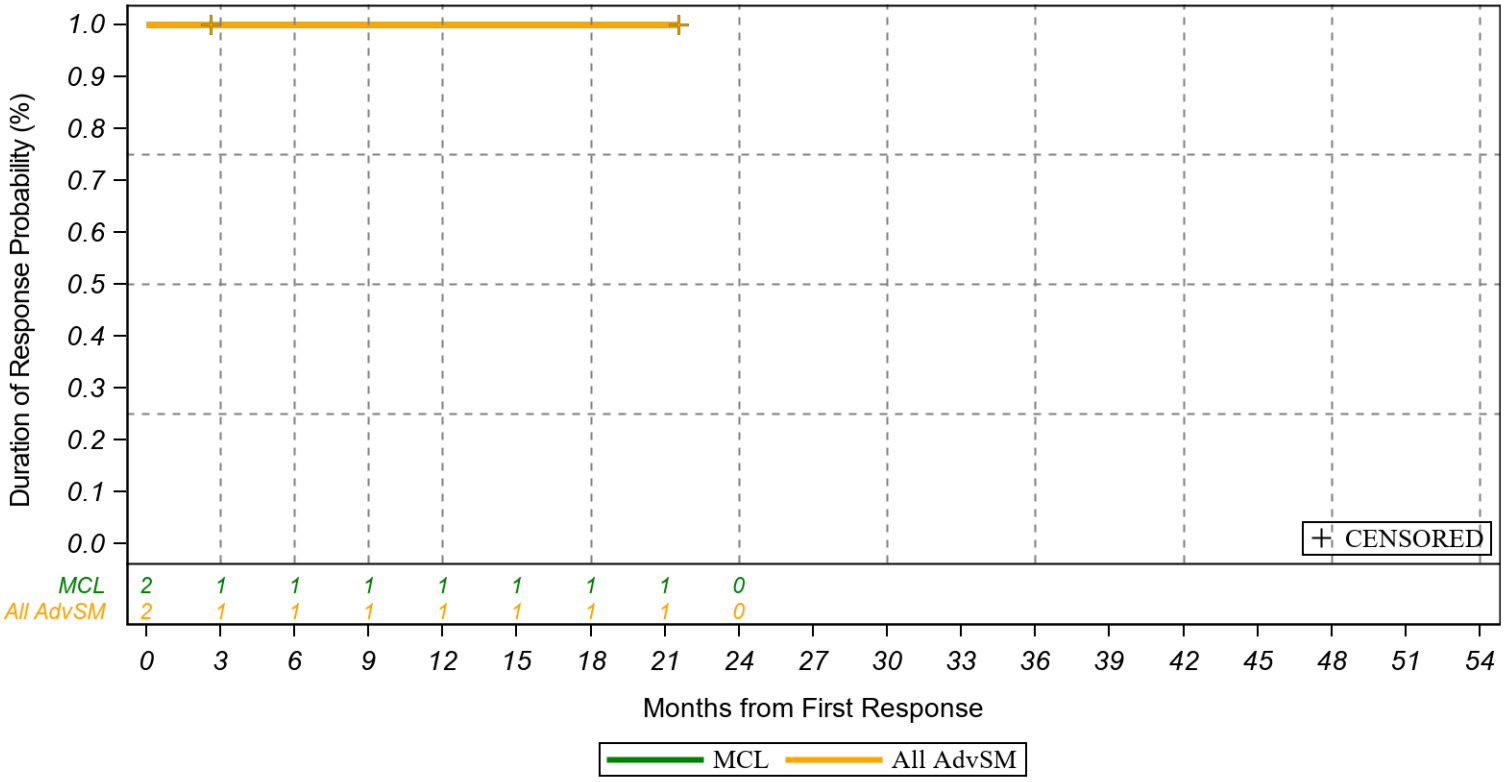

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: 200 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR)

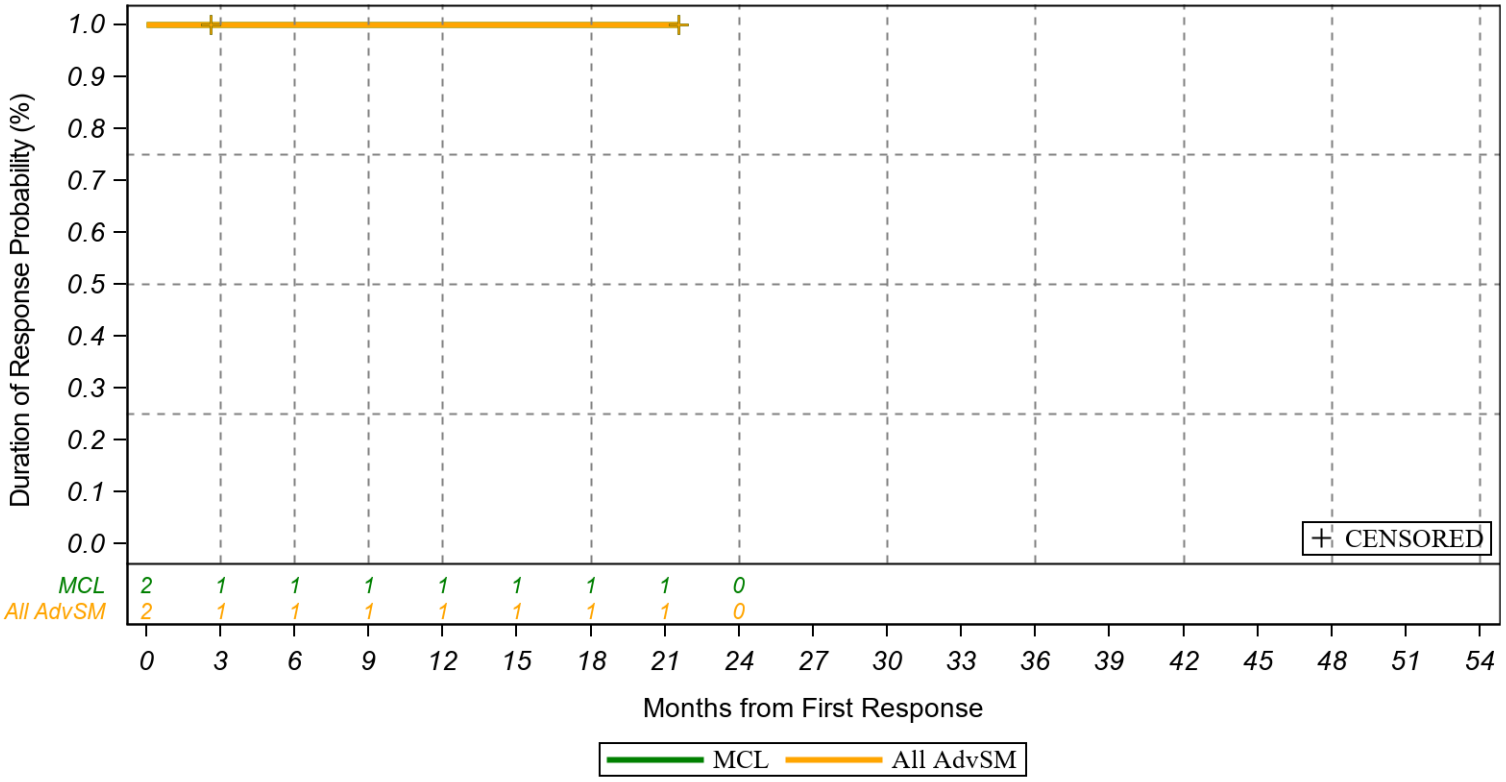

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR+CI)

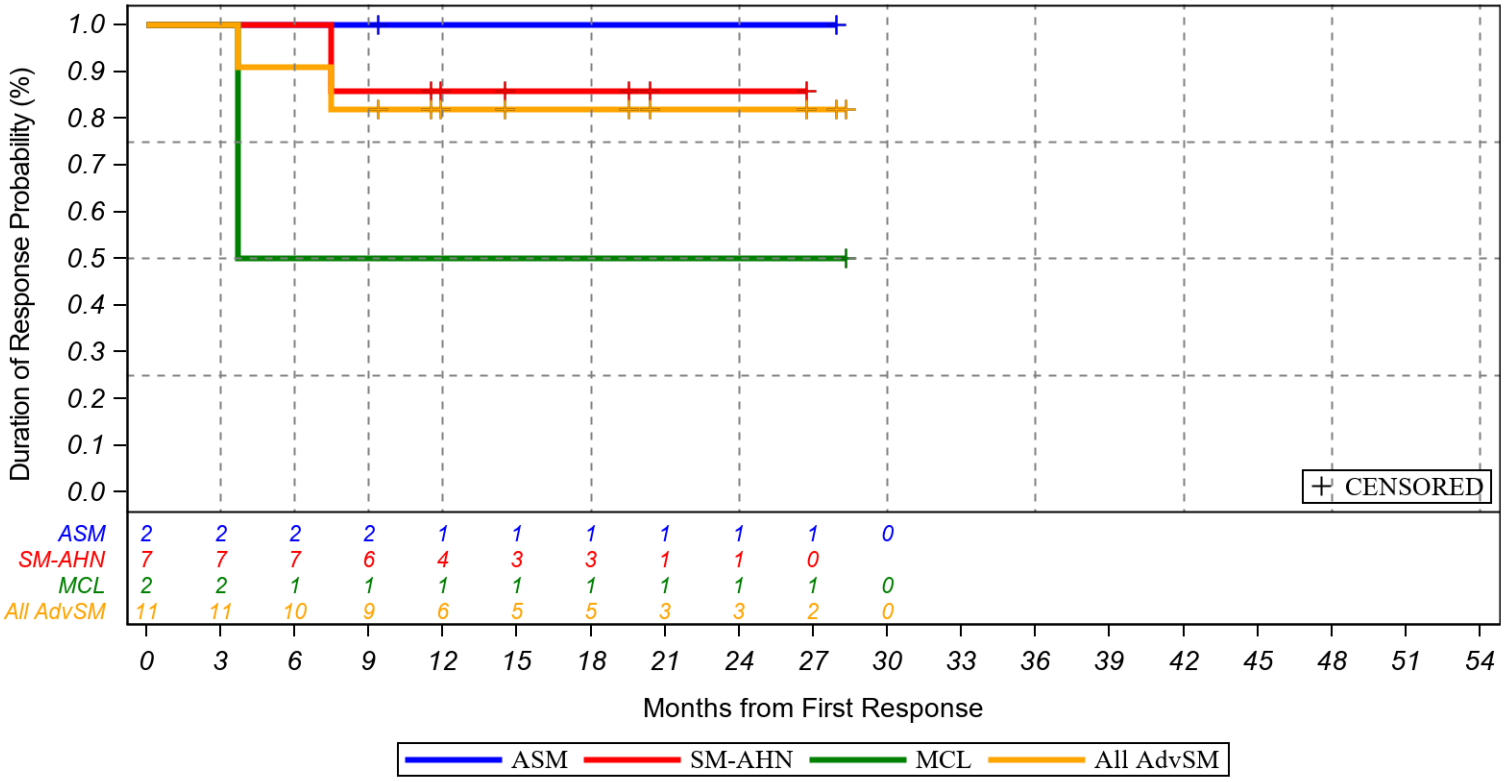

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR)

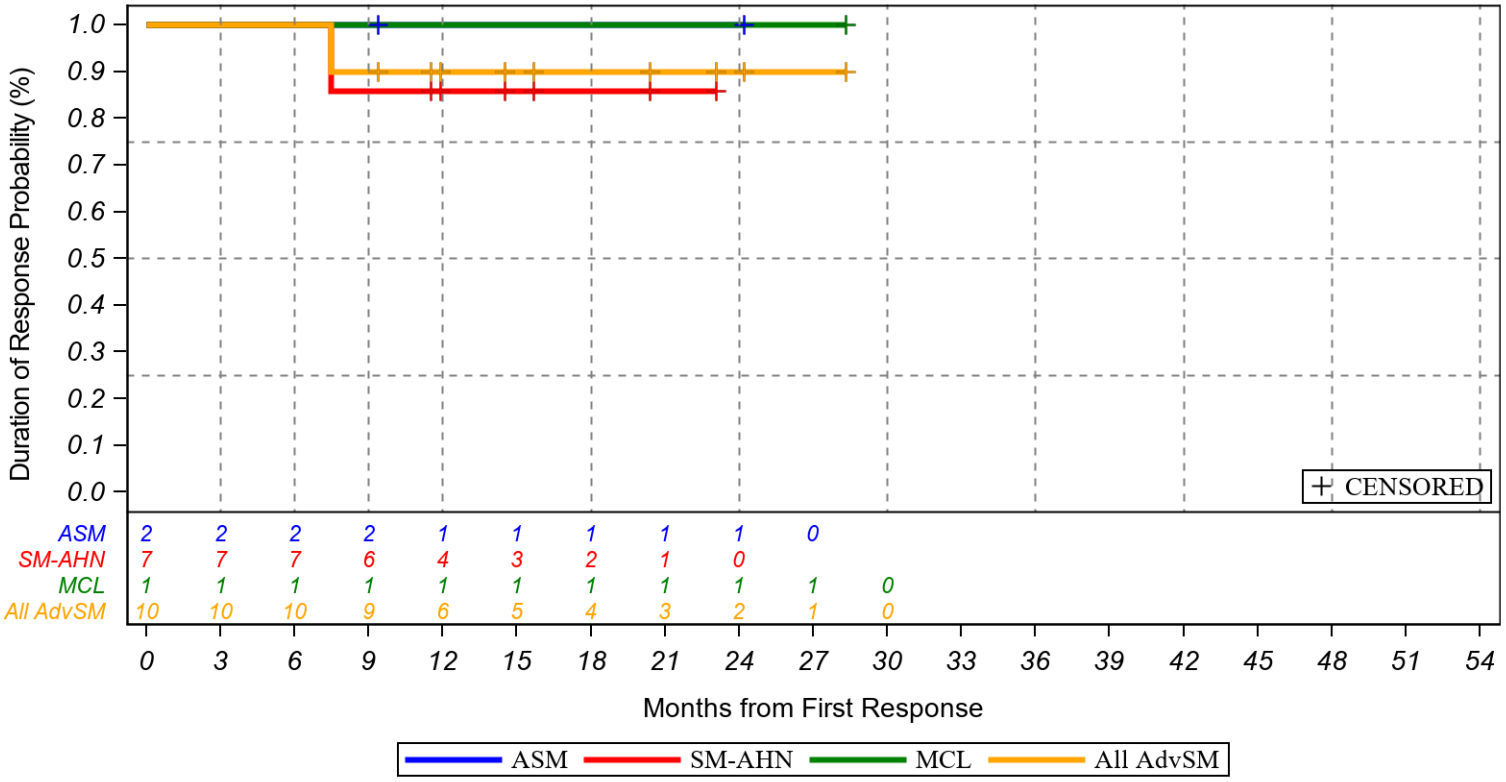

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR+CI)

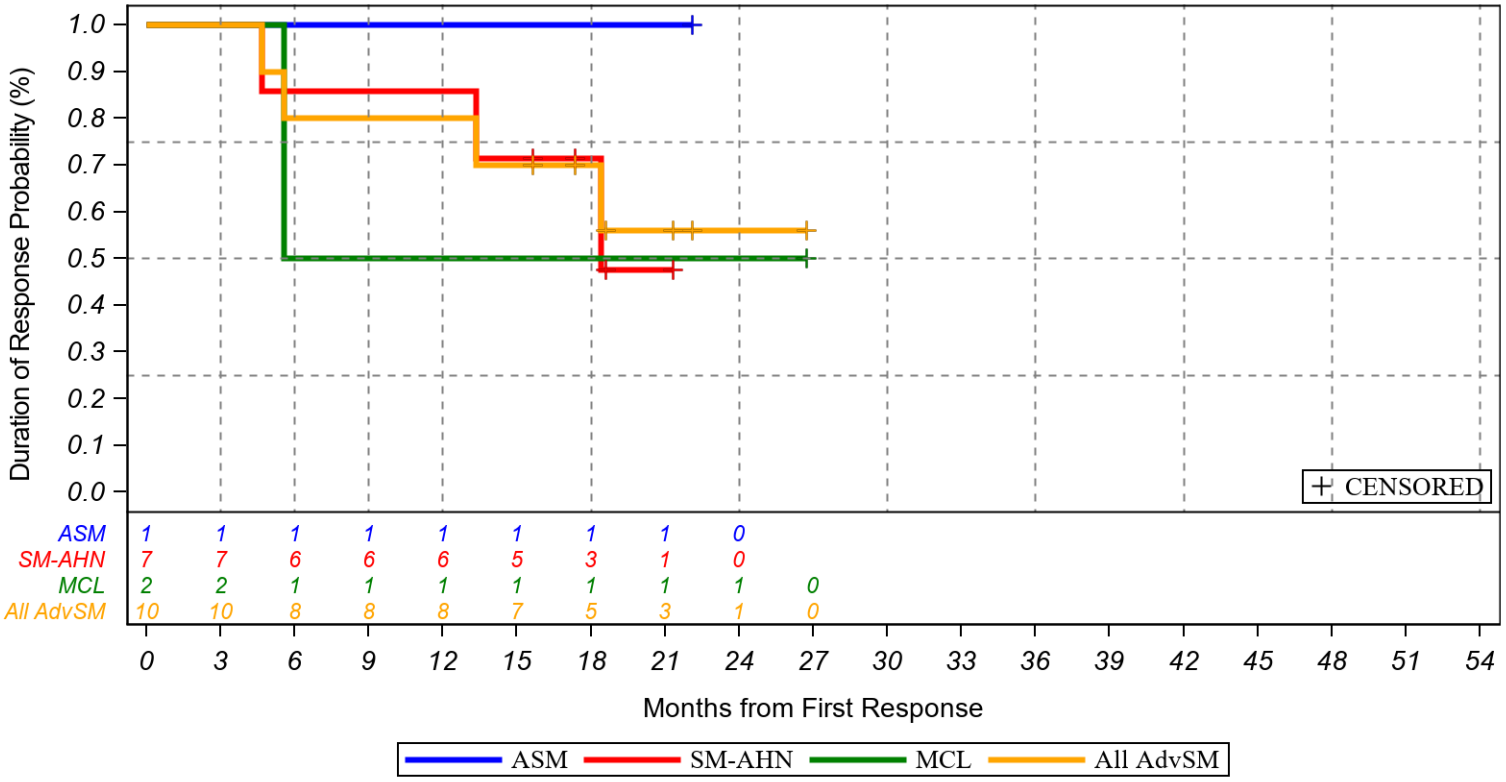

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR)

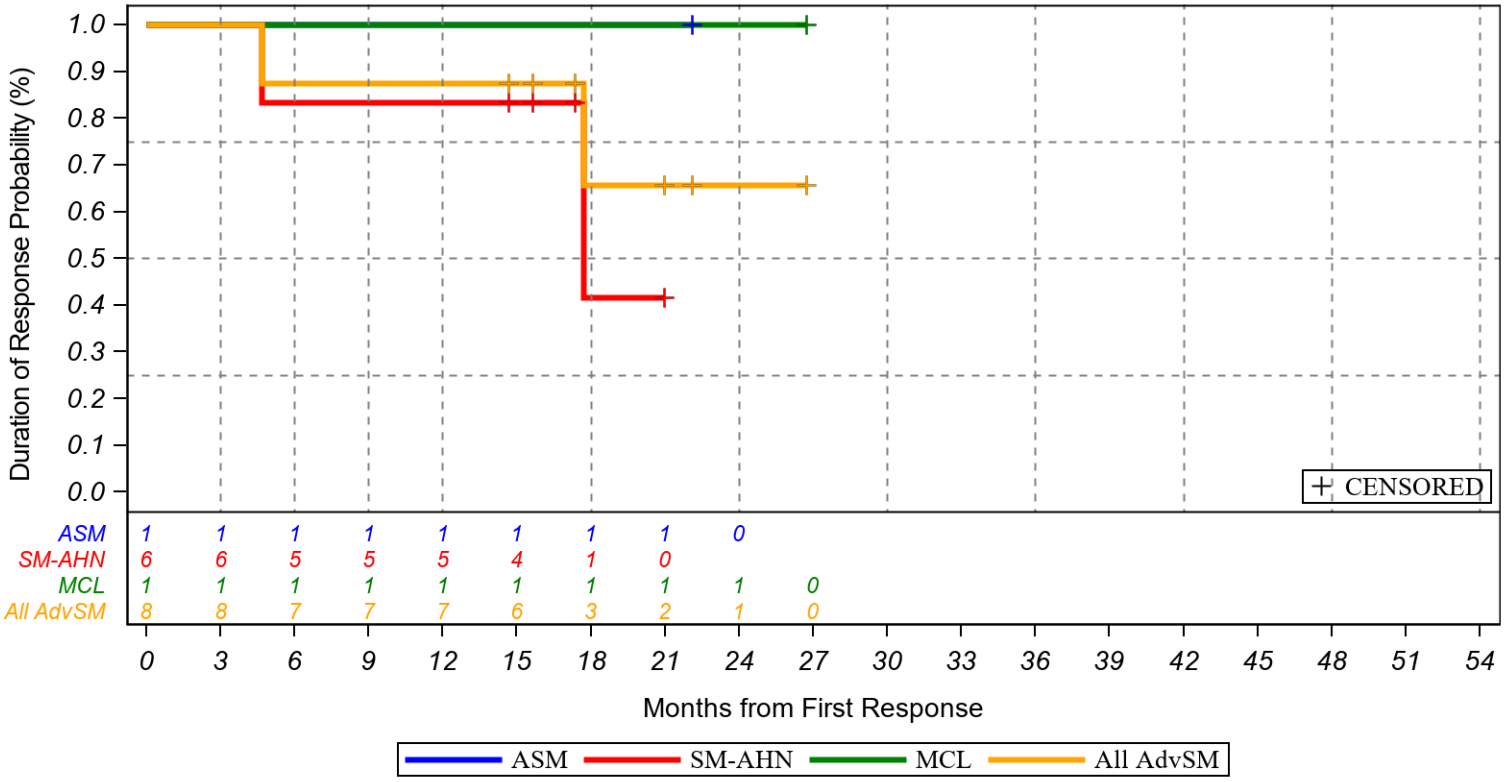

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: 200 mg and 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR+CI)

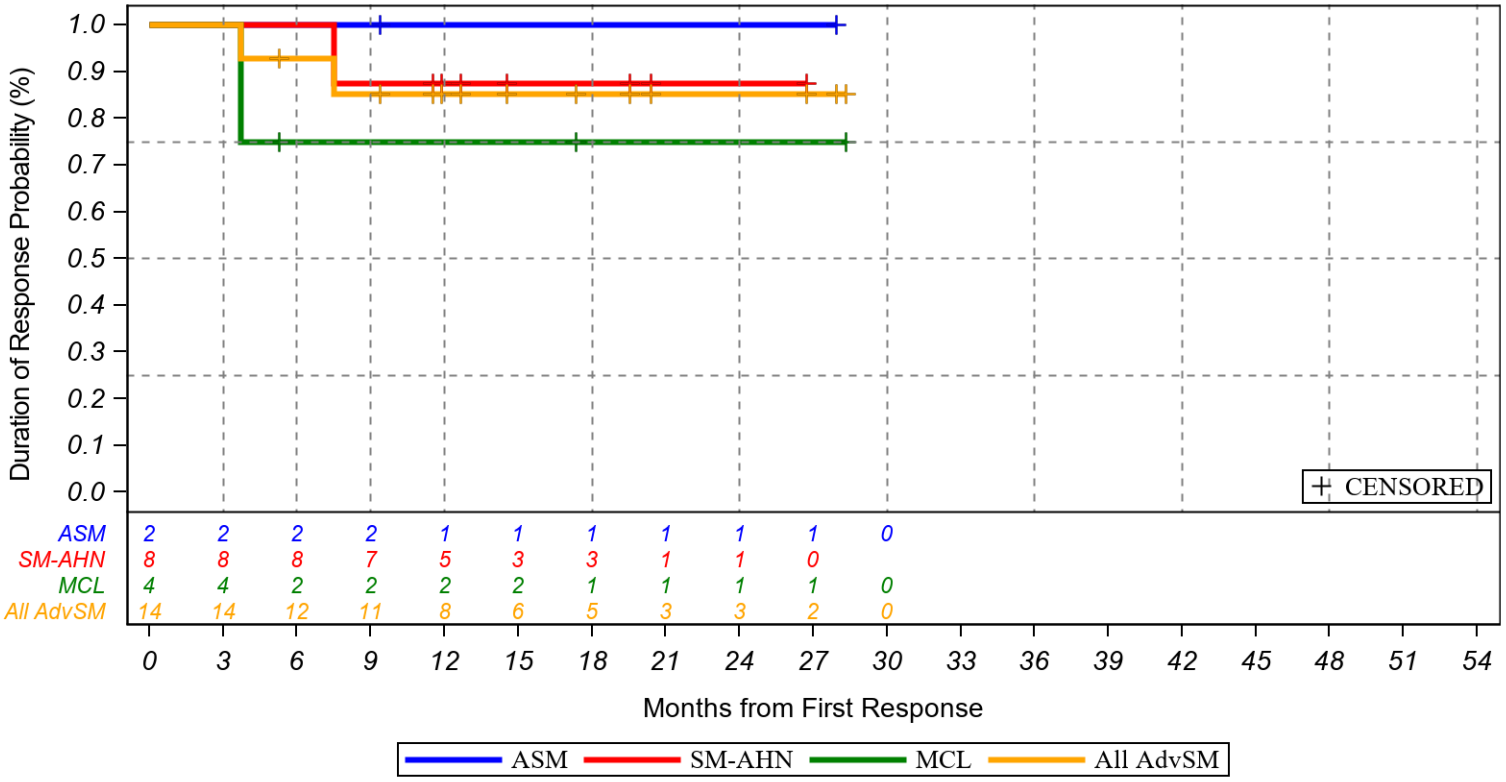

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: 200 mg and 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR)

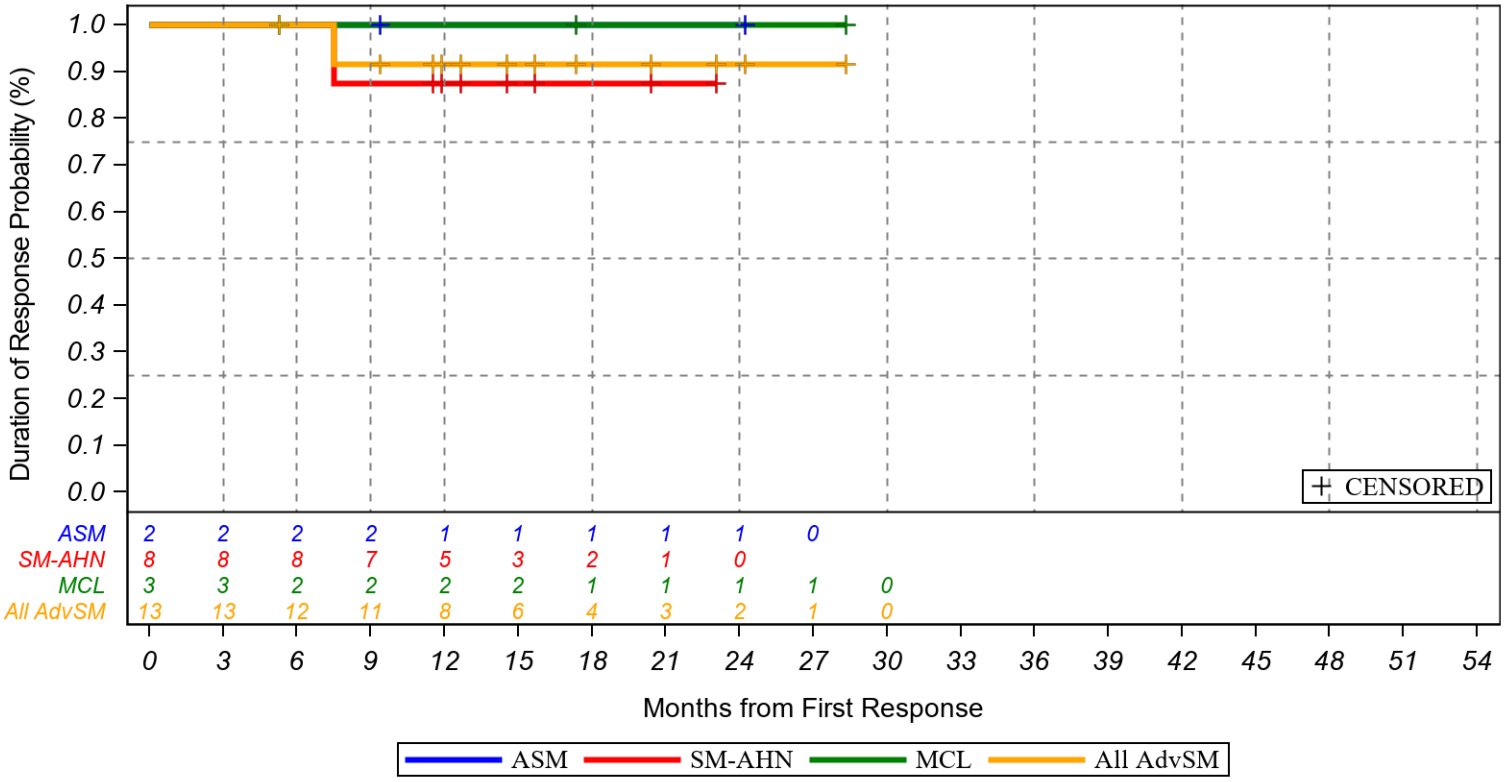

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: 200 mg and 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR+CI)

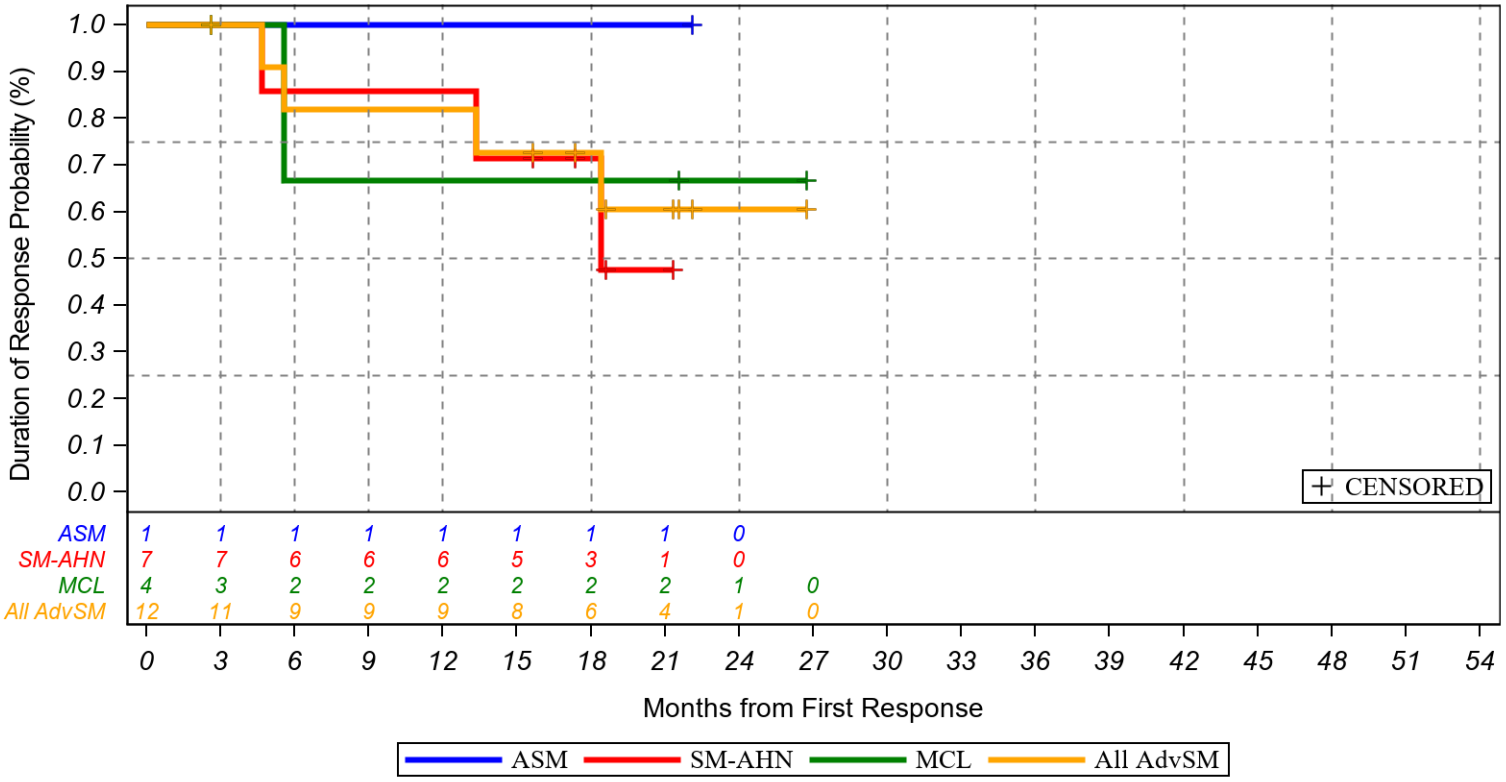

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: 200 mg and 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR)

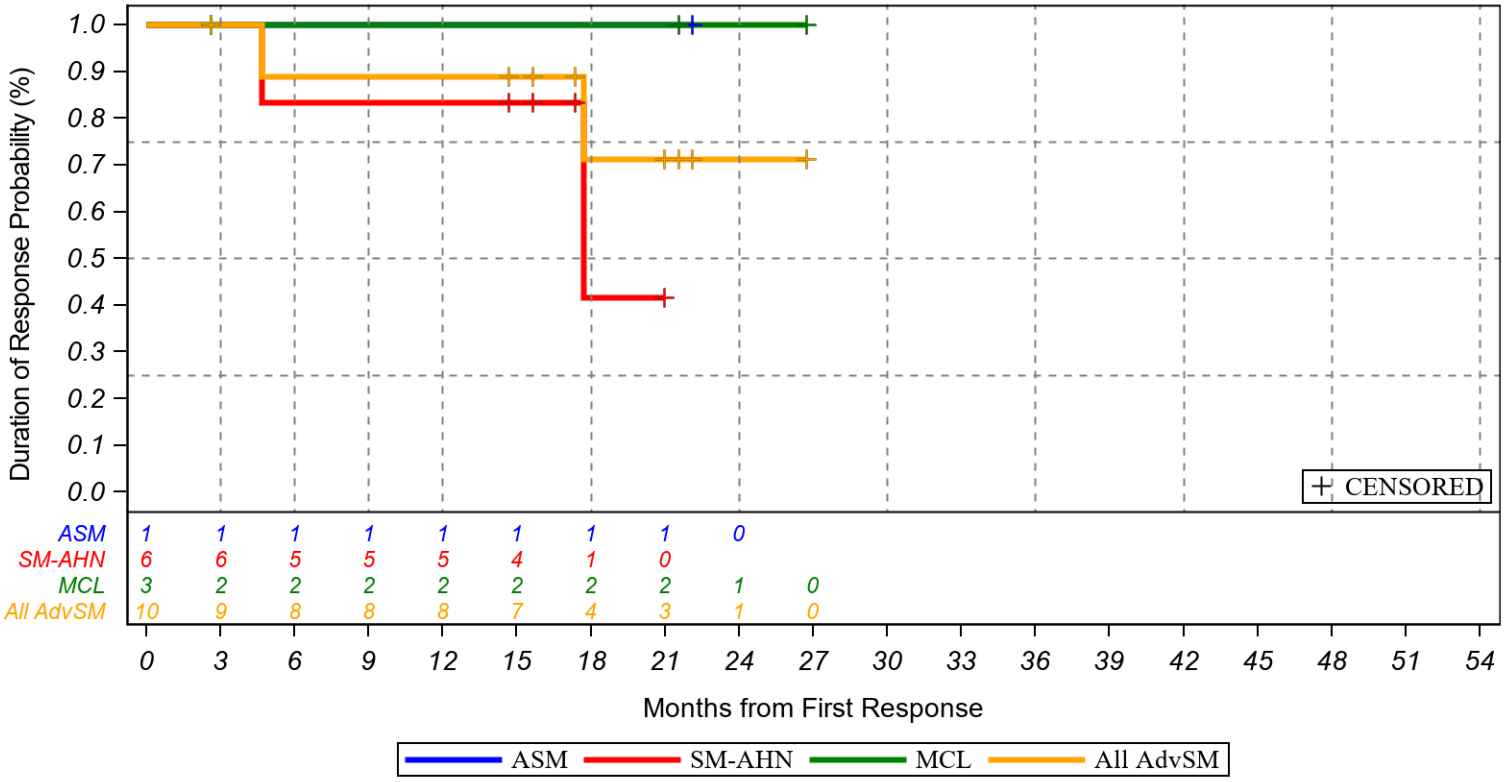

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: 400 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR+CI)

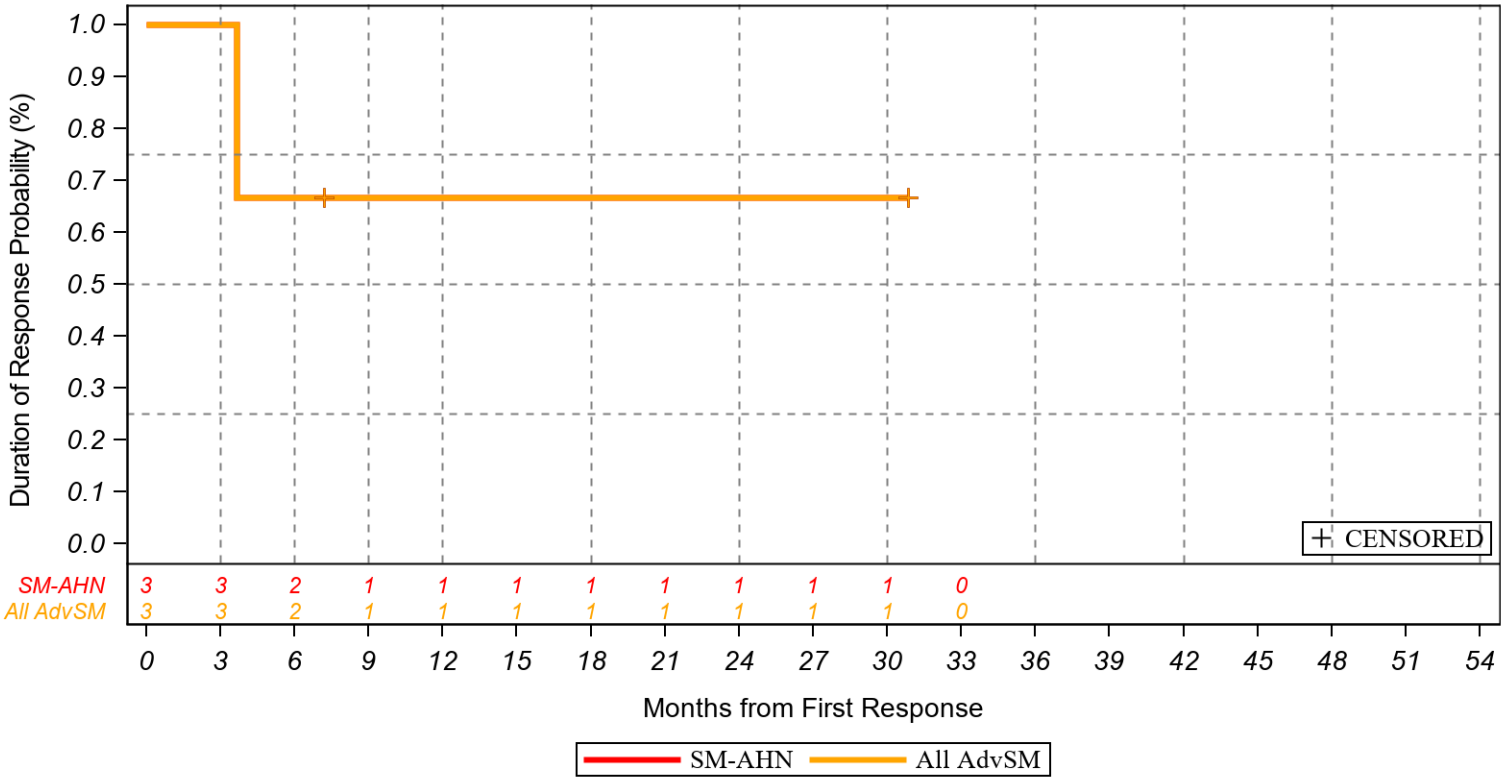

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: 400 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR)

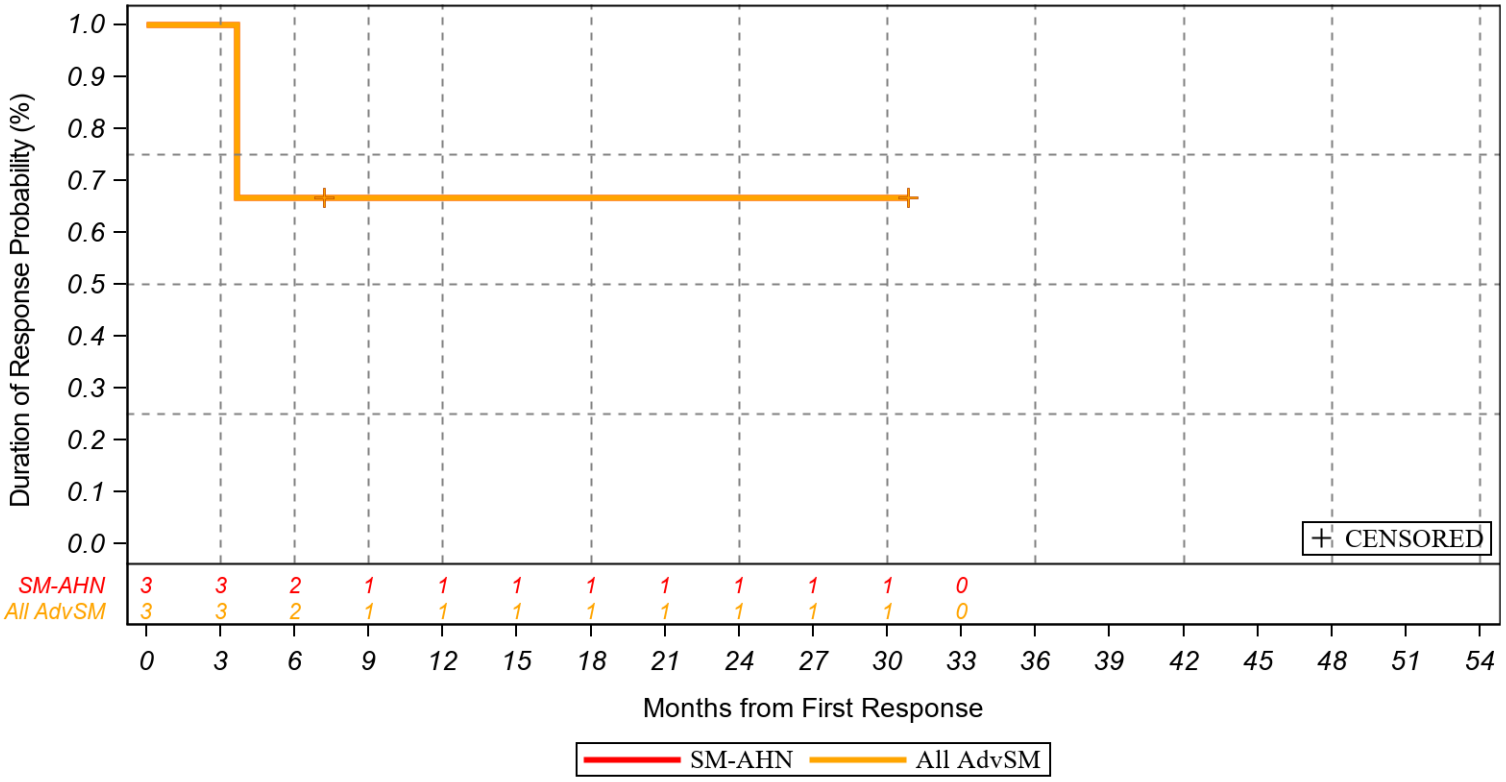

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: 400 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR+CI)

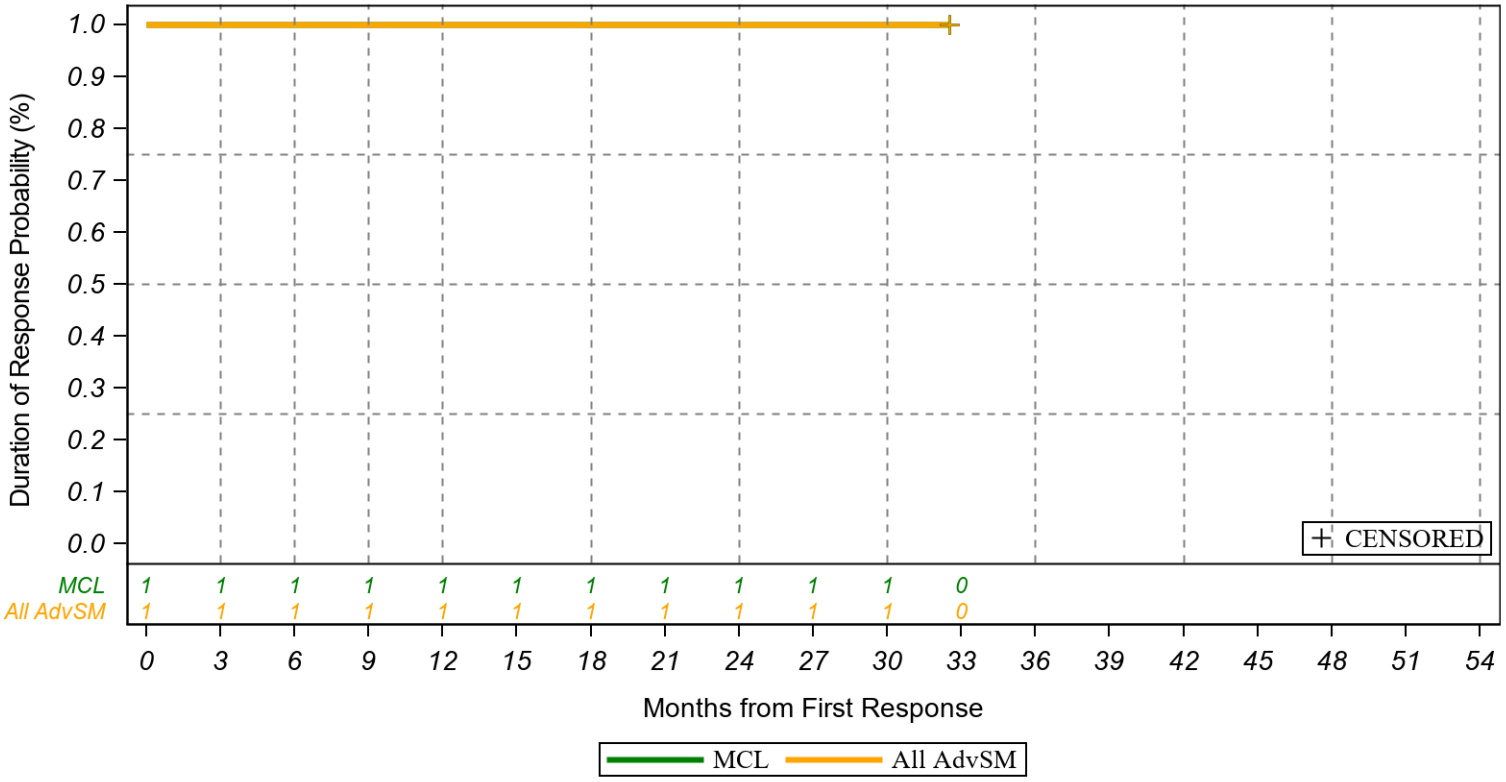

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: 400 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR)

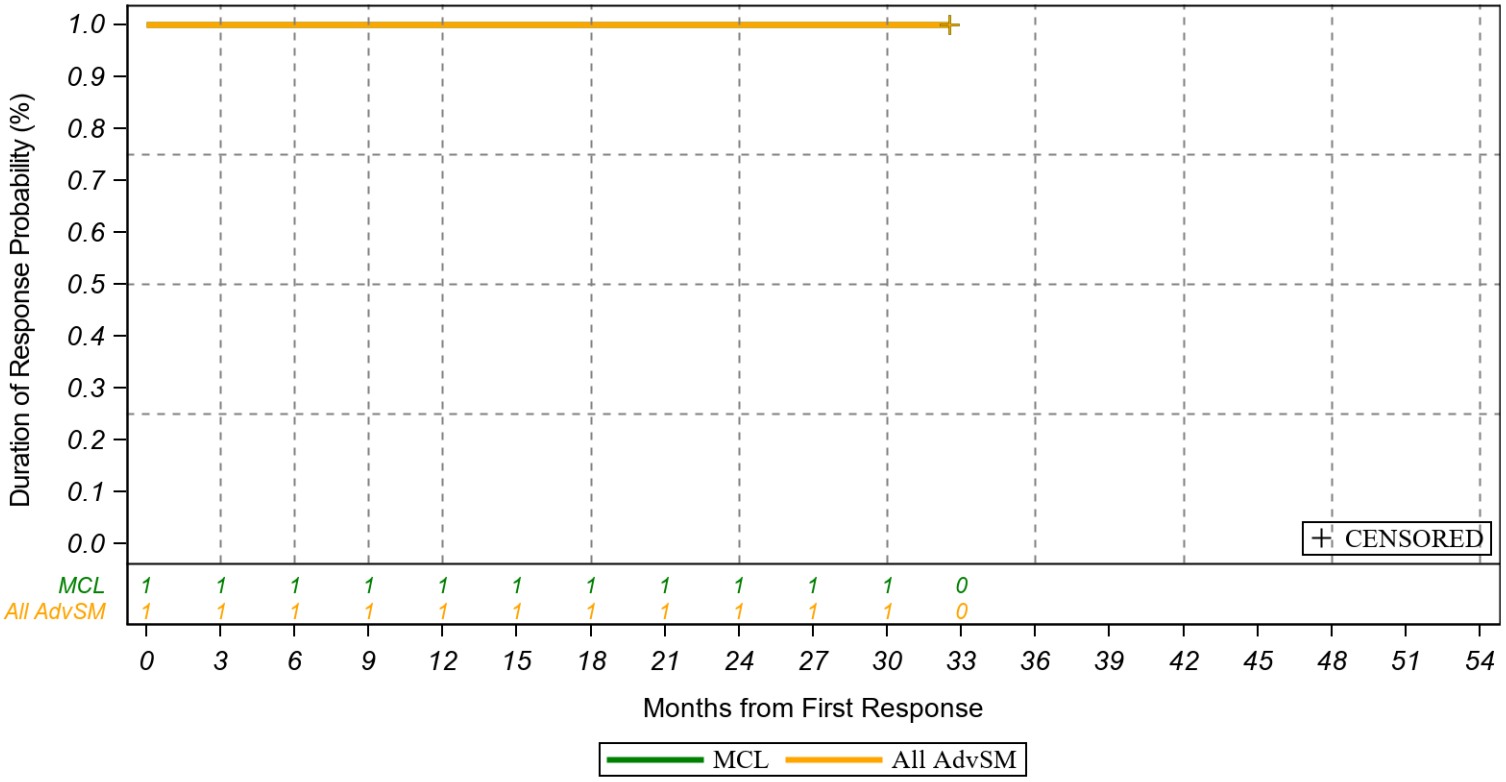

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Starting Dose: Overall
Prior Antineoplastic Therapy = Yes
Responders (CR+PR+CI)

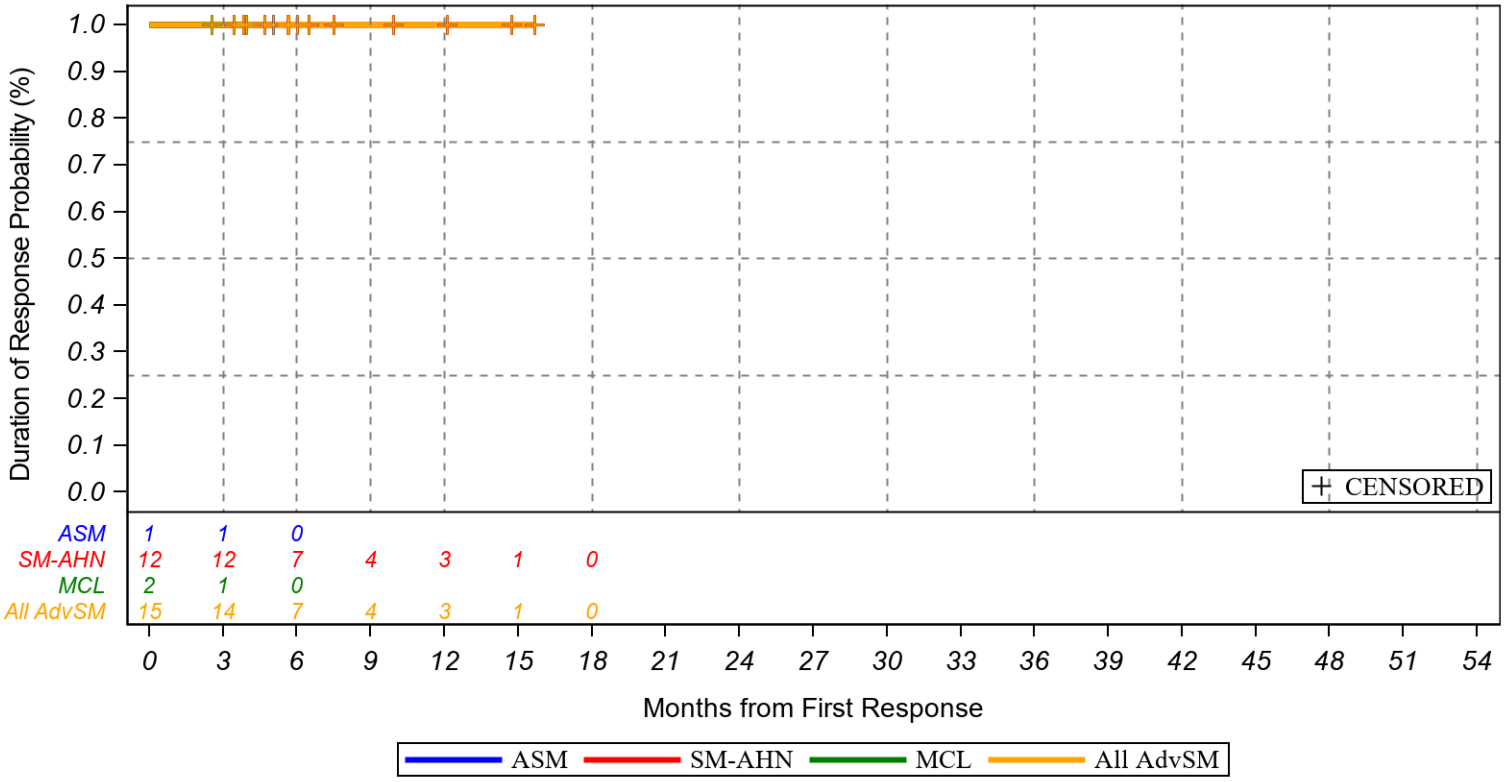

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Starting Dose: Overall
Prior Antineoplastic Therapy = Yes
Responders (CR+PR)

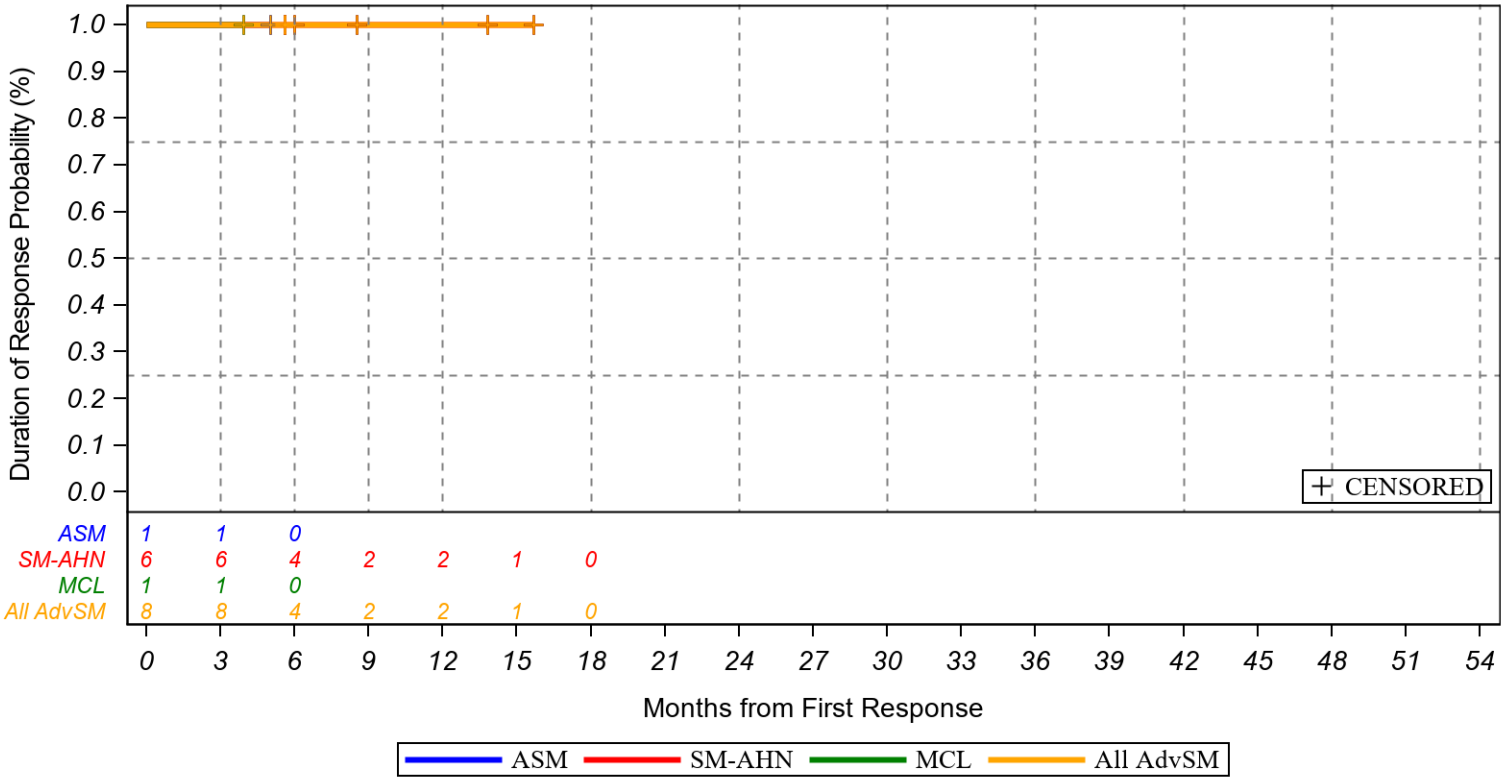

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Starting Dose: Overall
Prior Antineoplastic Therapy = No
Responders (CR+PR+CI)

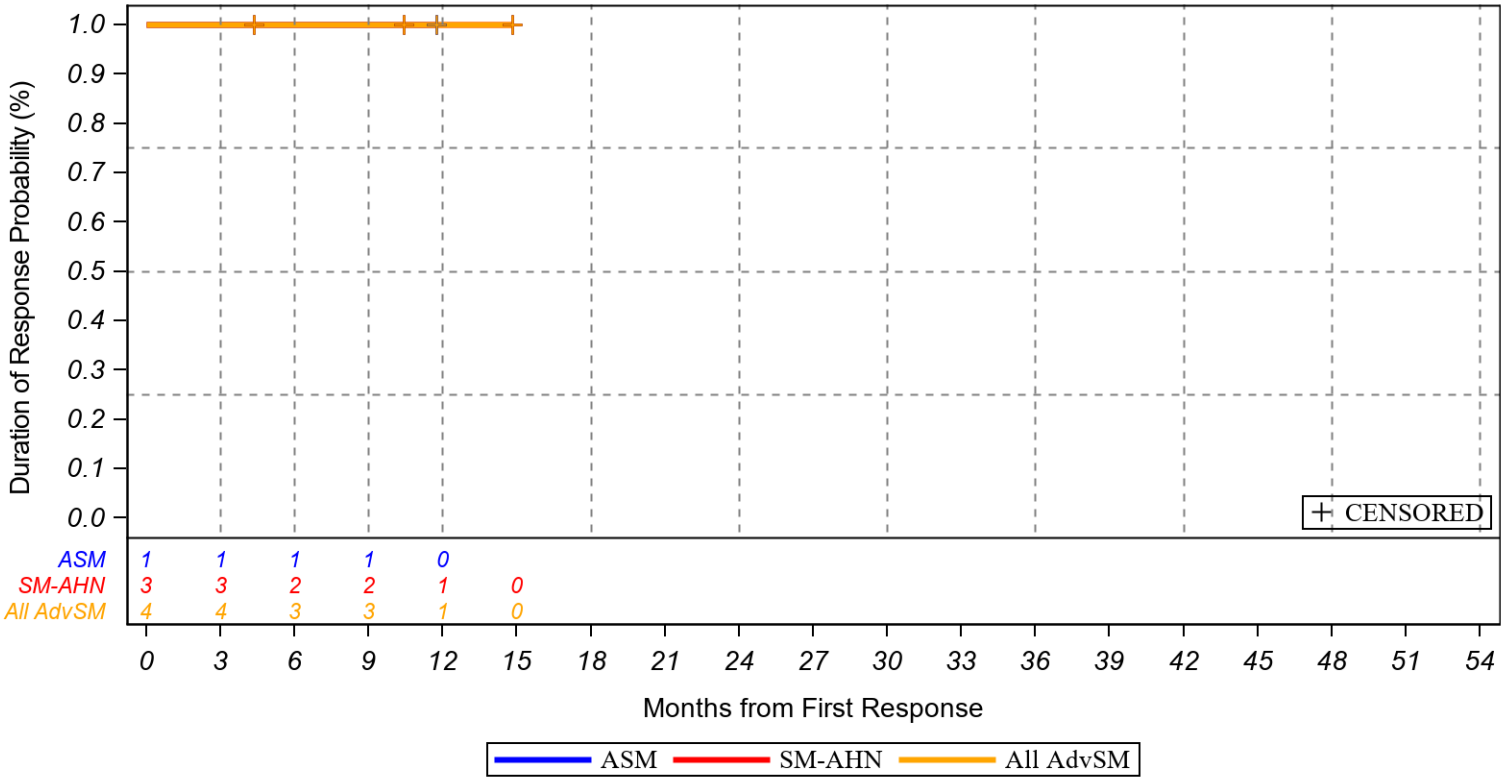

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Starting Dose: Overall
Prior Antineoplastic Therapy = No
Responders (CR+PR)

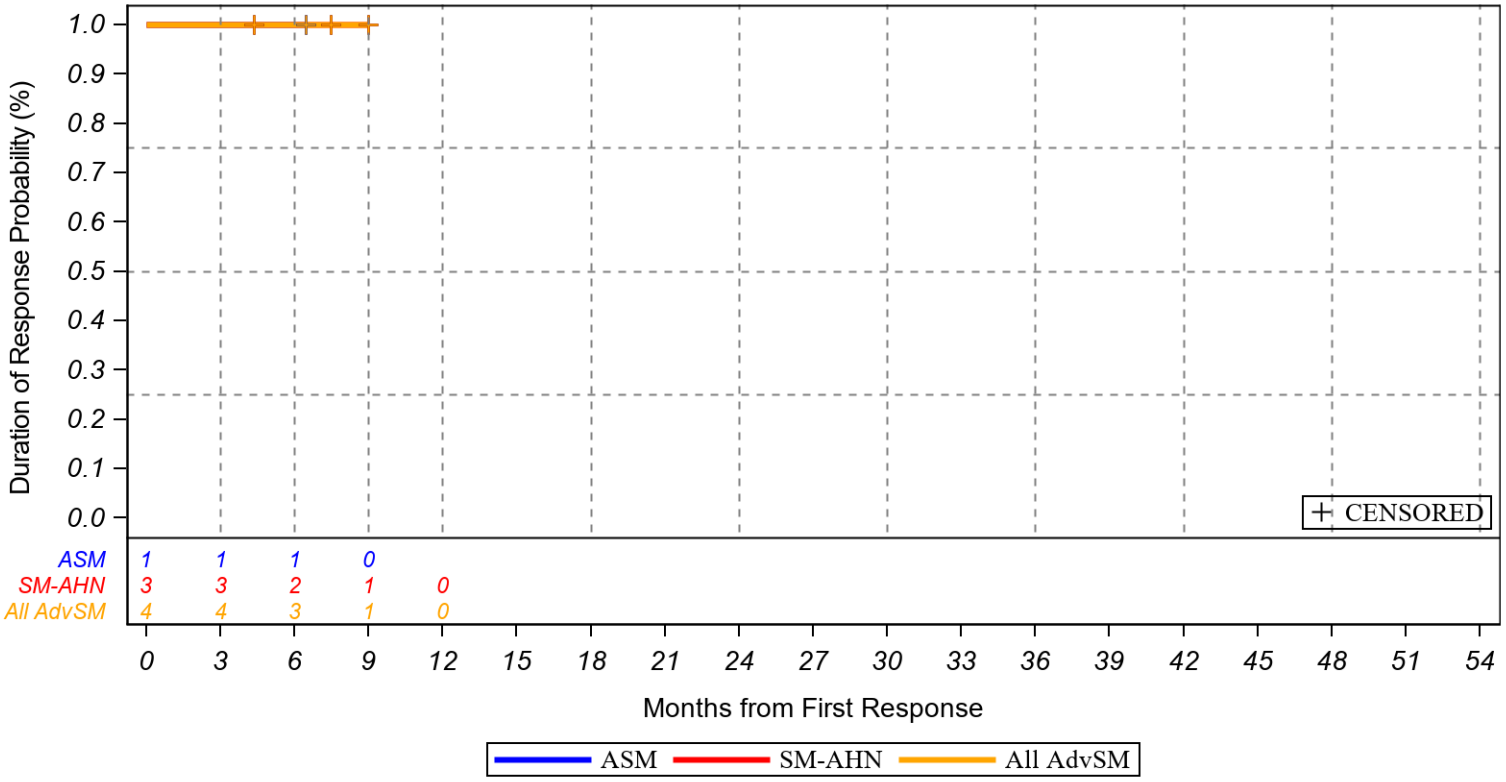

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Starting Dose: 200 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR+CI)

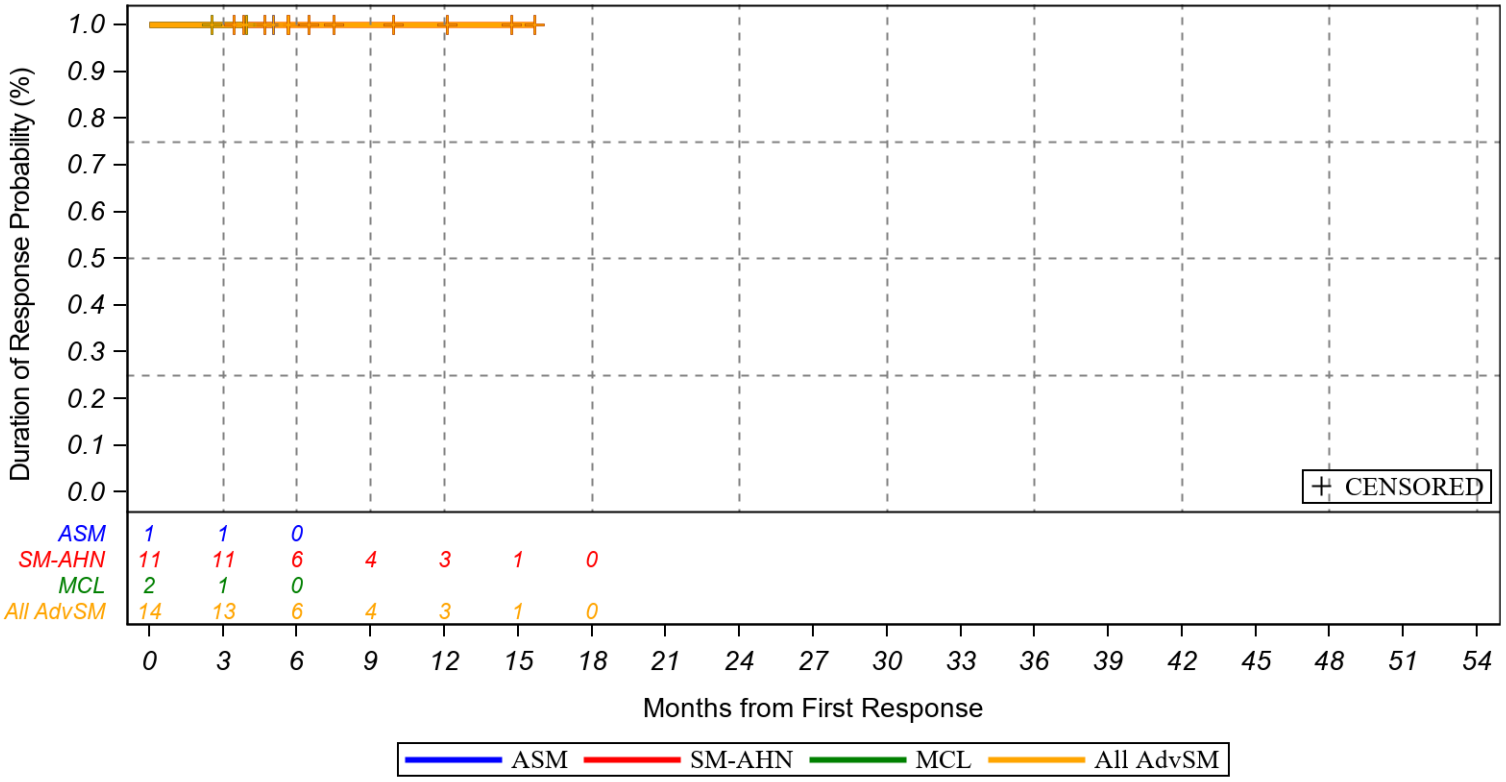

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Starting Dose: 200 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR)

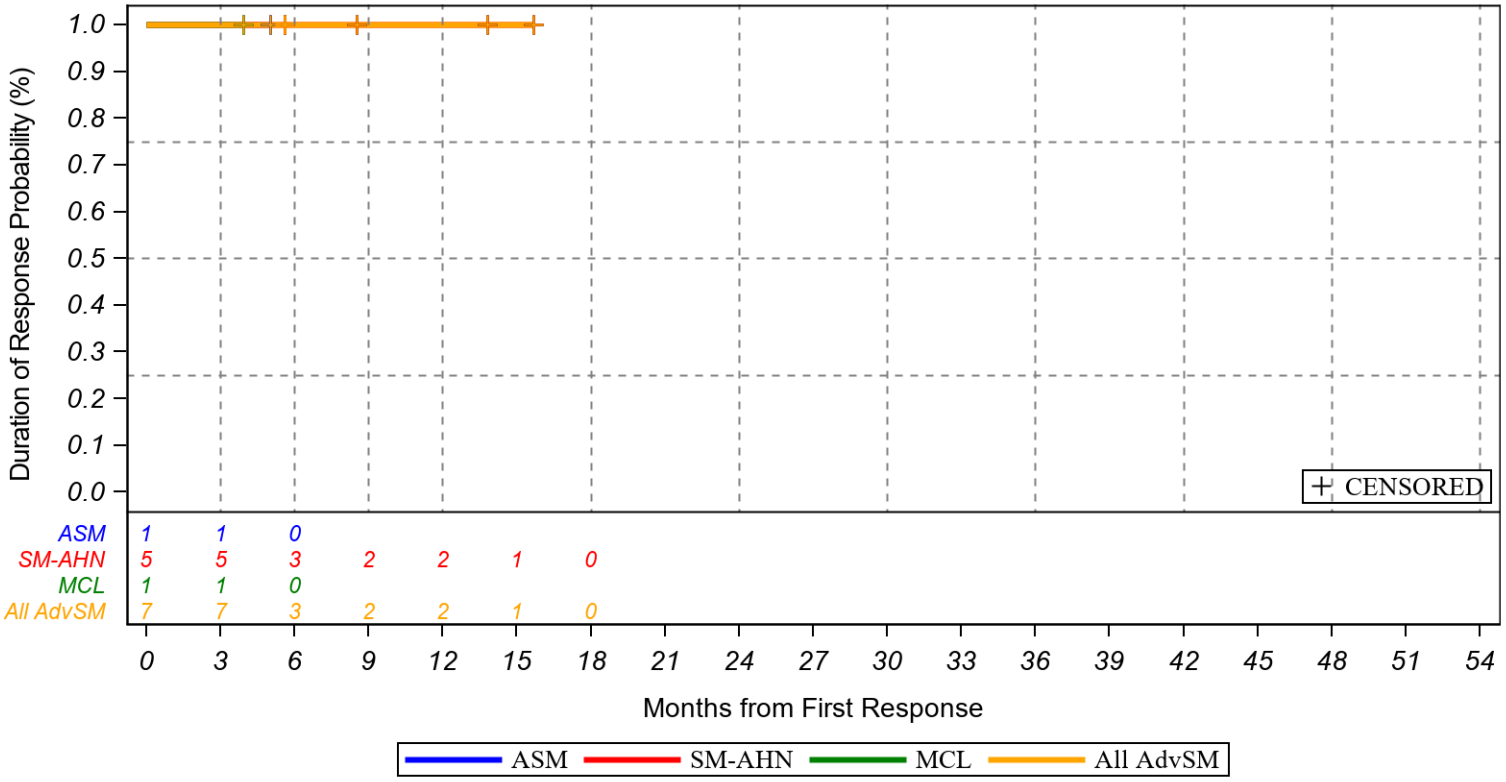

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Starting Dose: 200 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR+CI)

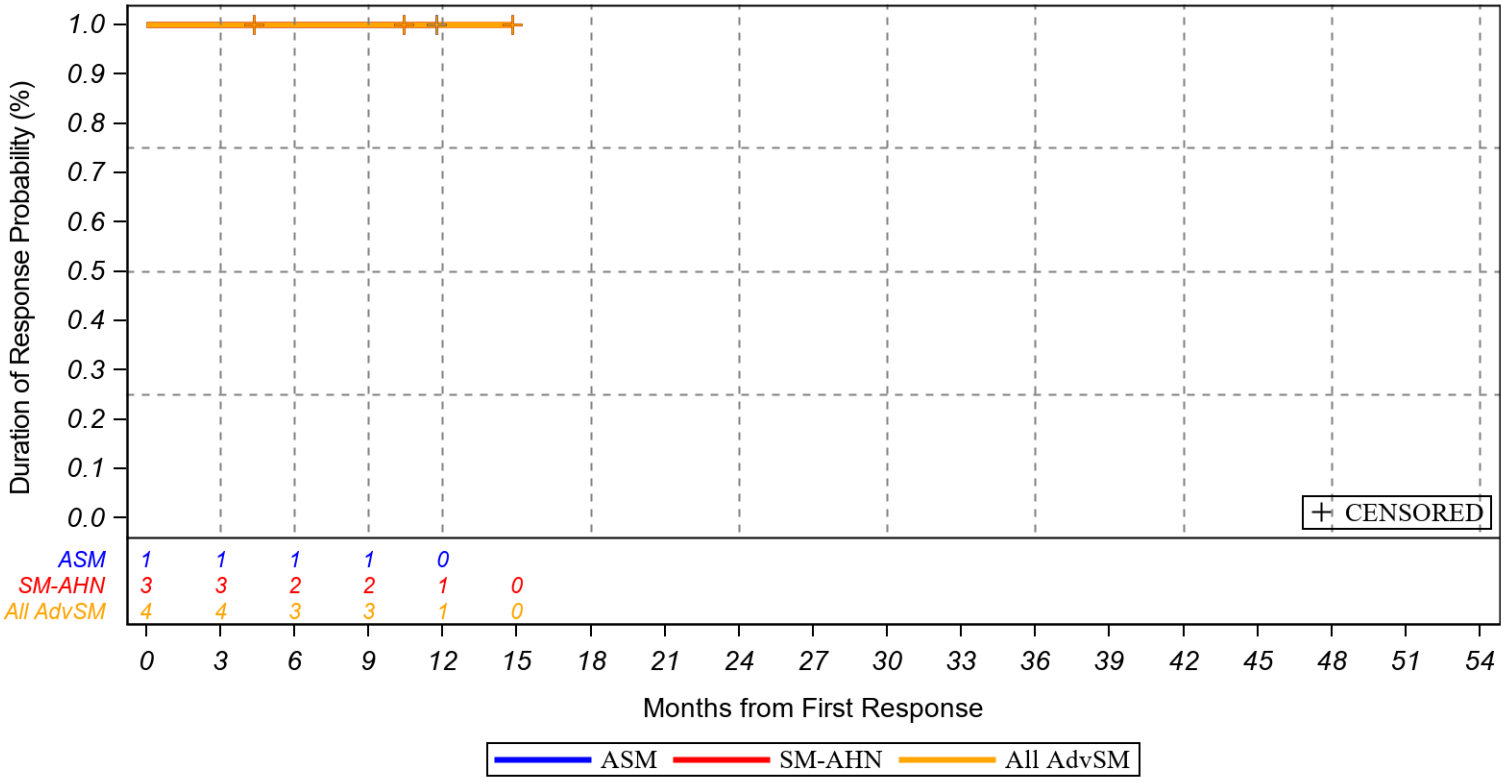

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Starting Dose: 200 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR)

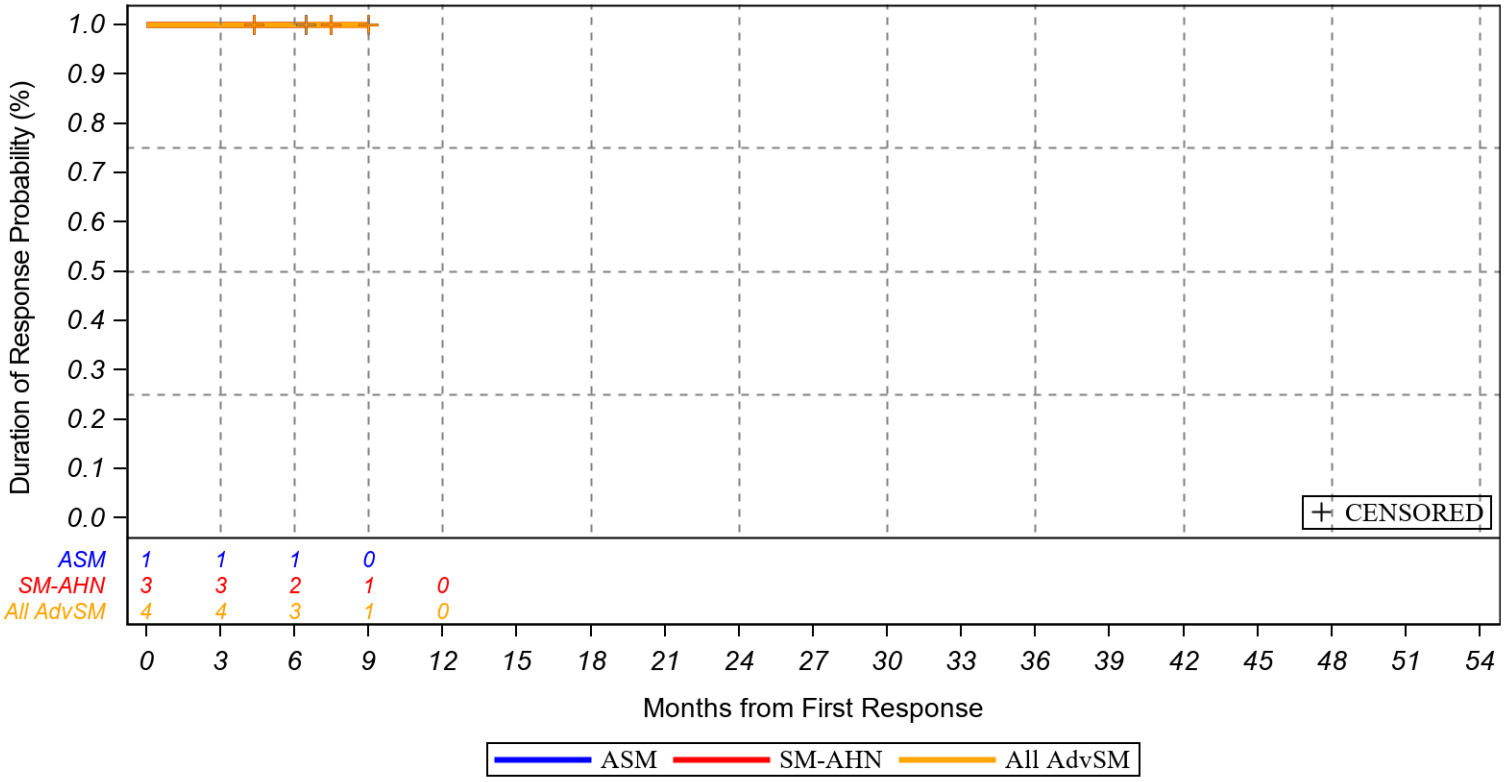

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall
Prior Antineoplastic Therapy = Yes
Responders (CR+PR+CI)

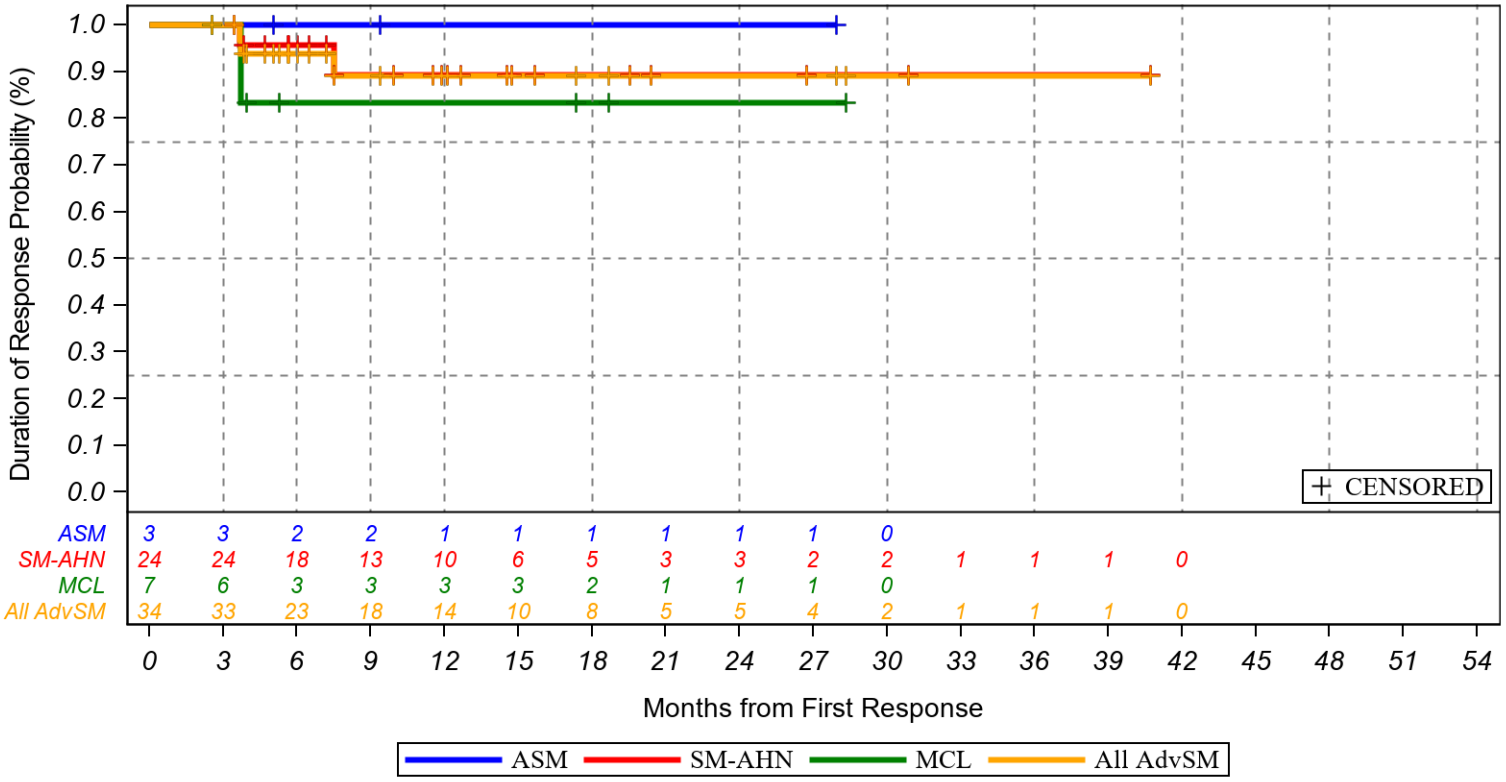

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall
Prior Antineoplastic Therapy = Yes
Responders (CR+PR)

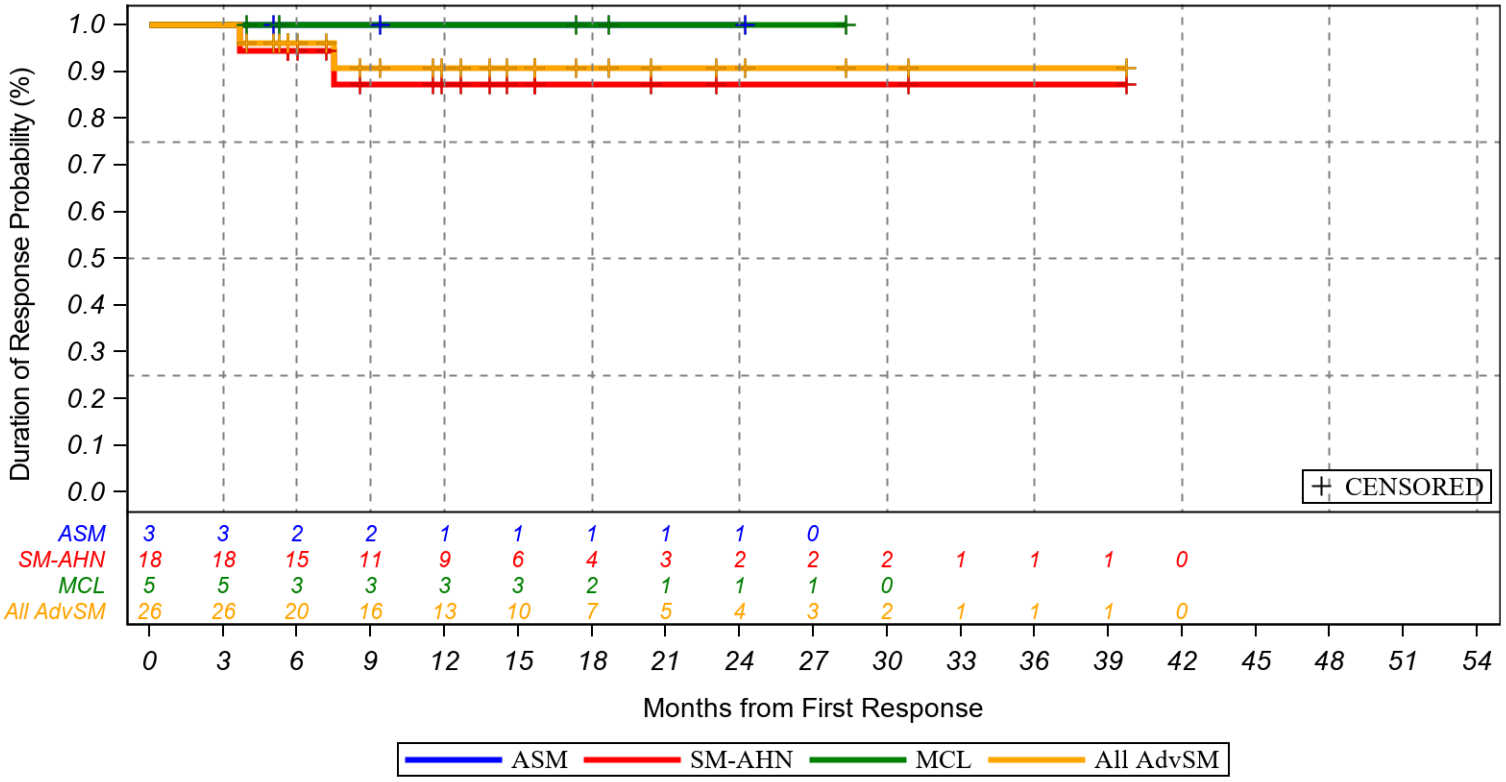

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall
Prior Antineoplastic Therapy = No
Responders (CR+PR+CI)

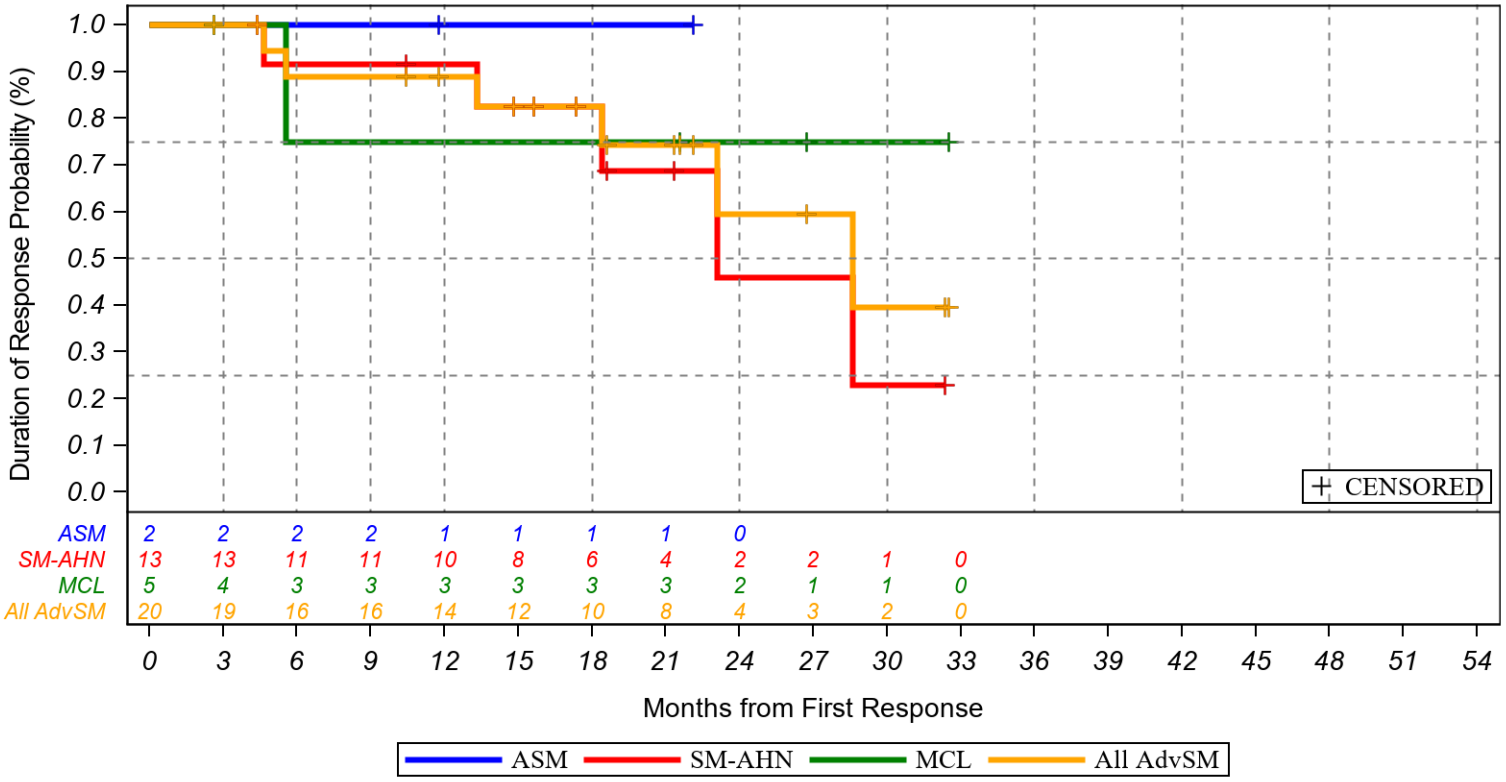

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall
Prior Antineoplastic Therapy = No
Responders (CR+PR)

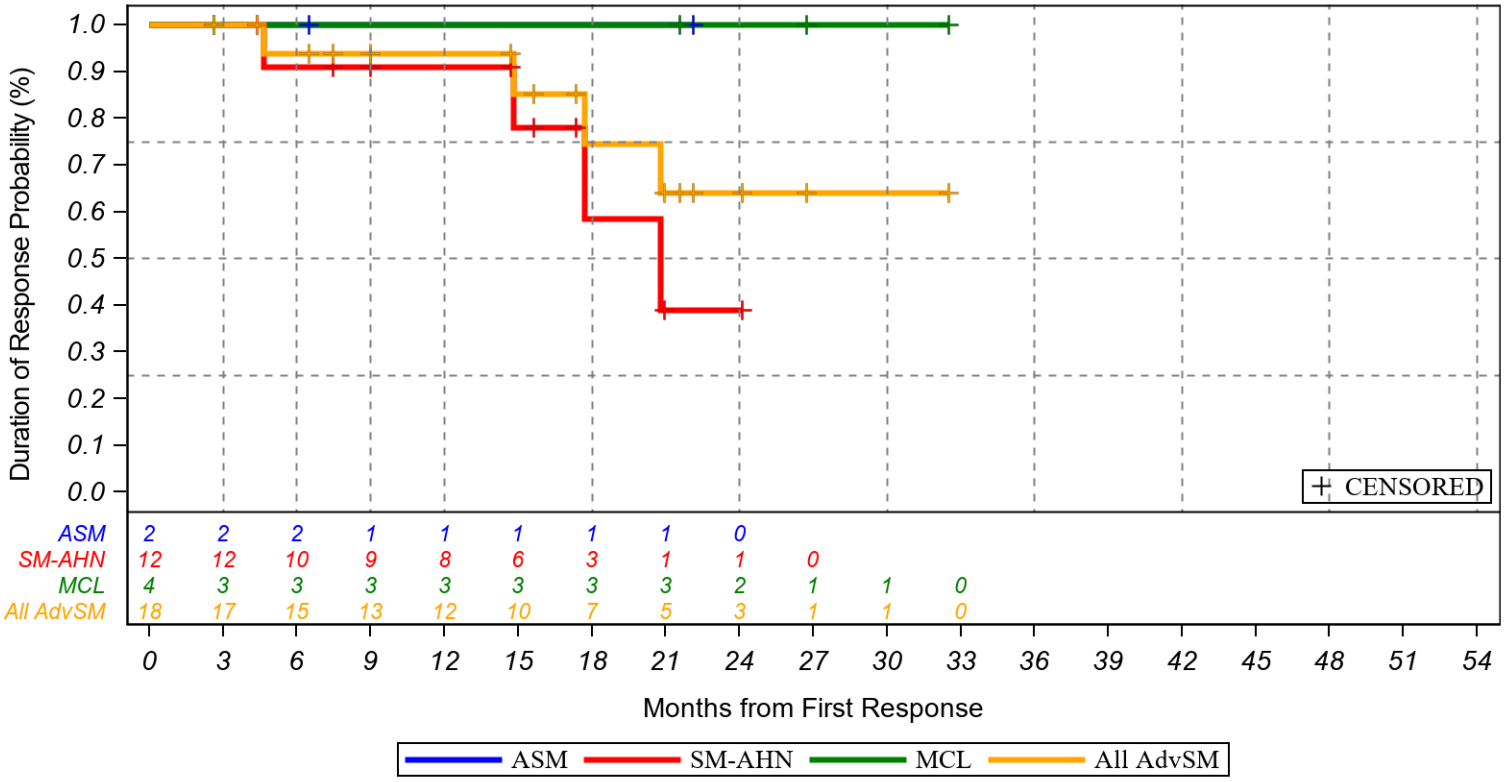

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR+CI)

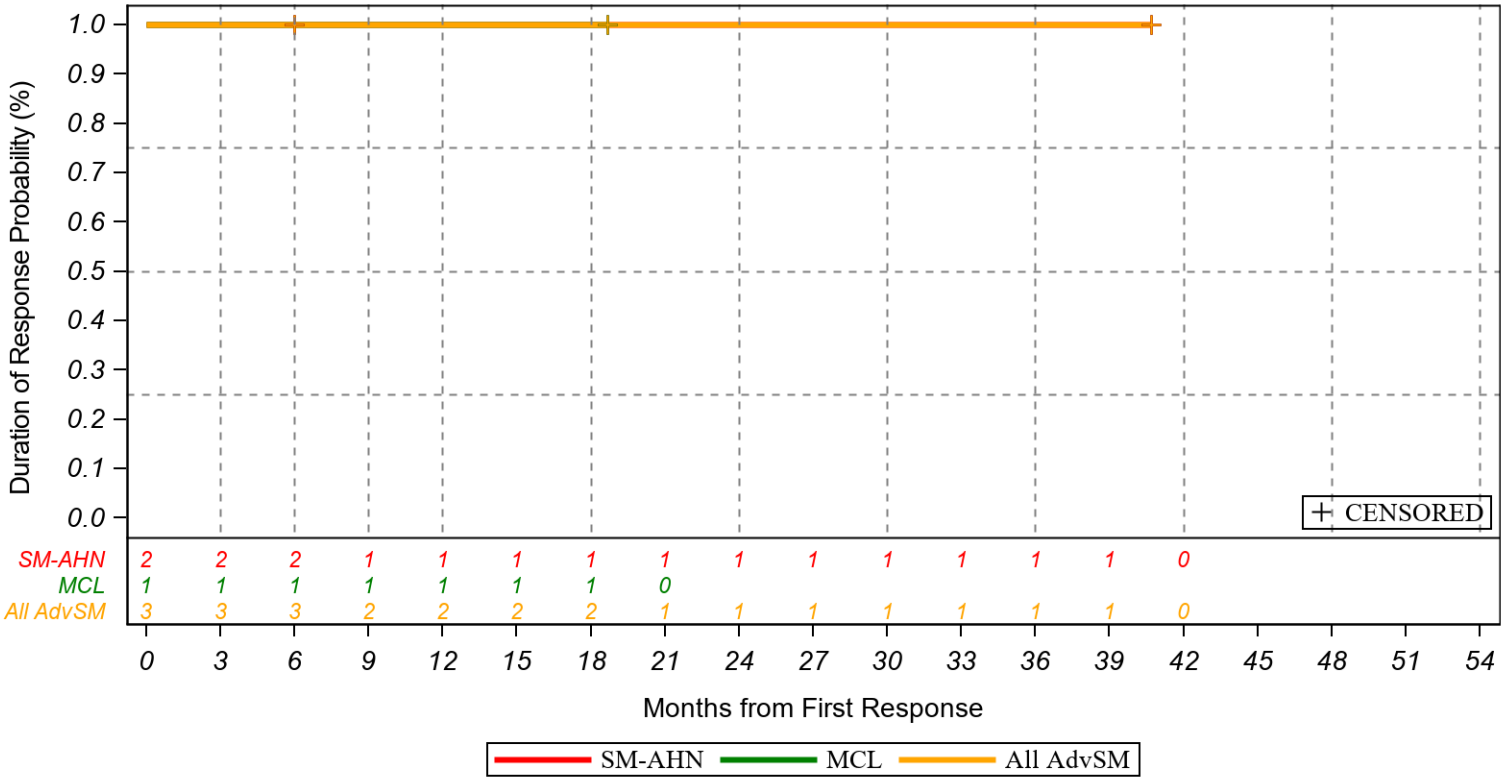

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR)

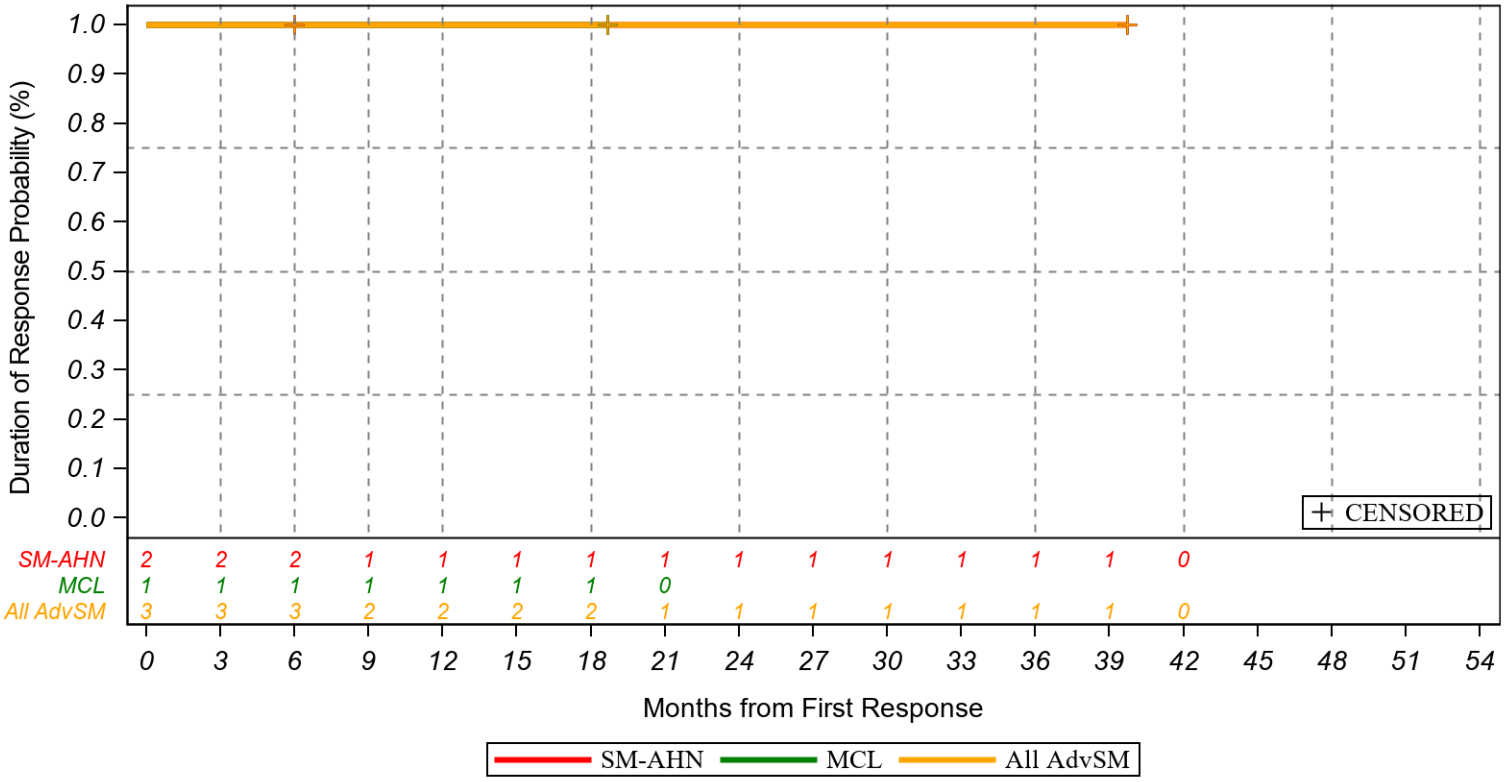

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Figure 15.2.2.7b
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RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR+CI)

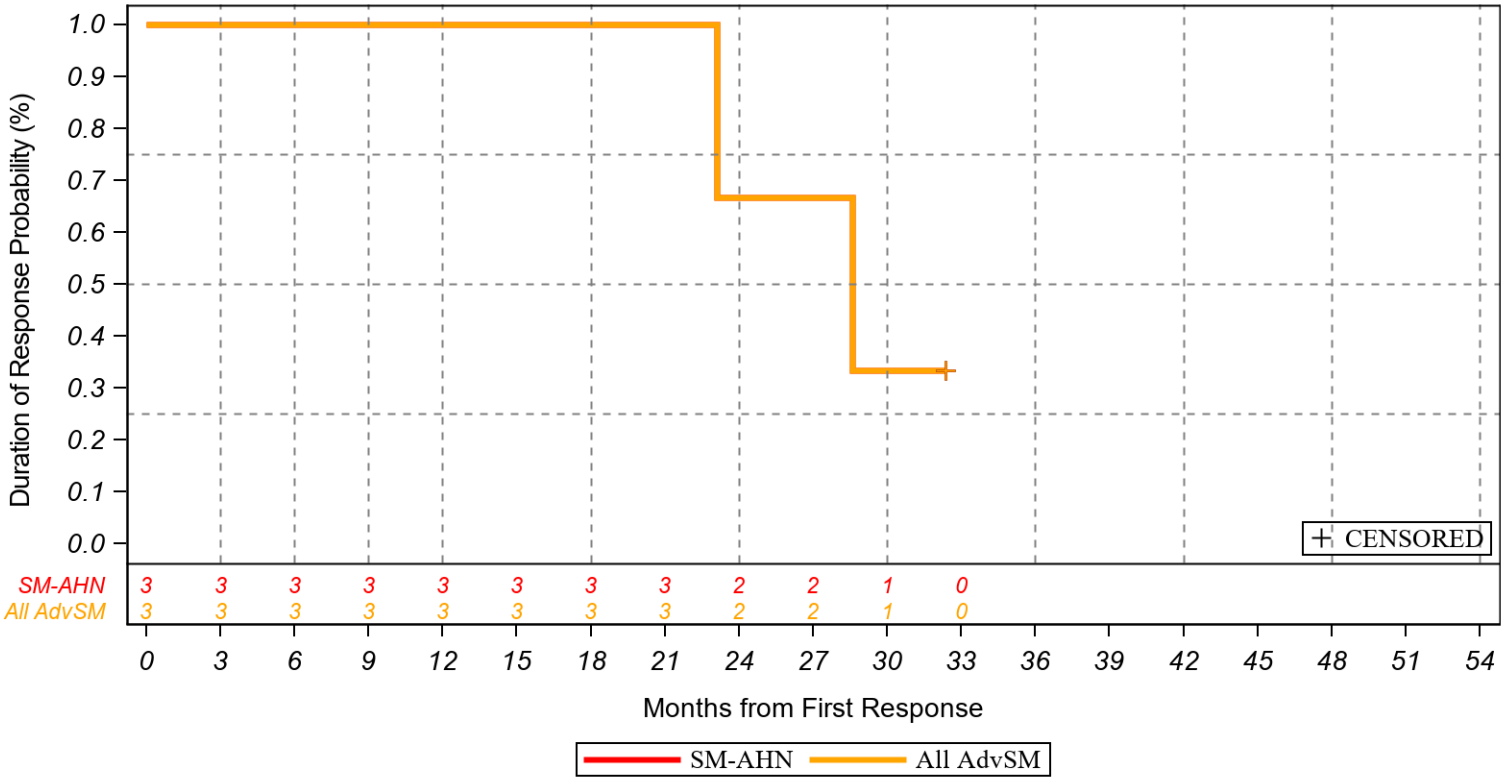

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Figure 15.2.2.7b
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Study: BLU-285-2101 and BLU-285-2202
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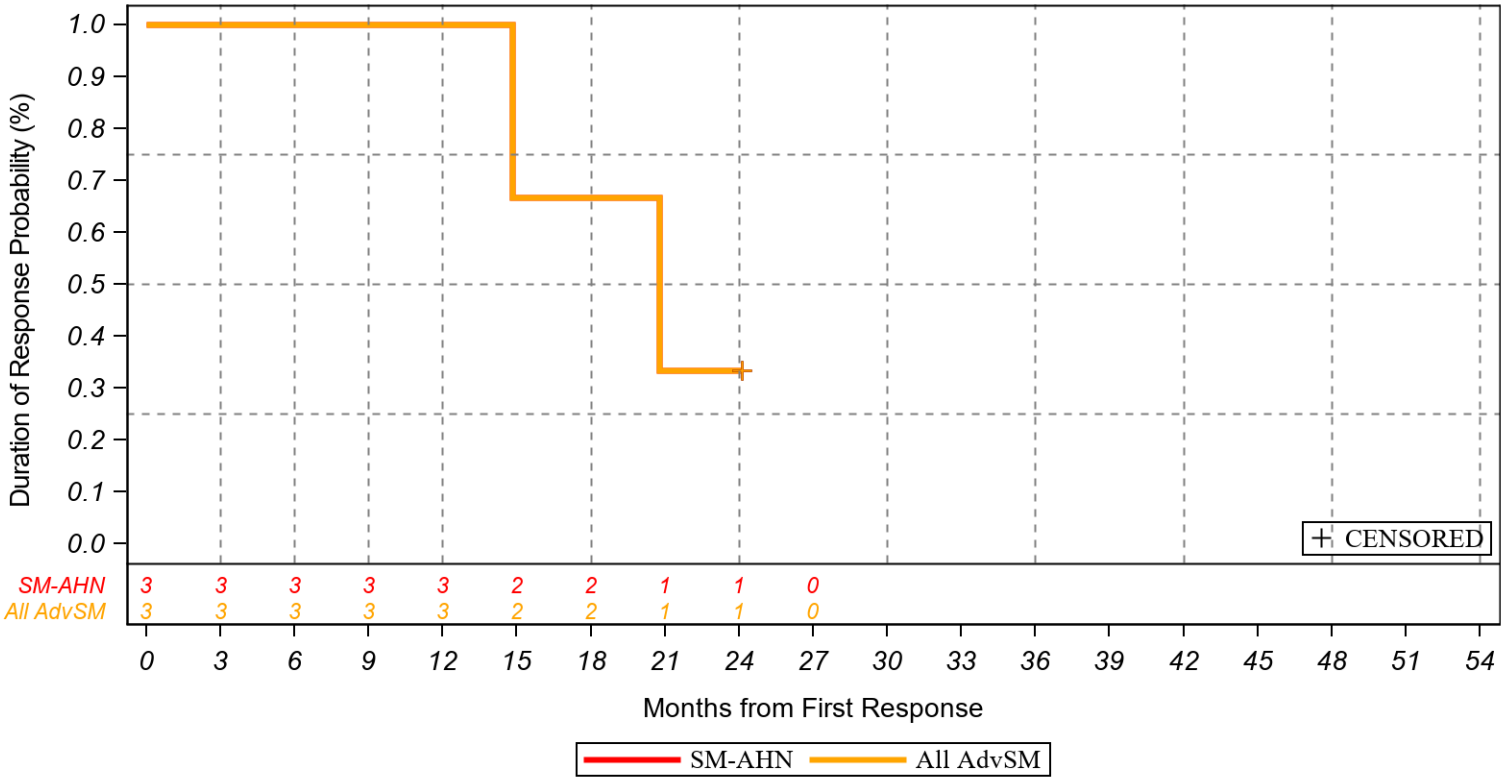

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg
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Responders (CR+PR+CI)

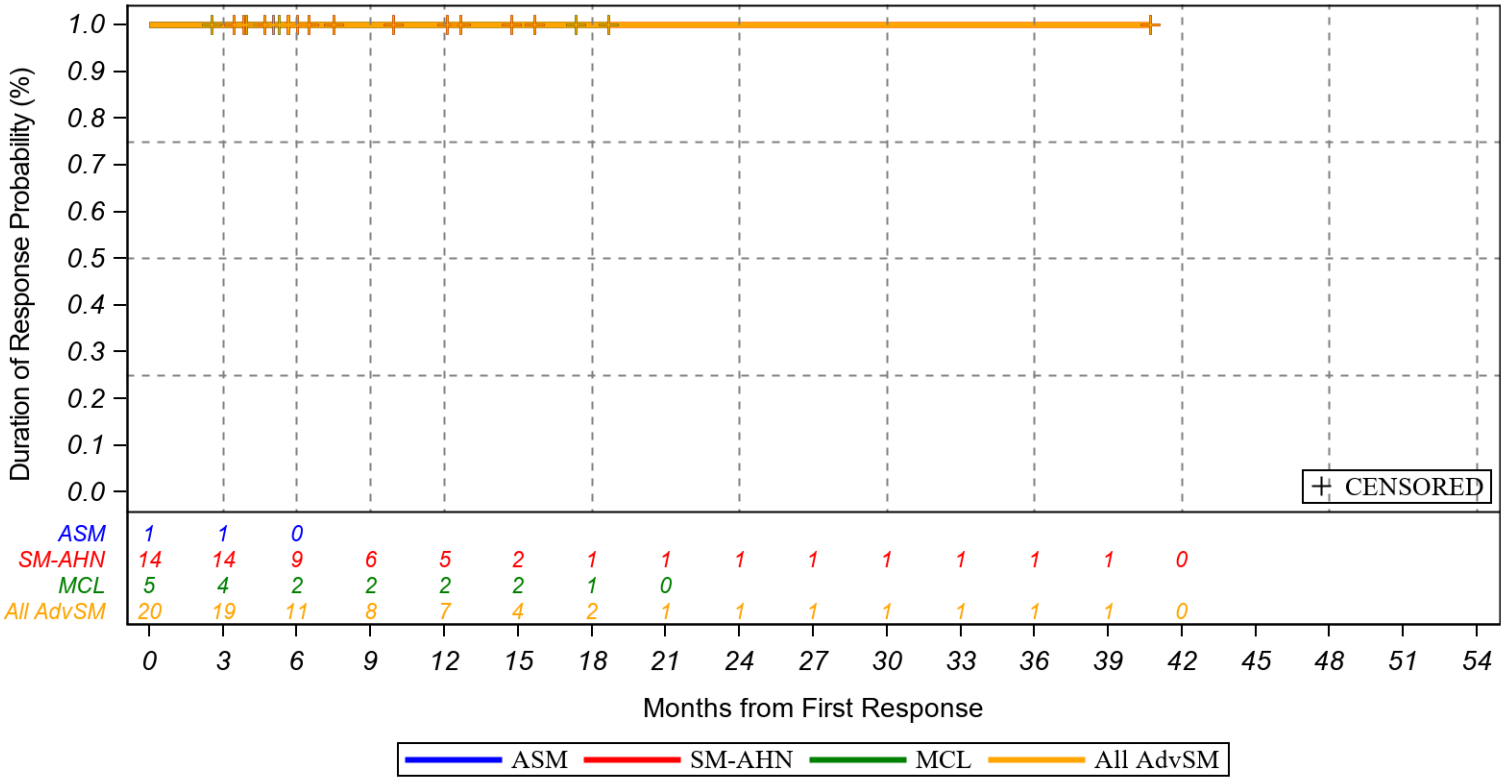

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg
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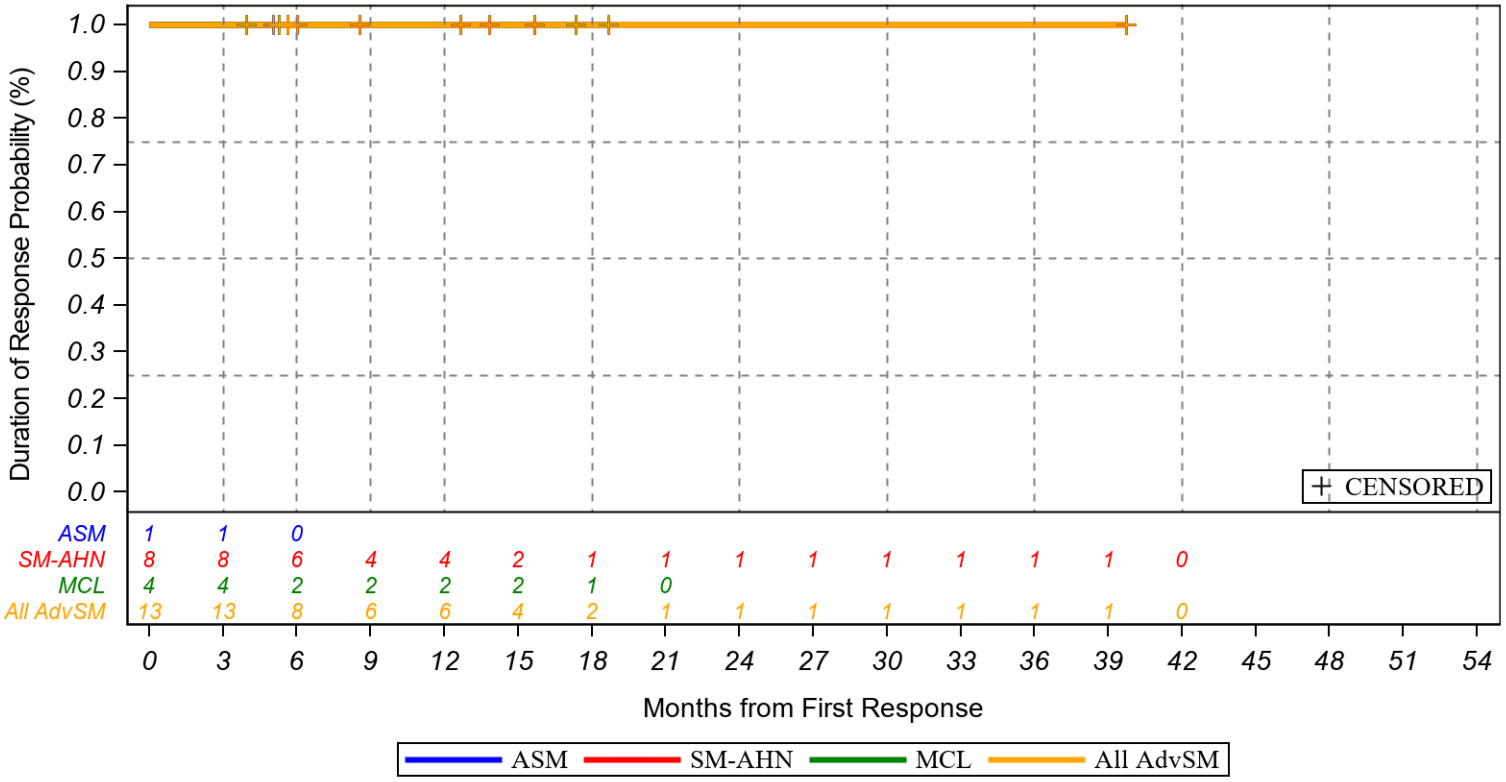

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Figure 15.2.2.7b
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RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg
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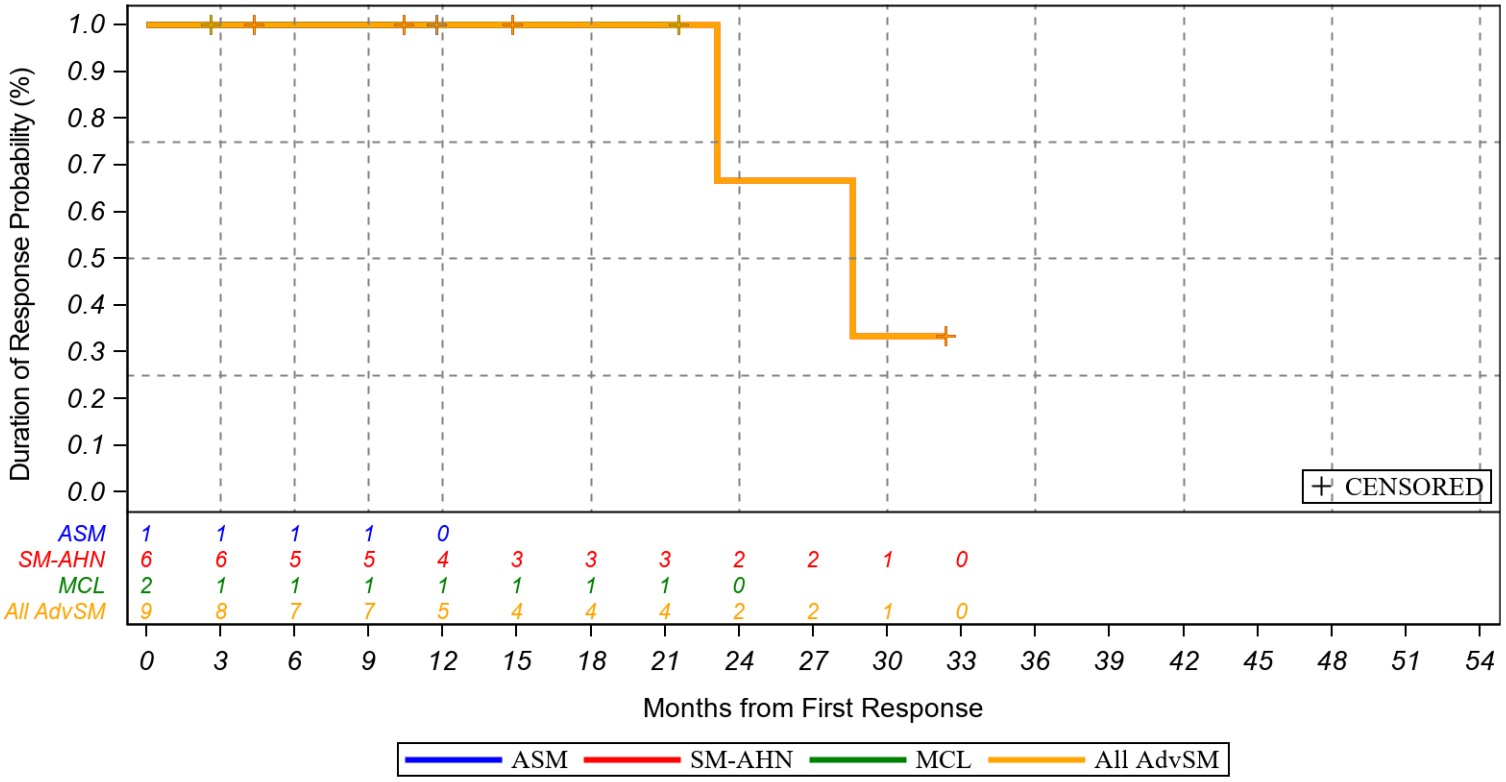

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg
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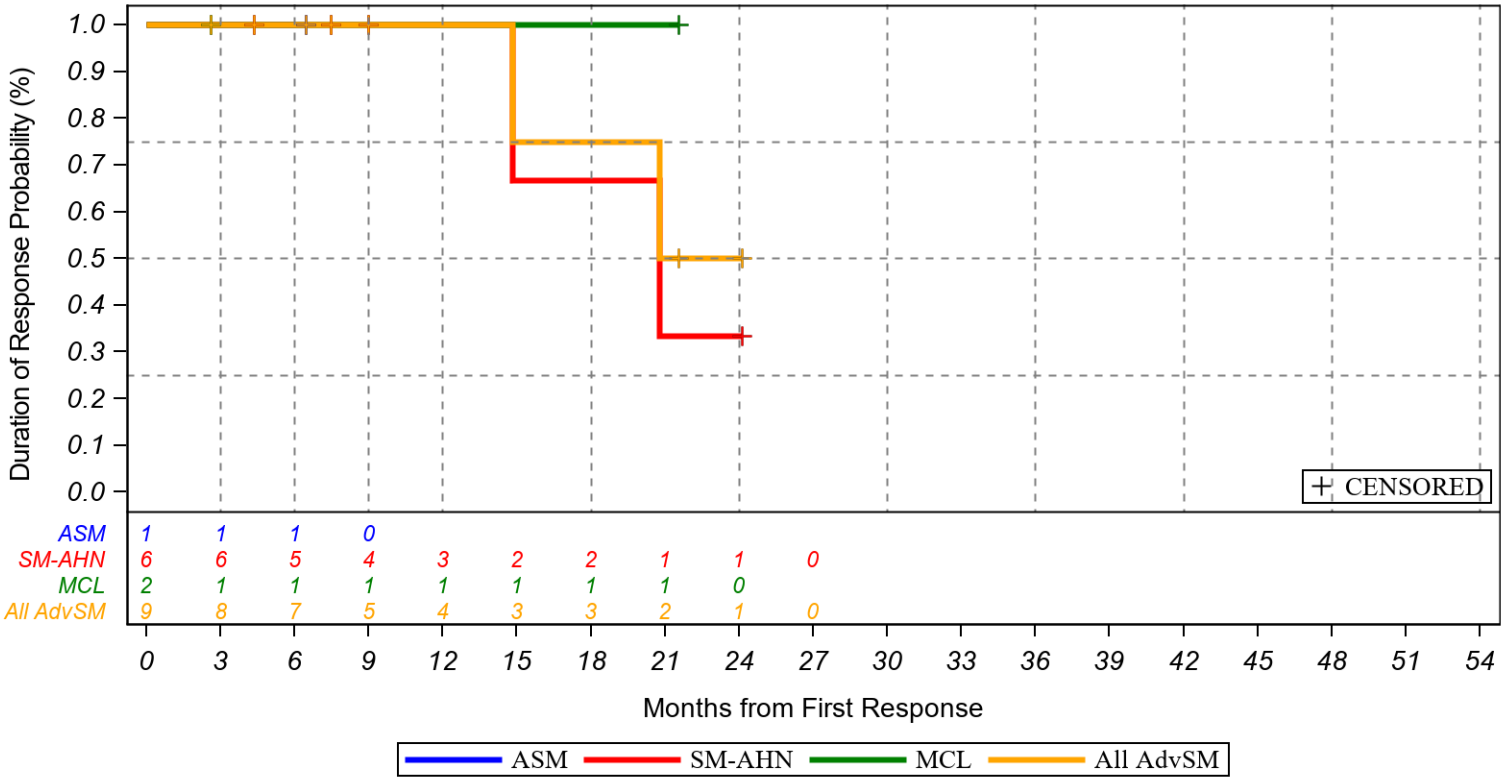

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR+CI)

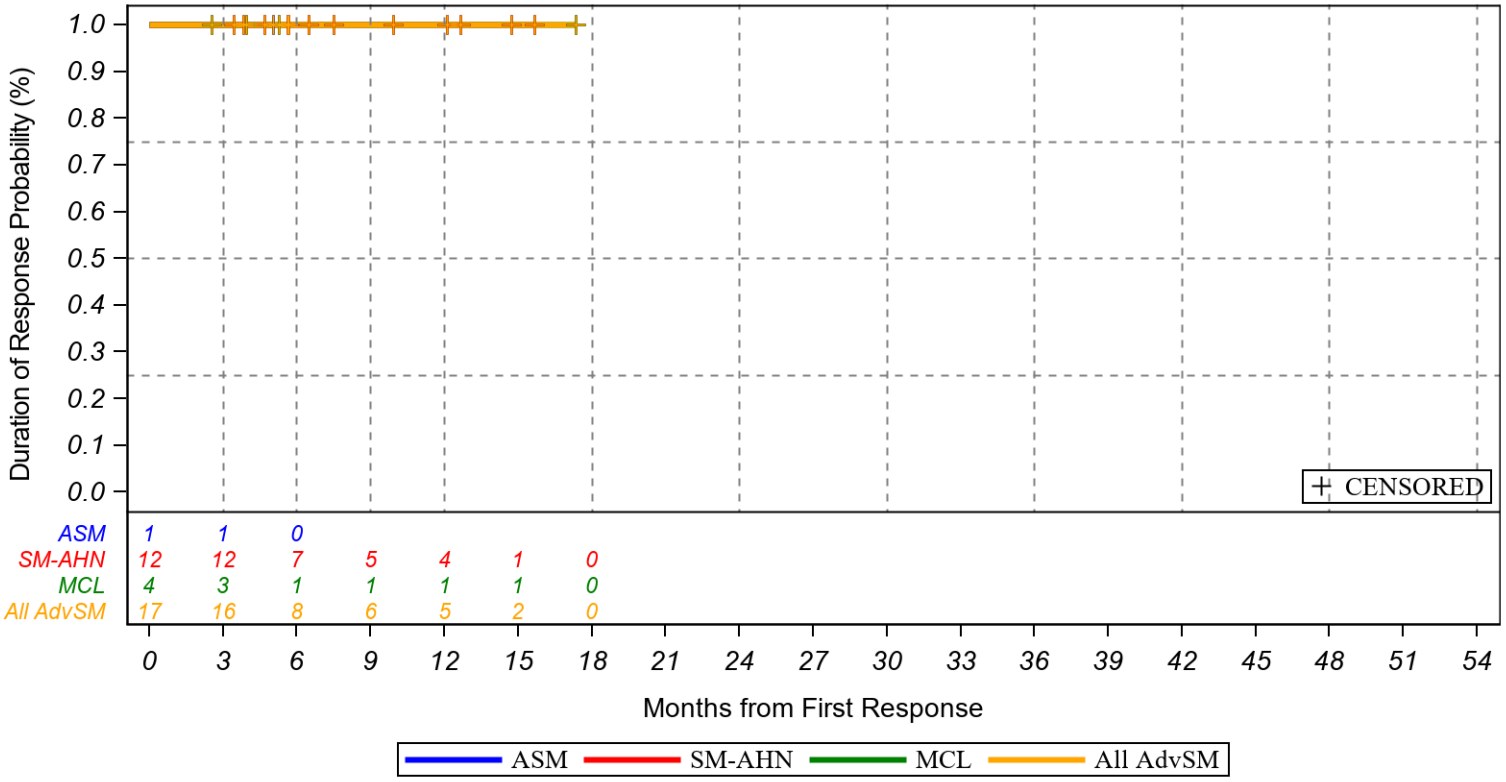

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg
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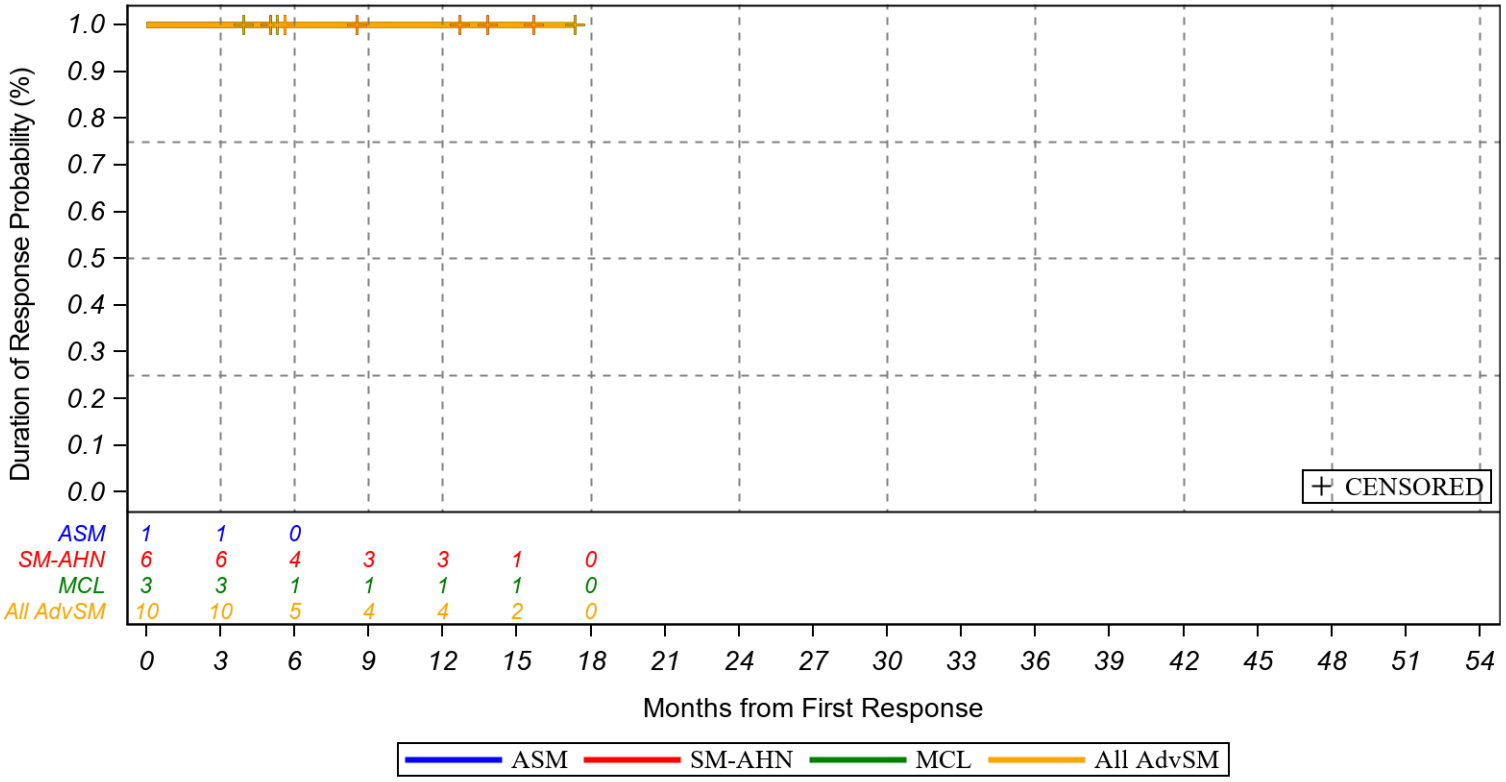

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
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Starting Dose: 200 mg
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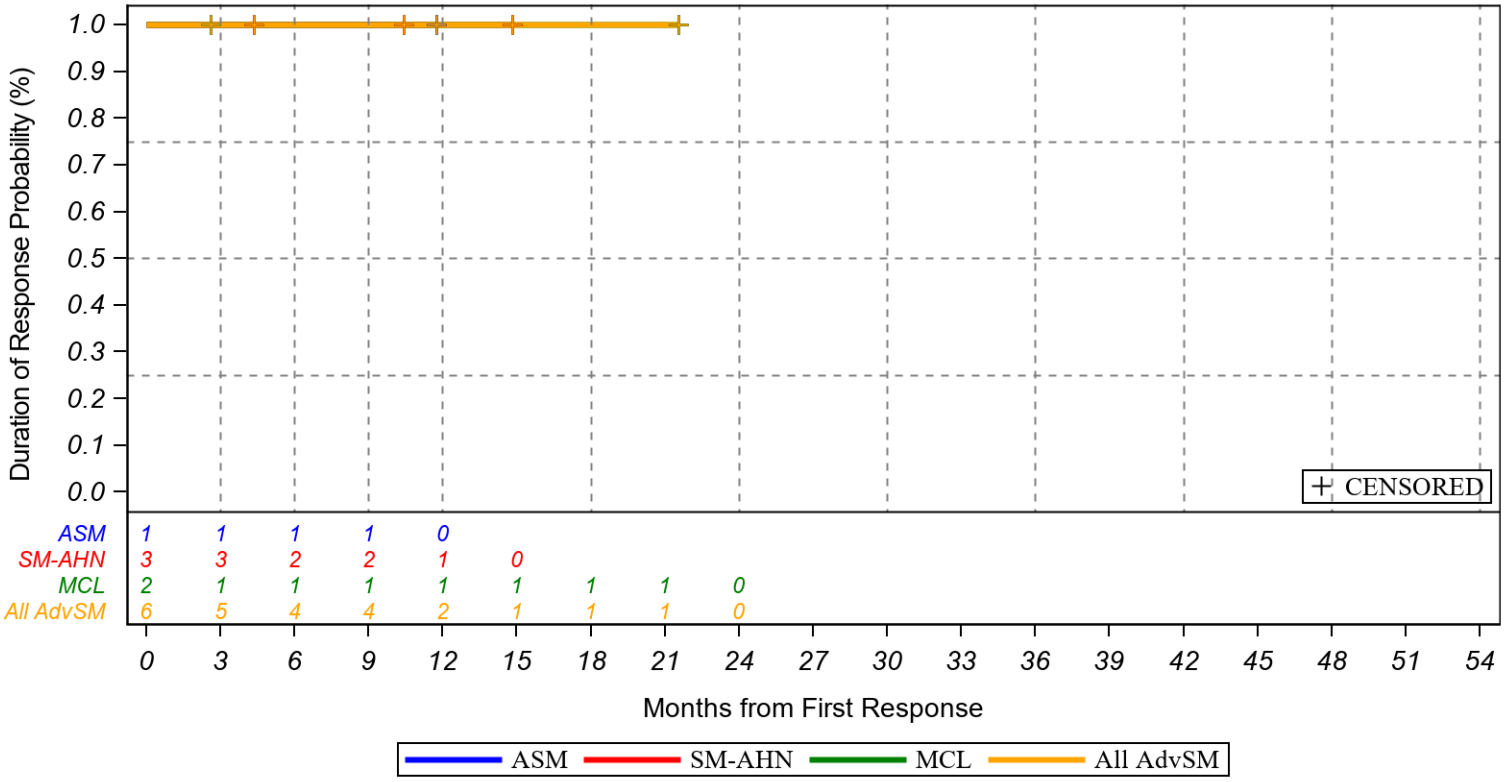

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR)

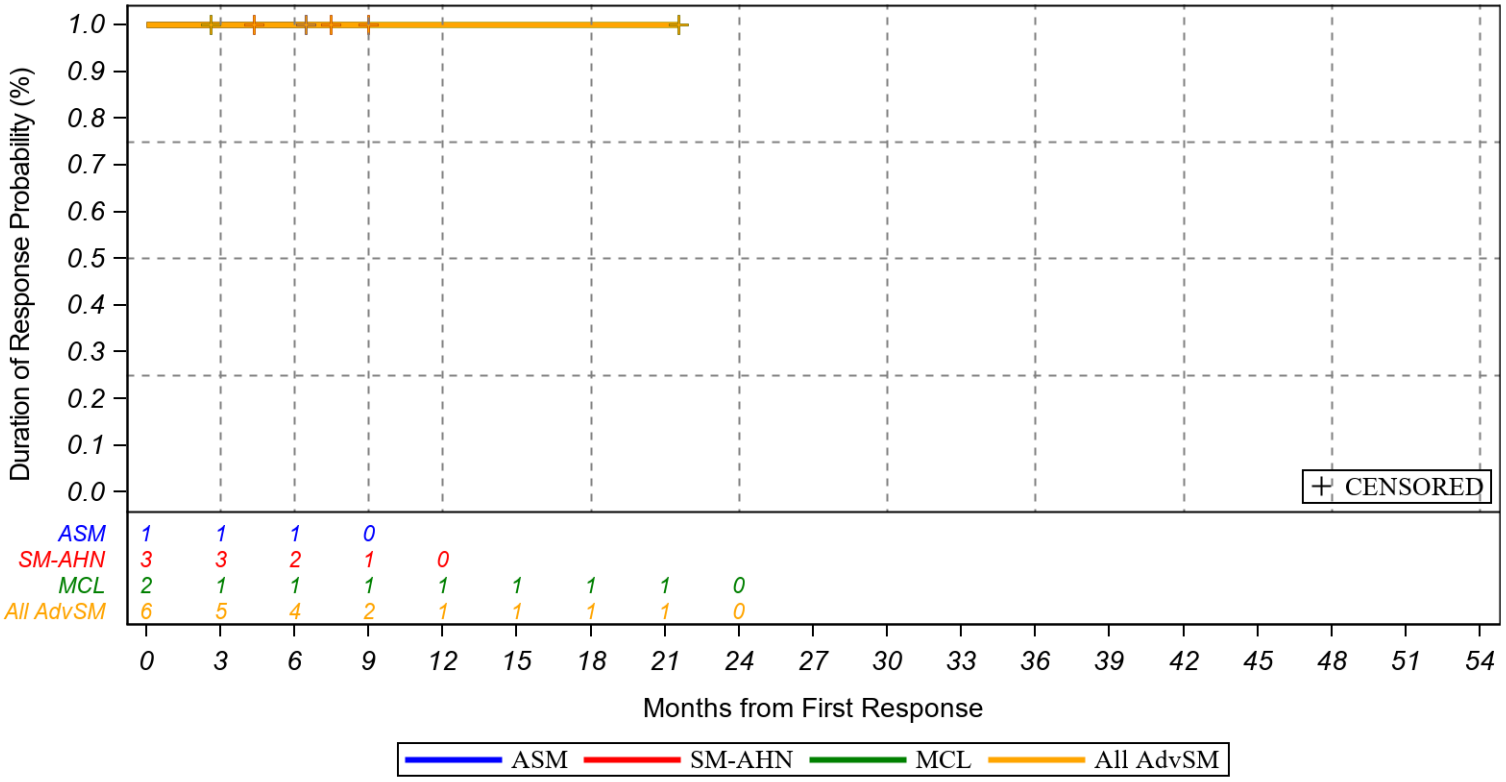

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR+CI)

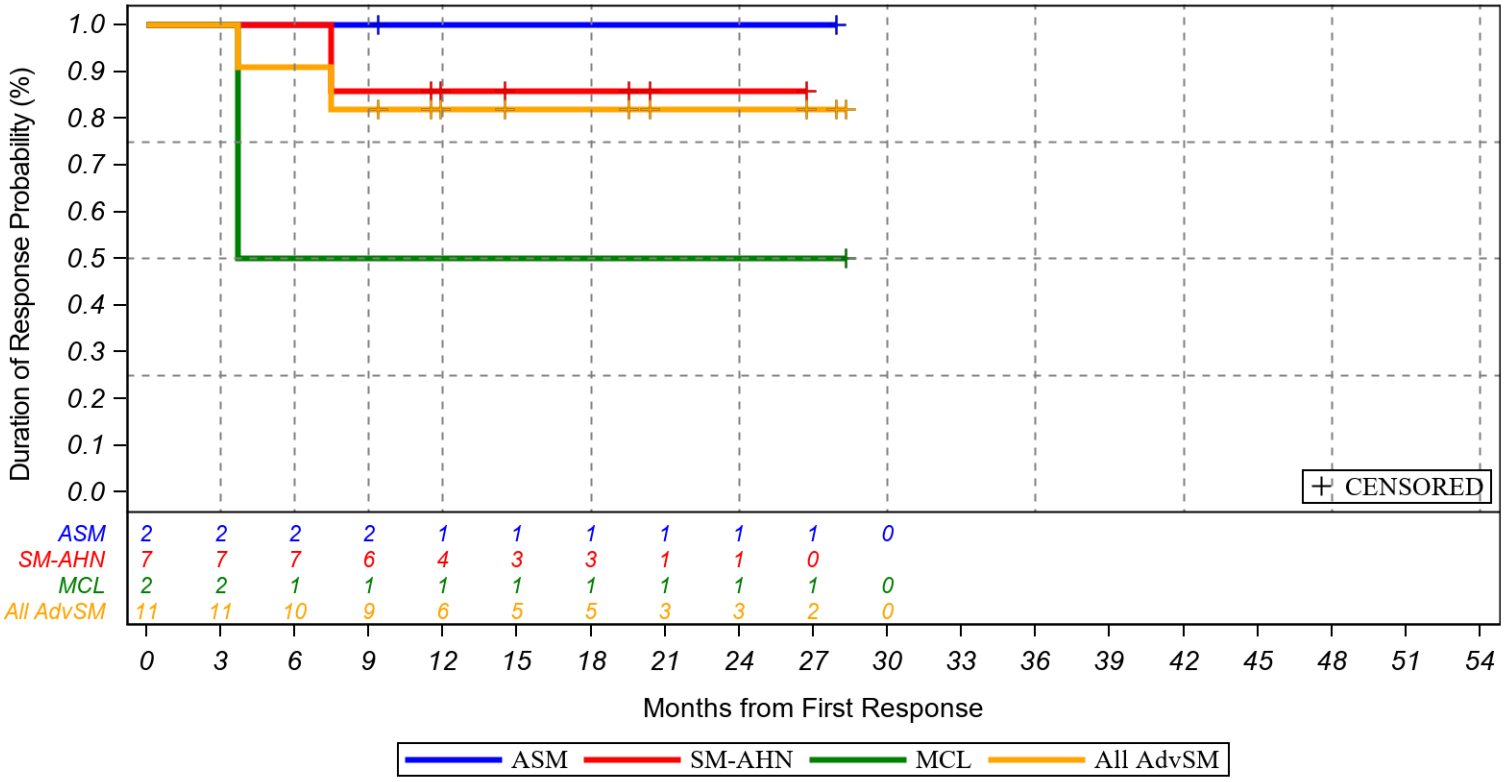

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR)

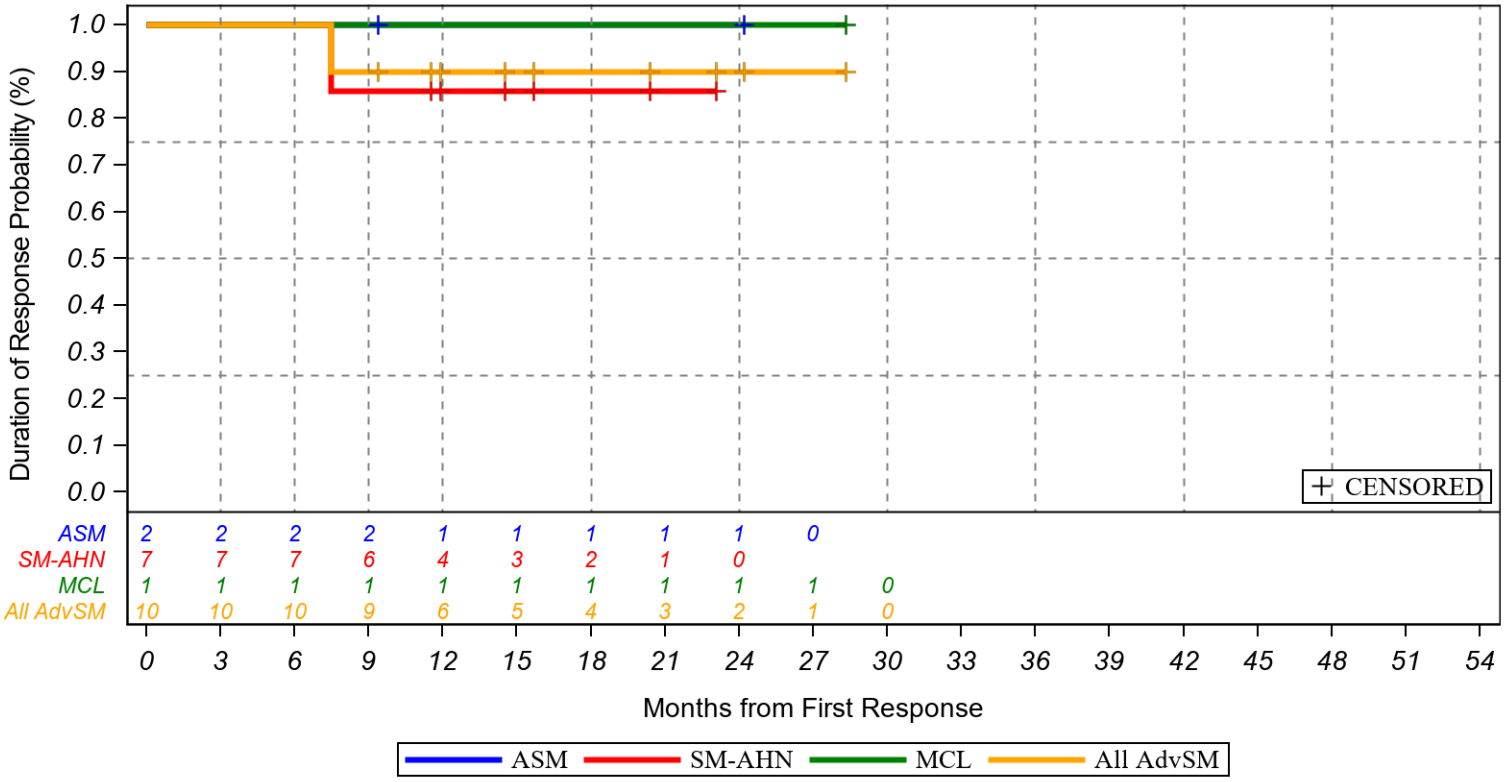

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR+CI)

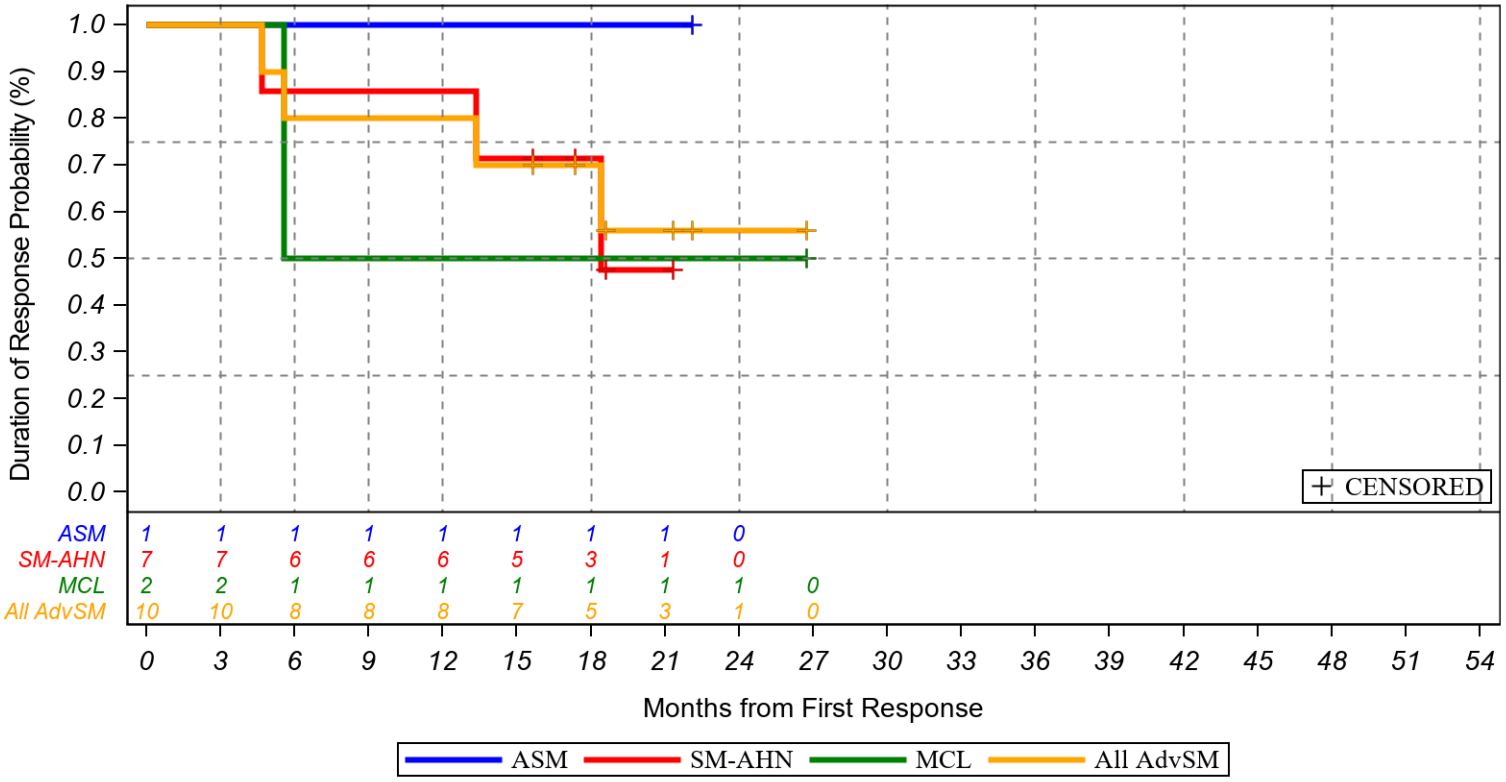

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR)

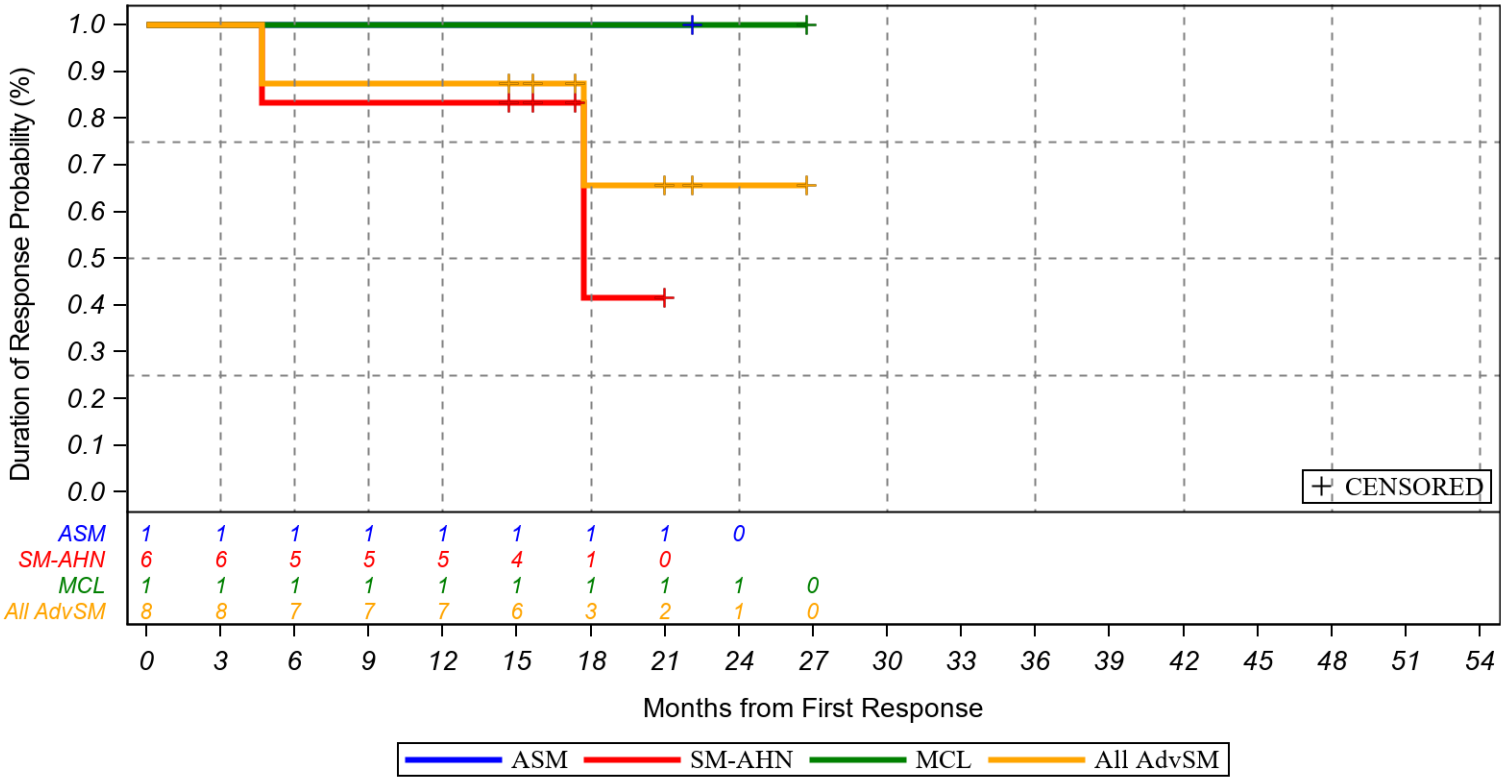

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR+CI)

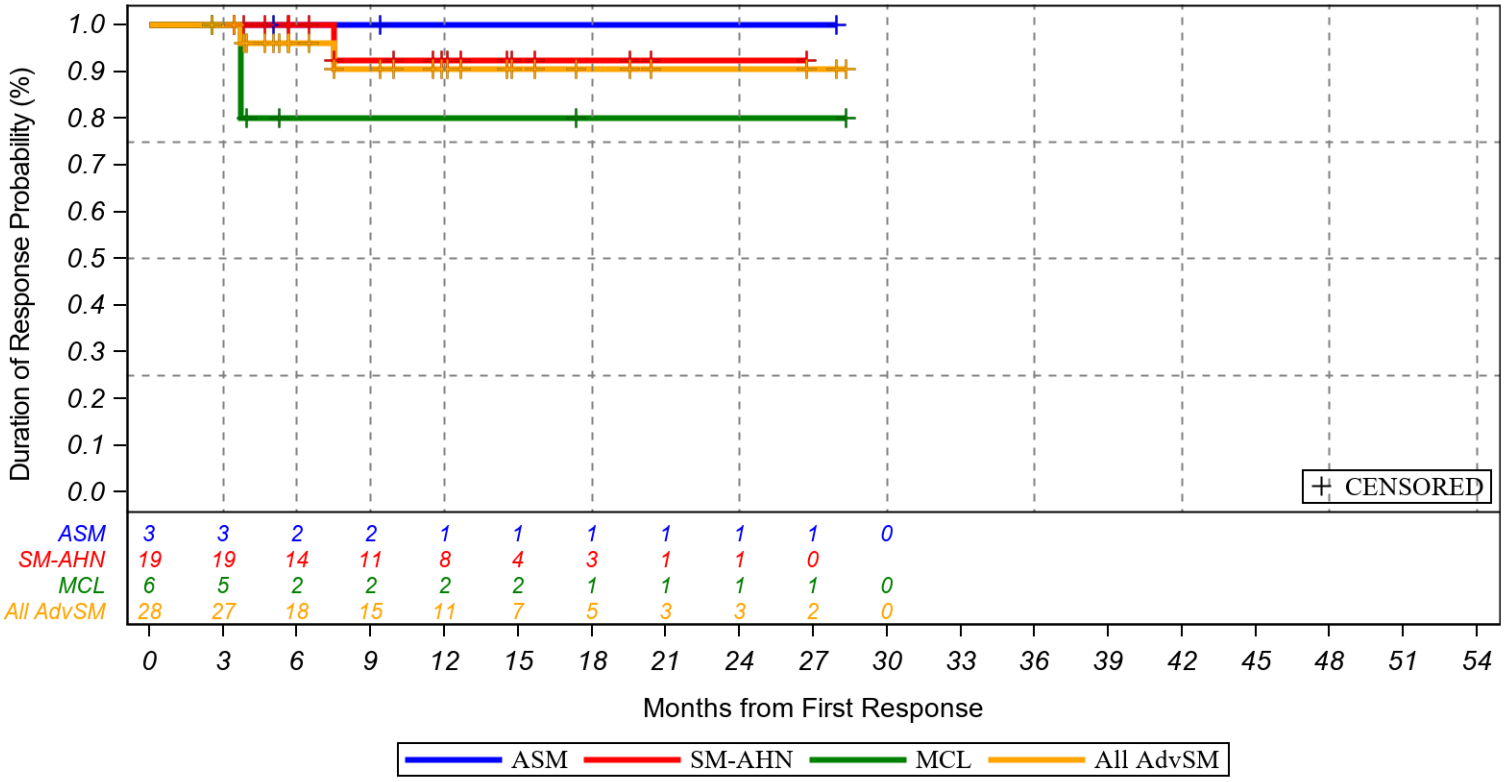

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR)

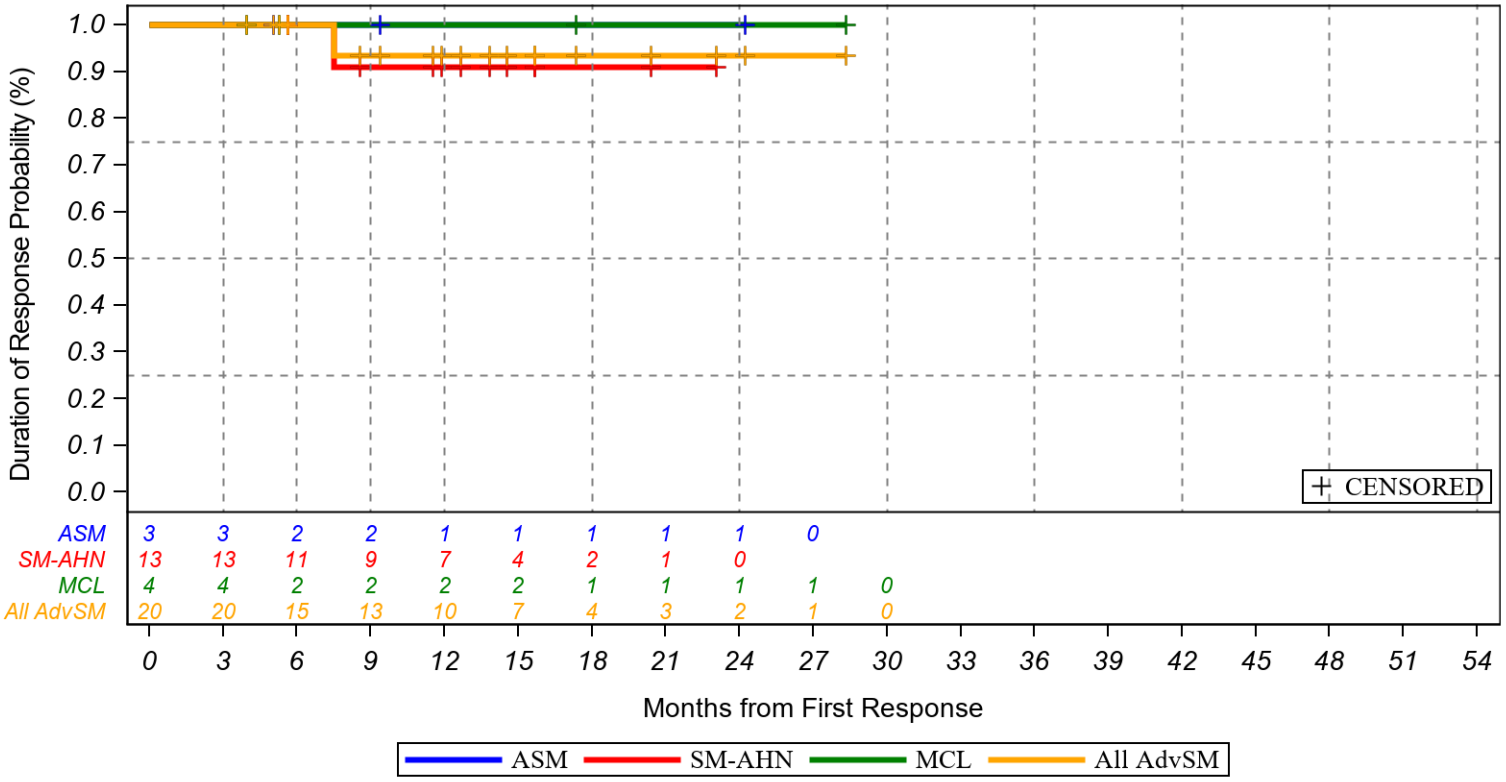

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR+CI)

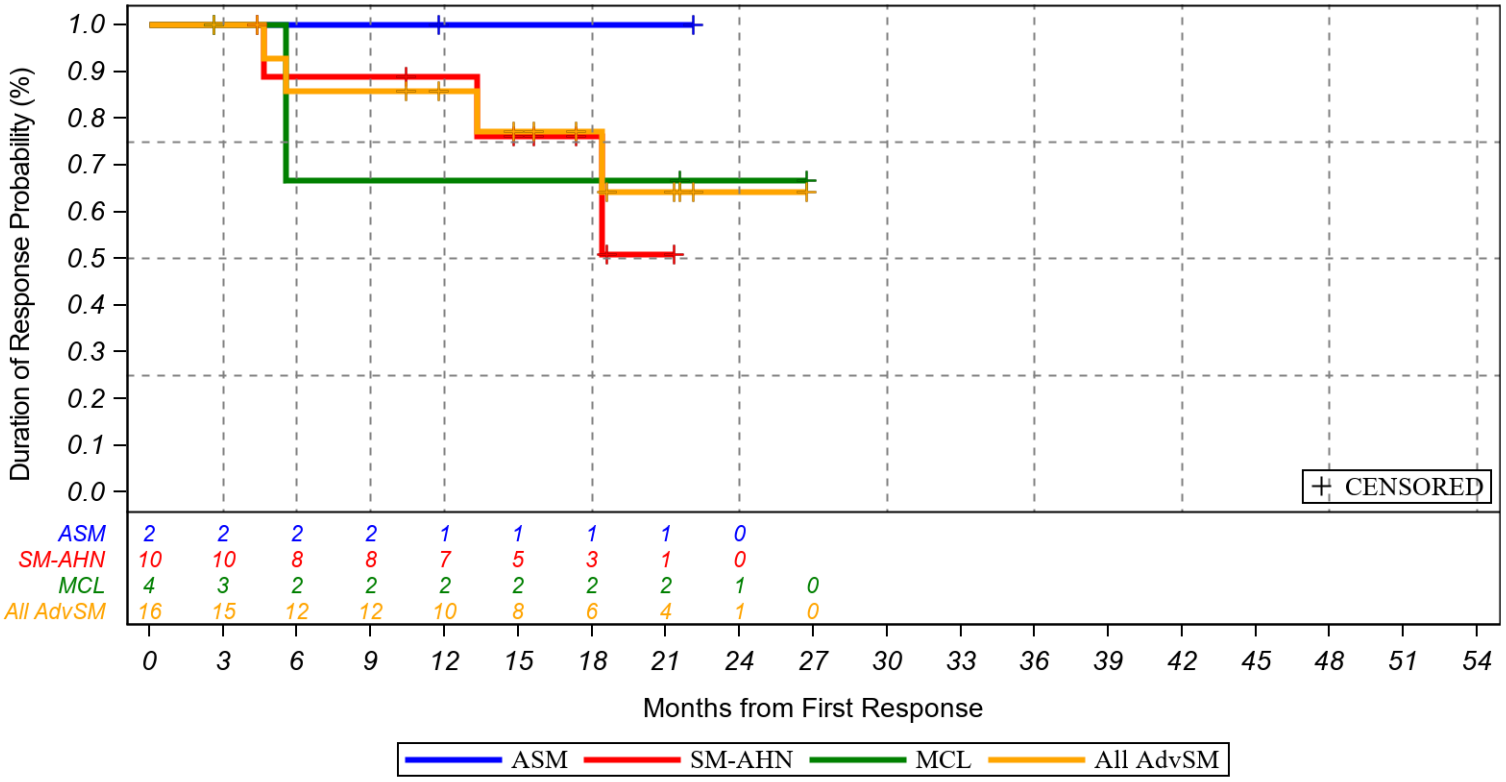

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR)

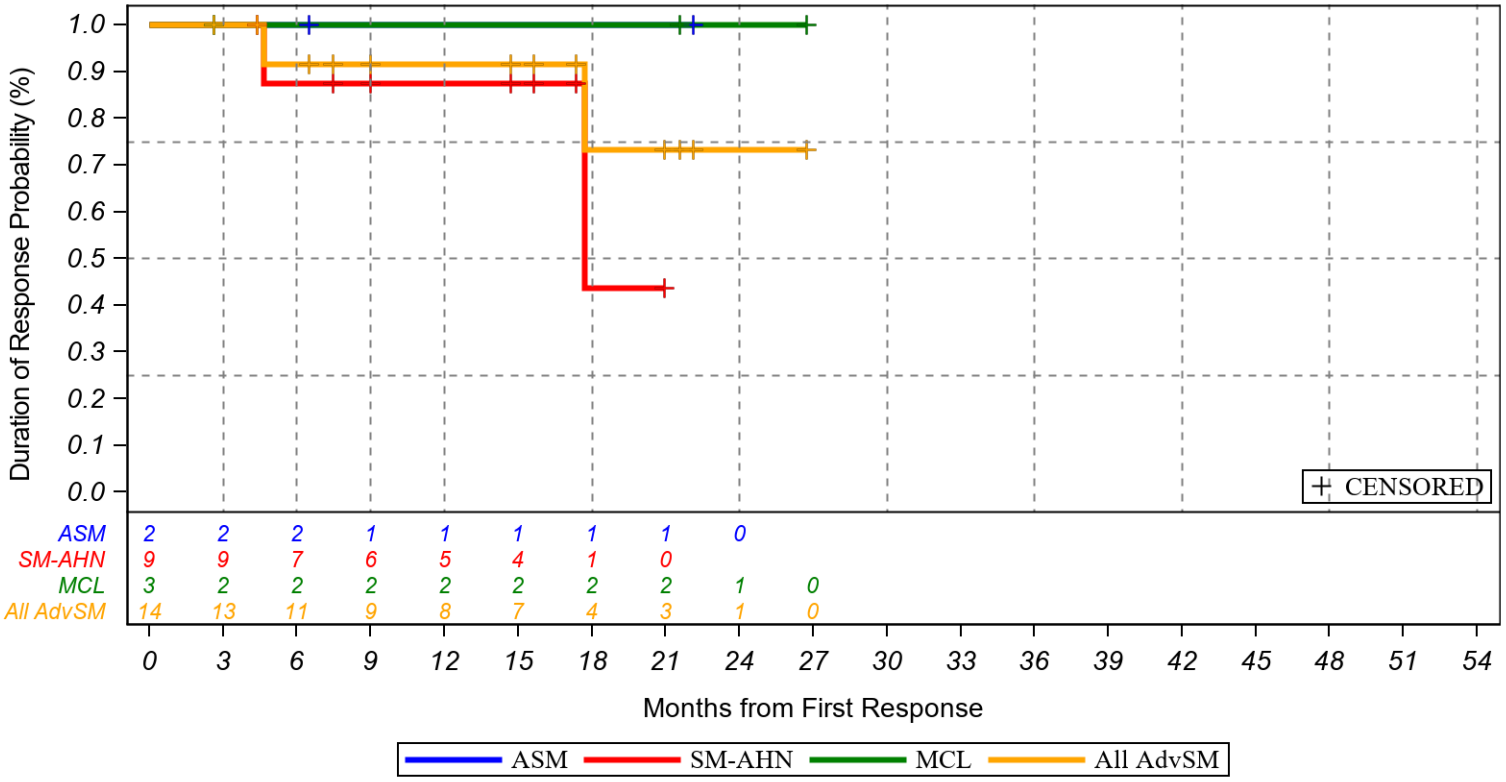

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR+CI)

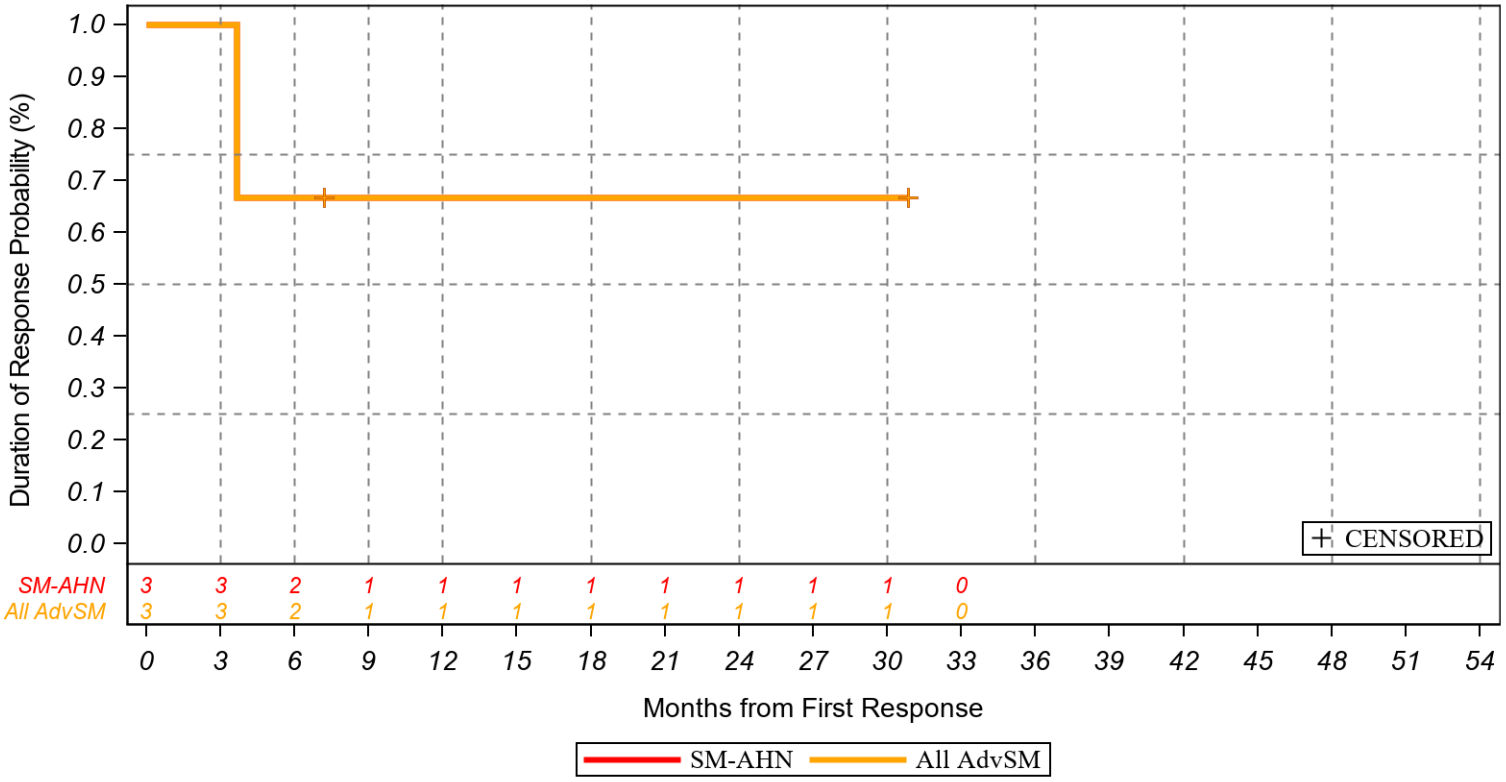

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Figure 15.2.2.7b
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RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR)

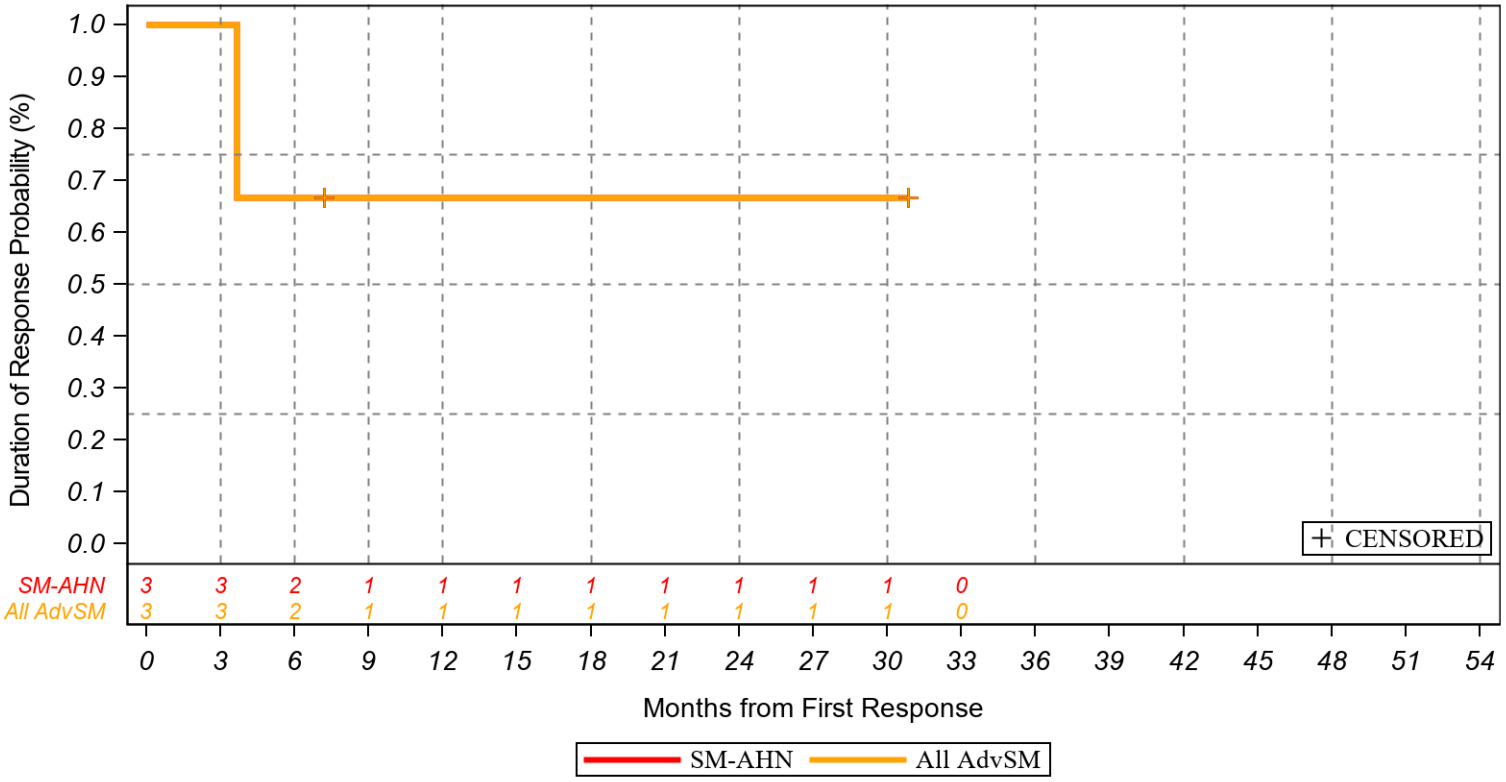

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR+CI)

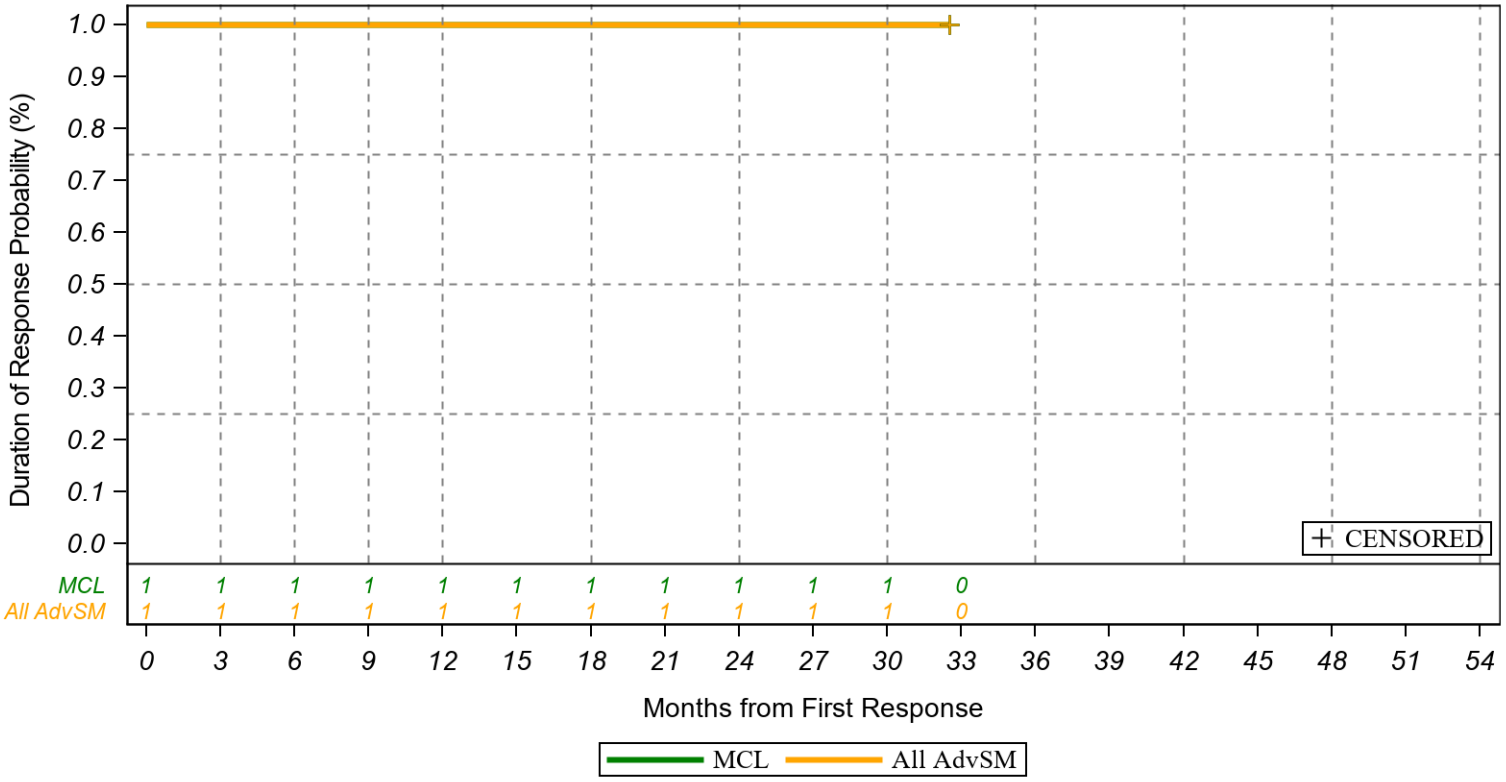

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR)

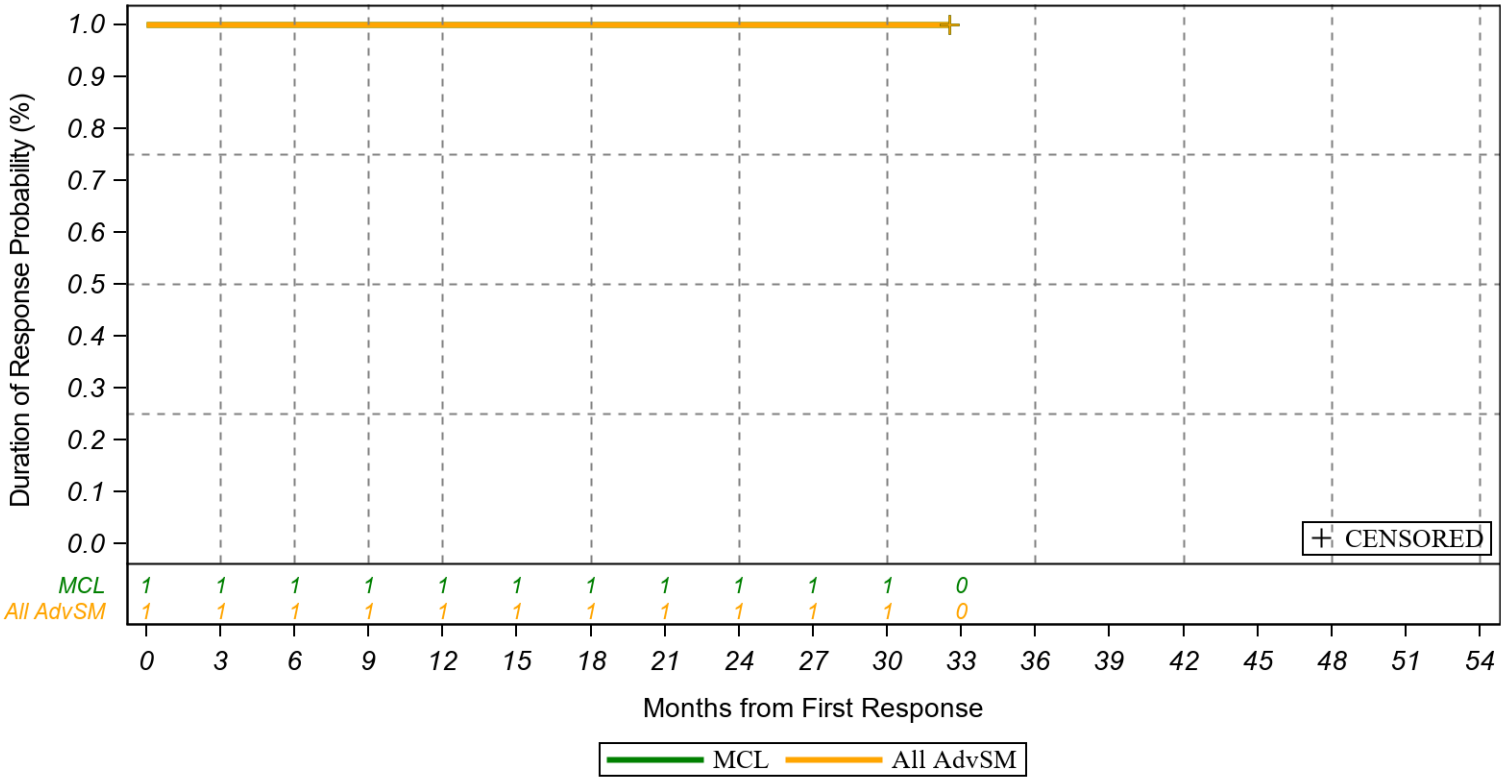

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Table 99.2.2.4.1
Summary of Adjudicated Time to Response and Time to Complete Remission by Modified IWG Criteria by Prior Antineoplastic Therapy
Study BLU-285-2101, RAC-RE Population - Responders (CR+CRh+PR+CI)
Prior Anti-Neoplastic Therapy = No

All Doses

	ASM (N=1)	SM-AHN (N=12)	MCL (N=5)	All AdvSM (N=18)
Time to Response (Months)				
n	1	12	5	18
Mean (StdDev)	1.87 (-)	2.16 (0.886)	1.87 (0.343)	2.06 (0.745)
Median	1.87	1.87	1.87	1.87
Min, Max	1.9, 1.9	1.0, 4.4	1.3, 2.2	1.0, 4.4
Time to CR+CRh (Months)				
n	1	7	2	10
Mean (StdDev)	1.87 (-)	11.74 (4.973)	3.88 (2.509)	9.18 (5.870)
Median	1.87	15.64	3.88	6.95
Min, Max	1.9, 1.9	5.5, 15.8	2.1, 5.7	1.9, 15.8
Time to CR+CRh+PR (Months)				
n	1	12	4	17
Mean (StdDev)	1.87 (-)	4.81 (4.180)	2.00 (0.210)	3.98 (3.715)
Median	1.87	3.15	1.99	2.10
Min, Max	1.9, 1.9	1.8, 15.7	1.8, 2.2	1.8, 15.7

Abbreviations: CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission.
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.2.4.1-t2cr-racre-nat.sas Date: 18:00/08DEC2020

Table 99.2.2.4.1
Summary of Adjudicated Time to Response and Time to Complete Remission by Modified IWG Criteria by Prior Antineoplastic Therapy
Study BLU-285-2101, RAC-RE Population - Responders (CR+CRh+PR+CI)
Prior Anti-Neoplastic Therapy = Yes

All Doses

	ASM (N=2)	SM-AHN (N=16)	MCL (N=4)	All AdvSM (N=22)
Time to Response (Months)				
n	2	16	4	22
Mean (StdDev)	1.05 (1.115)	4.62 (6.809)	8.02 (12.458)	4.91 (7.660)
Median	1.05	1.91	1.87	1.87
Min, Max	0.3, 1.8	0.7, 26.7	1.6, 26.7	0.3, 26.7
Time to CR+CRh (Months)				
n	1	7	1	9
Mean (StdDev)	12.52 (-)	13.65 (8.493)	37.91 (-)	16.22 (10.973)
Median	12.52	9.43	37.91	10.68
Min, Max	12.5, 12.5	9.2, 32.2	37.9, 37.9	9.2, 37.9
Time to CR+CRh+PR (Months)				
n	2	15	3	20
Mean (StdDev)	3.71 (2.602)	5.56 (6.909)	10.08 (14.407)	6.06 (7.791)
Median	3.71	1.97	1.87	1.95
Min, Max	1.9, 5.6	1.8, 26.7	1.6, 26.7	1.6, 26.7

Abbreviations: CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission.
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.2.4.1-t2cr-racre-nat.sas Date: 18:00/08DEC2020

Table 99.2.2.4.1
Summary of Adjudicated Time to Response and Time to Complete Remission by Modified IWG Criteria by Prior Antineoplastic Therapy
Study BLU-285-2101, RAC-RE Population - Responders (CR+CRh+PR+CI)
Prior Anti-Neoplastic Therapy = No

Starting Dose: < 200 mg	ASM (N=0)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=4)
Time to Response (Months)				
n	-	4	-	4
Mean (StdDev)		1.57 (0.488)		1.57 (0.488)
Median		1.64		1.64
Min, Max		1.0, 2.0		1.0, 2.0
Time to CR+CRh (Months)				
n	-	4	-	4
Mean (StdDev)		15.70 (0.089)		15.70 (0.089)
Median		15.67		15.67
Min, Max		15.6, 15.8		15.6, 15.8
Time to CR+CRh+PR (Months)				
n	-	4	-	4
Mean (StdDev)		7.66 (6.158)		7.66 (6.158)
Median		6.46		6.46
Min, Max		2.0, 15.7		2.0, 15.7

Abbreviations: CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission.
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.2.4.1-t2cr-racre-nat.sas Date: 18:00/08DEC2020

Table 99.2.2.4.1
Summary of Adjudicated Time to Response and Time to Complete Remission by Modified IWG Criteria by Prior Antineoplastic Therapy
Study BLU-285-2101, RAC-RE Population - Responders (CR+CRh+PR+CI)
Prior Anti-Neoplastic Therapy = Yes

Starting Dose: < 200 mg	ASM (N=0)	SM-AHN (N=2)	MCL (N=1)	All AdvSM (N=3)
Time to Response (Months)				
n	-	2	1	3
Mean (StdDev)		3.29 (3.206)	26.71 (-)	11.09 (13.713)
Median		3.29	26.71	5.55
Min, Max		1.0, 5.6	26.7, 26.7	1.0, 26.7
Time to CR+CRh (Months)				
n	-	2	1	3
Mean (StdDev)		12.34 (4.391)	37.91 (-)	20.86 (15.090)
Median		12.34	37.91	15.44
Min, Max		9.2, 15.4	37.9, 37.9	9.2, 37.9
Time to CR+CRh+PR (Months)				
n	-	2	1	3
Mean (StdDev)		7.39 (2.602)	26.71 (-)	13.83 (11.304)
Median		7.39	26.71	9.23
Min, Max		5.6, 9.2	26.7, 26.7	5.6, 26.7

Abbreviations: CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission.
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.2.4.1-t2cr-racre-nat.sas Date: 18:00/08DEC2020

Table 99.2.2.4.1
Summary of Adjudicated Time to Response and Time to Complete Remission by Modified IWG Criteria by Prior Antineoplastic Therapy
Study BLU-285-2101, RAC-RE Population - Responders (CR+CRh+PR+CI)
Prior Anti-Neoplastic Therapy = No

Starting Dose: < 300 mg

	ASM (N=0)	SM-AHN (N=5)	MCL (N=2)	All AdvSM (N=7)
Time to Response (Months)				
n	-	5	2	7
Mean (StdDev)		1.63 (0.444)	2.05 (0.256)	1.75 (0.430)
Median		1.87	2.05	1.87
Min, Max		1.0, 2.0	1.9, 2.2	1.0, 2.2
Time to CR+CRh (Months)				
n	-	4	0	4
Mean (StdDev)		15.70 (0.089)		15.70 (0.089)
Median		15.67		15.67
Min, Max		15.6, 15.8		15.6, 15.8
Time to CR+CRh+PR (Months)				
n	-	5	2	7
Mean (StdDev)		6.50 (5.927)	2.05 (0.256)	5.23 (5.304)
Median		3.71	2.05	2.23
Min, Max		1.9, 15.7	1.9, 2.2	1.9, 15.7

Abbreviations: CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission.
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.2.4.1-t2cr-racre-nat.sas Date: 18:00/08DEC2020

Table 99.2.2.4.1
Summary of Adjudicated Time to Response and Time to Complete Remission by Modified IWG Criteria by Prior Antineoplastic Therapy
Study BLU-285-2101, RAC-RE Population - Responders (CR+CRh+PR+CI)
Prior Anti-Neoplastic Therapy = Yes

Starting Dose: < 300 mg

	ASM (N=0)	SM-AHN (N=5)	MCL (N=2)	All AdvSM (N=7)
Time to Response (Months)				
n	-	5	2	7
Mean (StdDev)		7.41 (10.952)	14.18 (17.726)	9.34 (11.968)
Median		1.87	14.18	1.87
Min, Max		1.0, 26.7	1.6, 26.7	1.0, 26.7
Time to CR+CRh (Months)				
n	-	4	1	5
Mean (StdDev)		16.53 (10.866)	37.91 (-)	20.81 (13.415)
Median		12.34	37.91	15.44
Min, Max		9.2, 32.2	37.9, 37.9	9.2, 37.9
Time to CR+CRh+PR (Months)				
n	-	5	2	7
Mean (StdDev)		9.05 (10.354)	14.18 (17.726)	10.51 (11.406)
Median		5.55	14.18	5.55
Min, Max		1.8, 26.7	1.6, 26.7	1.6, 26.7

Abbreviations: CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission.
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.2.4.1-t2cr-racre-nat.sas Date: 18:00/08DEC2020

Table 99.2.2.4.1
Summary of Adjudicated Time to Response and Time to Complete Remission by Modified IWG Criteria by Prior Antineoplastic Therapy
Study BLU-285-2101, RAC-RE Population - Responders (CR+CRh+PR+CI)
Prior Anti-Neoplastic Therapy = No

Starting Dose: 200 mg

	ASM (N=0)	SM-AHN (N=1)	MCL (N=2)	All AdvSM (N=3)
Time to Response (Months)				
n	-	1	2	3
Mean (StdDev)		1.87 (-)	2.05 (0.256)	1.99 (0.209)
Median		1.87	2.05	1.87
Min, Max		1.9, 1.9	1.9, 2.2	1.9, 2.2
Time to CR+CRh (Months)				
n	-	0	0	0
Mean (StdDev)				
Median				
Min, Max				
Time to CR+CRh+PR (Months)				
n	-	1	2	3
Mean (StdDev)		1.87 (-)	2.05 (0.256)	1.99 (0.209)
Median		1.87	2.05	1.87
Min, Max		1.9, 1.9	1.9, 2.2	1.9, 2.2

Abbreviations: CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission.
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.2.4.1-t2cr-racre-nat.sas Date: 18:00/08DEC2020

Table 99.2.2.4.1
Summary of Adjudicated Time to Response and Time to Complete Remission by Modified IWG Criteria by Prior Antineoplastic Therapy
Study BLU-285-2101, RAC-RE Population - Responders (CR+CRh+PR+CI)
Prior Anti-Neoplastic Therapy = Yes

Starting Dose: 200 mg

	ASM (N=0)	SM-AHN (N=3)	MCL (N=1)	All AdvSM (N=4)
Time to Response (Months)				
n	-	3	1	4
Mean (StdDev)		10.15 (14.369)	1.64 (-)	8.02 (12.480)
Median		1.87	1.64	1.86
Min, Max		1.8, 26.7	1.6, 1.6	1.6, 26.7
Time to CR+CRh (Months)				
n	-	2	0	2
Mean (StdDev)		20.73 (16.262)		20.73 (16.262)
Median		20.73		20.73
Min, Max		9.2, 32.2		9.2, 32.2
Time to CR+CRh+PR (Months)				
n	-	3	1	4
Mean (StdDev)		10.15 (14.369)	1.64 (-)	8.02 (12.480)
Median		1.87	1.64	1.86
Min, Max		1.8, 26.7	1.6, 1.6	1.6, 26.7

Abbreviations: CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission.
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.2.4.1-t2cr-racre-nat.sas Date: 18:00/08DEC2020

Table 99.2.2.4.1
Summary of Adjudicated Time to Response and Time to Complete Remission by Modified IWG Criteria by Prior Antineoplastic Therapy
Study BLU-285-2101, RAC-RE Population - Responders (CR+CRh+PR+CI)
Prior Anti-Neoplastic Therapy = No

Starting Dose: 300 mg

	ASM (N=1)	SM-AHN (N=7)	MCL (N=2)	All AdvSM (N=10)
Time to Response (Months)				
n	1	7	2	10
Mean (StdDev)	1.87 (-)	2.54 (0.949)	1.56 (0.302)	2.28 (0.893)
Median	1.87	2.23	1.56	1.87
Min, Max	1.9, 1.9	1.8, 4.4	1.3, 1.8	1.3, 4.4
Time to CR+CRh (Months)				
n	1	3	1	5
Mean (StdDev)	1.87 (-)	6.45 (0.882)	5.65 (-)	5.37 (2.084)
Median	1.87	6.77	5.65	5.65
Min, Max	1.9, 1.9	5.5, 7.1	5.7, 5.7	1.9, 7.1
Time to CR+CRh+PR (Months)				
n	1	7	1	9
Mean (StdDev)	1.87 (-)	3.60 (2.132)	1.77 (-)	3.21 (2.007)
Median	1.87	2.60	1.77	1.87
Min, Max	1.9, 1.9	1.8, 7.1	1.8, 1.8	1.8, 7.1

Abbreviations: CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission.
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.2.4.1-t2cr-racre-nat.sas Date: 18:00/08DEC2020

Table 99.2.2.4.1
Summary of Adjudicated Time to Response and Time to Complete Remission by Modified IWG Criteria by Prior Antineoplastic Therapy
Study BLU-285-2101, RAC-RE Population - Responders (CR+CRh+PR+CI)
Prior Anti-Neoplastic Therapy = Yes

Starting Dose: 300 mg

	ASM (N=2)	SM-AHN (N=9)	MCL (N=2)	All AdvSM (N=13)
Time to Response (Months)				
n	2	9	2	13
Mean (StdDev)	1.05 (1.115)	3.63 (4.408)	1.87 (0.000)	2.96 (3.768)
Median	1.05	1.91	1.87	1.87
Min, Max	0.3, 1.8	0.7, 14.8	1.9, 1.9	0.3, 14.8
Time to CR+CRh (Months)				
n	1	2	0	3
Mean (StdDev)	12.52 (-)	9.38 (0.070)		10.43 (1.812)
Median	12.52	9.38		9.43
Min, Max	12.5, 12.5	9.3, 9.4		9.3, 12.5
Time to CR+CRh+PR (Months)				
n	2	8	1	11
Mean (StdDev)	3.71 (2.602)	4.25 (4.489)	1.87 (-)	3.93 (3.911)
Median	3.71	1.95	1.87	1.94
Min, Max	1.9, 5.6	1.9, 14.8	1.9, 1.9	1.9, 14.8

Abbreviations: CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission.
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.2.4.1-t2cr-racre-nat.sas Date: 18:00/08DEC2020

Table 99.2.2.4.1
Summary of Adjudicated Time to Response and Time to Complete Remission by Modified IWG Criteria by Prior Antineoplastic Therapy
Study BLU-285-2101, RAC-RE Population - Responders (CR+CRh+PR+CI)
Prior Anti-Neoplastic Therapy = No

Starting Dose: 200 mg and 300 mg

	ASM (N=1)	SM-AHN (N=8)	MCL (N=4)	All AdvSM (N=13)
Time to Response (Months)				
n	1	8	4	13
Mean (StdDev)	1.87 (-)	2.46 (0.910)	1.81 (0.365)	2.21 (0.788)
Median	1.87	2.05	1.82	1.87
Min, Max	1.9, 1.9	1.8, 4.4	1.3, 2.2	1.3, 4.4
Time to CR+CRh (Months)				
n	1	3	1	5
Mean (StdDev)	1.87 (-)	6.45 (0.882)	5.65 (-)	5.37 (2.084)
Median	1.87	6.77	5.65	5.65
Min, Max	1.9, 1.9	5.5, 7.1	5.7, 5.7	1.9, 7.1
Time to CR+CRh+PR (Months)				
n	1	8	3	12
Mean (StdDev)	1.87 (-)	3.39 (2.067)	1.96 (0.242)	2.90 (1.800)
Median	1.87	2.23	1.87	1.87
Min, Max	1.9, 1.9	1.8, 7.1	1.8, 2.2	1.8, 7.1

Abbreviations: CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission.
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.2.4.1-t2cr-racre-nat.sas Date: 18:00/08DEC2020

Table 99.2.2.4.1
Summary of Adjudicated Time to Response and Time to Complete Remission by Modified IWG Criteria by Prior Antineoplastic Therapy
Study BLU-285-2101, RAC-RE Population - Responders (CR+CRh+PR+CI)
Prior Anti-Neoplastic Therapy = Yes

Starting Dose: 200 mg and 300 mg	ASM (N=2)	SM-AHN (N=12)	MCL (N=3)	All AdvSM (N=17)
Time to Response (Months)				
n	2	12	3	17
Mean (StdDev)	1.05 (1.115)	5.26 (7.770)	1.80 (0.133)	4.15 (6.689)
Median	1.05	1.91	1.87	1.87
Min, Max	0.3, 1.8	0.7, 26.7	1.6, 1.9	0.3, 26.7
Time to CR+CRh (Months)				
n	1	4	0	5
Mean (StdDev)	12.52 (-)	15.06 (11.450)		14.55 (9.981)
Median	12.52	9.38		9.43
Min, Max	12.5, 12.5	9.2, 32.2		9.2, 32.2
Time to CR+CRh+PR (Months)				
n	2	11	2	15
Mean (StdDev)	3.71 (2.602)	5.86 (7.938)	1.76 (0.163)	5.02 (6.914)
Median	3.71	1.94	1.76	1.91
Min, Max	1.9, 5.6	1.8, 26.7	1.6, 1.9	1.6, 26.7

Abbreviations: CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission.
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.2.4.1-t2cr-racre-nat.sas Date: 18:00/08DEC2020

Table 99.2.2.4.1
Summary of Adjudicated Time to Response and Time to Complete Remission by Modified IWG Criteria by Prior Antineoplastic Therapy
Study BLU-285-2101, RAC-RE Population - Responders (CR+CRh+PR+CI)
Prior Anti-Neoplastic Therapy = No

Starting Dose: 400 mg	ASM (N=0)	SM-AHN (N=0)	MCL (N=1)	All AdvSM (N=1)
Time to Response (Months)				
n	-	-	1	1
Mean (StdDev)			2.10 (-)	2.10 (-)
Median			2.10	2.10
Min, Max			2.1, 2.1	2.1, 2.1
Time to CR+CRh (Months)				
n	-	-	1	1
Mean (StdDev)			2.10 (-)	2.10 (-)
Median			2.10	2.10
Min, Max			2.1, 2.1	2.1, 2.1
Time to CR+CRh+PR (Months)				
n	-	-	1	1
Mean (StdDev)			2.10 (-)	2.10 (-)
Median			2.10	2.10
Min, Max			2.1, 2.1	2.1, 2.1

Abbreviations: CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission.
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.2.4.1-t2cr-racre-nat.sas Date: 18:00/08DEC2020

Table 99.2.2.4.1
Summary of Adjudicated Time to Response and Time to Complete Remission by Modified IWG Criteria by Prior Antineoplastic Therapy
Study BLU-285-2101, RAC-RE Population - Responders (CR+CRh+PR+CI)
Prior Anti-Neoplastic Therapy = Yes

Starting Dose: 400 mg	ASM (N=0)	SM-AHN (N=2)	MCL (N=0)	All AdvSM (N=2)
Time to Response (Months)				
n	-	2	-	2
Mean (StdDev)		2.12 (0.348)		2.12 (0.348)
Median		2.12		2.12
Min, Max		1.9, 2.4		1.9, 2.4
Time to CR+CRh (Months)				
n	-	1	-	1
Mean (StdDev)		10.68 (-)		10.68 (-)
Median		10.68		10.68
Min, Max		10.7, 10.7		10.7, 10.7
Time to CR+CRh+PR (Months)				
n	-	2	-	2
Mean (StdDev)		2.12 (0.348)		2.12 (0.348)
Median		2.12		2.12
Min, Max		1.9, 2.4		1.9, 2.4

Abbreviations: CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission.
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.2.4.1-t2cr-racre-nat.sas Date: 18:00/08DEC2020

Table 99.2.2.4.1
Summary of Adjudicated Time to Response and Time to Complete Remission by Modified IWG Criteria by Prior Antineoplastic Therapy
Study BLU-285-2202, RAC-RE Population - Responders (CR+CRh+PR+CI)
Prior Anti-Neoplastic Therapy = No

All Doses

	ASM (N=1)	SM-AHN (N=6)	MCL (N=0)	All AdvSM (N=7)
Time to Response (Months)				
n	1	6	-	7
Mean (StdDev)	0.26 (-)	2.35 (1.693)		2.06 (1.736)
Median	0.26	1.92		1.87
Min, Max	0.3, 0.3	0.5, 5.6		0.3, 5.6
Time to CR+CRh (Months)				
n	0	3	-	3
Mean (StdDev)		5.73 (0.303)		5.73 (0.303)
Median		5.55		5.55
Min, Max		5.6, 6.1		5.6, 6.1
Time to CR+CRh+PR (Months)				
n	1	5	-	6
Mean (StdDev)	5.55 (-)	2.72 (1.599)		3.19 (1.839)
Median	5.55	1.94		2.17
Min, Max	5.6, 5.6	1.8, 5.6		1.8, 5.6

Abbreviations: CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission.
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.2.4.1-t2cr-racre-nat.sas Date: 18:00/08DEC2020

Table 99.2.2.4.1
Summary of Adjudicated Time to Response and Time to Complete Remission by Modified IWG Criteria by Prior Antineoplastic Therapy
Study BLU-285-2202, RAC-RE Population - Responders (CR+CRh+PR+CI)
Prior Anti-Neoplastic Therapy = Yes

All Doses

	ASM (N=1)	SM-AHN (N=15)	MCL (N=1)	All AdvSM (N=17)
Time to Response (Months)				
n	1	15	1	17
Mean (StdDev)	3.71 (-)	3.21 (2.232)	12.19 (-)	3.77 (3.014)
Median	3.71	2.10	12.19	2.56
Min, Max	3.7, 3.7	0.5, 9.3	12.2, 12.2	0.5, 12.2
Time to CR+CRh (Months)				
n	1	2	0	3
Mean (StdDev)	3.71 (-)	3.71 (2.648)		3.71 (1.873)
Median	3.71	3.71		3.71
Min, Max	3.7, 3.7	1.8, 5.6		1.8, 5.6
Time to CR+CRh+PR (Months)				
n	1	8	1	10
Mean (StdDev)	3.71 (-)	3.25 (2.754)	12.19 (-)	4.19 (3.718)
Median	3.71	1.92	12.19	1.94
Min, Max	3.7, 3.7	1.7, 9.3	12.2, 12.2	1.7, 12.2

Abbreviations: CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission.
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.2.4.1-t2cr-racre-nat.sas Date: 18:00/08DEC2020

Table 99.2.2.4.1
Summary of Adjudicated Time to Response and Time to Complete Remission by Modified IWG Criteria by Prior Antineoplastic Therapy
Study BLU-285-2202, RAC-RE Population - Responders (CR+CRh+PR+CI)
Prior Anti-Neoplastic Therapy = No

Starting Dose: 200 mg

	ASM (N=1)	SM-AHN (N=6)	MCL (N=0)	All AdvSM (N=7)
Time to Response (Months)				
n	1	6	-	7
Mean (StdDev)	0.26 (-)	2.35 (1.693)		2.06 (1.736)
Median	0.26	1.92		1.87
Min, Max	0.3, 0.3	0.5, 5.6		0.3, 5.6
Time to CR+CRh (Months)				
n	0	3	-	3
Mean (StdDev)		5.73 (0.303)		5.73 (0.303)
Median		5.55		5.55
Min, Max		5.6, 6.1		5.6, 6.1
Time to CR+CRh+PR (Months)				
n	1	5	-	6
Mean (StdDev)	5.55 (-)	2.72 (1.599)		3.19 (1.839)
Median	5.55	1.94		2.17
Min, Max	5.6, 5.6	1.8, 5.6		1.8, 5.6

Abbreviations: CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission.
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.2.4.1-t2cr-racre-nat.sas Date: 18:00/08DEC2020

Table 99.2.2.4.1
Summary of Adjudicated Time to Response and Time to Complete Remission by Modified IWG Criteria by Prior Antineoplastic Therapy
Study BLU-285-2202, RAC-RE Population - Responders (CR+CRh+PR+CI)
Prior Anti-Neoplastic Therapy = Yes

Starting Dose: 200 mg

	ASM (N=1)	SM-AHN (N=14)	MCL (N=1)	All AdvSM (N=16)
Time to Response (Months)				
n	1	14	1	16
Mean (StdDev)	3.71 (-)	3.02 (2.192)	12.19 (-)	3.64 (3.064)
Median	3.71	2.02	12.19	2.33
Min, Max	3.7, 3.7	0.5, 9.3	12.2, 12.2	0.5, 12.2
Time to CR+CRh (Months)				
n	1	2	0	3
Mean (StdDev)	3.71 (-)	3.71 (2.648)		3.71 (1.873)
Median	3.71	3.71		3.71
Min, Max	3.7, 3.7	1.8, 5.6		1.8, 5.6
Time to CR+CRh+PR (Months)				
n	1	8	1	10
Mean (StdDev)	3.71 (-)	3.25 (2.754)	12.19 (-)	4.19 (3.718)
Median	3.71	1.92	12.19	1.94
Min, Max	3.7, 3.7	1.7, 9.3	12.2, 12.2	1.7, 12.2

Abbreviations: CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission.
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.2.4.1-t2cr-racre-nat.sas Date: 18:00/08DEC2020

Table 99.2.2.4.1
Summary of Adjudicated Time to Response and Time to Complete Remission by Modified IWG Criteria by Prior Antineoplastic Therapy
Studies: BLU-285-2101 and BLU-285-2202, RAC-RE Population - Responders (CR+CRh+PR+CI)
Prior Anti-Neoplastic Therapy = No

All Doses

	ASM (N=2)	SM-AHN (N=18)	MCL (N=5)	All AdvSM (N=25)
Time to Response (Months)				
n	2	18	5	25
Mean (StdDev)	1.07 (1.138)	2.23 (1.166)	1.87 (0.343)	2.06 (1.071)
Median	1.07	1.87	1.87	1.87
Min, Max	0.3, 1.9	0.5, 5.6	1.3, 2.2	0.3, 5.6
Time to CR+CRh (Months)				
n	1	10	2	13
Mean (StdDev)	1.87 (-)	9.94 (4.994)	3.88 (2.509)	8.38 (5.306)
Median	1.87	6.95	3.88	6.08
Min, Max	1.9, 1.9	5.5, 15.8	2.1, 5.7	1.9, 15.8
Time to CR+CRh+PR (Months)				
n	2	17	4	23
Mean (StdDev)	3.71 (2.602)	4.20 (3.690)	2.00 (0.210)	3.77 (3.306)
Median	3.71	2.40	1.99	2.10
Min, Max	1.9, 5.6	1.8, 15.7	1.8, 2.2	1.8, 15.7

Abbreviations: CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission.
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.2.4.1-t2cr-racre-nat.sas Date: 18:00/08DEC2020

Table 99.2.2.4.1
Summary of Adjudicated Time to Response and Time to Complete Remission by Modified IWG Criteria by Prior Antineoplastic Therapy
Studies: BLU-285-2101 and BLU-285-2202, RAC-RE Population - Responders (CR+CRh+PR+CI)
Prior Anti-Neoplastic Therapy = Yes

All Doses

	ASM (N=3)	SM-AHN (N=31)	MCL (N=5)	All AdvSM (N=39)
Time to Response (Months)				
n	3	31	5	39
Mean (StdDev)	1.94 (1.727)	3.94 (5.101)	8.86 (10.948)	4.42 (6.048)
Median	1.84	1.94	1.87	1.94
Min, Max	0.3, 3.7	0.5, 26.7	1.6, 26.7	0.3, 26.7
Time to CR+CRh (Months)				
n	2	9	1	12
Mean (StdDev)	8.11 (6.226)	11.44 (8.613)	37.91 (-)	13.10 (10.964)
Median	8.11	9.33	37.91	9.38
Min, Max	3.7, 12.5	1.8, 32.2	37.9, 37.9	1.8, 37.9
Time to CR+CRh+PR (Months)				
n	3	23	4	30
Mean (StdDev)	3.71 (1.840)	4.76 (5.836)	10.60 (11.811)	5.43 (6.698)
Median	3.71	1.94	7.03	1.94
Min, Max	1.9, 5.6	1.7, 26.7	1.6, 26.7	1.6, 26.7

Abbreviations: CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission.
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.2.4.1-t2cr-racre-nat.sas Date: 18:00/08DEC2020

Table 99.2.2.4.1
Summary of Adjudicated Time to Response and Time to Complete Remission by Modified IWG Criteria by Prior Antineoplastic Therapy
Studies: BLU-285-2101 and BLU-285-2202, RAC-RE Population - Responders (CR+CRh+PR+CI)
Prior Anti-Neoplastic Therapy = No

Starting Dose: < 200 mg

	ASM (N=0)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=4)
Time to Response (Months)				
n	-	4	-	4
Mean (StdDev)		1.57 (0.488)		1.57 (0.488)
Median		1.64		1.64
Min, Max		1.0, 2.0		1.0, 2.0
Time to CR+CRh (Months)				
n	-	4	-	4
Mean (StdDev)		15.70 (0.089)		15.70 (0.089)
Median		15.67		15.67
Min, Max		15.6, 15.8		15.6, 15.8
Time to CR+CRh+PR (Months)				
n	-	4	-	4
Mean (StdDev)		7.66 (6.158)		7.66 (6.158)
Median		6.46		6.46
Min, Max		2.0, 15.7		2.0, 15.7

Abbreviations: CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission.
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.2.4.1-t2cr-racre-nat.sas Date: 18:00/08DEC2020

Table 99.2.2.4.1
Summary of Adjudicated Time to Response and Time to Complete Remission by Modified IWG Criteria by Prior Antineoplastic Therapy
Studies: BLU-285-2101 and BLU-285-2202, RAC-RE Population - Responders (CR+CRh+PR+CI)
Prior Anti-Neoplastic Therapy = Yes

Starting Dose: < 200 mg	ASM (N=0)	SM-AHN (N=3)	MCL (N=1)	All AdvSM (N=4)
Time to Response (Months)				
n	-	3	1	4
Mean (StdDev)		4.13 (2.697)	26.71 (-)	9.77 (11.504)
Median		5.55	26.71	5.68
Min, Max		1.0, 5.8	26.7, 26.7	1.0, 26.7
Time to CR+CRh (Months)				
n	-	2	1	3
Mean (StdDev)		12.34 (4.391)	37.91 (-)	20.86 (15.090)
Median		12.34	37.91	15.44
Min, Max		9.2, 15.4	37.9, 37.9	9.2, 37.9
Time to CR+CRh+PR (Months)				
n	-	2	1	3
Mean (StdDev)		7.39 (2.602)	26.71 (-)	13.83 (11.304)
Median		7.39	26.71	9.23
Min, Max		5.6, 9.2	26.7, 26.7	5.6, 26.7

Abbreviations: CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission.
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.2.4.1-t2cr-racre-nat.sas Date: 18:00/08DEC2020

Table 99.2.2.4.1
Summary of Adjudicated Time to Response and Time to Complete Remission by Modified IWG Criteria by Prior Antineoplastic Therapy
Studies: BLU-285-2101 and BLU-285-2202, RAC-RE Population - Responders (CR+CRh+PR+CI)
Prior Anti-Neoplastic Therapy = No

Starting Dose: < 300 mg

	ASM (N=1)	SM-AHN (N=11)	MCL (N=2)	All AdvSM (N=14)
Time to Response (Months)				
n	1	11	2	14
Mean (StdDev)	0.26 (-)	2.03 (1.287)	2.05 (0.256)	1.90 (1.226)
Median	0.26	1.87	2.05	1.87
Min, Max	0.3, 0.3	0.5, 5.6	1.9, 2.2	0.3, 5.6
Time to CR+CRh (Months)				
n	0	7	0	7
Mean (StdDev)		11.43 (5.336)		11.43 (5.336)
Median		15.64		15.64
Min, Max		5.6, 15.8		5.6, 15.8
Time to CR+CRh+PR (Months)				
n	1	10	2	13
Mean (StdDev)	5.55 (-)	4.61 (4.551)	2.05 (0.256)	4.29 (4.073)
Median	5.55	2.22	2.05	2.23
Min, Max	5.6, 5.6	1.8, 15.7	1.9, 2.2	1.8, 15.7

Abbreviations: CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission.
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.2.4.1-t2cr-racre-nat.sas Date: 18:00/08DEC2020

Table 99.2.2.4.1
Summary of Adjudicated Time to Response and Time to Complete Remission by Modified IWG Criteria by Prior Antineoplastic Therapy
Studies: BLU-285-2101 and BLU-285-2202, RAC-RE Population - Responders (CR+CRh+PR+CI)
Prior Anti-Neoplastic Therapy = Yes

Starting Dose: < 300 mg

	ASM (N=1)	SM-AHN (N=20)	MCL (N=3)	All AdvSM (N=24)
Time to Response (Months)				
n	1	20	3	24
Mean (StdDev)	3.71 (-)	4.26 (5.692)	13.51 (12.586)	5.39 (7.098)
Median	3.71	2.02	12.19	2.33
Min, Max	3.7, 3.7	0.5, 26.7	1.6, 26.7	0.5, 26.7
Time to CR+CRh (Months)				
n	1	6	1	8
Mean (StdDev)	3.71 (-)	12.26 (10.774)	37.91 (-)	14.40 (13.496)
Median	3.71	9.23	37.91	9.23
Min, Max	3.7, 3.7	1.8, 32.2	37.9, 37.9	1.8, 37.9
Time to CR+CRh+PR (Months)				
n	1	13	3	17
Mean (StdDev)	3.71 (-)	5.48 (6.985)	13.51 (12.586)	6.79 (8.176)
Median	3.71	1.94	12.19	1.94
Min, Max	3.7, 3.7	1.7, 26.7	1.6, 26.7	1.6, 26.7

Abbreviations: CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission.
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.2.4.1-t2cr-racre-nat.sas Date: 18:00/08DEC2020

Table 99.2.2.4.1
Summary of Adjudicated Time to Response and Time to Complete Remission by Modified IWG Criteria by Prior Antineoplastic Therapy
Studies: BLU-285-2101 and BLU-285-2202, RAC-RE Population - Responders (CR+CRh+PR+CI)
Prior Anti-Neoplastic Therapy = No

Starting Dose: 200 mg

	ASM (N=1)	SM-AHN (N=7)	MCL (N=2)	All AdvSM (N=10)
Time to Response (Months)				
n	1	7	2	10
Mean (StdDev)	0.26 (-)	2.29 (1.557)	2.05 (0.256)	2.04 (1.421)
Median	0.26	1.87	2.05	1.87
Min, Max	0.3, 0.3	0.5, 5.6	1.9, 2.2	0.3, 5.6
Time to CR+CRh (Months)				
n	0	3	0	3
Mean (StdDev)		5.73 (0.303)		5.73 (0.303)
Median		5.55		5.55
Min, Max		5.6, 6.1		5.6, 6.1
Time to CR+CRh+PR (Months)				
n	1	6	2	9
Mean (StdDev)	5.55 (-)	2.58 (1.472)	2.05 (0.256)	2.79 (1.576)
Median	5.55	1.91	2.05	1.94
Min, Max	5.6, 5.6	1.8, 5.6	1.9, 2.2	1.8, 5.6

Abbreviations: CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission.
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.2.4.1-t2cr-racre-nat.sas Date: 18:00/08DEC2020

Table 99.2.2.4.1
Summary of Adjudicated Time to Response and Time to Complete Remission by Modified IWG Criteria by Prior Antineoplastic Therapy
Studies: BLU-285-2101 and BLU-285-2202, RAC-RE Population - Responders (CR+CRh+PR+CI)
Prior Anti-Neoplastic Therapy = Yes

Starting Dose: 200 mg

	ASM (N=1)	SM-AHN (N=17)	MCL (N=2)	All AdvSM (N=20)
Time to Response (Months)				
n	1	17	2	20
Mean (StdDev)	3.71 (-)	4.28 (6.128)	6.92 (7.457)	4.52 (5.936)
Median	3.71	1.94	6.92	2.02
Min, Max	3.7, 3.7	0.5, 26.7	1.6, 12.2	0.5, 26.7
Time to CR+CRh (Months)				
n	1	4	0	5
Mean (StdDev)	3.71 (-)	12.22 (13.676)		10.52 (12.440)
Median	3.71	7.41		5.59
Min, Max	3.7, 3.7	1.8, 32.2		1.8, 32.2
Time to CR+CRh+PR (Months)				
n	1	11	2	14
Mean (StdDev)	3.71 (-)	5.13 (7.550)	6.92 (7.457)	5.28 (6.982)
Median	3.71	1.91	6.92	1.92
Min, Max	3.7, 3.7	1.7, 26.7	1.6, 12.2	1.6, 26.7

Abbreviations: CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission.
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis.
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Table 99.2.2.4.1
Summary of Adjudicated Time to Response and Time to Complete Remission by Modified IWG Criteria by Prior Antineoplastic Therapy
Studies: BLU-285-2101 and BLU-285-2202, RAC-RE Population - Responders (CR+CRh+PR+CI)
Prior Anti-Neoplastic Therapy = No

Starting Dose: 300 mg

	ASM (N=1)	SM-AHN (N=7)	MCL (N=2)	All AdvSM (N=10)
Time to Response (Months)				
n	1	7	2	10
Mean (StdDev)	1.87 (-)	2.54 (0.949)	1.56 (0.302)	2.28 (0.893)
Median	1.87	2.23	1.56	1.87
Min, Max	1.9, 1.9	1.8, 4.4	1.3, 1.8	1.3, 4.4
Time to CR+CRh (Months)				
n	1	3	1	5
Mean (StdDev)	1.87 (-)	6.45 (0.882)	5.65 (-)	5.37 (2.084)
Median	1.87	6.77	5.65	5.65
Min, Max	1.9, 1.9	5.5, 7.1	5.7, 5.7	1.9, 7.1
Time to CR+CRh+PR (Months)				
n	1	7	1	9
Mean (StdDev)	1.87 (-)	3.60 (2.132)	1.77 (-)	3.21 (2.007)
Median	1.87	2.60	1.77	1.87
Min, Max	1.9, 1.9	1.8, 7.1	1.8, 1.8	1.8, 7.1

Abbreviations: CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission.
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.2.4.1-t2cr-racre-nat.sas Date: 18:00/08DEC2020

Table 99.2.2.4.1
Summary of Adjudicated Time to Response and Time to Complete Remission by Modified IWG Criteria by Prior Antineoplastic Therapy
Studies: BLU-285-2101 and BLU-285-2202, RAC-RE Population - Responders (CR+CRh+PR+CI)
Prior Anti-Neoplastic Therapy = Yes

Starting Dose: 300 mg

	ASM (N=2)	SM-AHN (N=9)	MCL (N=2)	All AdvSM (N=13)
Time to Response (Months)				
n	2	9	2	13
Mean (StdDev)	1.05 (1.115)	3.63 (4.408)	1.87 (0.000)	2.96 (3.768)
Median	1.05	1.91	1.87	1.87
Min, Max	0.3, 1.8	0.7, 14.8	1.9, 1.9	0.3, 14.8
Time to CR+CRh (Months)				
n	1	2	0	3
Mean (StdDev)	12.52 (-)	9.38 (0.070)		10.43 (1.812)
Median	12.52	9.38		9.43
Min, Max	12.5, 12.5	9.3, 9.4		9.3, 12.5
Time to CR+CRh+PR (Months)				
n	2	8	1	11
Mean (StdDev)	3.71 (2.602)	4.25 (4.489)	1.87 (-)	3.93 (3.911)
Median	3.71	1.95	1.87	1.94
Min, Max	1.9, 5.6	1.9, 14.8	1.9, 1.9	1.9, 14.8

Abbreviations: CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission.
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.2.4.1-t2cr-racre-nat.sas Date: 18:00/08DEC2020

Table 99.2.2.4.1
Summary of Adjudicated Time to Response and Time to Complete Remission by Modified IWG Criteria by Prior Antineoplastic Therapy
Studies: BLU-285-2101 and BLU-285-2202, RAC-RE Population - Responders (CR+CRh+PR+CI)
Prior Anti-Neoplastic Therapy = No

Starting Dose: 200 mg and 300 mg	ASM (N=2)	SM-AHN (N=14)	MCL (N=4)	All AdvSM (N=20)
Time to Response (Months)				
n	2	14	4	20
Mean (StdDev)	1.07 (1.138)	2.41 (1.246)	1.81 (0.365)	2.16 (1.162)
Median	1.07	1.92	1.82	1.87
Min, Max	0.3, 1.9	0.5, 5.6	1.3, 2.2	0.3, 5.6
Time to CR+CRh (Months)				
n	1	6	1	8
Mean (StdDev)	1.87 (-)	6.09 (0.710)	5.65 (-)	5.51 (1.594)
Median	1.87	5.82	5.65	5.60
Min, Max	1.9, 1.9	5.5, 7.1	5.7, 5.7	1.9, 7.1
Time to CR+CRh+PR (Months)				
n	2	13	3	18
Mean (StdDev)	3.71 (2.602)	3.13 (1.860)	1.96 (0.242)	3.00 (1.764)
Median	3.71	1.94	1.87	1.91
Min, Max	1.9, 5.6	1.8, 7.1	1.8, 2.2	1.8, 7.1

Abbreviations: CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission.
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.2.4.1-t2cr-racre-nat.sas Date: 18:00/08DEC2020

Table 99.2.2.4.1
Summary of Adjudicated Time to Response and Time to Complete Remission by Modified IWG Criteria by Prior Antineoplastic Therapy
Studies: BLU-285-2101 and BLU-285-2202, RAC-RE Population - Responders (CR+CRh+PR+CI)
Prior Anti-Neoplastic Therapy = Yes

Starting Dose: 200 mg and 300 mg	ASM (N=3)	SM-AHN (N=26)	MCL (N=4)	All AdvSM (N=33)
Time to Response (Months)				
n	3	26	4	33
Mean (StdDev)	1.94 (1.727)	4.06 (5.509)	4.39 (5.198)	3.90 (5.181)
Median	1.84	1.94	1.87	1.91
Min, Max	0.3, 3.7	0.5, 26.7	1.6, 12.2	0.3, 26.7
Time to CR+CRh (Months)				
n	2	6	0	8
Mean (StdDev)	8.11 (6.226)	11.27 (10.695)		10.48 (9.454)
Median	8.11	9.28		9.28
Min, Max	3.7, 12.5	1.8, 32.2		1.8, 32.2
Time to CR+CRh+PR (Months)				
n	3	19	3	25
Mean (StdDev)	3.71 (1.840)	4.76 (6.301)	5.23 (6.024)	4.69 (5.766)
Median	3.71	1.94	1.87	1.94
Min, Max	1.9, 5.6	1.7, 26.7	1.6, 12.2	1.6, 26.7

Abbreviations: CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission.
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.2.4.1-t2cr-racre-nat.sas Date: 18:00/08DEC2020

Table 99.2.2.4.1
Summary of Adjudicated Time to Response and Time to Complete Remission by Modified IWG Criteria by Prior Antineoplastic Therapy
Studies: BLU-285-2101 and BLU-285-2202, RAC-RE Population - Responders (CR+CRh+PR+CI)
Prior Anti-Neoplastic Therapy = No

Starting Dose: 400 mg	ASM (N=0)	SM-AHN (N=0)	MCL (N=1)	All AdvSM (N=1)
Time to Response (Months)				
n	-	-	1	1
Mean (StdDev)			2.10 (-)	2.10 (-)
Median			2.10	2.10
Min, Max			2.1, 2.1	2.1, 2.1
Time to CR+CRh (Months)				
n	-	-	1	1
Mean (StdDev)			2.10 (-)	2.10 (-)
Median			2.10	2.10
Min, Max			2.1, 2.1	2.1, 2.1
Time to CR+CRh+PR (Months)				
n	-	-	1	1
Mean (StdDev)			2.10 (-)	2.10 (-)
Median			2.10	2.10
Min, Max			2.1, 2.1	2.1, 2.1

Abbreviations: CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission.
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.2.4.1-t2cr-racre-nat.sas Date: 18:00/08DEC2020

Table 99.2.2.4.1
Summary of Adjudicated Time to Response and Time to Complete Remission by Modified IWG Criteria by Prior Antineoplastic Therapy
Studies: BLU-285-2101 and BLU-285-2202, RAC-RE Population - Responders (CR+CRh+PR+CI)
Prior Anti-Neoplastic Therapy = Yes

Starting Dose: 400 mg

	ASM (N=0)	SM-AHN (N=2)	MCL (N=0)	All AdvSM (N=2)
Time to Response (Months)				
n	-	2	-	2
Mean (StdDev)		2.12 (0.348)		2.12 (0.348)
Median		2.12		2.12
Min, Max		1.9, 2.4		1.9, 2.4
Time to CR+CRh (Months)				
n	-	1	-	1
Mean (StdDev)		10.68 (-)		10.68 (-)
Median		10.68		10.68
Min, Max		10.7, 10.7		10.7, 10.7
Time to CR+CRh+PR (Months)				
n	-	2	-	2
Mean (StdDev)		2.12 (0.348)		2.12 (0.348)
Median		2.12		2.12
Min, Max		1.9, 2.4		1.9, 2.4

Abbreviations: CR=Complete remission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission.
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/SmPC/t99.2.2.4.1-t2cr-racre-nat.sas Date: 18:00/08DEC2020

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Avapritinib Systemic Mastocytosis Integrated Summary of Efficacy
BLU-285 SM Germany HTA Analysis
Cutoff date: 27may2020 (2101), 23jun2020 (2202)

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Study BLU-285-2101
Starting Dose: Overall

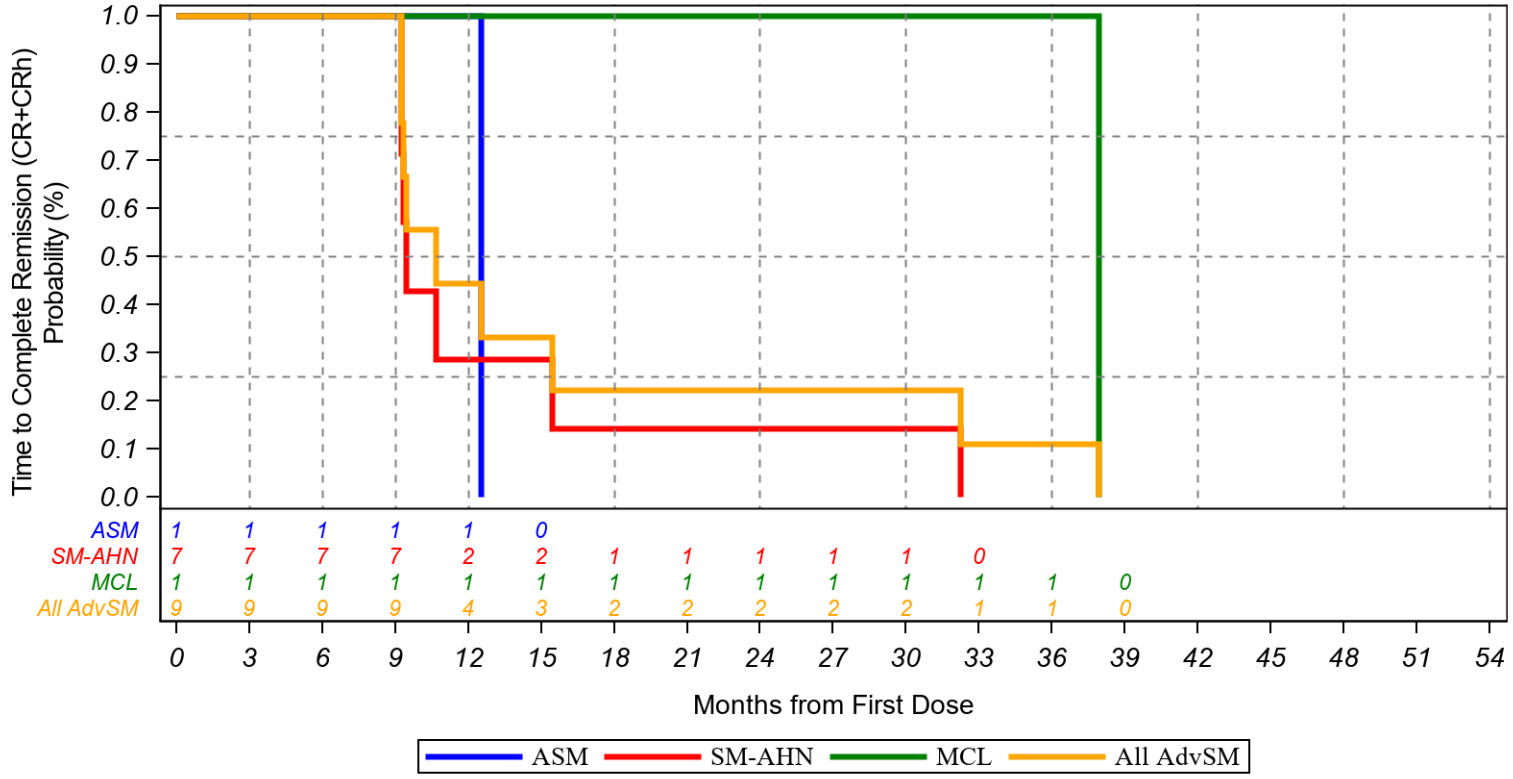

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Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Study BLU-285-2101
Starting Dose: Overall

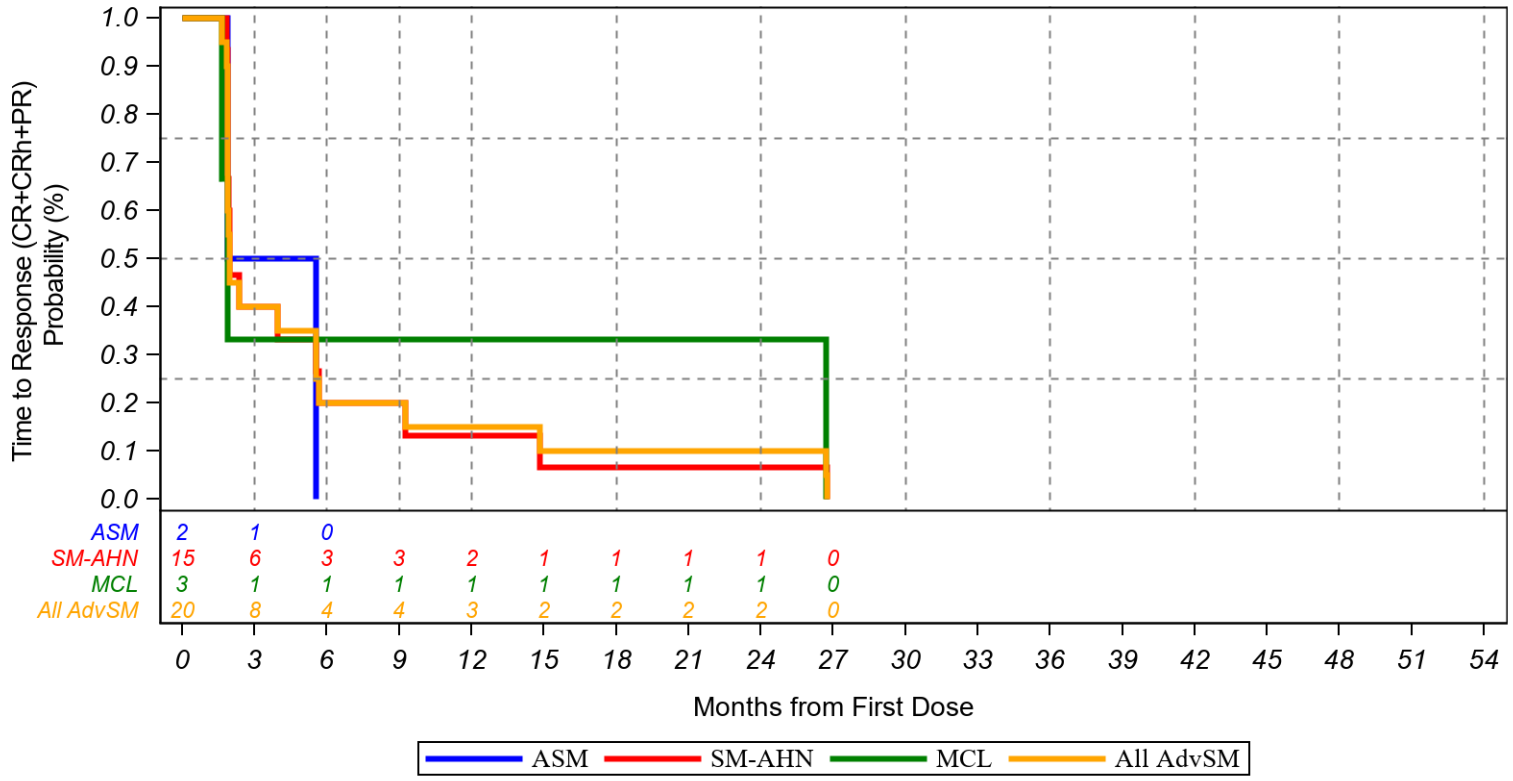

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: Overall

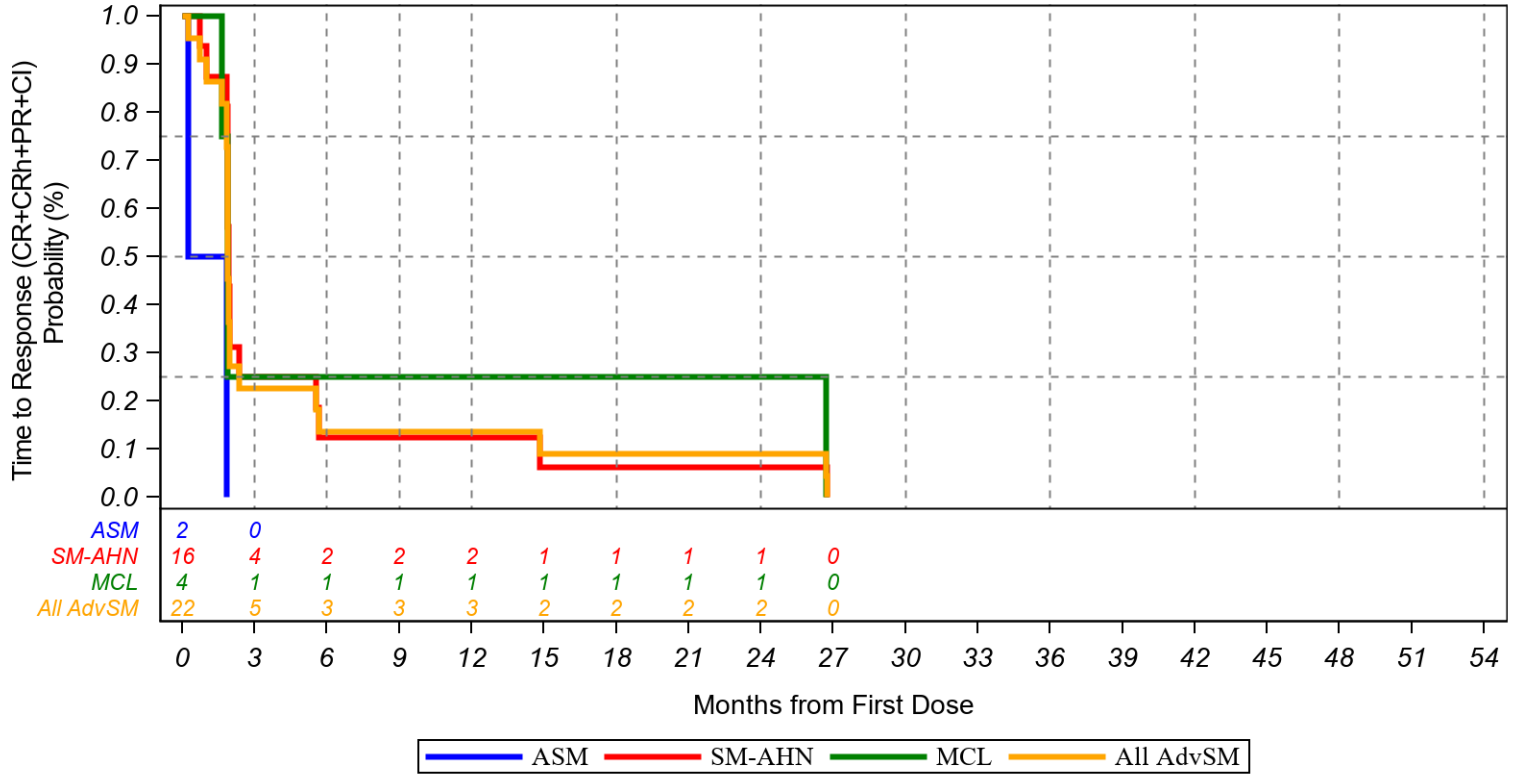

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Study BLU-285-2101
Starting Dose: < 200 mg

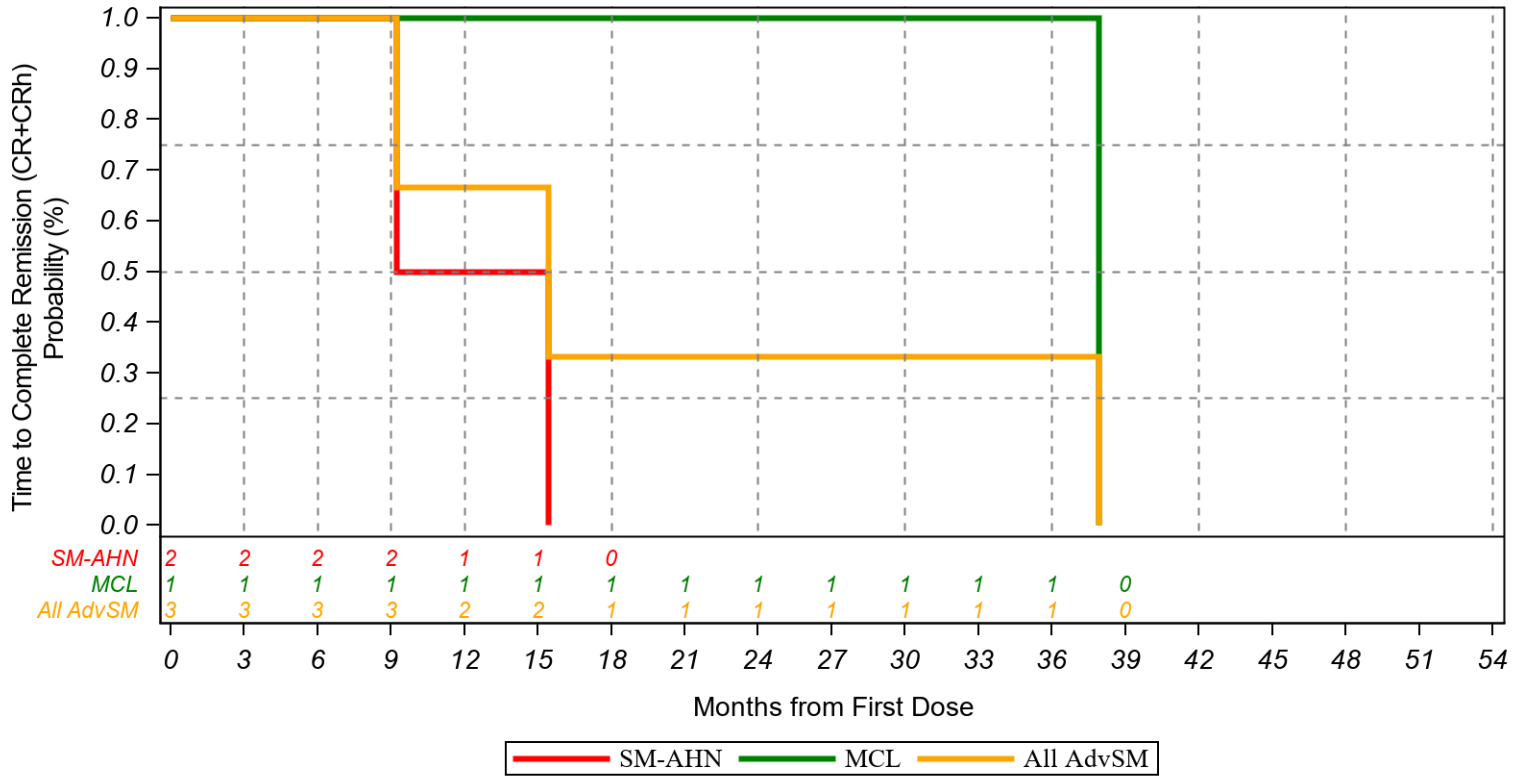

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Study BLU-285-2101
Starting Dose: < 200 mg

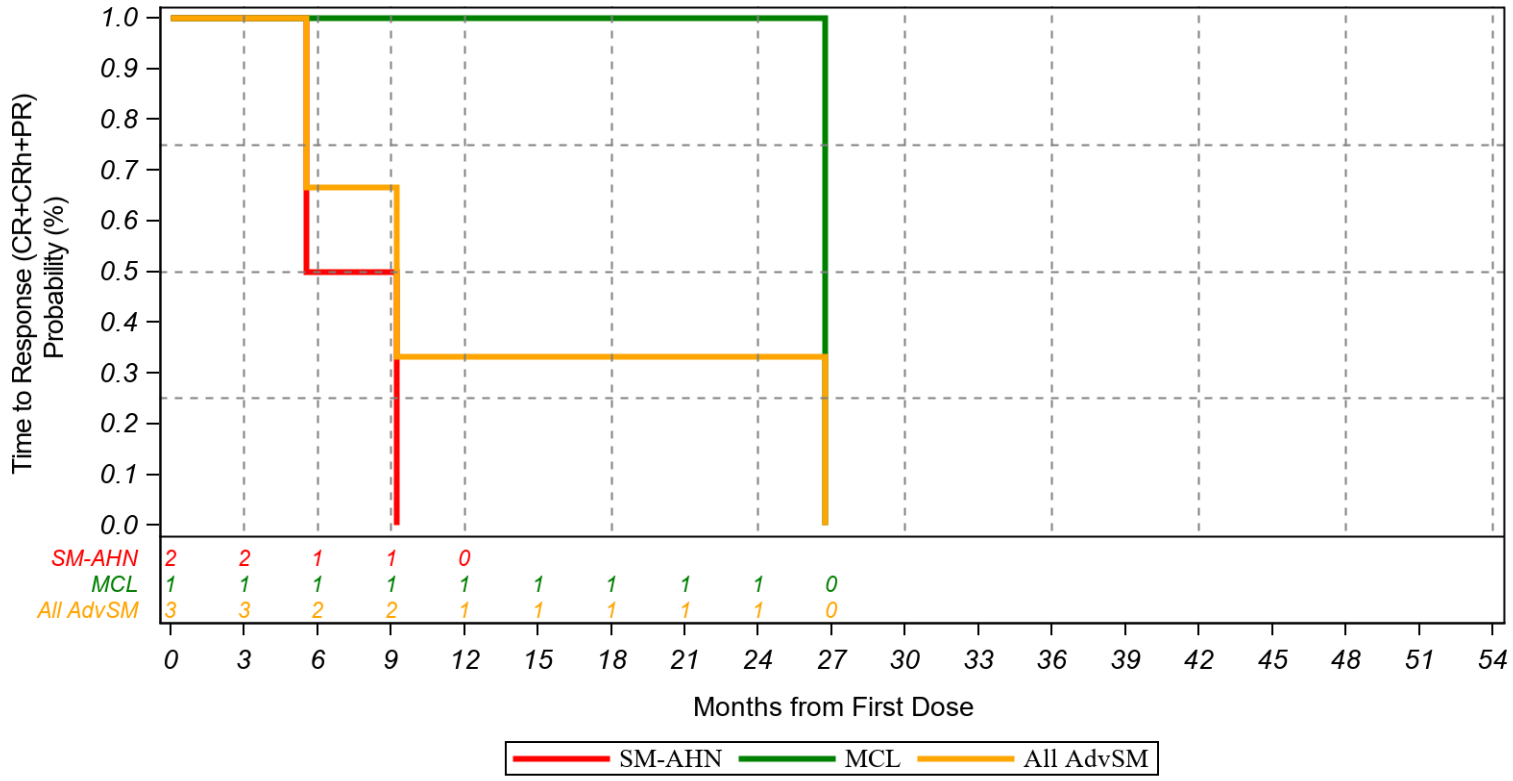

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: < 200 mg

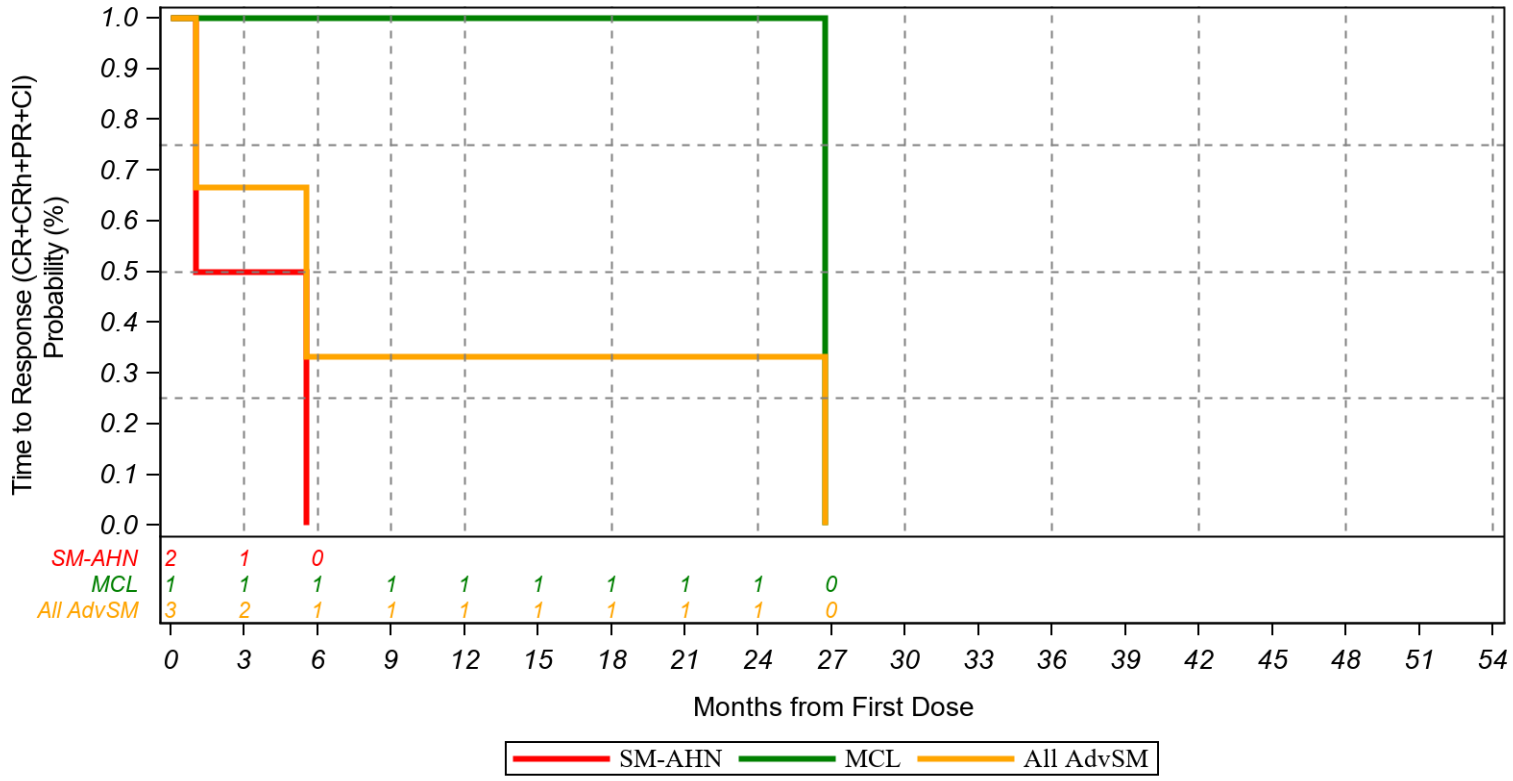

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Study BLU-285-2101
Starting Dose: < 300 mg

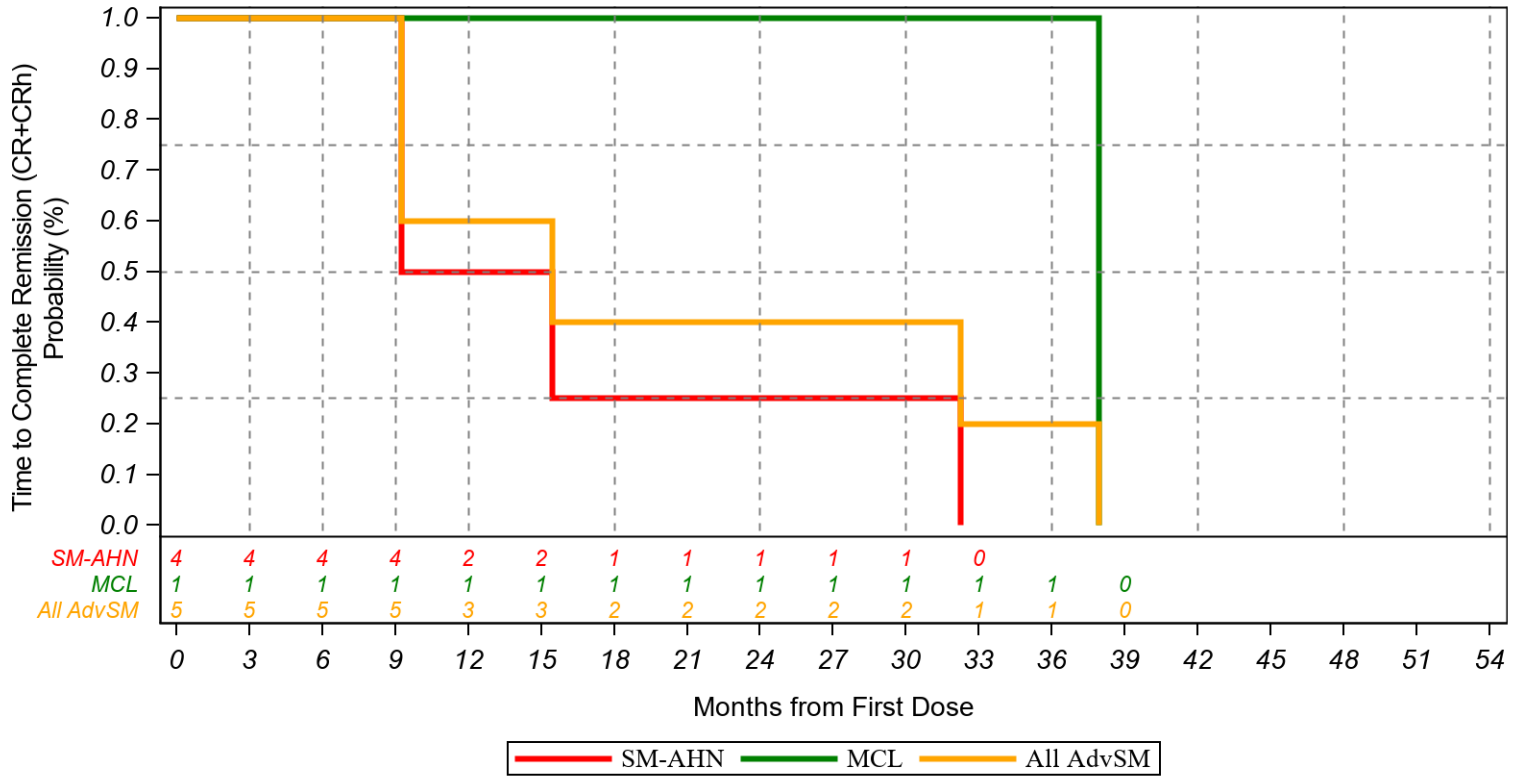

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Study BLU-285-2101
Starting Dose: < 300 mg

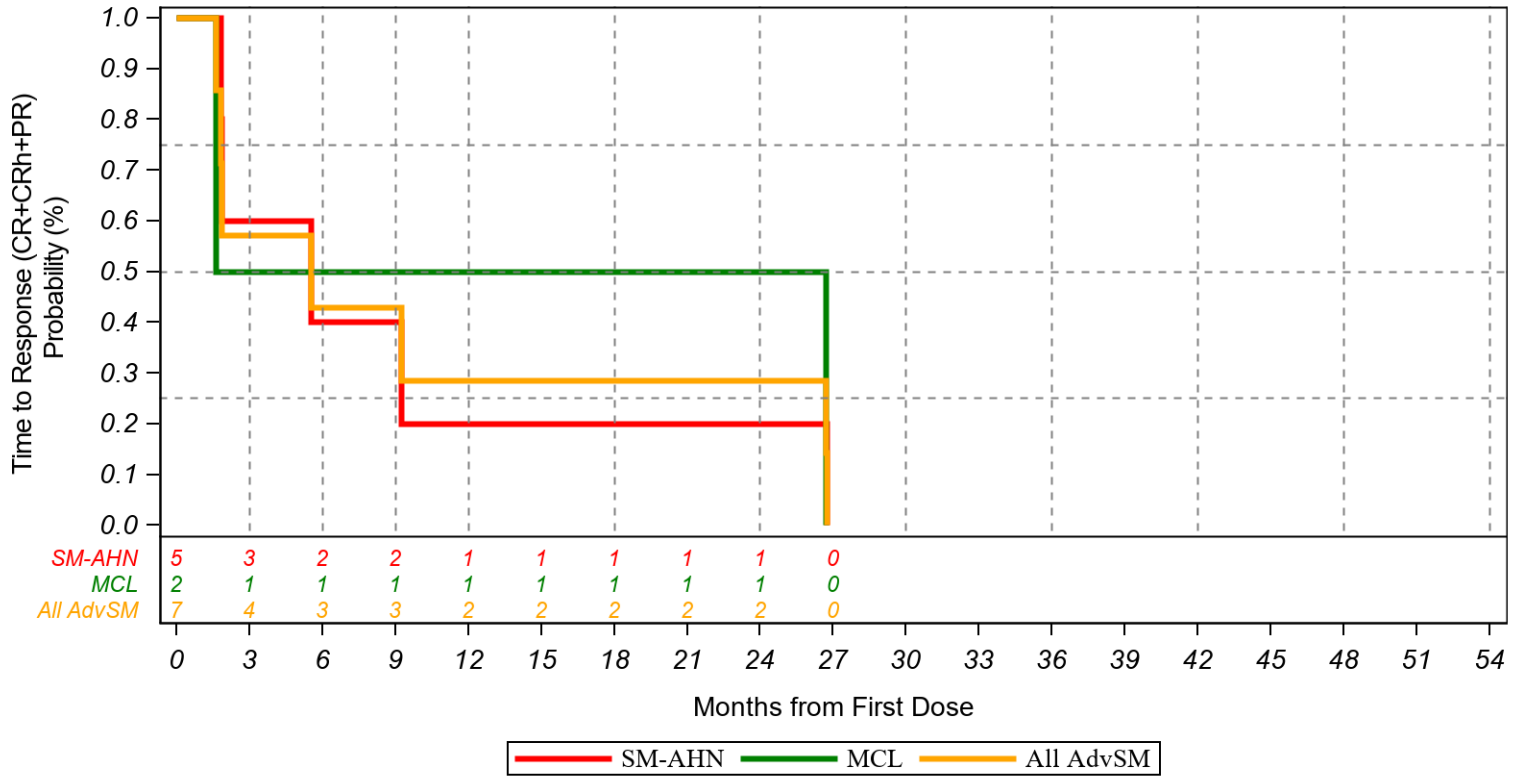

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: < 300 mg

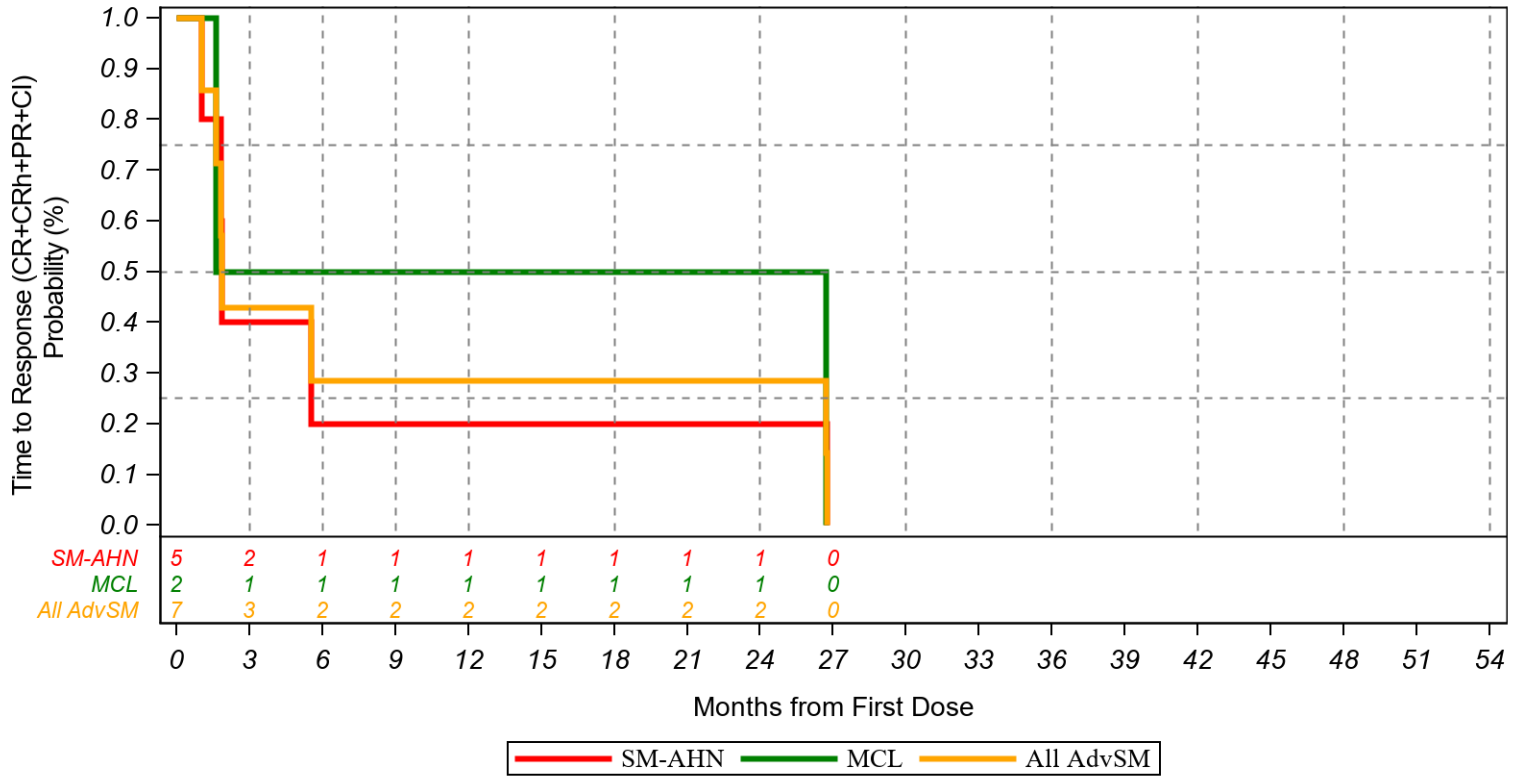

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Study BLU-285-2101
Starting Dose: 200 mg

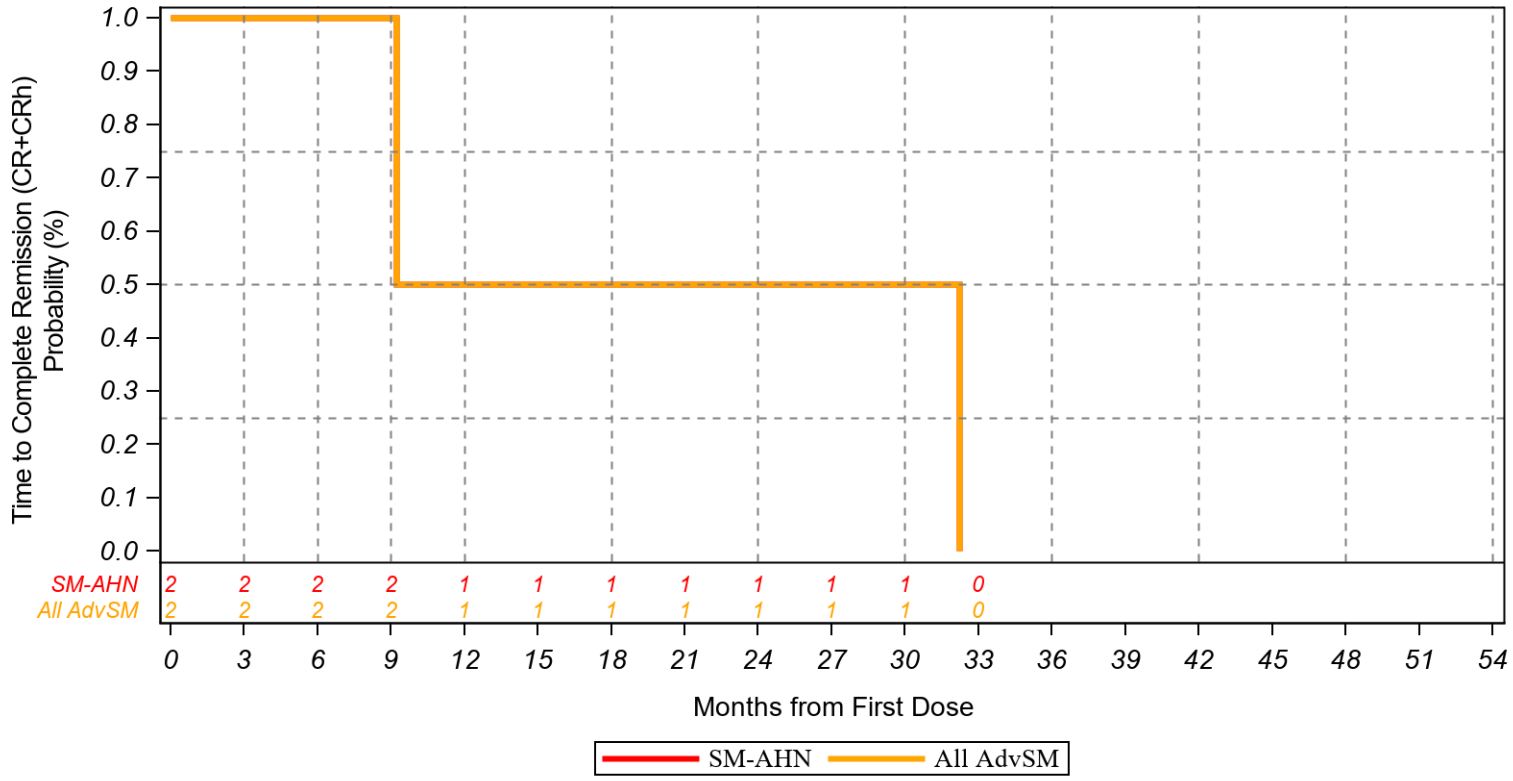

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Study BLU-285-2101
Starting Dose: 200 mg

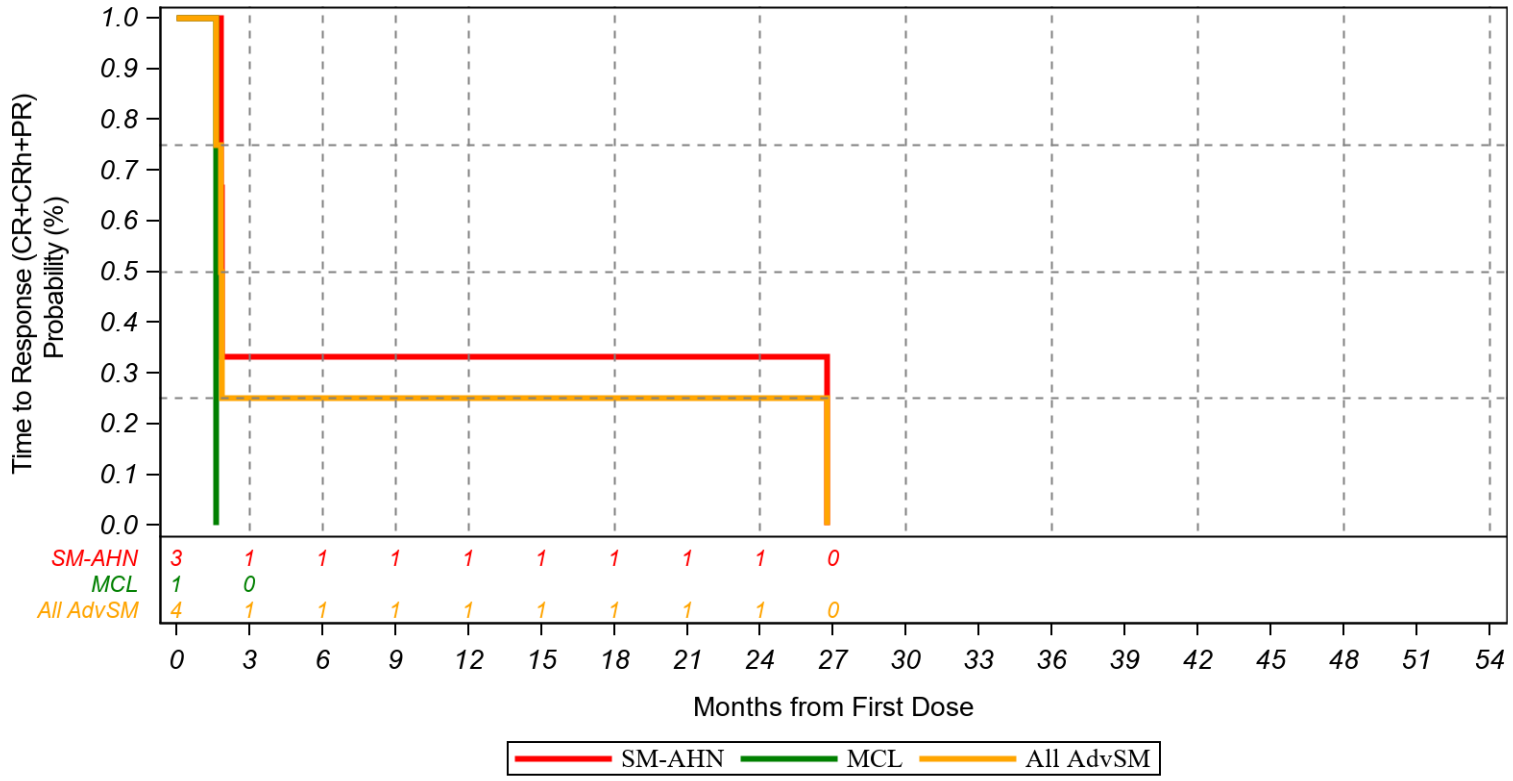

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: 200 mg

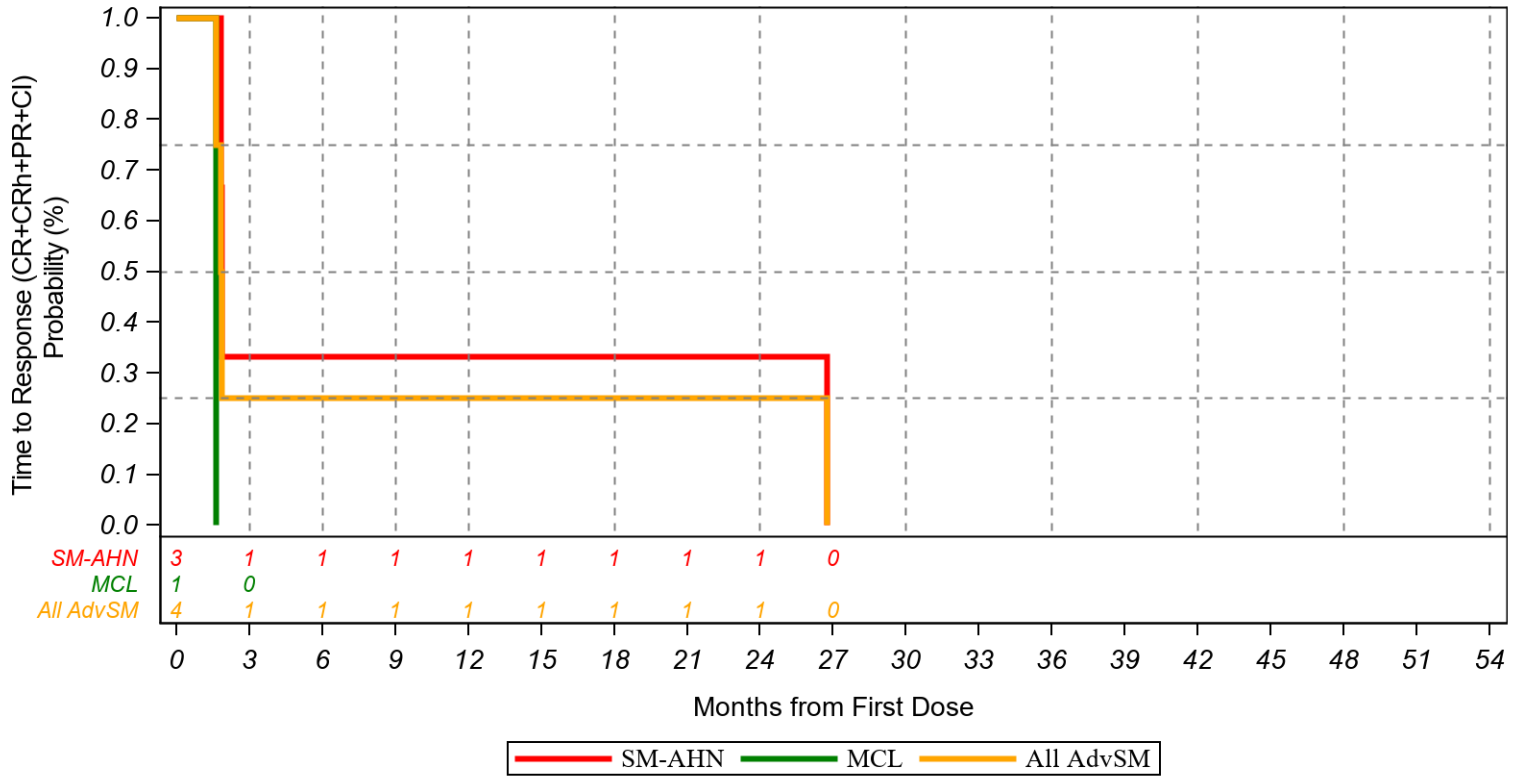

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Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Study BLU-285-2101
Starting Dose: 300 mg

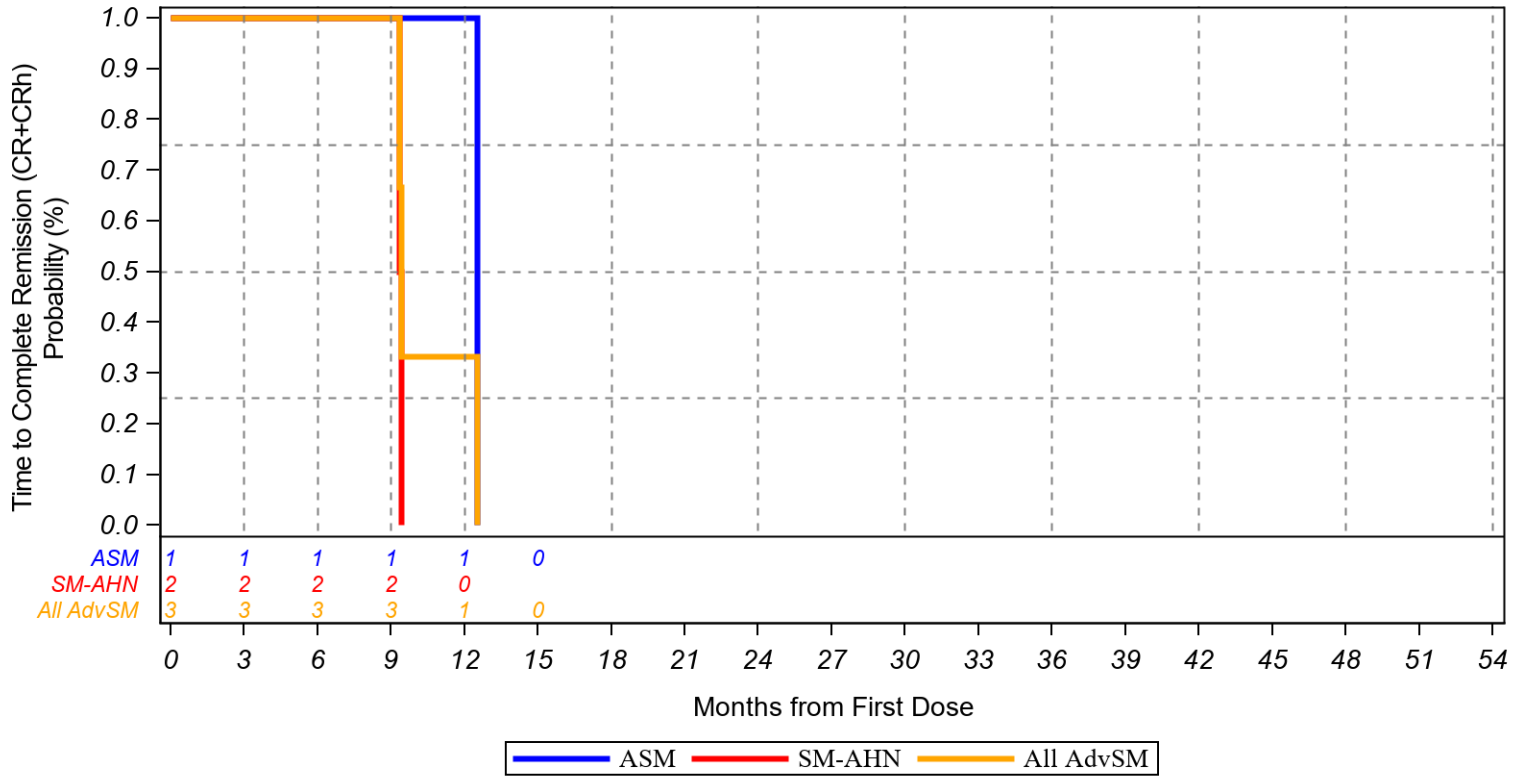

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Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Study BLU-285-2101
Starting Dose: 300 mg

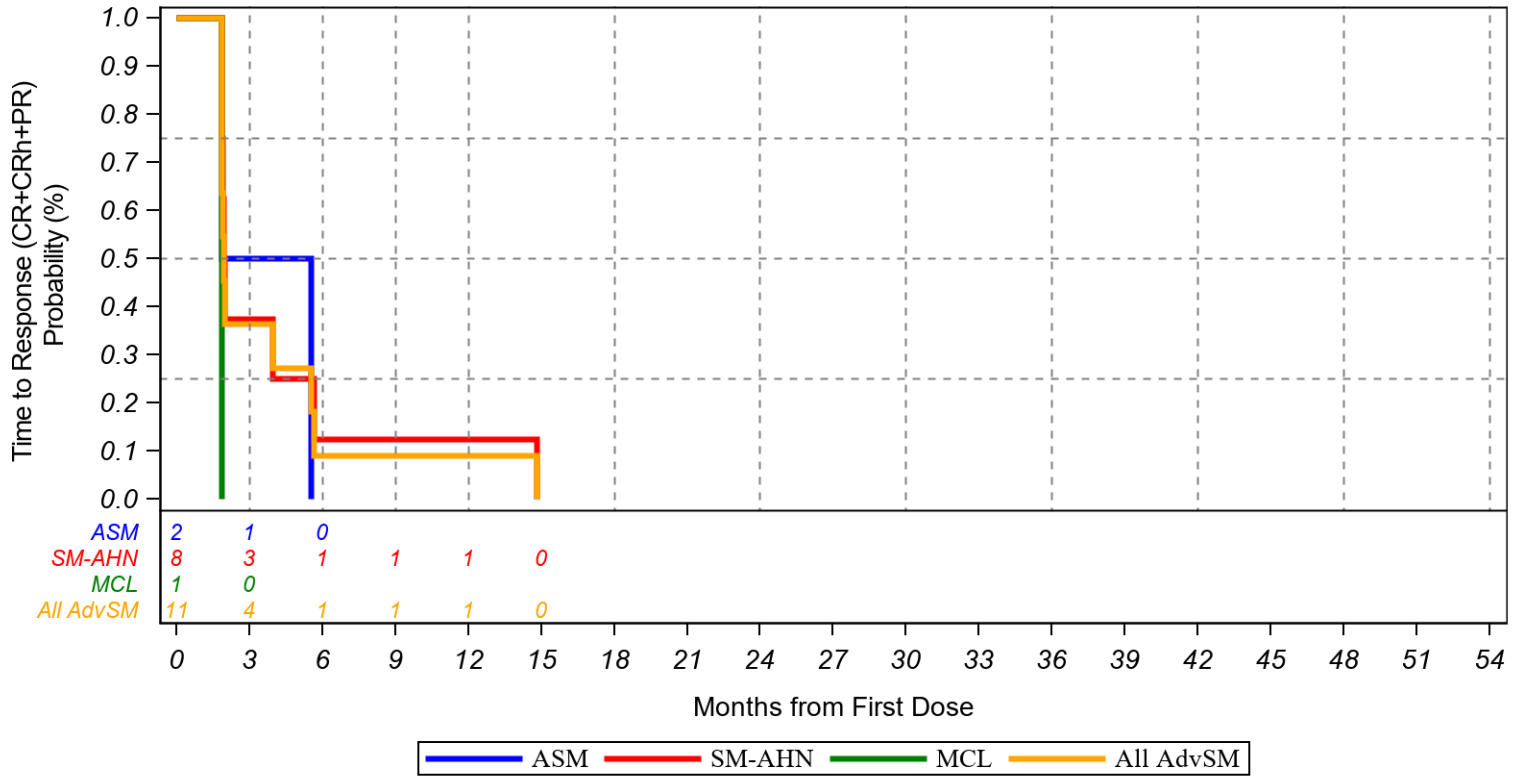

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: 300 mg

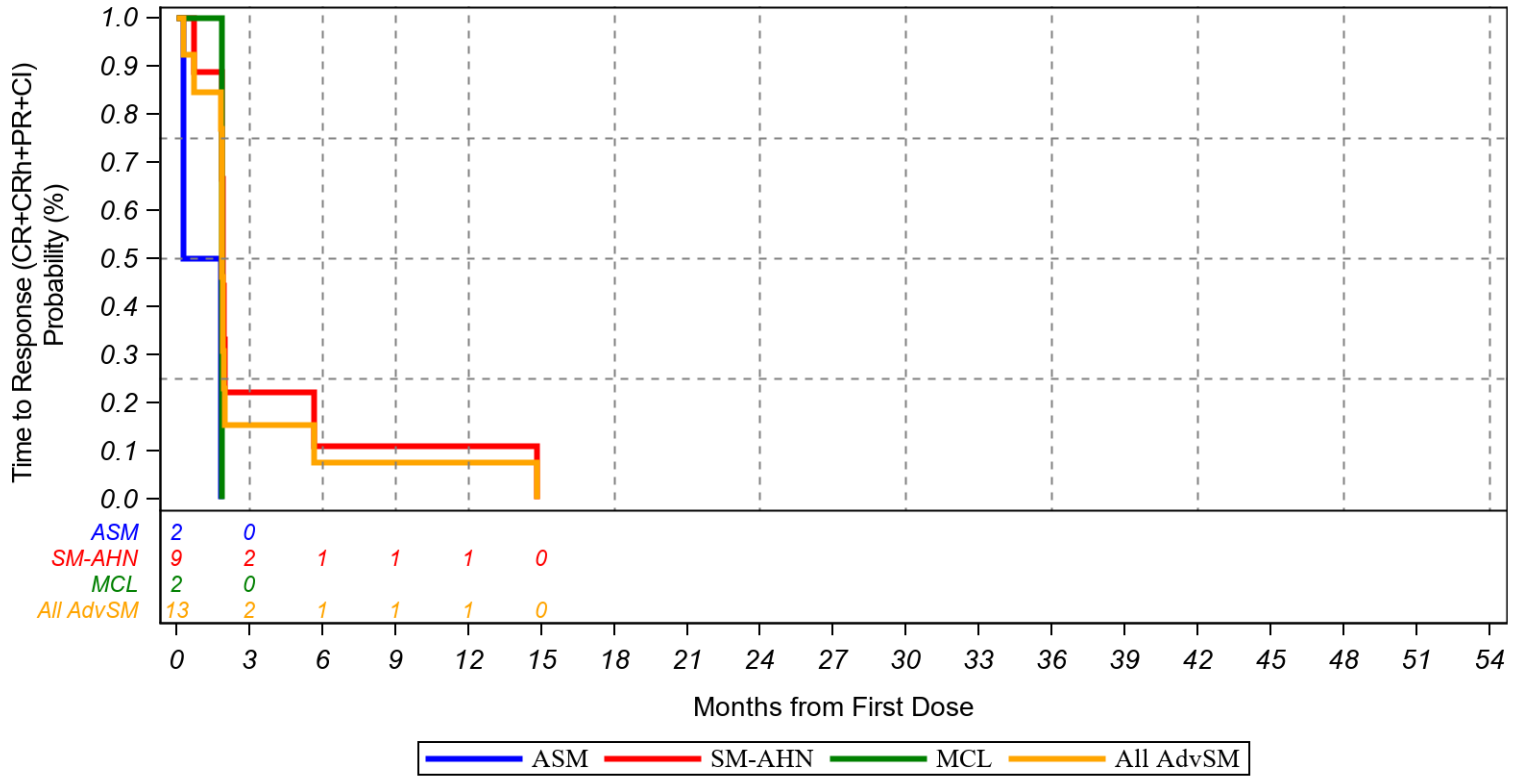

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Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Study BLU-285-2101
Starting Dose: 200 mg and 300 mg

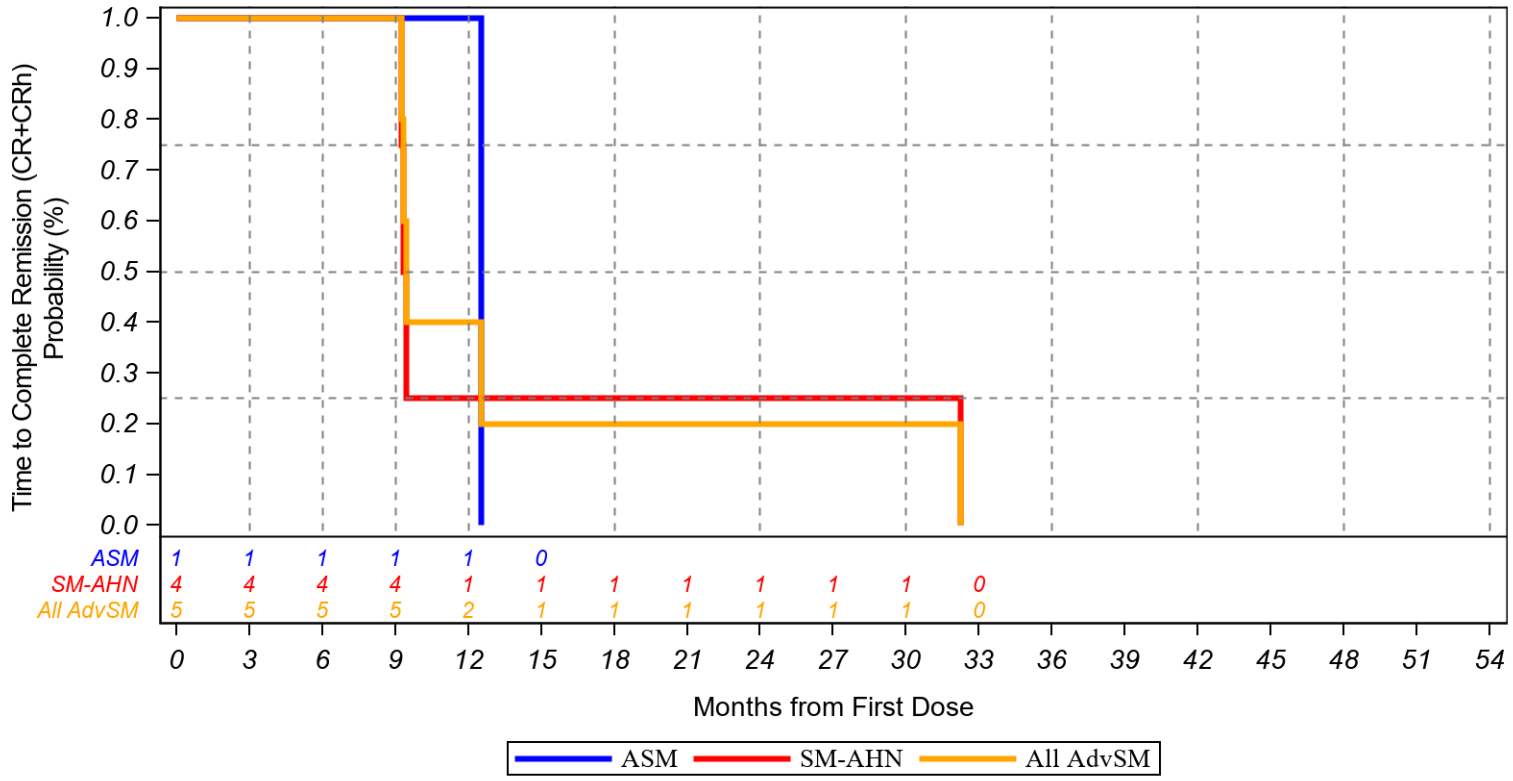

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Study BLU-285-2101
Starting Dose: 200 mg and 300 mg

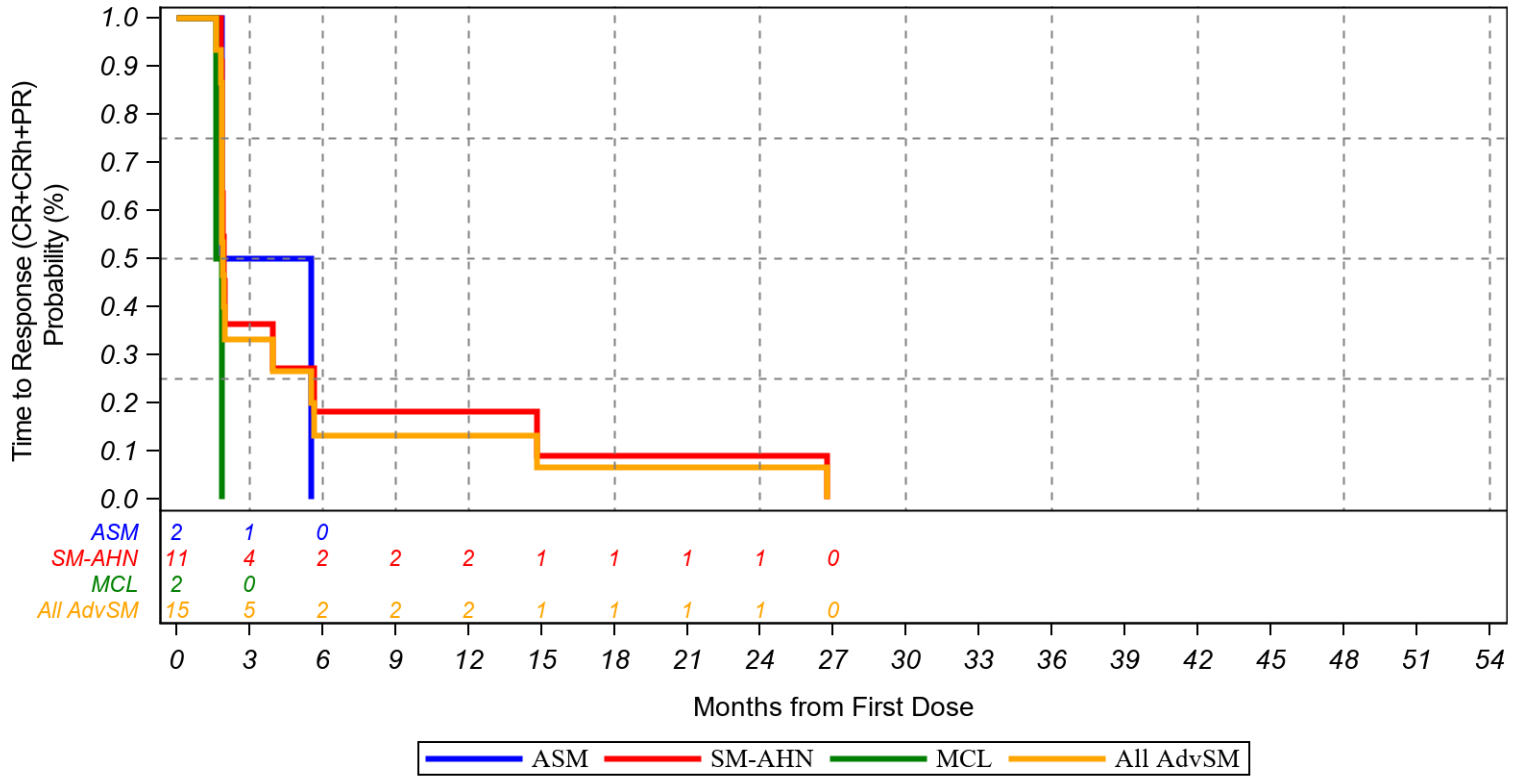

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: 200 mg and 300 mg

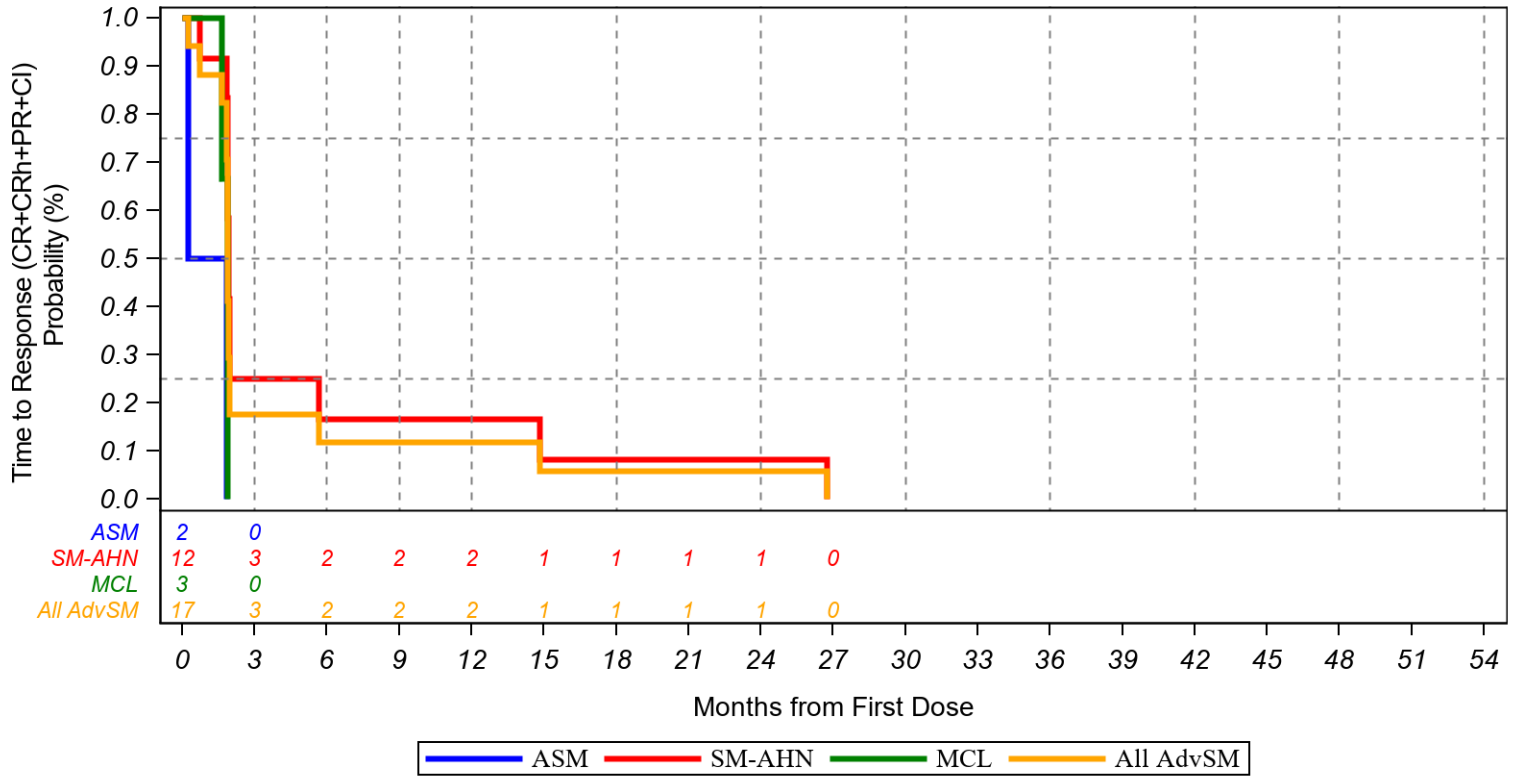

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Study BLU-285-2101
Starting Dose: 400 mg

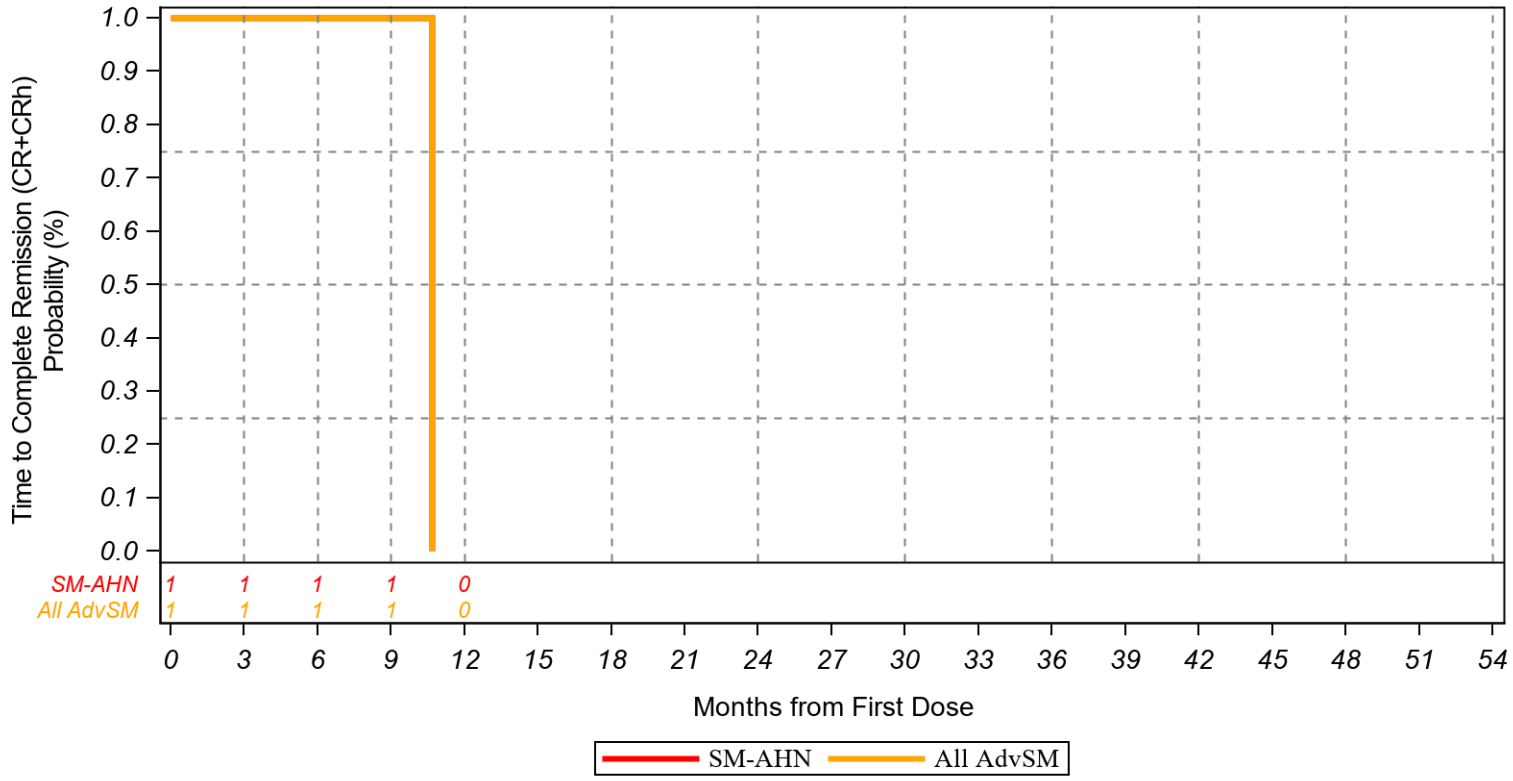

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Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Study BLU-285-2101
Starting Dose: 400 mg

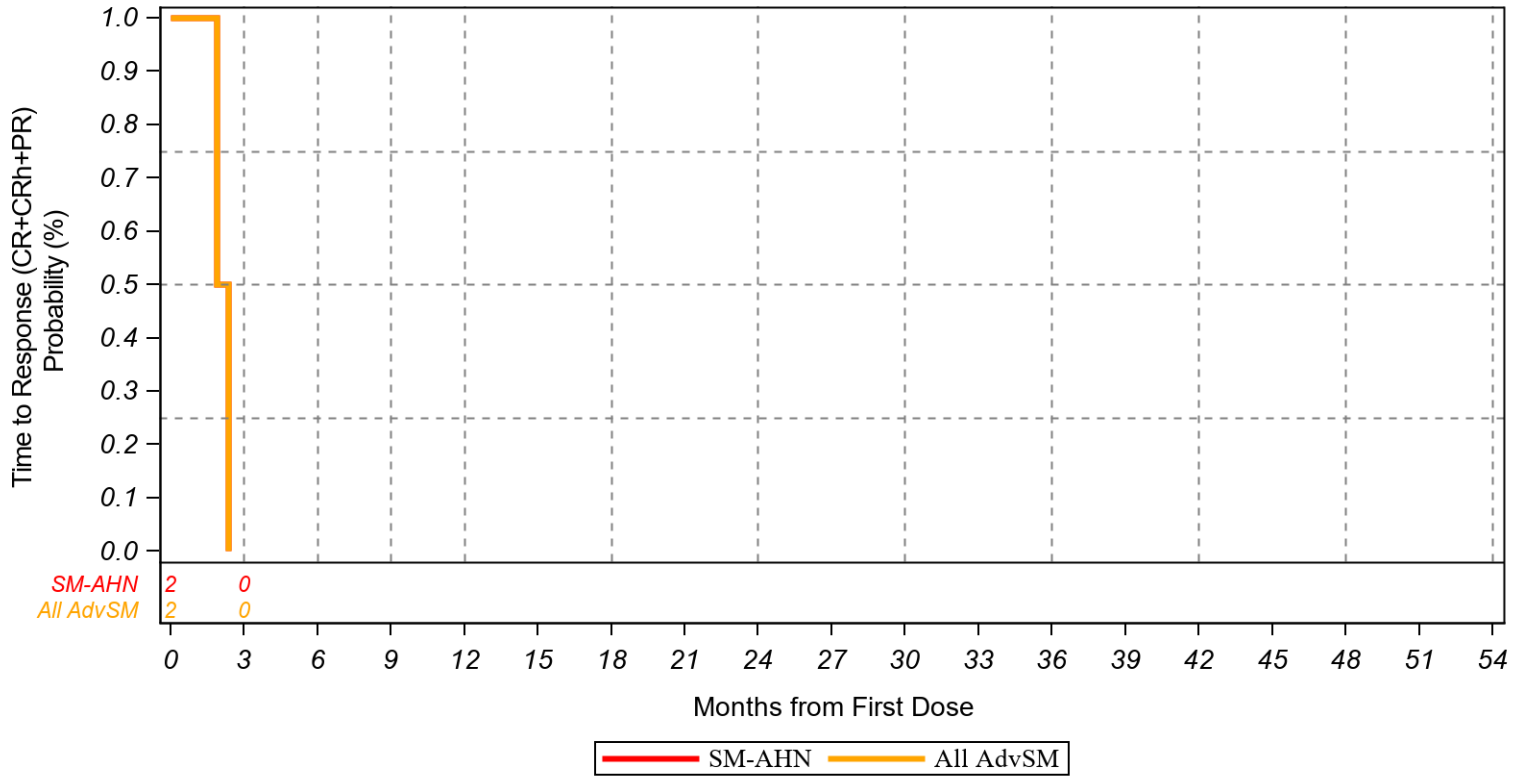

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: 400 mg

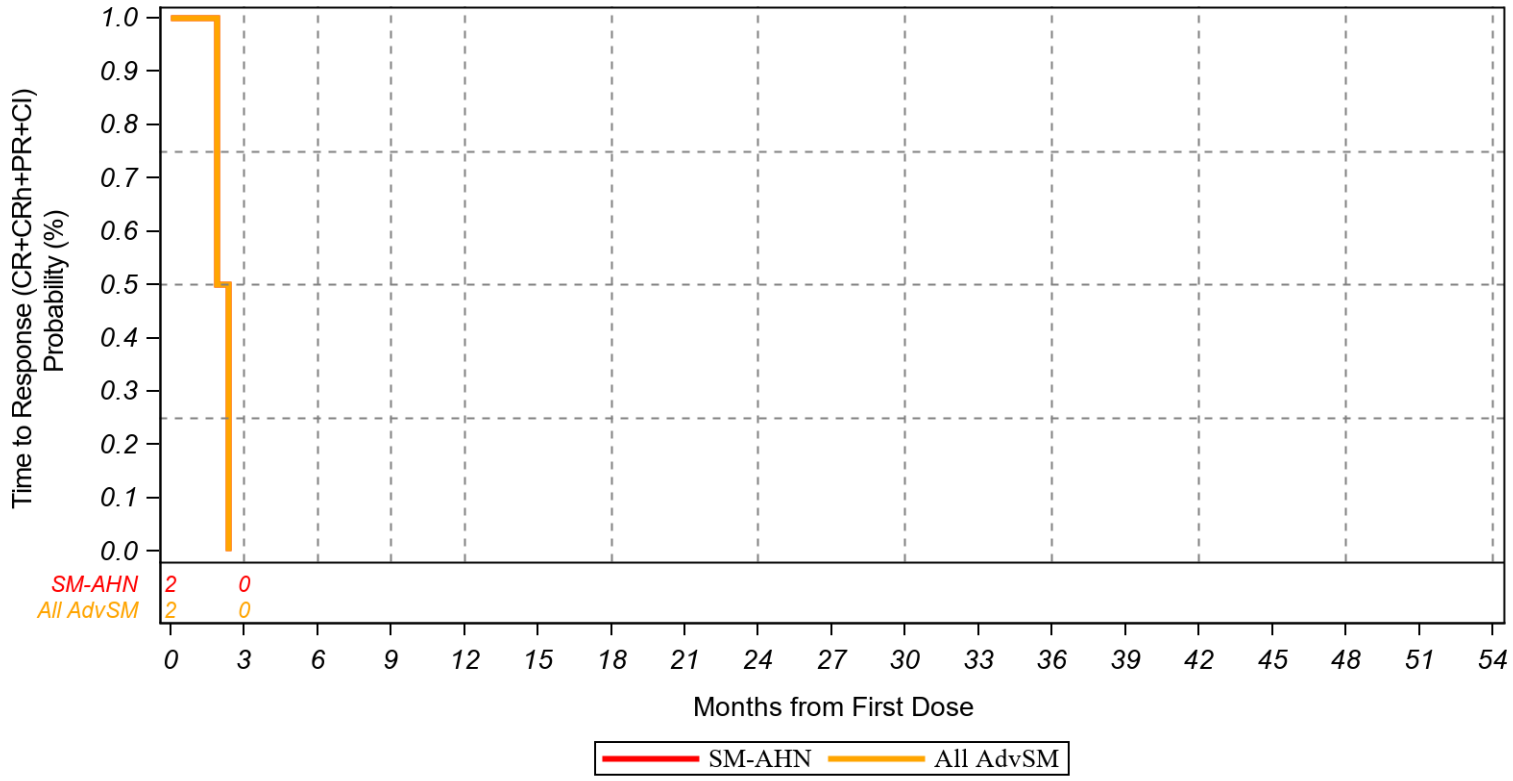

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Study BLU-285-2202
Starting Dose: Overall

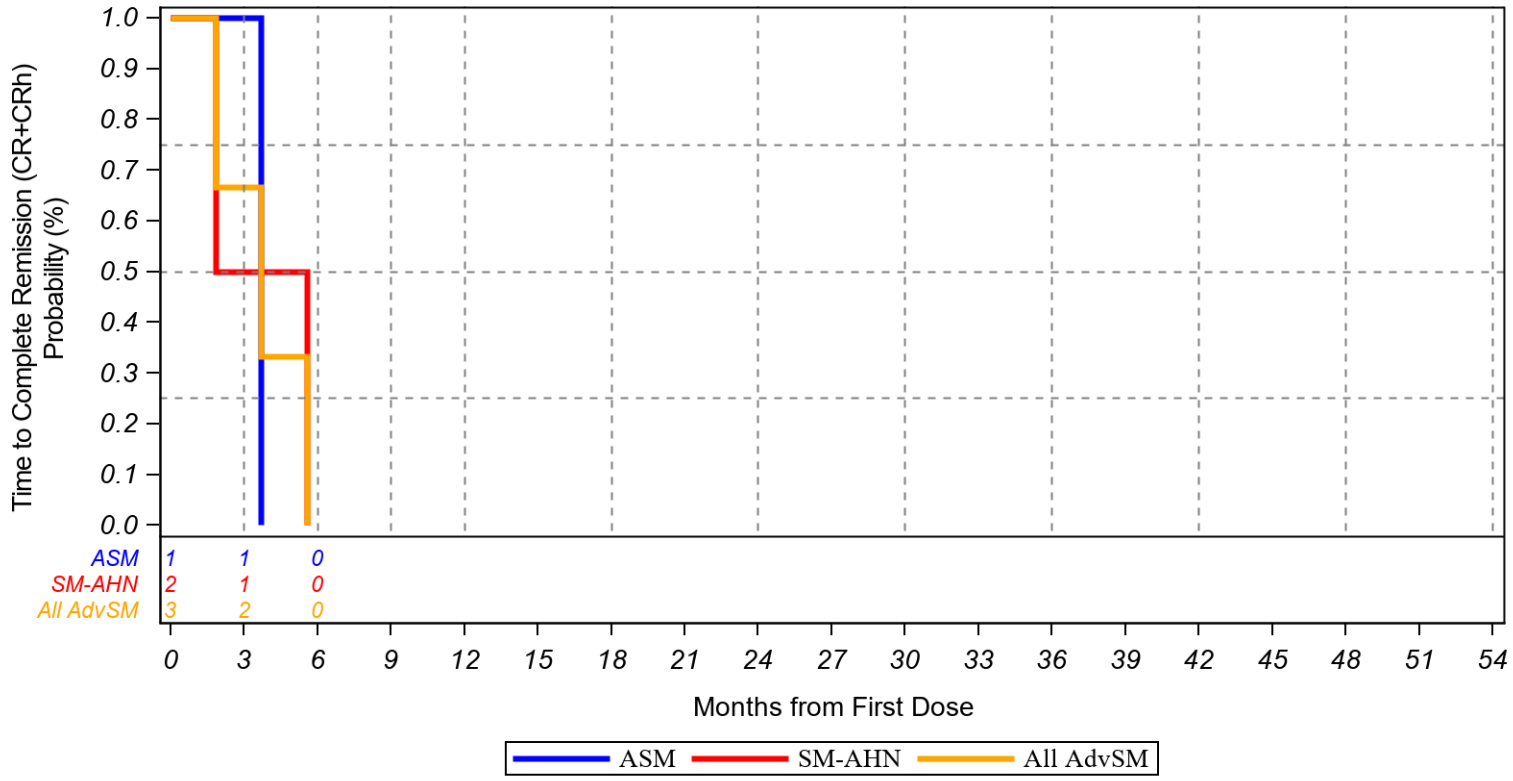

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Study BLU-285-2202
Starting Dose: Overall

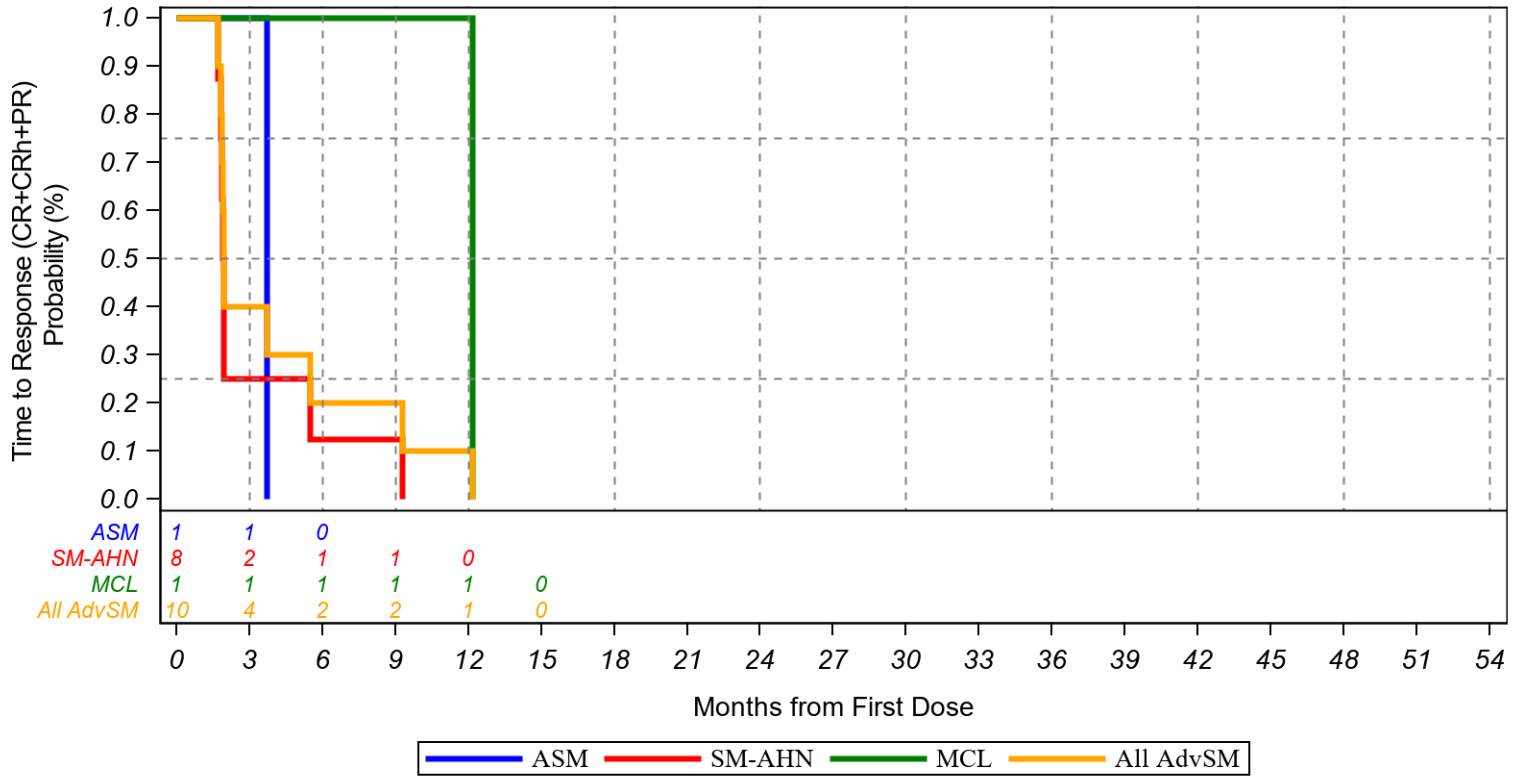

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Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Study BLU-285-2202
Starting Dose: Overall

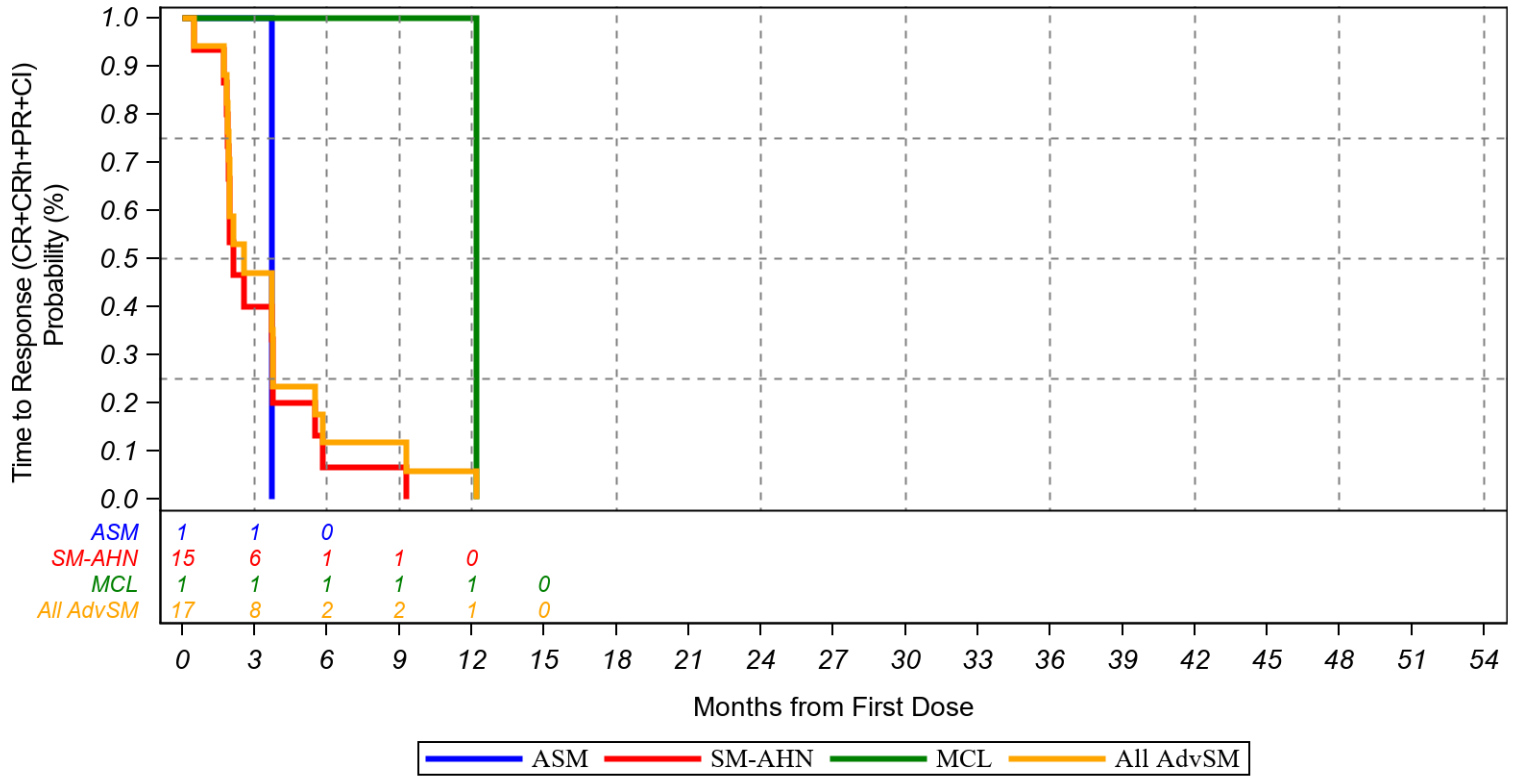

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Study BLU-285-2202
Starting Dose: 200 mg

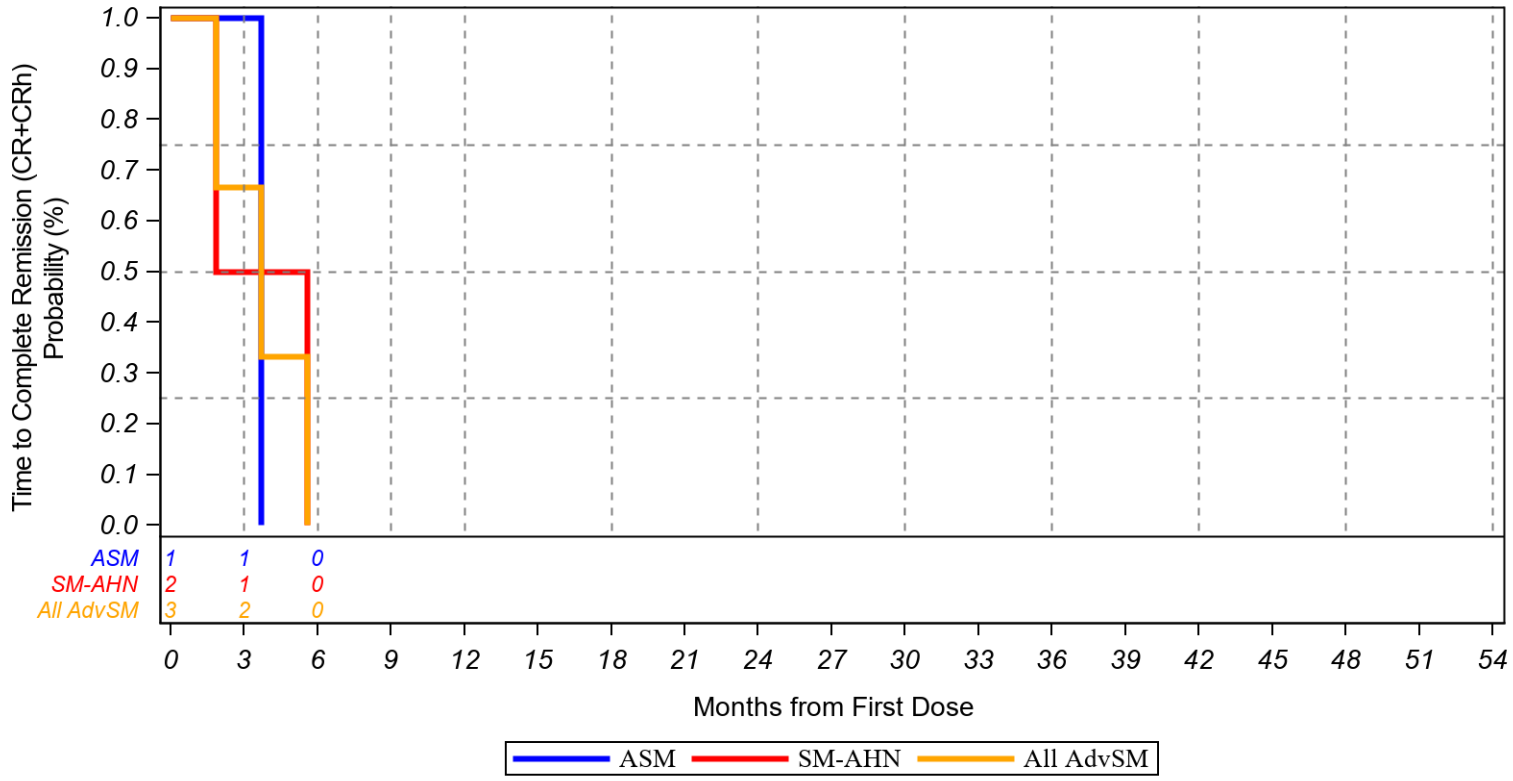

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Study BLU-285-2202
Starting Dose: 200 mg

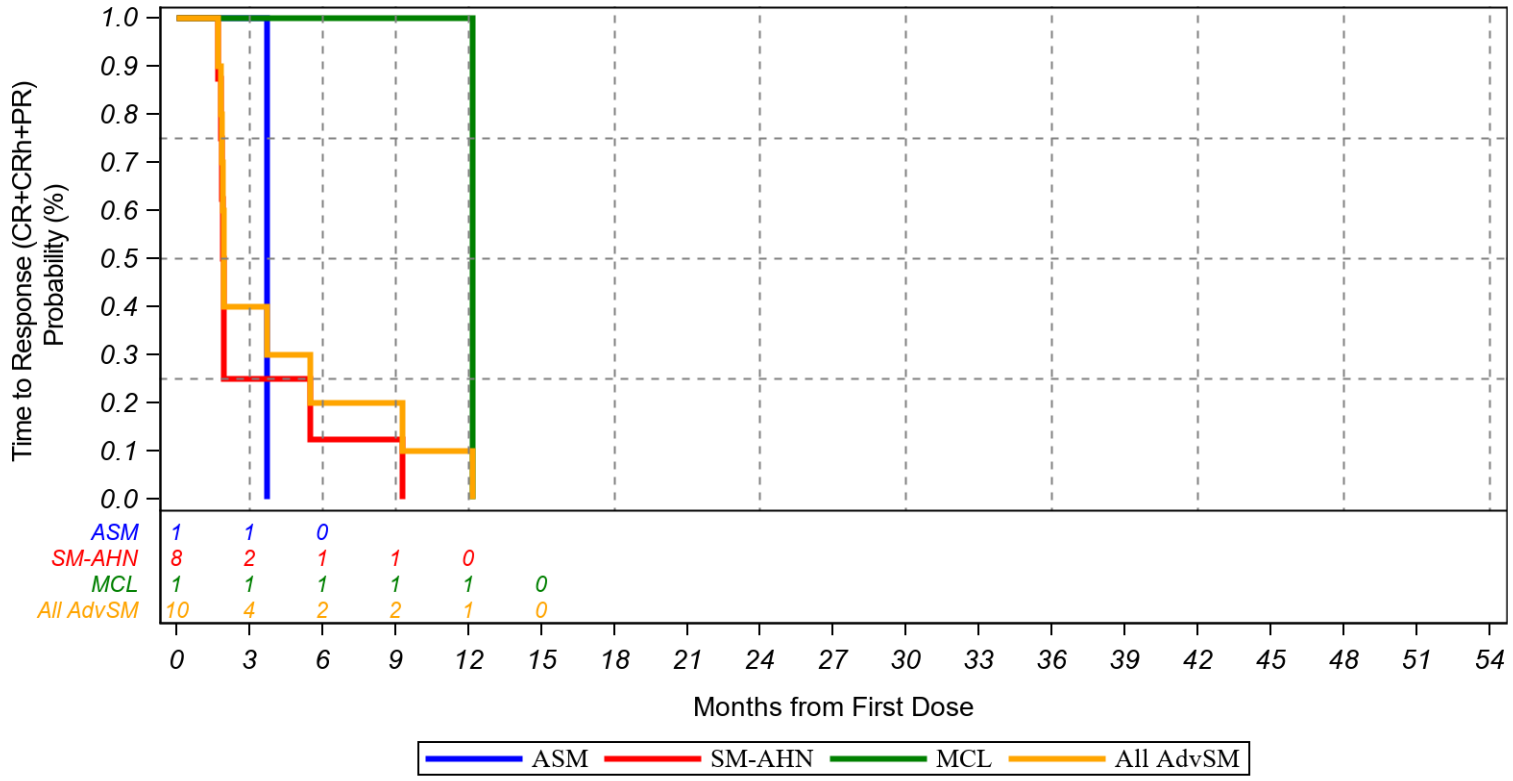

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Study BLU-285-2202
Starting Dose: 200 mg

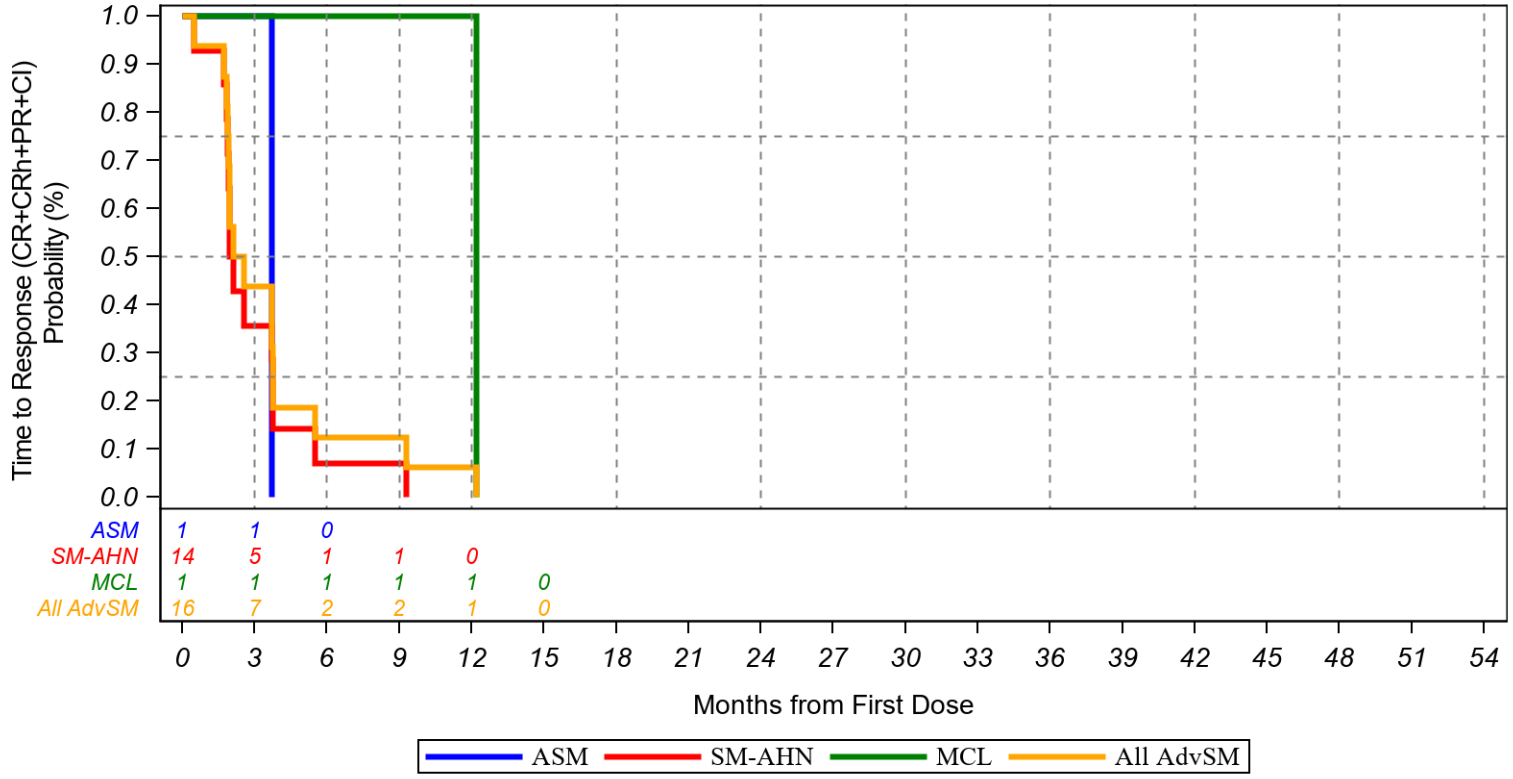

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall

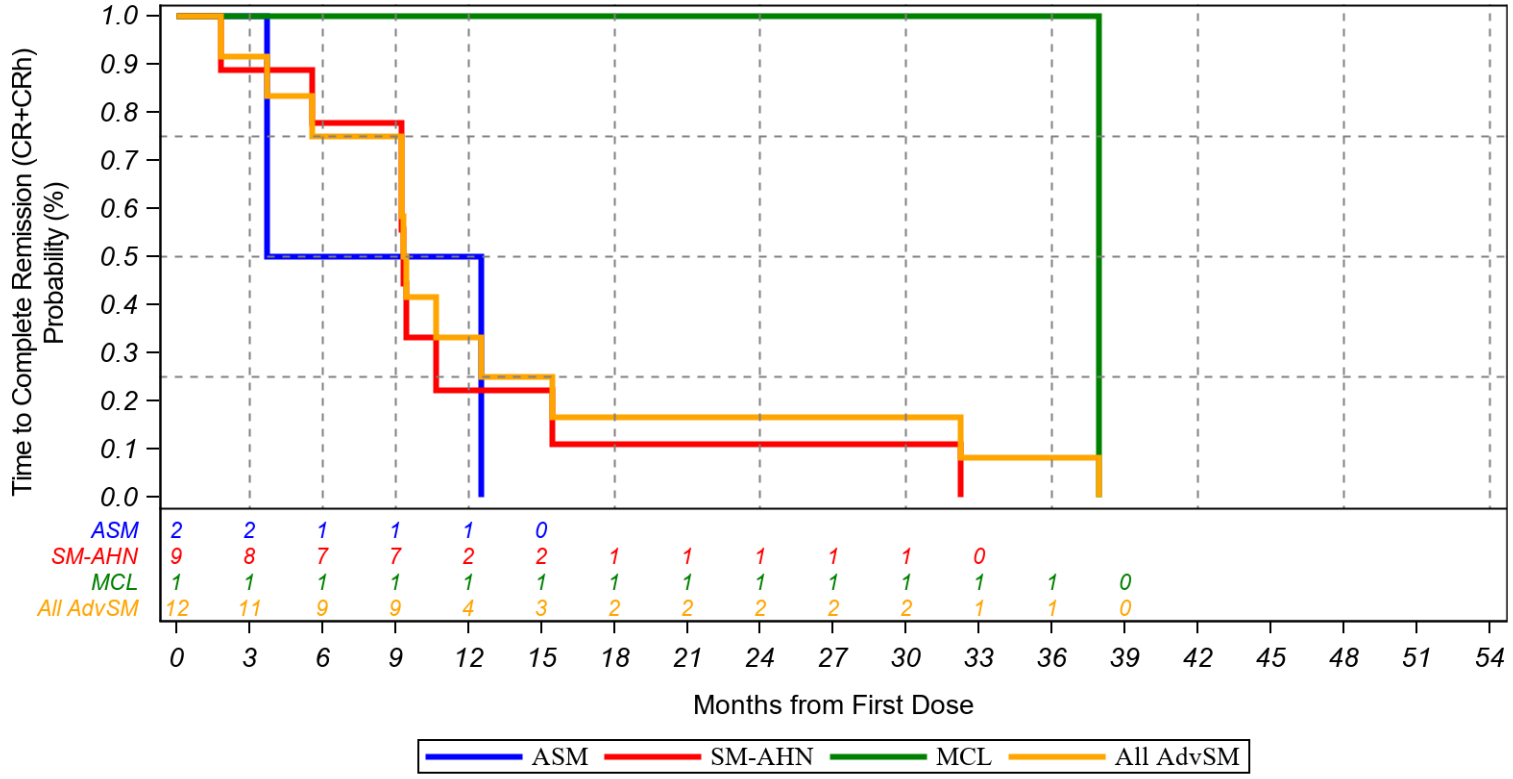

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall

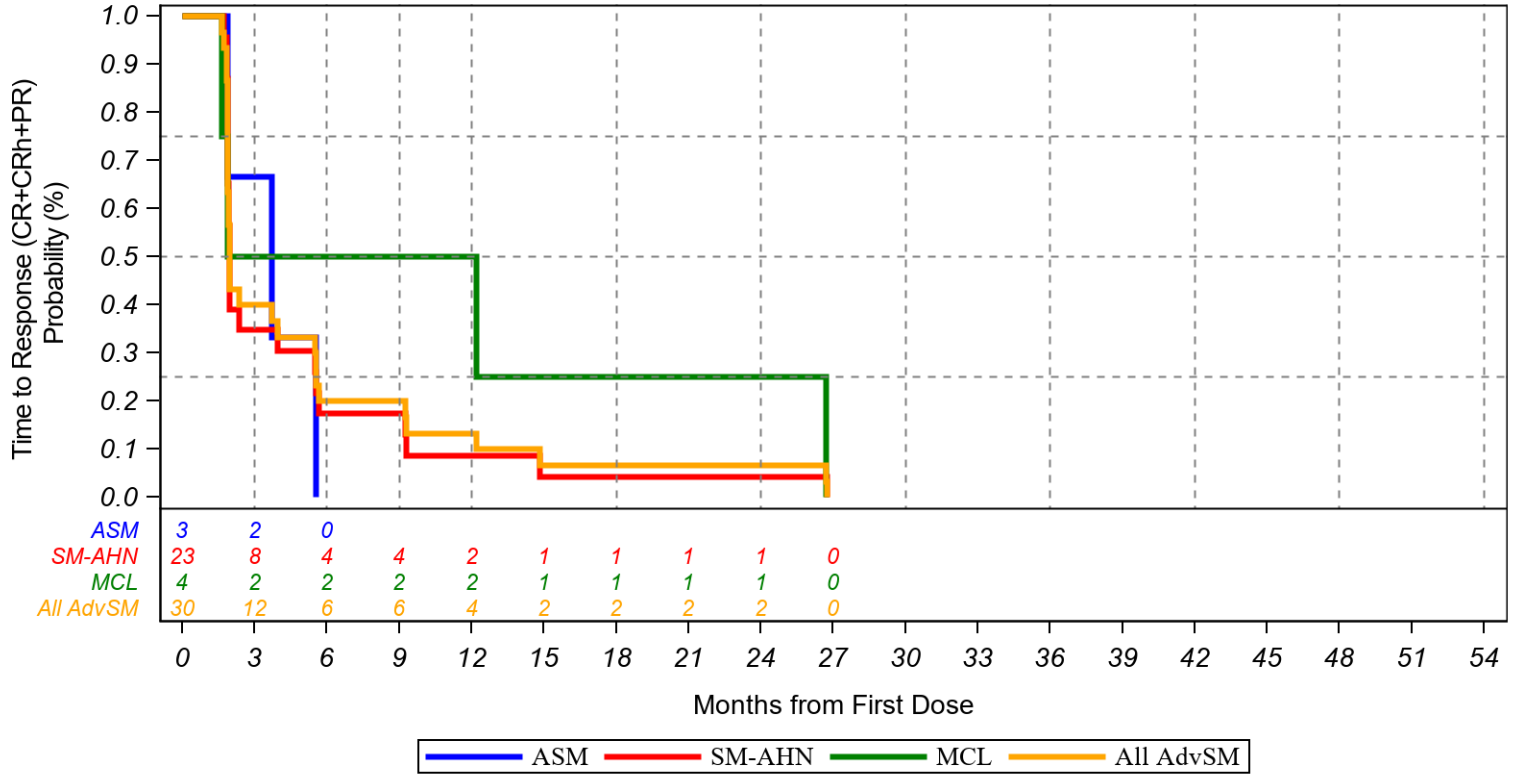

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall

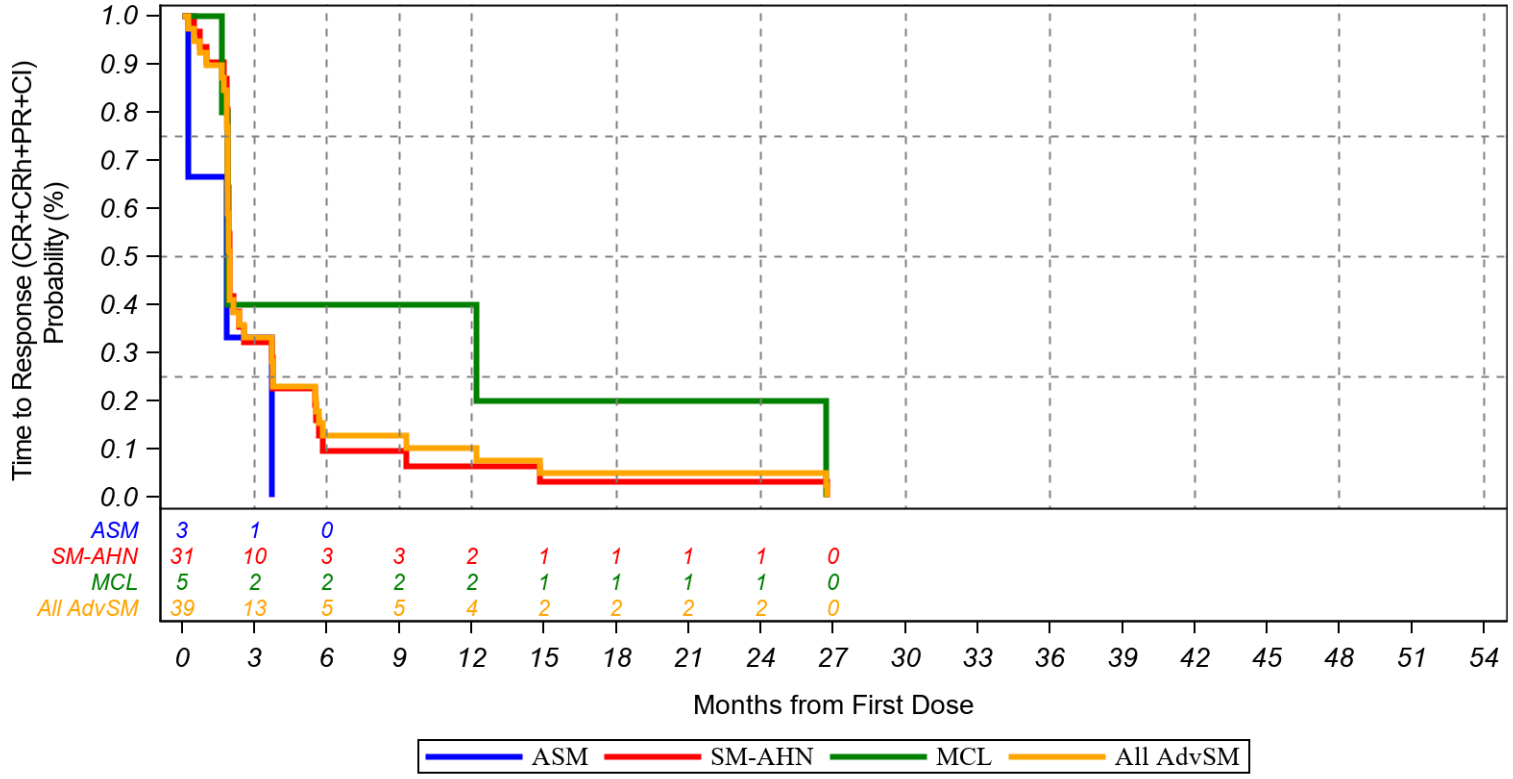

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg

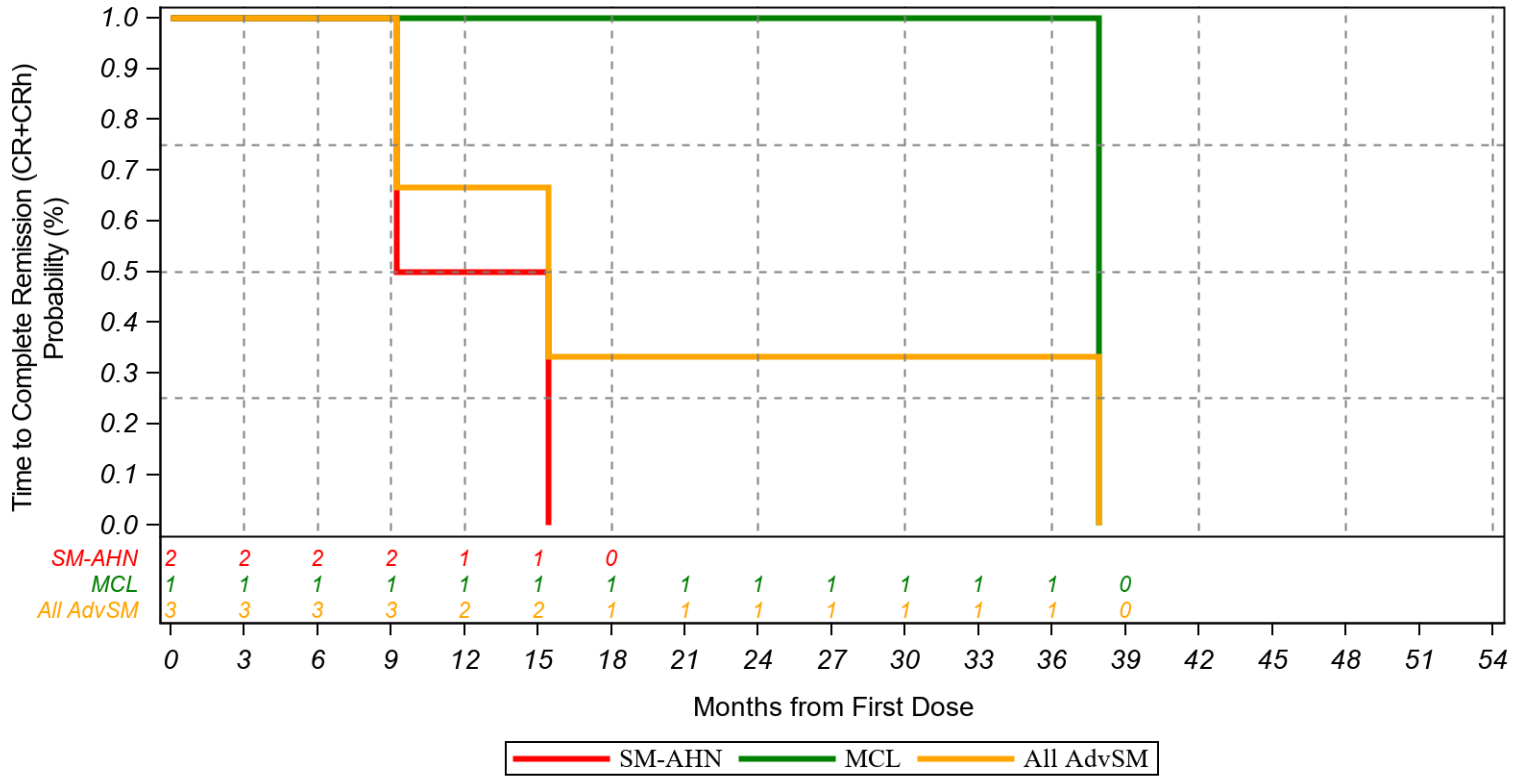

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg

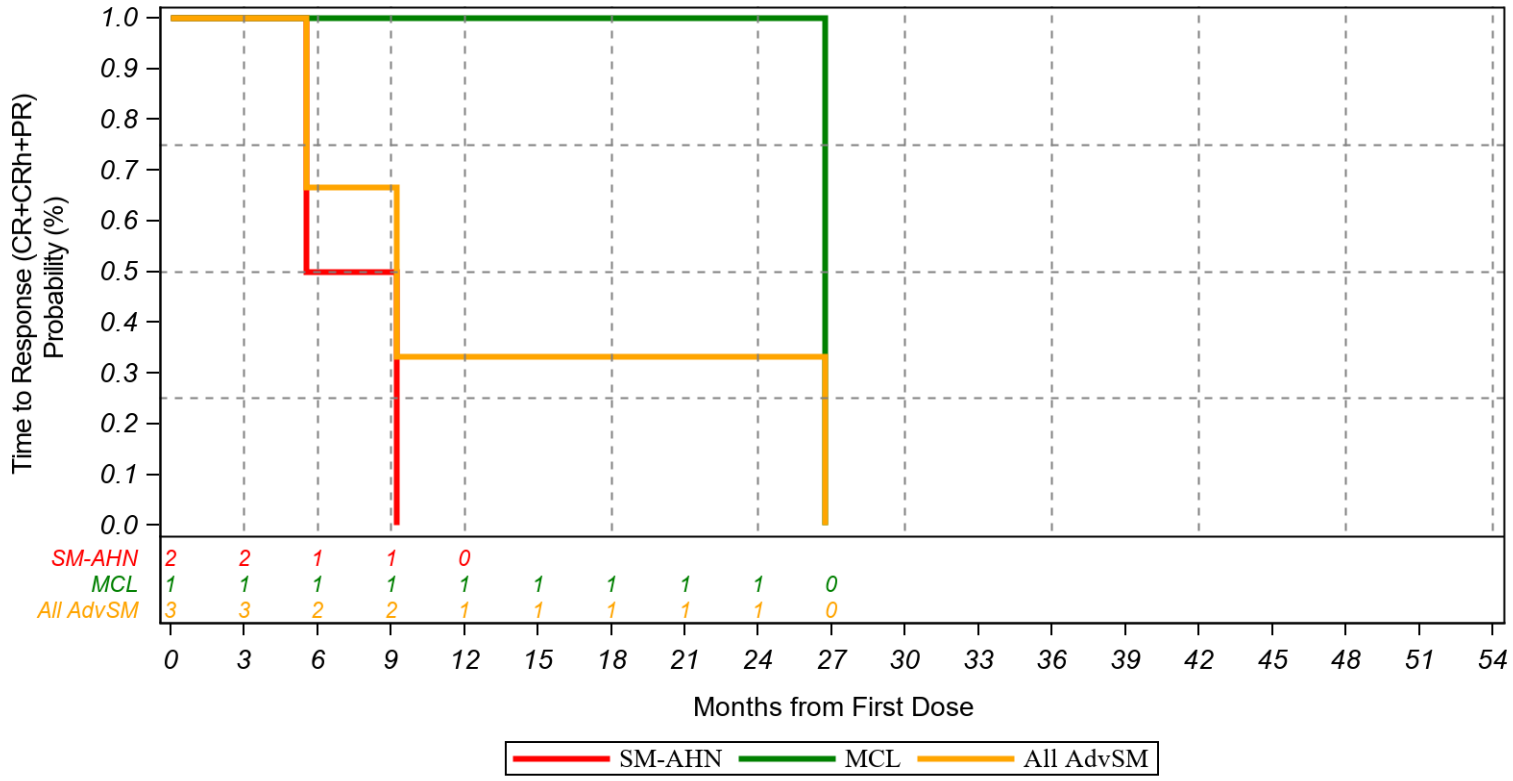

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Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg

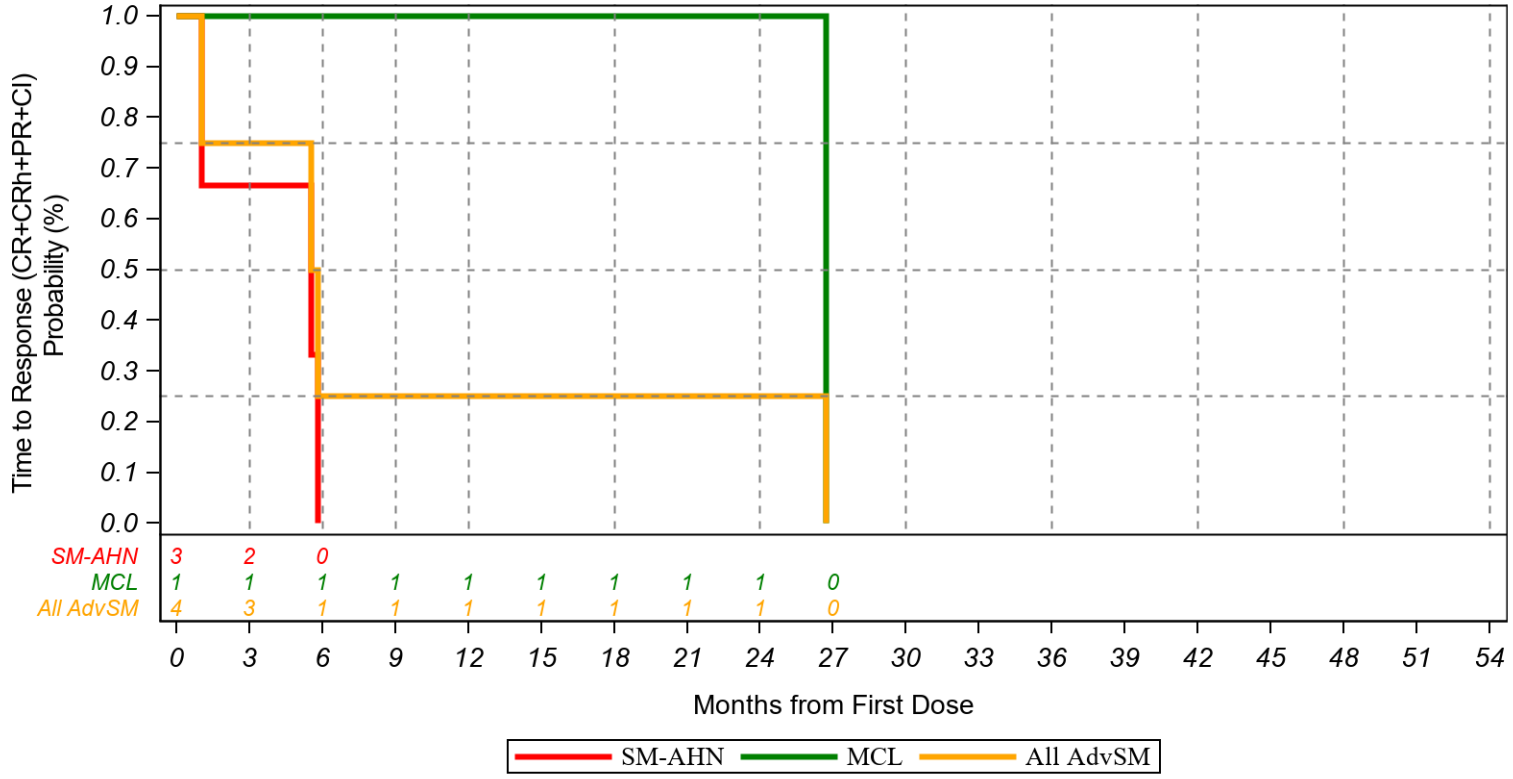

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg

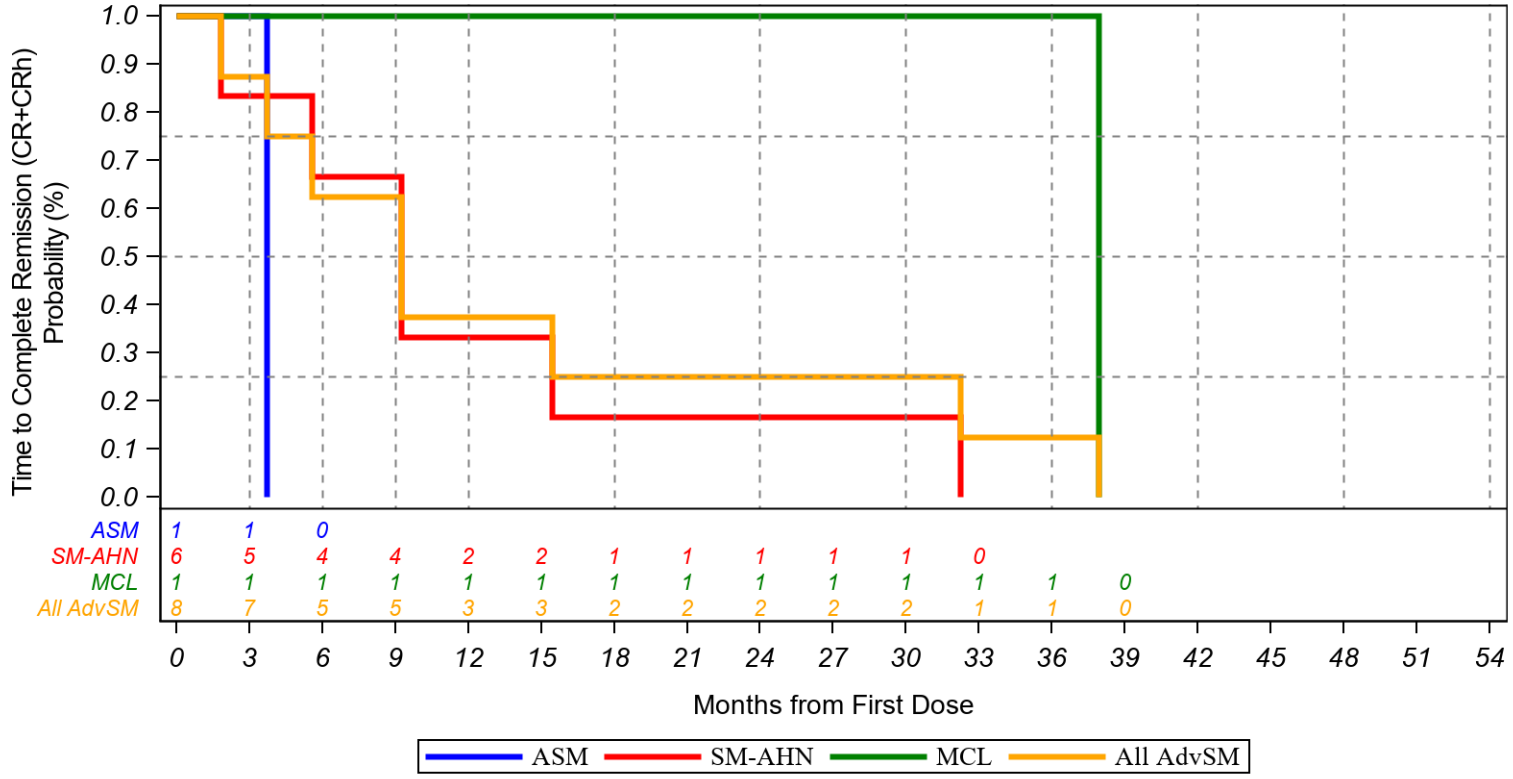

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg

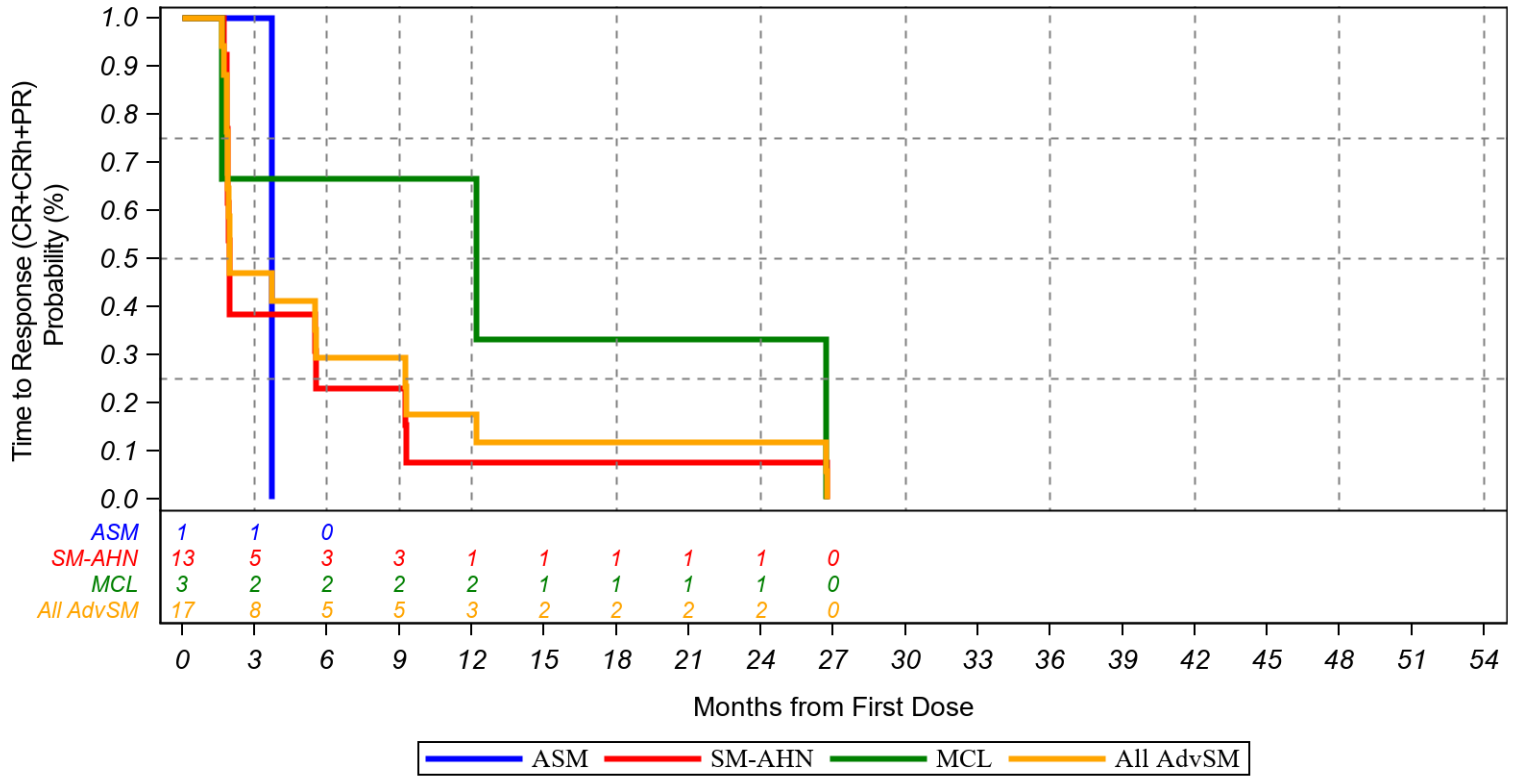

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg

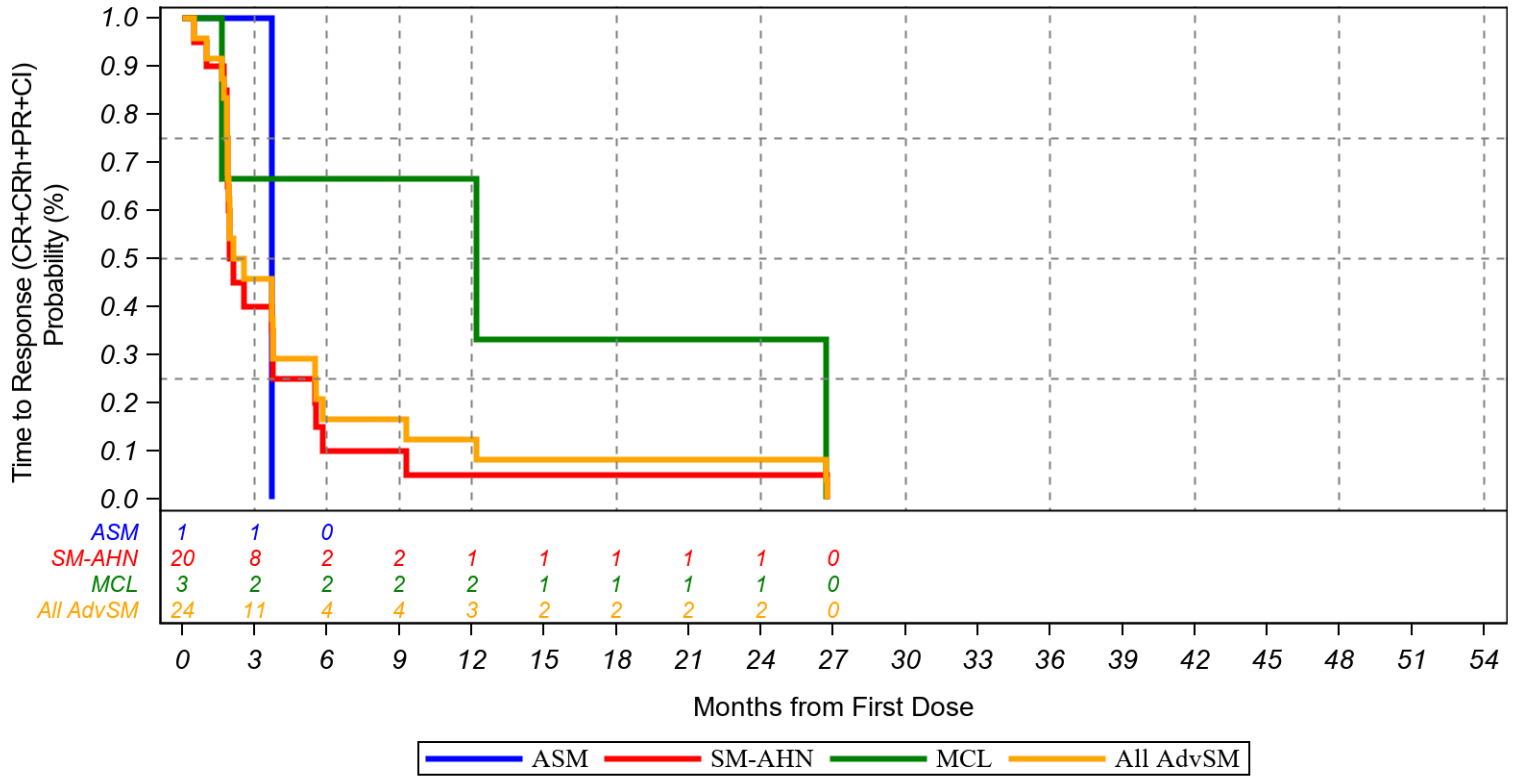

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg

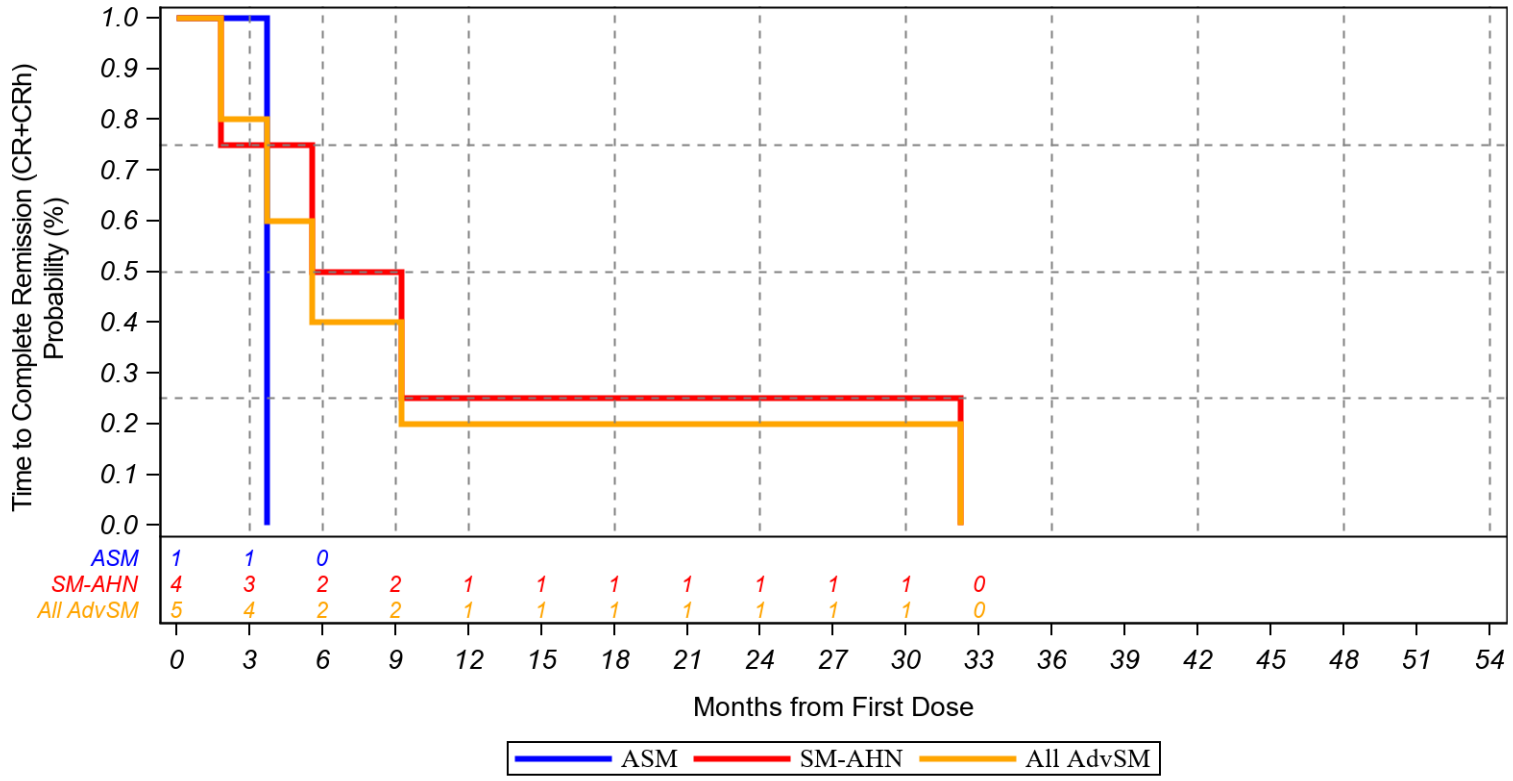

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg

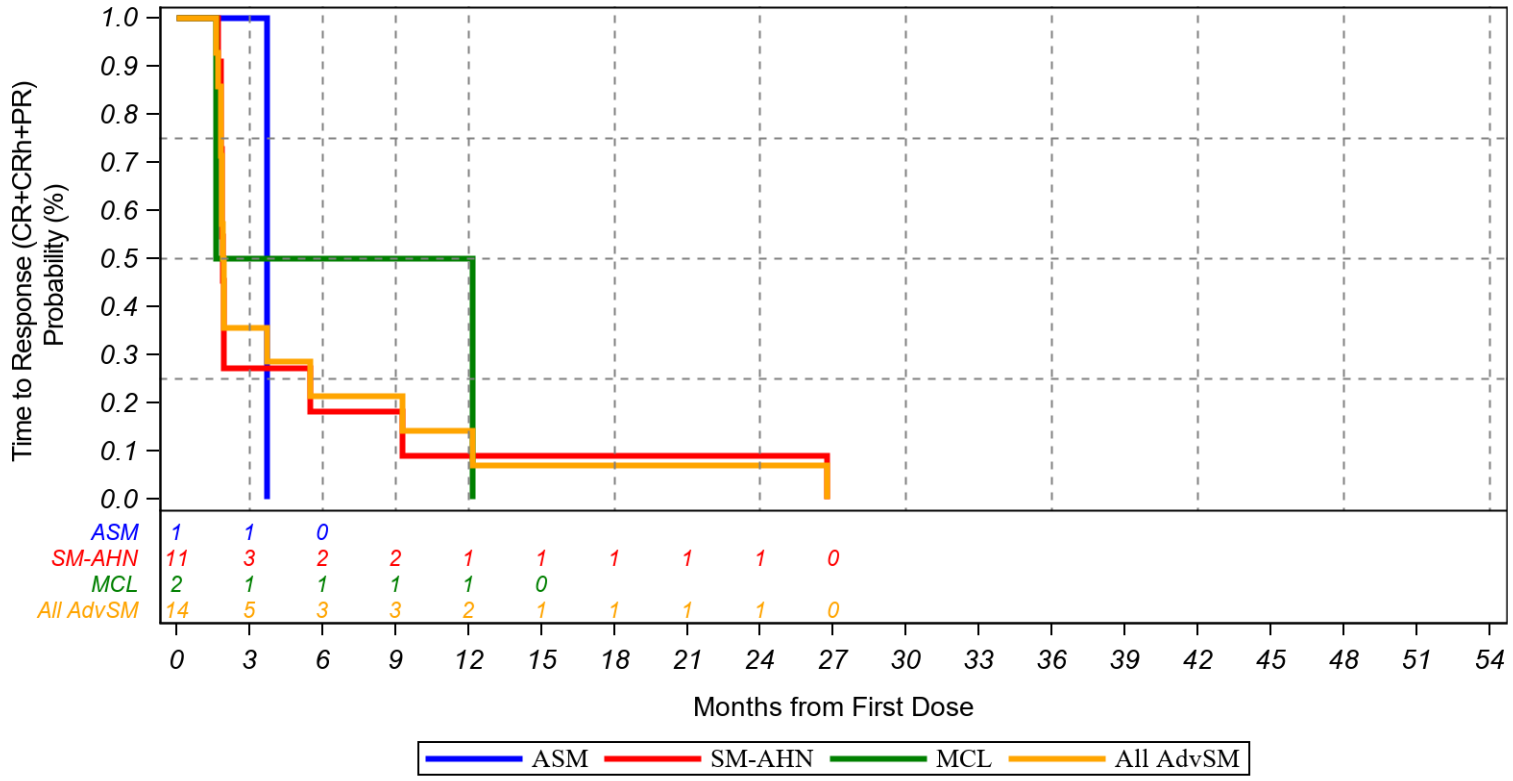

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg

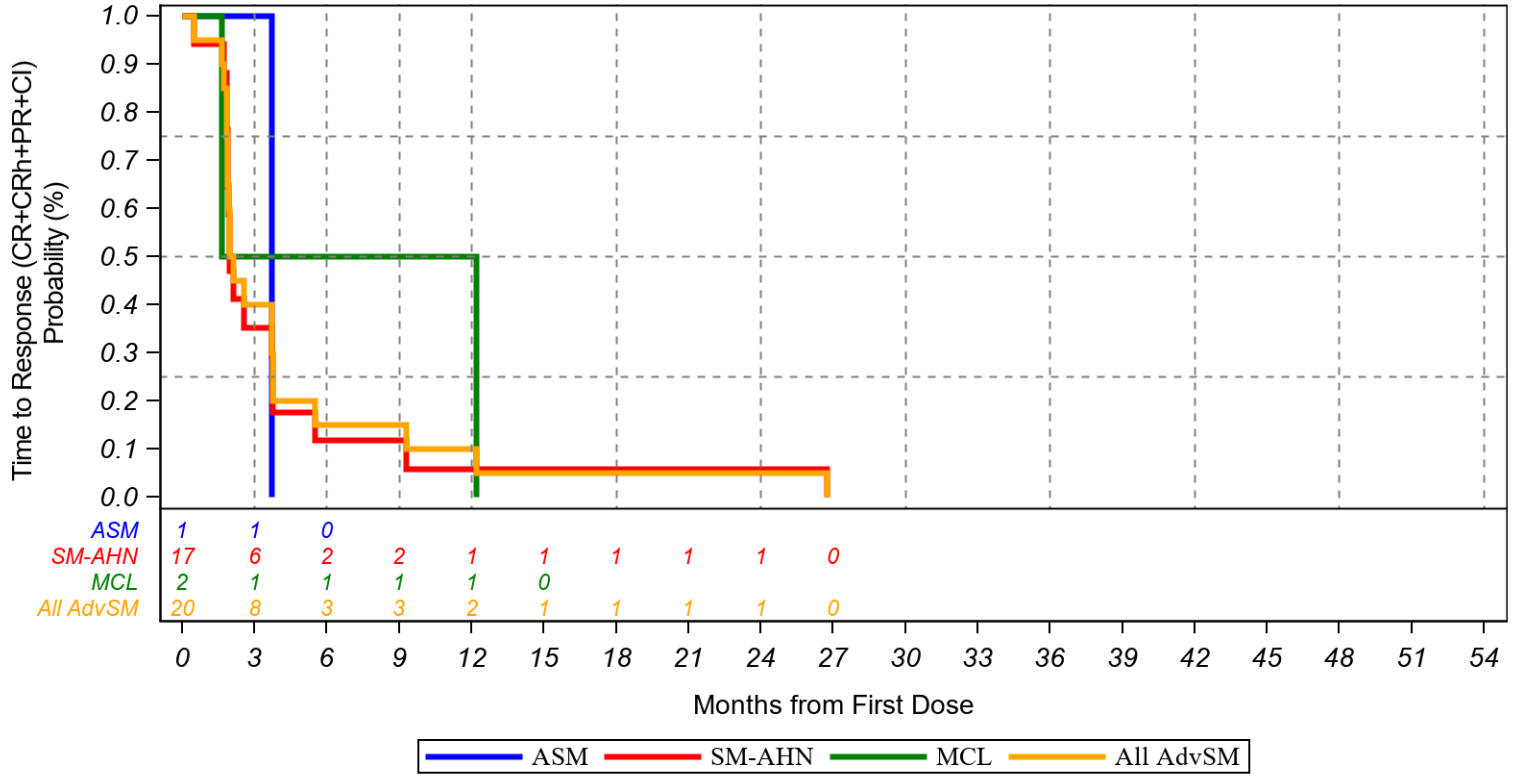

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg

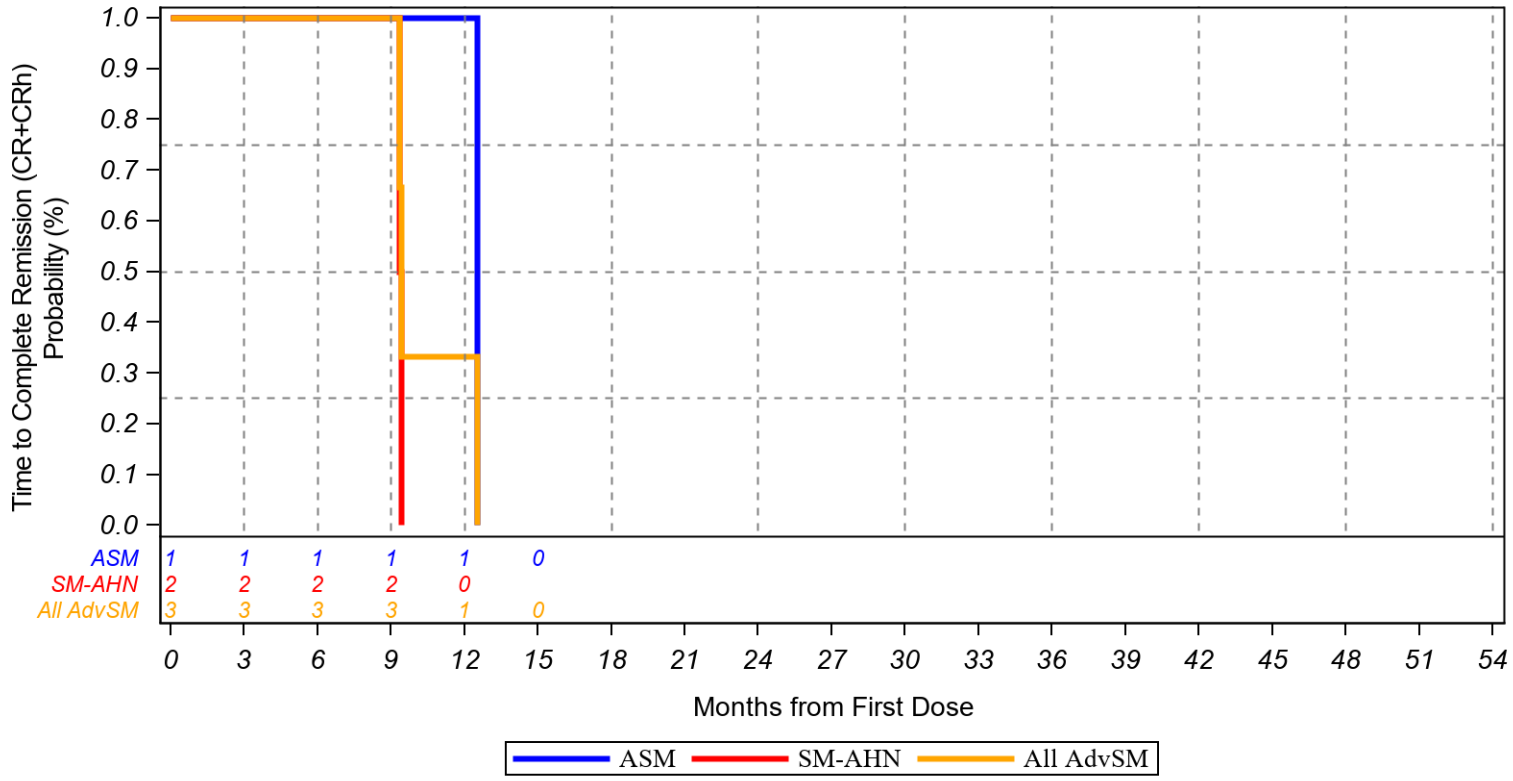

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Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg

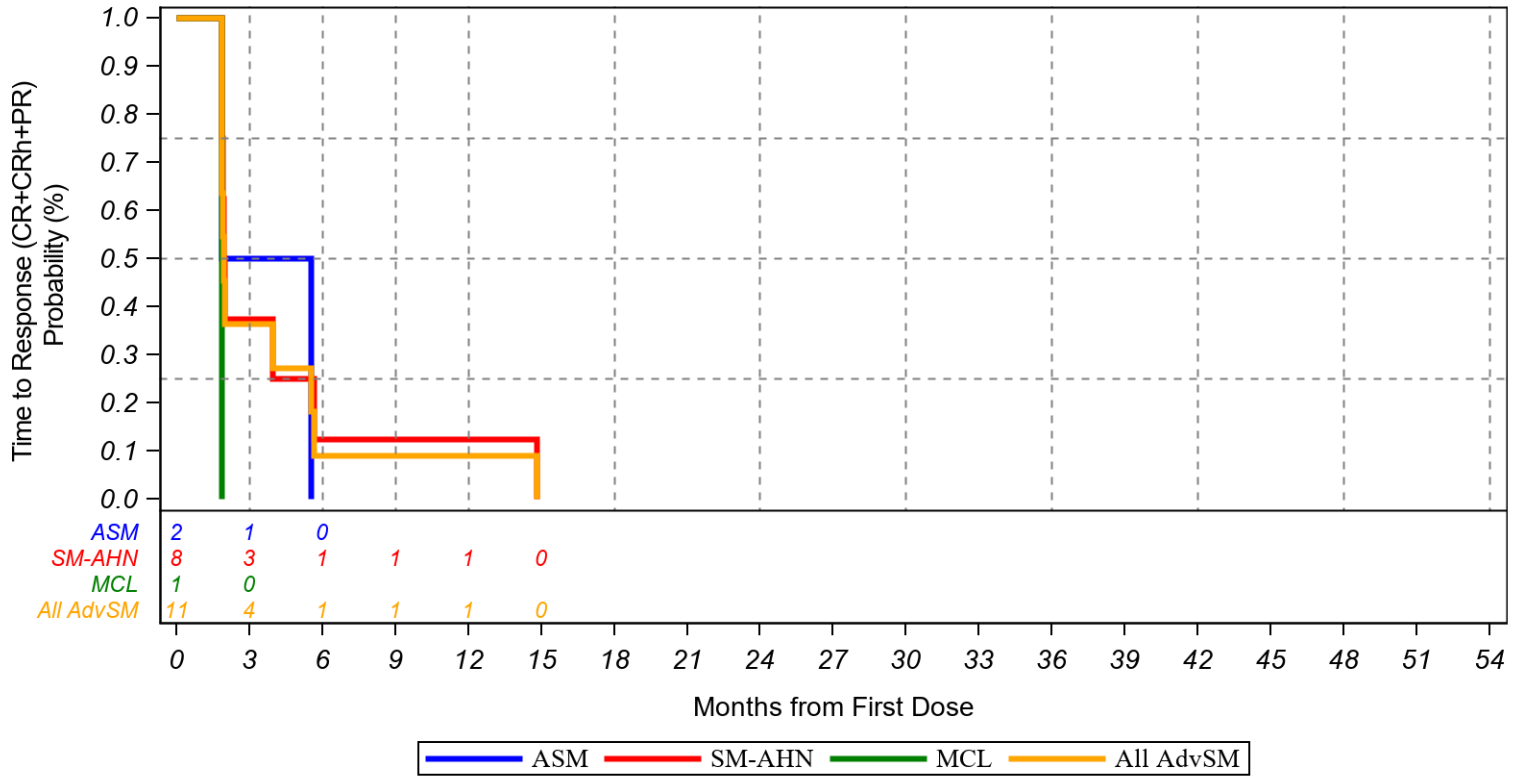

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Figure 35.2.2.6
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RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg

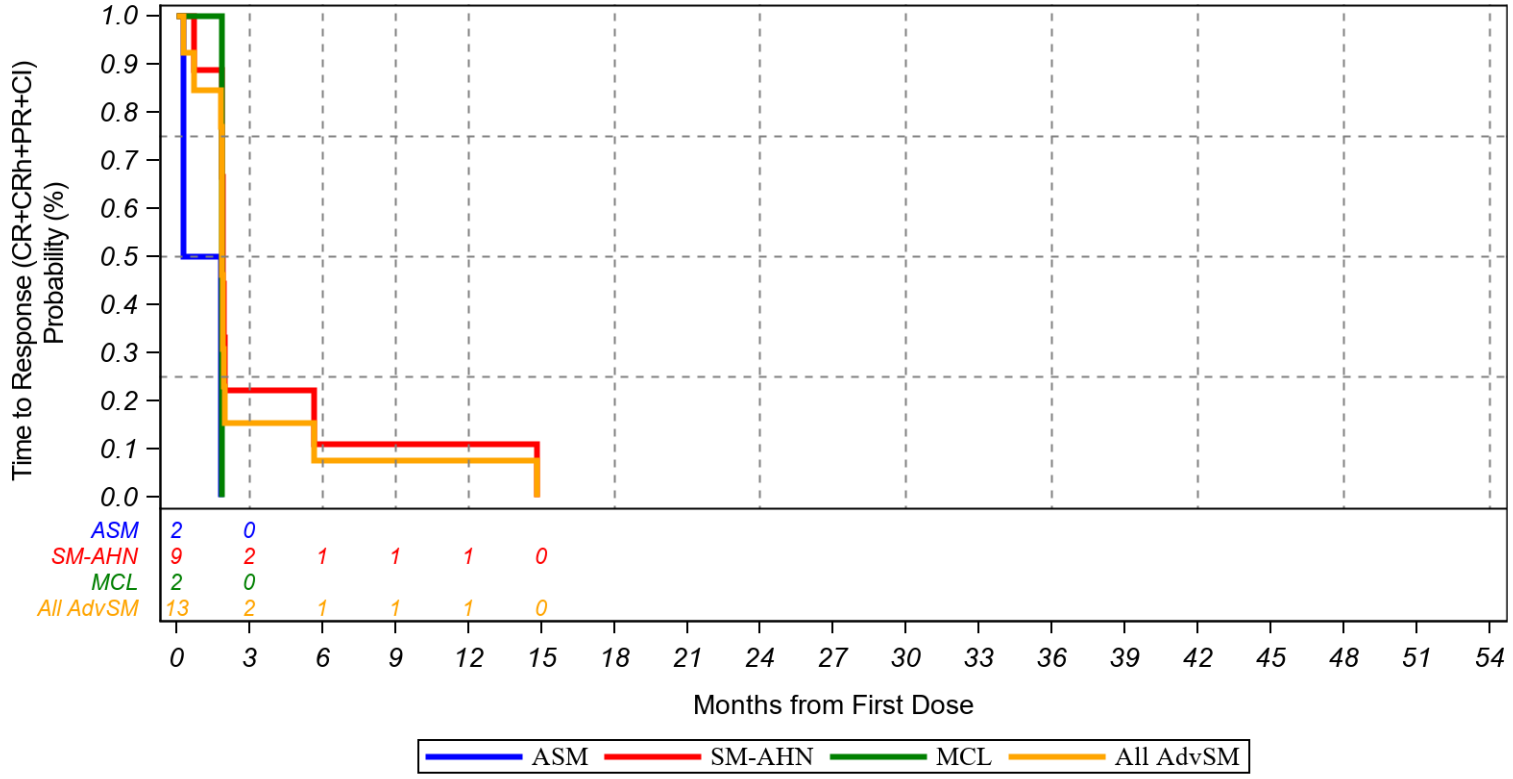


Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg

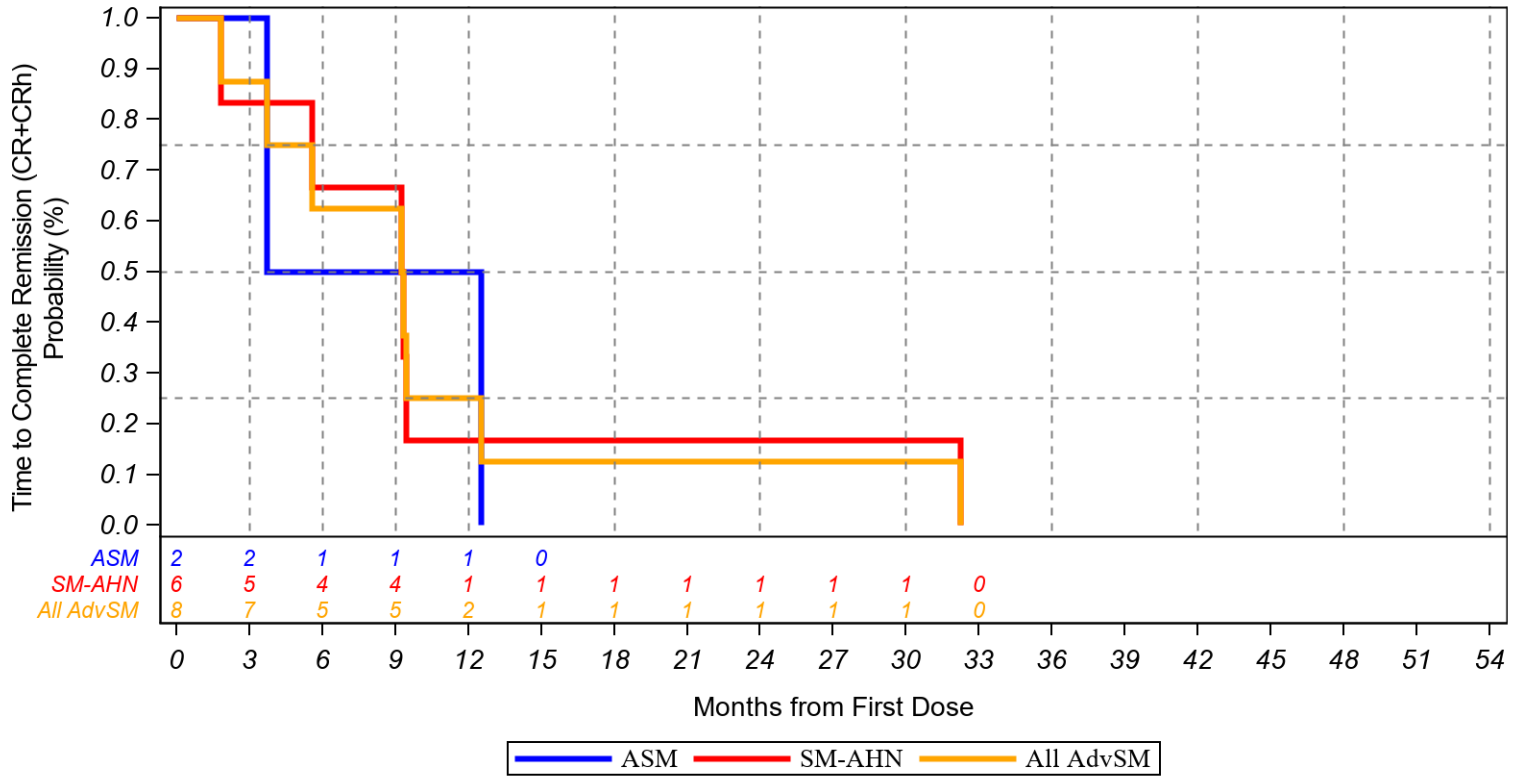
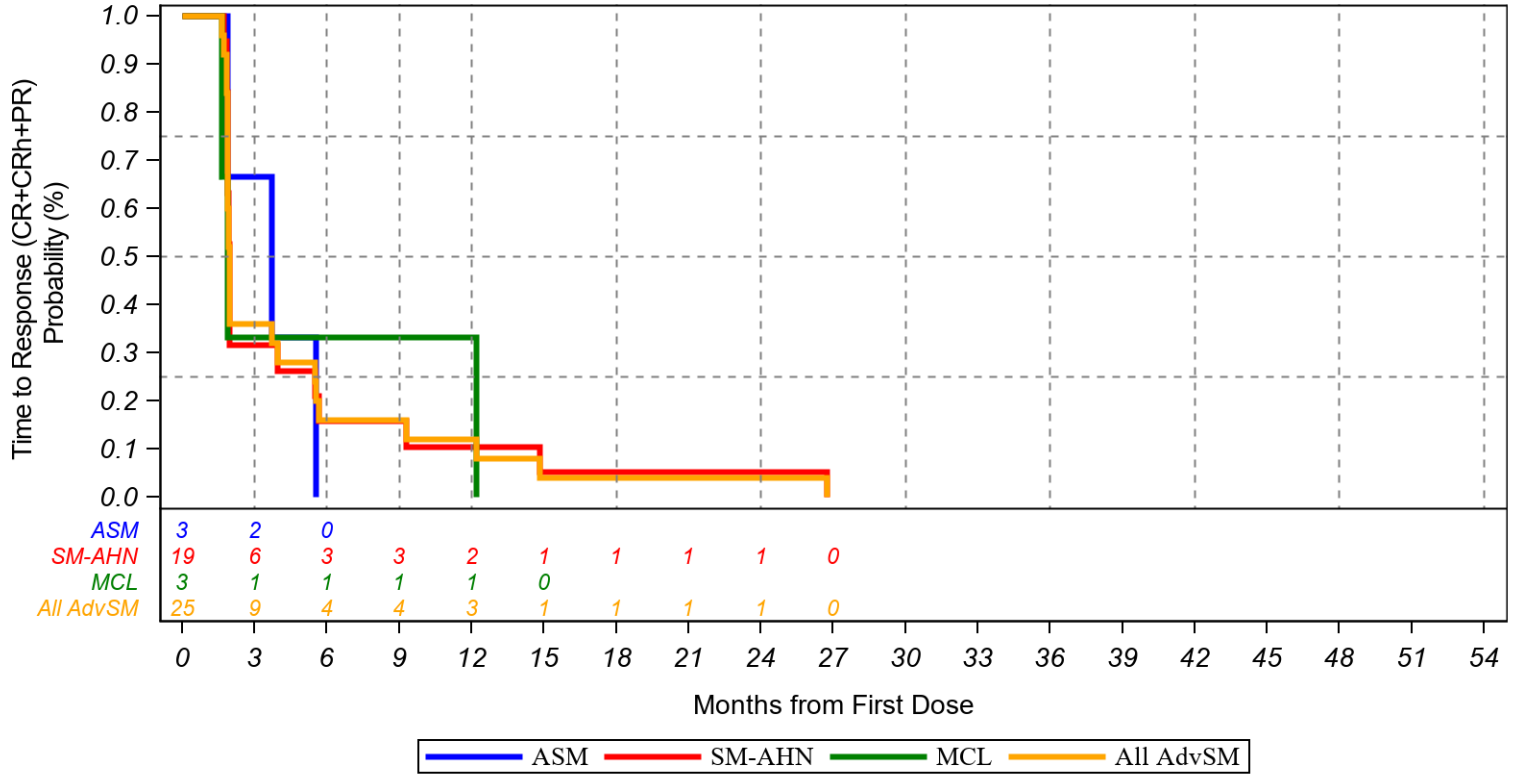


Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg



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BLU-285 SM Germany HTA Analysis
Cutoff date: 27may2020 (2101), 23jun2020 (2202)

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg

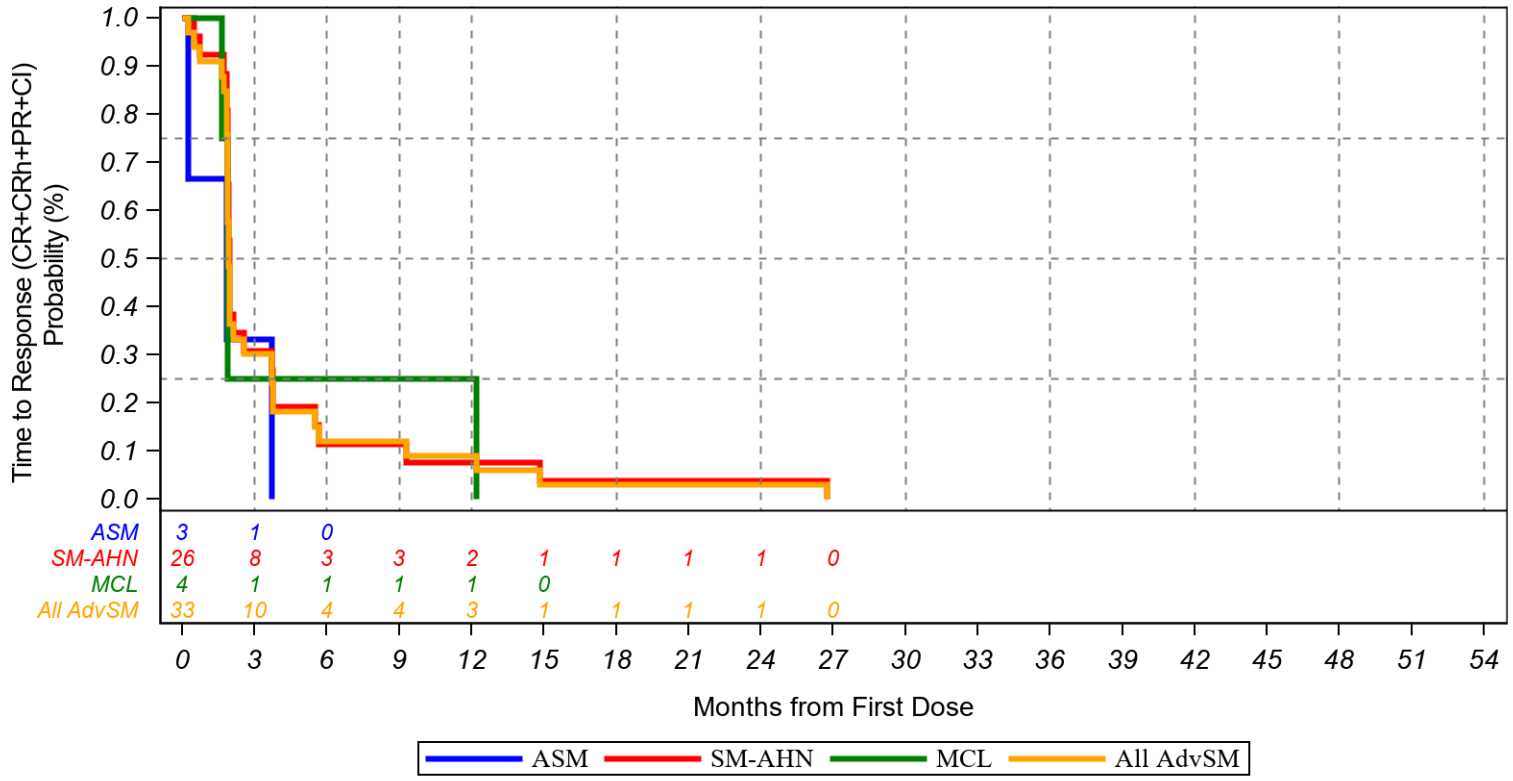

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Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg

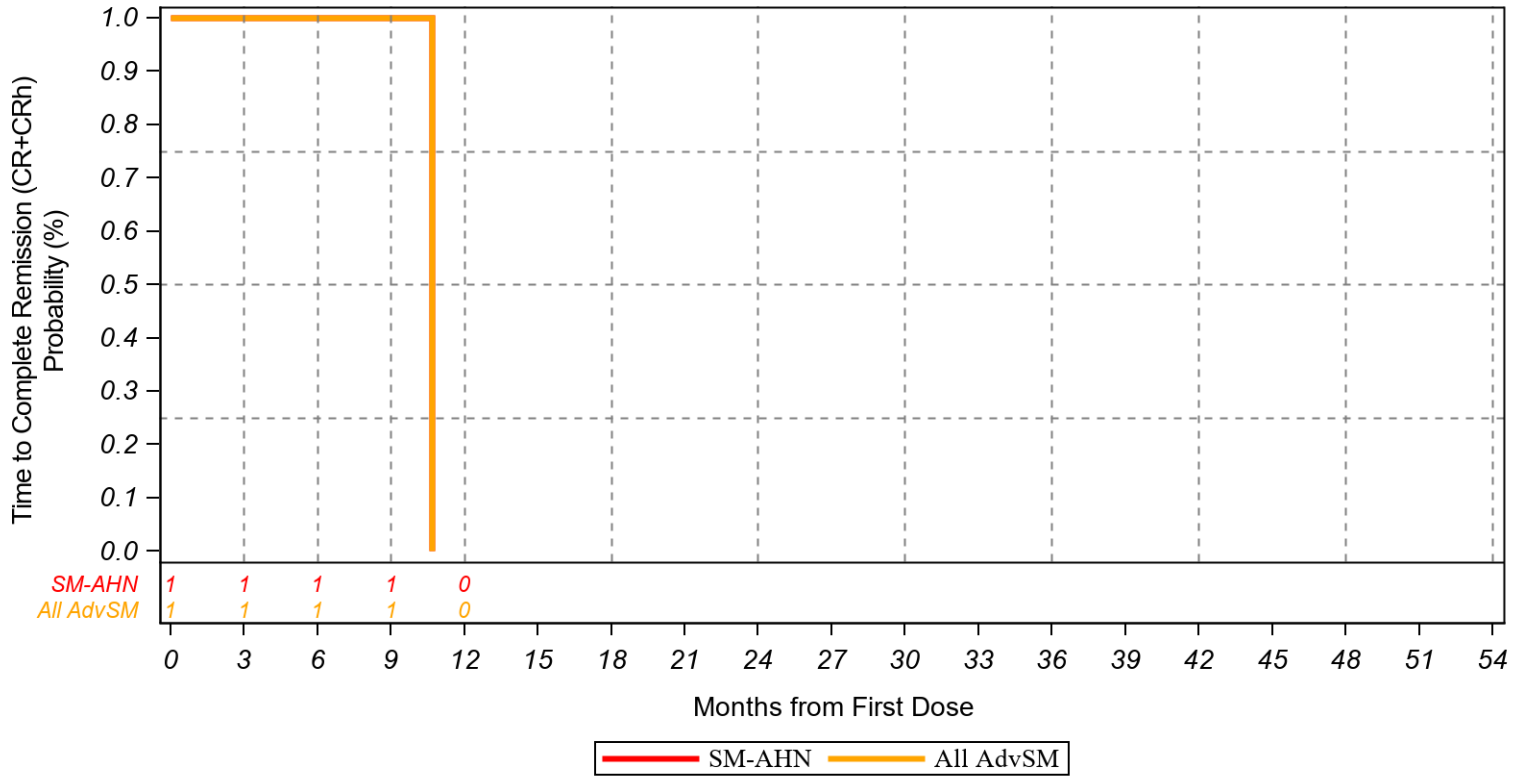

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Figure 35.2.2.6
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RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg

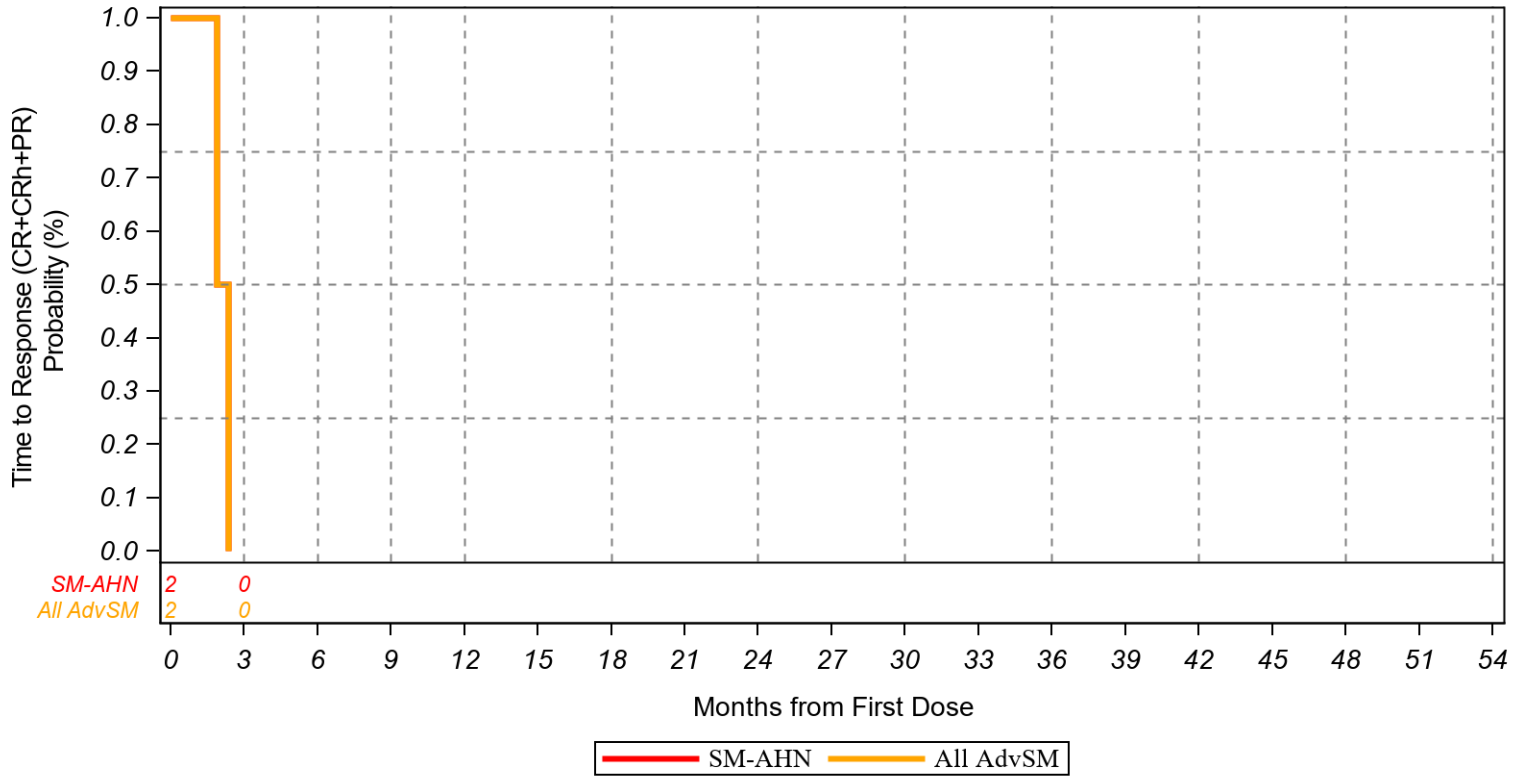

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg

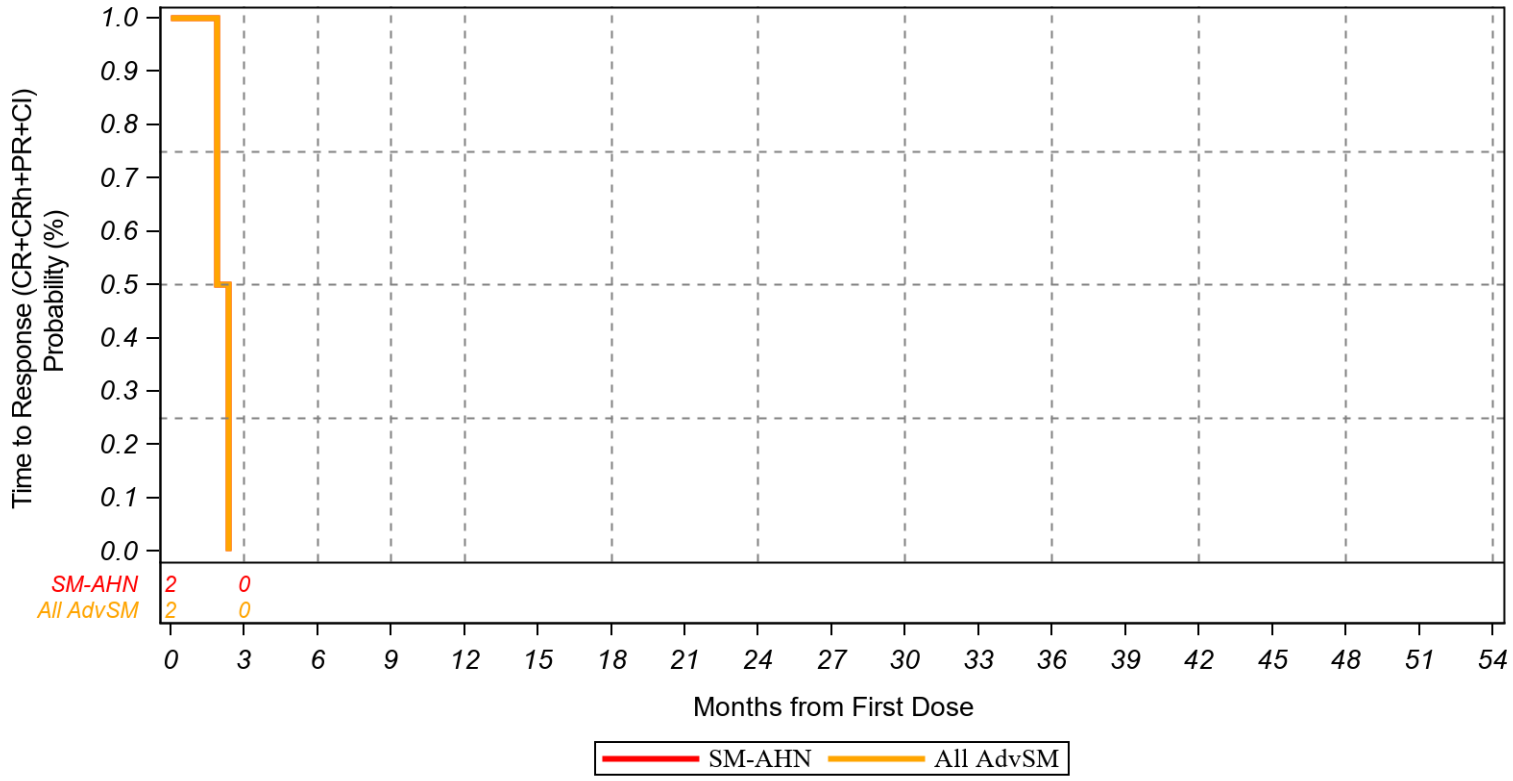

Table 35.2.2.7
Summary of Investigator Assessed Time to Response and Time to Complete Remission
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study 2101

All Doses

	ASM (N=2)	SM-AHN (N=15)	MCL (N=4)	All AdvSM (N=21)
Time to Response (Months)				
n	2	15	4	21
Mean (StdDev)	3.70 (2.579)	3.80 (4.037)	4.53 (3.581)	3.93 (3.709)
Median	3.70	1.87	3.63	1.87
Min, Max	1.9, 5.5	1.8, 16.2	1.6, 9.2	1.6, 16.2
Time to CR+CRh (Months)				
n	1	6	1	8
Mean (StdDev)	9.30 (-)	14.06 (5.598)	37.82 (-)	16.43 (9.991)
Median	9.30	15.98	37.82	15.98
Min, Max	9.3, 9.3	5.6, 21.2	37.8, 37.8	5.6, 37.8
Time to CR+CRh+PR (Months)				
n	2	13	3	18
Mean (StdDev)	11.42 (13.497)	4.70 (4.201)	14.96 (19.883)	7.16 (9.337)
Median	11.42	1.94	5.42	3.61
Min, Max	1.9, 21.0	1.9, 16.2	1.6, 37.8	1.6, 37.8

Source: Listing 16.3.9.5
Abbreviations: CR=Complete reimission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR/CI) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis. Time to CR+CRh+PR is defined as the time from the start of treatment to the time a CR/CRh/PR is first met. Patients without confirmed CR/CRh/PR are excluded from this analysis.
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Table 35.2.2.7
Summary of Investigator Assessed Time to Response and Time to Complete Remission
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study 2101

Starting Dose: < 200 mg

	ASM (N=0)	SM-AHN (N=2)	MCL (N=1)	All AdvSM (N=3)
Time to Response (Months)				
n	-	2	1	3
Mean (StdDev)		7.39 (2.602)	9.23 (-)	8.01 (2.124)
Median		7.39	9.23	9.23
Min, Max		5.6, 9.2	9.2, 9.2	5.6, 9.2
Time to CR+CRh (Months)				
n	-	1	1	2
Mean (StdDev)		15.80 (-)	37.82 (-)	26.81 (15.565)
Median		15.80	37.82	26.81
Min, Max		15.8, 15.8	37.8, 37.8	15.8, 37.8
Time to CR+CRh+PR (Months)				
n	-	1	1	2
Mean (StdDev)		5.55 (-)	37.82 (-)	21.68 (22.813)
Median		5.55	37.82	21.68
Min, Max		5.6, 5.6	37.8, 37.8	5.6, 37.8

Source: Listing 16.3.9.5
Abbreviations: CR=Complete reimission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR/CI) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis. Time to CR+CRh+PR is defined as the time from the start of treatment to the time a CR/CRh/PR is first met. Patients without confirmed CR/CRh/PR are excluded from this analysis.
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Table 35.2.2.7
Summary of Investigator Assessed Time to Response and Time to Complete Remission
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study 2101

Starting Dose: < 300 mg

	ASM (N=0)	SM-AHN (N=5)	MCL (N=3)	All AdvSM (N=8)
Time to Response (Months)				
n	-	5	3	8
Mean (StdDev)		4.07 (3.297)	4.24 (4.326)	4.14 (3.401)
Median		1.87	1.84	1.87
Min, Max		1.8, 9.2	1.6, 9.2	1.6, 9.2
Time to CR+CRh (Months)				
n	-	3	1	4
Mean (StdDev)		14.18 (7.944)	37.82 (-)	20.09 (13.480)
Median		15.80	37.82	18.50
Min, Max		5.6, 21.2	37.8, 37.8	5.6, 37.8
Time to CR+CRh+PR (Months)				
n	-	3	2	5
Mean (StdDev)		3.10 (2.124)	19.73 (25.578)	9.75 (15.773)
Median		1.87	19.73	1.87
Min, Max		1.9, 5.6	1.6, 37.8	1.6, 37.8

Source: Listing 16.3.9.5
Abbreviations: CR=Complete reimission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR/CI) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis. Time to CR+CRh+PR is defined as the time from the start of treatment to the time a CR/CRh/PR is first met. Patients without confirmed CR/CRh/PR are excluded from this analysis.
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Table 35.2.2.7
Summary of Investigator Assessed Time to Response and Time to Complete Remission
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study 2101

Starting Dose: 200 mg

	ASM (N=0)	SM-AHN (N=3)	MCL (N=2)	All AdvSM (N=5)
Time to Response (Months)				
n	-	3	2	5
Mean (StdDev)		1.86 (0.019)	1.74 (0.139)	1.81 (0.097)
Median		1.87	1.74	1.84
Min, Max		1.8, 1.9	1.6, 1.8	1.6, 1.9
Time to CR+CRh (Months)				
n	-	2	0	2
Mean (StdDev)		13.37 (11.058)		13.37 (11.058)
Median		13.37		13.37
Min, Max		5.6, 21.2		5.6, 21.2
Time to CR+CRh+PR (Months)				
n	-	2	1	3
Mean (StdDev)		1.87 (0.000)	1.64 (-)	1.80 (0.133)
Median		1.87	1.64	1.87
Min, Max		1.9, 1.9	1.6, 1.6	1.6, 1.9

Source: Listing 16.3.9.5
Abbreviations: CR=Complete reimission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR/CI) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis. Time to CR+CRh+PR is defined as the time from the start of treatment to the time a CR/CRh/PR is first met. Patients without confirmed CR/CRh/PR are excluded from this analysis.
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Table 35.2.2.7
Summary of Investigator Assessed Time to Response and Time to Complete Remission
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study 2101

Starting Dose: 300 mg

	ASM (N=2)	SM-AHN (N=8)	MCL (N=1)	All AdvSM (N=11)
Time to Response (Months)				
n	2	8	1	11
Mean (StdDev)	3.70 (2.579)	2.32 (1.202)	5.42 (-)	2.85 (1.646)
Median	3.70	1.89	5.42	1.91
Min, Max	1.9, 5.5	1.9, 5.3	5.4, 5.4	1.9, 5.5
Time to CR+CRh (Months)				
n	1	1	0	2
Mean (StdDev)	9.30 (-)	9.43 (-)		9.36 (0.093)
Median	9.30	9.43		9.36
Min, Max	9.3, 9.3	9.4, 9.4		9.3, 9.4
Time to CR+CRh+PR (Months)				
n	2	8	1	11
Mean (StdDev)	11.42 (13.497)	3.70 (2.778)	5.42 (-)	5.26 (5.757)
Median	11.42	1.92	5.42	1.94
Min, Max	1.9, 21.0	1.9, 9.3	5.4, 5.4	1.9, 21.0

Source: Listing 16.3.9.5
Abbreviations: CR=Complete reimission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR/CI) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis. Time to CR+CRh+PR is defined as the time from the start of treatment to the time a CR/CRh/PR is first met. Patients without confirmed CR/CRh/PR are excluded from this analysis.
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Table 35.2.2.7
Summary of Investigator Assessed Time to Response and Time to Complete Remission
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study 2101

Starting Dose: 200 mg and 300 mg

	ASM (N=2)	SM-AHN (N=11)	MCL (N=3)	All AdvSM (N=16)
Time to Response (Months)				
n	2	11	3	16
Mean (StdDev)	3.70 (2.579)	2.19 (1.028)	2.97 (2.127)	2.53 (1.433)
Median	3.70	1.87	1.84	1.87
Min, Max	1.9, 5.5	1.8, 5.3	1.6, 5.4	1.6, 5.5
Time to CR+CRh (Months)				
n	1	3	0	4
Mean (StdDev)	9.30 (-)	12.06 (8.144)		11.37 (6.791)
Median	9.30	9.43		9.36
Min, Max	9.3, 9.3	5.6, 21.2		5.6, 21.2
Time to CR+CRh+PR (Months)				
n	2	10	2	14
Mean (StdDev)	11.42 (13.497)	3.34 (2.568)	3.53 (2.672)	4.52 (5.260)
Median	11.42	1.89	3.53	1.89
Min, Max	1.9, 21.0	1.9, 9.3	1.6, 5.4	1.6, 21.0

Source: Listing 16.3.9.5
Abbreviations: CR=Complete reimission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR/CI) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis. Time to CR+CRh+PR is defined as the time from the start of treatment to the time a CR/CRh/PR is first met. Patients without confirmed CR/CRh/PR are excluded from this analysis.
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Table 35.2.2.7
Summary of Investigator Assessed Time to Response and Time to Complete Remission
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study 2101

Starting Dose: 400 mg

	ASM (N=0)	SM-AHN (N=2)	MCL (N=0)	All AdvSM (N=2)
Time to Response (Months)				
n	-	2	-	2
Mean (StdDev)		9.02 (10.106)		9.02 (10.106)
Median		9.02		9.02
Min, Max		1.9, 16.2		1.9, 16.2
Time to CR+CRh (Months)				
n	-	2	-	2
Mean (StdDev)		16.18 (0.023)		16.18 (0.023)
Median		16.18		16.18
Min, Max		16.2, 16.2		16.2, 16.2
Time to CR+CRh+PR (Months)				
n	-	2	-	2
Mean (StdDev)		11.09 (7.179)		11.09 (7.179)
Median		11.09		11.09
Min, Max		6.0, 16.2		6.0, 16.2

Source: Listing 16.3.9.5
Abbreviations: CR=Complete reimission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR/CI) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis. Time to CR+CRh+PR is defined as the time from the start of treatment to the time a CR/CRh/PR is first met. Patients without confirmed CR/CRh/PR are excluded from this analysis.
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Table 35.2.2.7
Summary of Investigator Assessed Time to Response and Time to Complete Remission
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study 2202

All Doses

	ASM (N=0)	SM-AHN (N=12)	MCL (N=1)	All AdvSM (N=13)
Time to Response (Months)				
n	-	12	1	13
Mean (StdDev)		2.90 (1.056)	5.75 (-)	3.12 (1.283)
Median		2.79	5.75	3.65
Min, Max		1.8, 4.4	5.7, 5.7	1.8, 5.7
Time to CR+CRh (Months)				
n	-	2	0	2
Mean (StdDev)		4.67 (1.301)		4.67 (1.301)
Median		4.67		4.67
Min, Max		3.7, 5.6		3.7, 5.6
Time to CR+CRh+PR (Months)				
n	-	7	1	8
Mean (StdDev)		3.26 (1.446)	5.75 (-)	3.57 (1.603)
Median		3.65	5.75	3.70
Min, Max		1.9, 5.8	5.7, 5.7	1.9, 5.8

Source: Listing 16.3.9.5
Abbreviations: CR=Complete reimission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR/CI) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis. Time to CR+CRh+PR is defined as the time from the start of treatment to the time a CR/CRh/PR is first met. Patients without confirmed CR/CRh/PR are excluded from this analysis.
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Table 35.2.2.7
Summary of Investigator Assessed Time to Response and Time to Complete Remission
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study 2202

Starting Dose: 200 mg

	ASM (N=0)	SM-AHN (N=11)	MCL (N=1)	All AdvSM (N=12)
Time to Response (Months)				
n	-	11	1	12
Mean (StdDev)		2.82 (1.069)	5.75 (-)	3.06 (1.324)
Median		1.94	5.75	2.79
Min, Max		1.8, 4.4	5.7, 5.7	1.8, 5.7
Time to CR+CRh (Months)				
n	-	2	0	2
Mean (StdDev)		4.67 (1.301)		4.67 (1.301)
Median		4.67		4.67
Min, Max		3.7, 5.6		3.7, 5.6
Time to CR+CRh+PR (Months)				
n	-	6	1	7
Mean (StdDev)		2.83 (0.991)	5.75 (-)	3.25 (1.427)
Median		2.79	5.75	3.65
Min, Max		1.9, 3.8	5.7, 5.7	1.9, 5.7

Source: Listing 16.3.9.5
Abbreviations: CR=Complete reimission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR/CI) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis. Time to CR+CRh+PR is defined as the time from the start of treatment to the time a CR/CRh/PR is first met. Patients without confirmed CR/CRh/PR are excluded from this analysis.
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Table 35.2.2.7
Summary of Investigator Assessed Time to Response and Time to Complete Remission
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies 2101 and 2202

All Doses

	ASM (N=2)	SM-AHN (N=27)	MCL (N=5)	All AdvSM (N=34)
Time to Response (Months)				
n	2	27	5	34
Mean (StdDev)	3.70 (2.579)	3.40 (3.075)	4.78 (3.149)	3.62 (3.016)
Median	3.70	1.94	5.42	1.94
Min, Max	1.9, 5.5	1.8, 16.2	1.6, 9.2	1.6, 16.2
Time to CR+CRh (Months)				
n	1	8	1	10
Mean (StdDev)	9.30 (-)	11.71 (6.444)	37.82 (-)	14.08 (10.121)
Median	9.30	12.62	37.82	12.62
Min, Max	9.3, 9.3	3.7, 21.2	37.8, 37.8	3.7, 37.8
Time to CR+CRh+PR (Months)				
n	2	20	4	26
Mean (StdDev)	11.42 (13.497)	4.20 (3.508)	12.66 (16.875)	6.05 (7.928)
Median	11.42	2.79	5.59	3.70
Min, Max	1.9, 21.0	1.9, 16.2	1.6, 37.8	1.6, 37.8

Source: Listing 16.3.9.5
Abbreviations: CR=Complete reimission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR/CI) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis. Time to CR+CRh+PR is defined as the time from the start of treatment to the time a CR/CRh/PR is first met. Patients without confirmed CR/CRh/PR are excluded from this analysis.
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Table 35.2.2.7
Summary of Investigator Assessed Time to Response and Time to Complete Remission
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies 2101 and 2202

Starting Dose: < 200 mg

	ASM (N=0)	SM-AHN (N=3)	MCL (N=1)	All AdvSM (N=4)
Time to Response (Months)				
n	-	3	1	4
Mean (StdDev)		6.19 (2.782)	9.23 (-)	6.95 (2.734)
Median		5.55	9.23	7.39
Min, Max		3.8, 9.2	9.2, 9.2	3.8, 9.2
Time to CR+CRh (Months)				
n	-	1	1	2
Mean (StdDev)		15.80 (-)	37.82 (-)	26.81 (15.565)
Median		15.80	37.82	26.81
Min, Max		15.8, 15.8	37.8, 37.8	15.8, 37.8
Time to CR+CRh+PR (Months)				
n	-	2	1	3
Mean (StdDev)		5.68 (0.186)	37.82 (-)	16.39 (18.552)
Median		5.68	37.82	5.82
Min, Max		5.6, 5.8	37.8, 37.8	5.6, 37.8

Source: Listing 16.3.9.5
Abbreviations: CR=Complete reimission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR/CI) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis. Time to CR+CRh+PR is defined as the time from the start of treatment to the time a CR/CRh/PR is first met. Patients without confirmed CR/CRh/PR are excluded from this analysis.
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Table 35.2.2.7
Summary of Investigator Assessed Time to Response and Time to Complete Remission
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies 2101 and 2202

Starting Dose: < 300 mg

	ASM (N=0)	SM-AHN (N=17)	MCL (N=4)	All AdvSM (N=21)
Time to Response (Months)				
n	-	17	4	21
Mean (StdDev)		3.24 (1.946)	4.62 (3.612)	3.51 (2.300)
Median		1.94	3.79	1.94
Min, Max		1.8, 9.2	1.6, 9.2	1.6, 9.2
Time to CR+CRh (Months)				
n	-	5	1	6
Mean (StdDev)		10.38 (7.691)	37.82 (-)	14.95 (13.146)
Median		5.59	37.82	10.69
Min, Max		3.7, 21.2	37.8, 37.8	3.7, 37.8
Time to CR+CRh+PR (Months)				
n	-	10	3	13
Mean (StdDev)		3.21 (1.550)	15.07 (19.805)	5.95 (9.707)
Median		2.79	5.75	3.65
Min, Max		1.9, 5.8	1.6, 37.8	1.6, 37.8

Source: Listing 16.3.9.5
Abbreviations: CR=Complete reimission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR/CI) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis. Time to CR+CRh+PR is defined as the time from the start of treatment to the time a CR/CRh/PR is first met. Patients without confirmed CR/CRh/PR are excluded from this analysis.
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Table 35.2.2.7
Summary of Investigator Assessed Time to Response and Time to Complete Remission
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies 2101 and 2202

Starting Dose: 200 mg

	ASM (N=0)	SM-AHN (N=14)	MCL (N=3)	All AdvSM (N=17)
Time to Response (Months)				
n	-	14	3	17
Mean (StdDev)		2.61 (1.022)	3.08 (2.316)	2.70 (1.246)
Median		1.94	1.84	1.94
Min, Max		1.8, 4.4	1.6, 5.7	1.6, 5.7
Time to CR+CRh (Months)				
n	-	4	0	4
Mean (StdDev)		9.02 (8.160)		9.02 (8.160)
Median		5.57		5.57
Min, Max		3.7, 21.2		3.7, 21.2
Time to CR+CRh+PR (Months)				
n	-	8	2	10
Mean (StdDev)		2.59 (0.948)	3.70 (2.904)	2.81 (1.361)
Median		1.94	3.70	1.94
Min, Max		1.9, 3.8	1.6, 5.7	1.6, 5.7

Source: Listing 16.3.9.5
Abbreviations: CR=Complete reimission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR/CI) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis. Time to CR+CRh+PR is defined as the time from the start of treatment to the time a CR/CRh/PR is first met. Patients without confirmed CR/CRh/PR are excluded from this analysis.
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Table 35.2.2.7
Summary of Investigator Assessed Time to Response and Time to Complete Remission
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies 2101 and 2202

Starting Dose: 300 mg

	ASM (N=2)	SM-AHN (N=8)	MCL (N=1)	All AdvSM (N=11)
Time to Response (Months)				
n	2	8	1	11
Mean (StdDev)	3.70 (2.579)	2.32 (1.202)	5.42 (-)	2.85 (1.646)
Median	3.70	1.89	5.42	1.91
Min, Max	1.9, 5.5	1.9, 5.3	5.4, 5.4	1.9, 5.5
Time to CR+CRh (Months)				
n	1	1	0	2
Mean (StdDev)	9.30 (-)	9.43 (-)		9.36 (0.093)
Median	9.30	9.43		9.36
Min, Max	9.3, 9.3	9.4, 9.4		9.3, 9.4
Time to CR+CRh+PR (Months)				
n	2	8	1	11
Mean (StdDev)	11.42 (13.497)	3.70 (2.778)	5.42 (-)	5.26 (5.757)
Median	11.42	1.92	5.42	1.94
Min, Max	1.9, 21.0	1.9, 9.3	5.4, 5.4	1.9, 21.0

Source: Listing 16.3.9.5
Abbreviations: CR=Complete reimission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR/CI) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis. Time to CR+CRh+PR is defined as the time from the start of treatment to the time a CR/CRh/PR is first met. Patients without confirmed CR/CRh/PR are excluded from this analysis.
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Table 35.2.2.7
Summary of Investigator Assessed Time to Response and Time to Complete Remission
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies 2101 and 2202

Starting Dose: 200 mg and 300 mg

	ASM (N=2)	SM-AHN (N=22)	MCL (N=4)	All AdvSM (N=28)
Time to Response (Months)				
n	2	22	4	28
Mean (StdDev)	3.70 (2.579)	2.51 (1.072)	3.66 (2.225)	2.76 (1.389)
Median	3.70	1.91	3.63	1.91
Min, Max	1.9, 5.5	1.8, 5.3	1.6, 5.7	1.6, 5.7
Time to CR+CRh (Months)				
n	1	5	0	6
Mean (StdDev)	9.30 (-)	9.10 (7.069)		9.13 (6.324)
Median	9.30	5.59		7.44
Min, Max	9.3, 9.3	3.7, 21.2		3.7, 21.2
Time to CR+CRh+PR (Months)				
n	2	16	3	21
Mean (StdDev)	11.42 (13.497)	3.15 (2.086)	4.27 (2.282)	4.10 (4.356)
Median	11.42	1.94	5.42	1.94
Min, Max	1.9, 21.0	1.9, 9.3	1.6, 5.7	1.6, 21.0

Source: Listing 16.3.9.5
Abbreviations: CR=Complete reimission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR/CI) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis. Time to CR+CRh+PR is defined as the time from the start of treatment to the time a CR/CRh/PR is first met. Patients without confirmed CR/CRh/PR are excluded from this analysis.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-tm.sas Date: 15:05/18OCT2021

Table 35.2.2.7
Summary of Investigator Assessed Time to Response and Time to Complete Remission
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies 2101 and 2202

Starting Dose: 400 mg

	ASM (N=0)	SM-AHN (N=2)	MCL (N=0)	All AdvSM (N=2)
Time to Response (Months)				
n	-	2	-	2
Mean (StdDev)		9.02 (10.106)		9.02 (10.106)
Median		9.02		9.02
Min, Max		1.9, 16.2		1.9, 16.2
Time to CR+CRh (Months)				
n	-	2	-	2
Mean (StdDev)		16.18 (0.023)		16.18 (0.023)
Median		16.18		16.18
Min, Max		16.2, 16.2		16.2, 16.2
Time to CR+CRh+PR (Months)				
n	-	2	-	2
Mean (StdDev)		11.09 (7.179)		11.09 (7.179)
Median		11.09		11.09
Min, Max		6.0, 16.2		6.0, 16.2

Source: Listing 16.3.9.5
Abbreviations: CR=Complete reimission, CRh=Complete remission with partial recovery of peripheral blood counts, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/CRh/PR/CI) is first met. Patients without confirmed response are excluded from this analysis. Time to complete remission is defined as the time from the start of treatment to the time a CR/CRh is first met. Patients without confirmed CR/CRh are excluded from this analysis. Time to CR+CRh+PR is defined as the time from the start of treatment to the time a CR/CRh/PR is first met. Patients without confirmed CR/CRh/PR are excluded from this analysis.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-tm.sas Date: 15:05/18OCT2021

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Study BLU-285-2101
Starting Dose: Overall

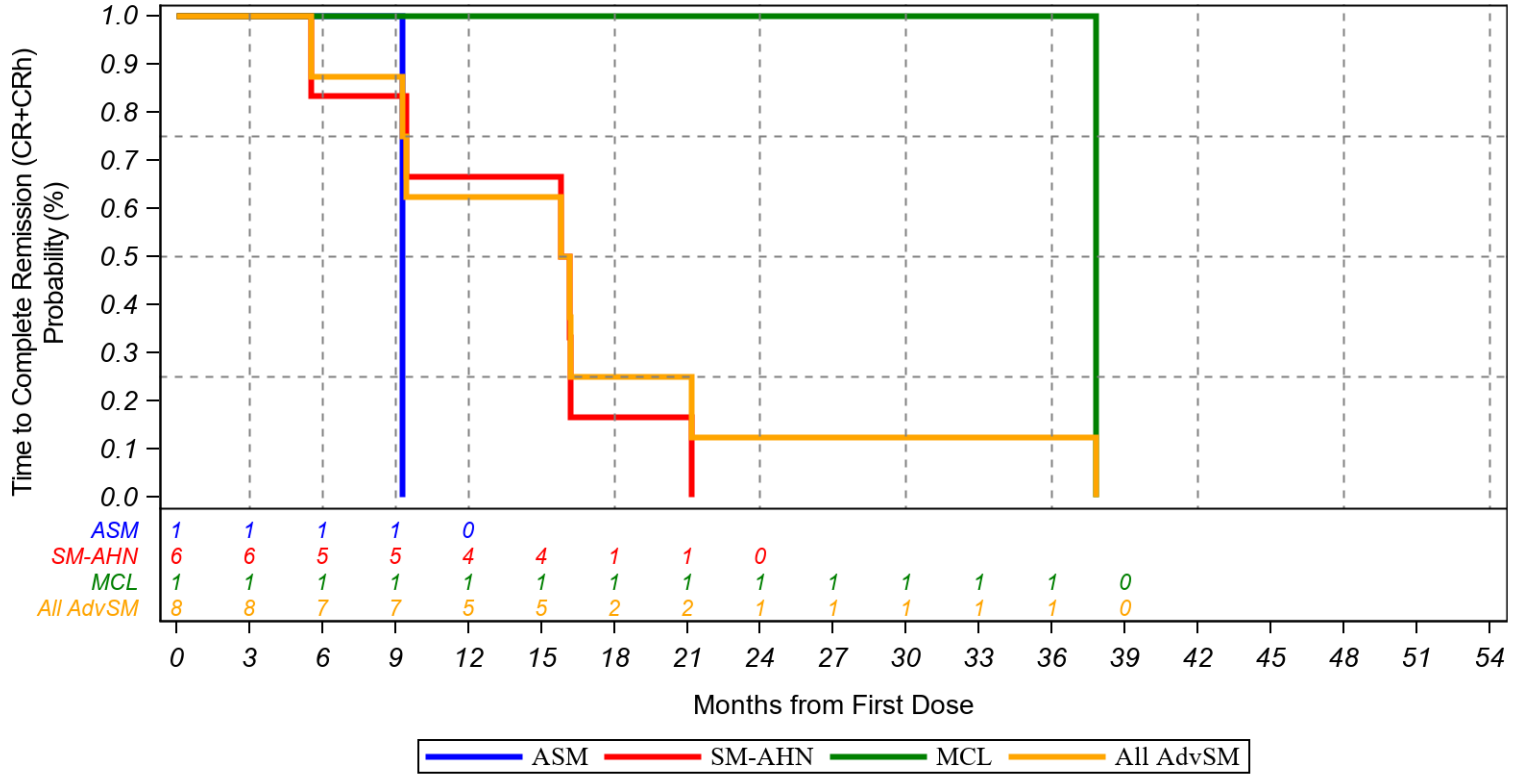


Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Study BLU-285-2101
Starting Dose: Overall

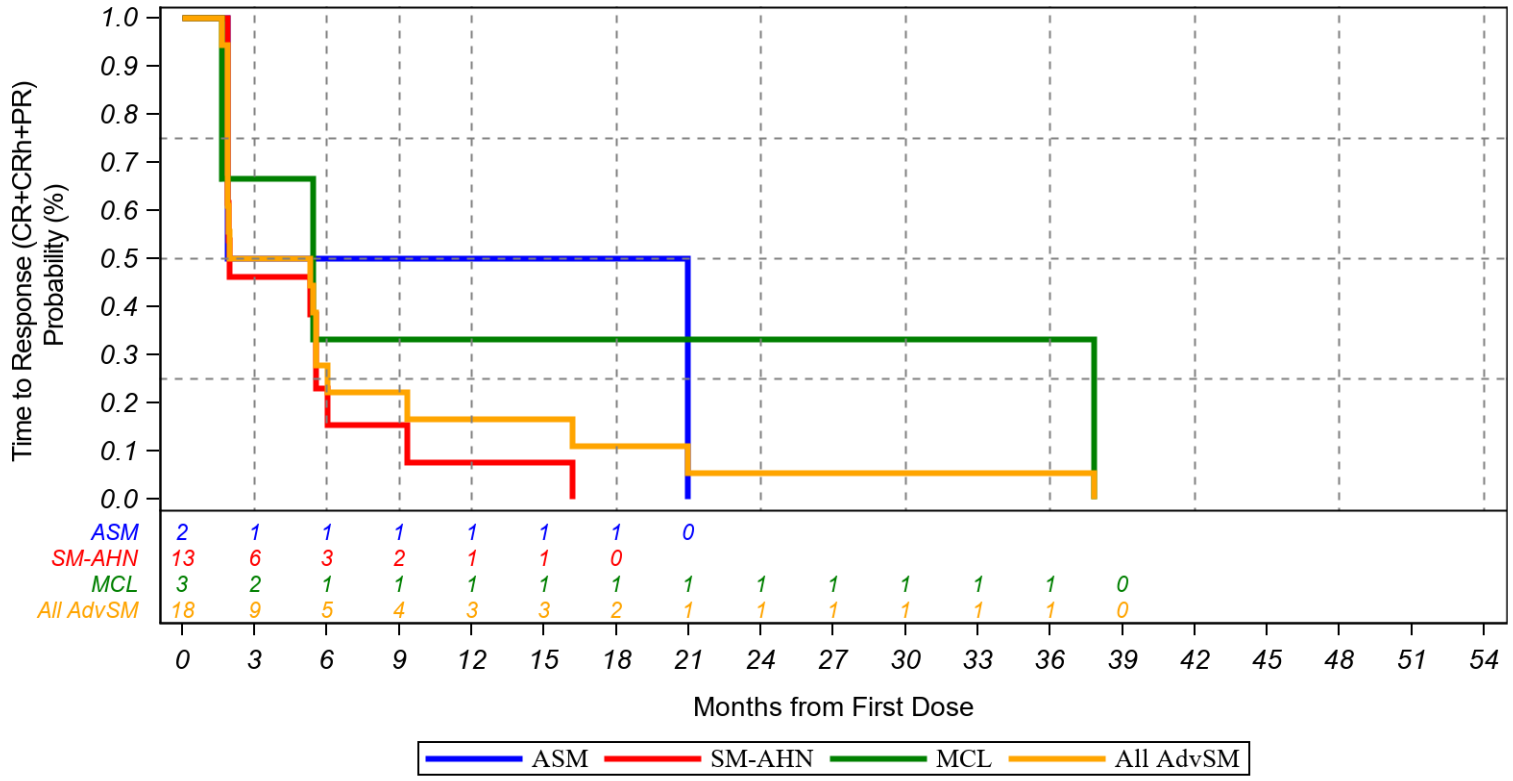
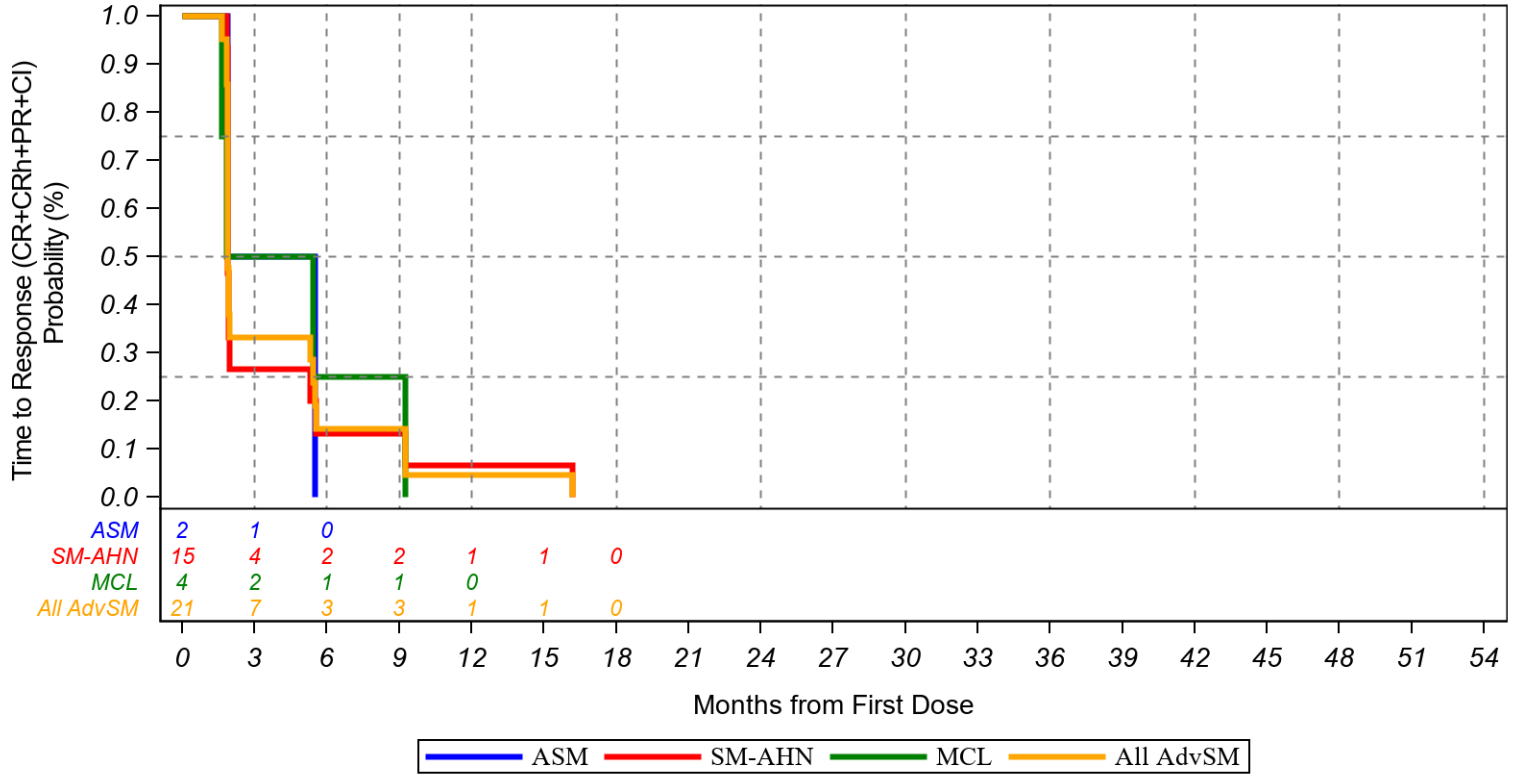


Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: Overall



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Date: 12:21/19OCT2021

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Study BLU-285-2101
Starting Dose: < 200 mg

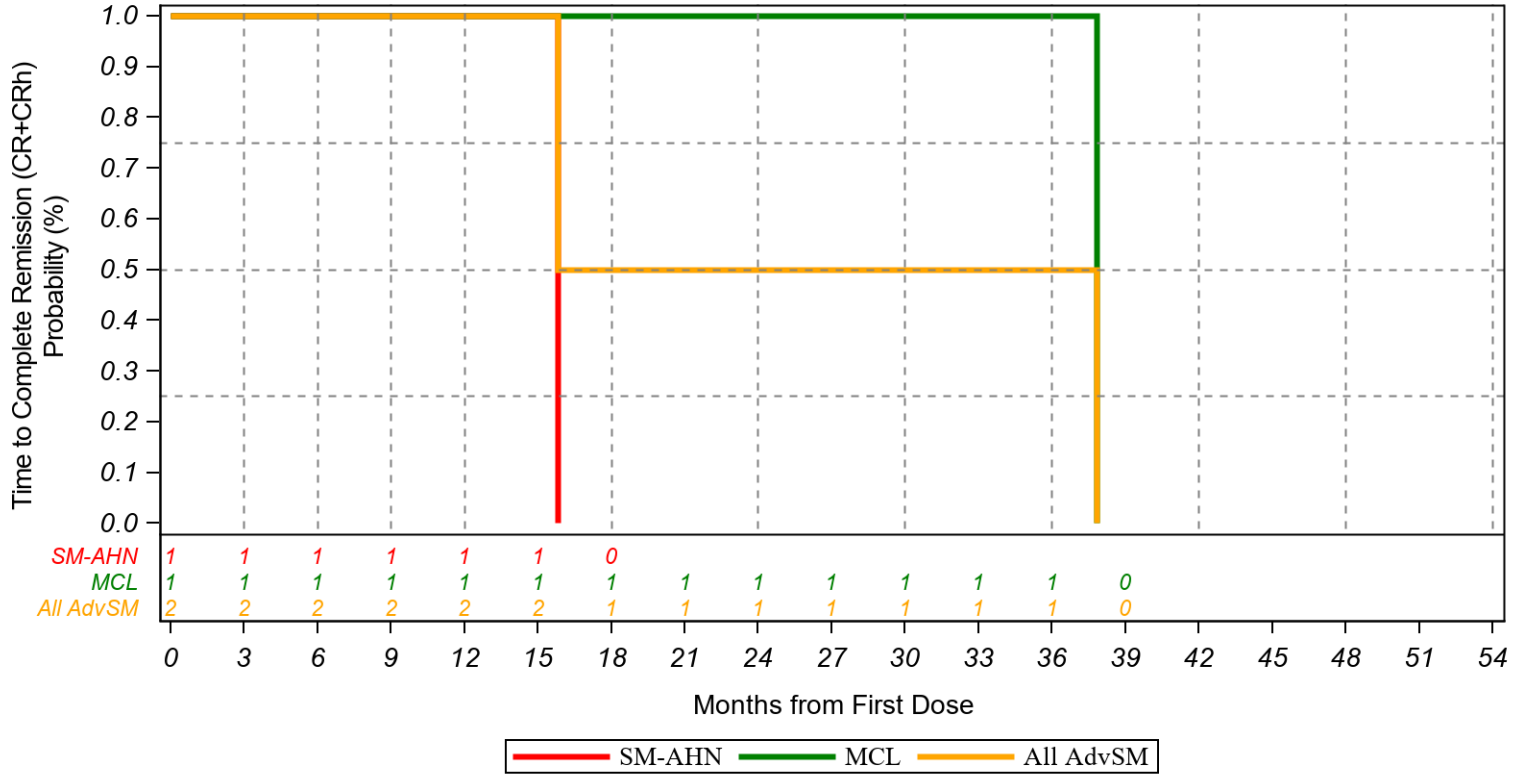

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Study BLU-285-2101
Starting Dose: < 200 mg

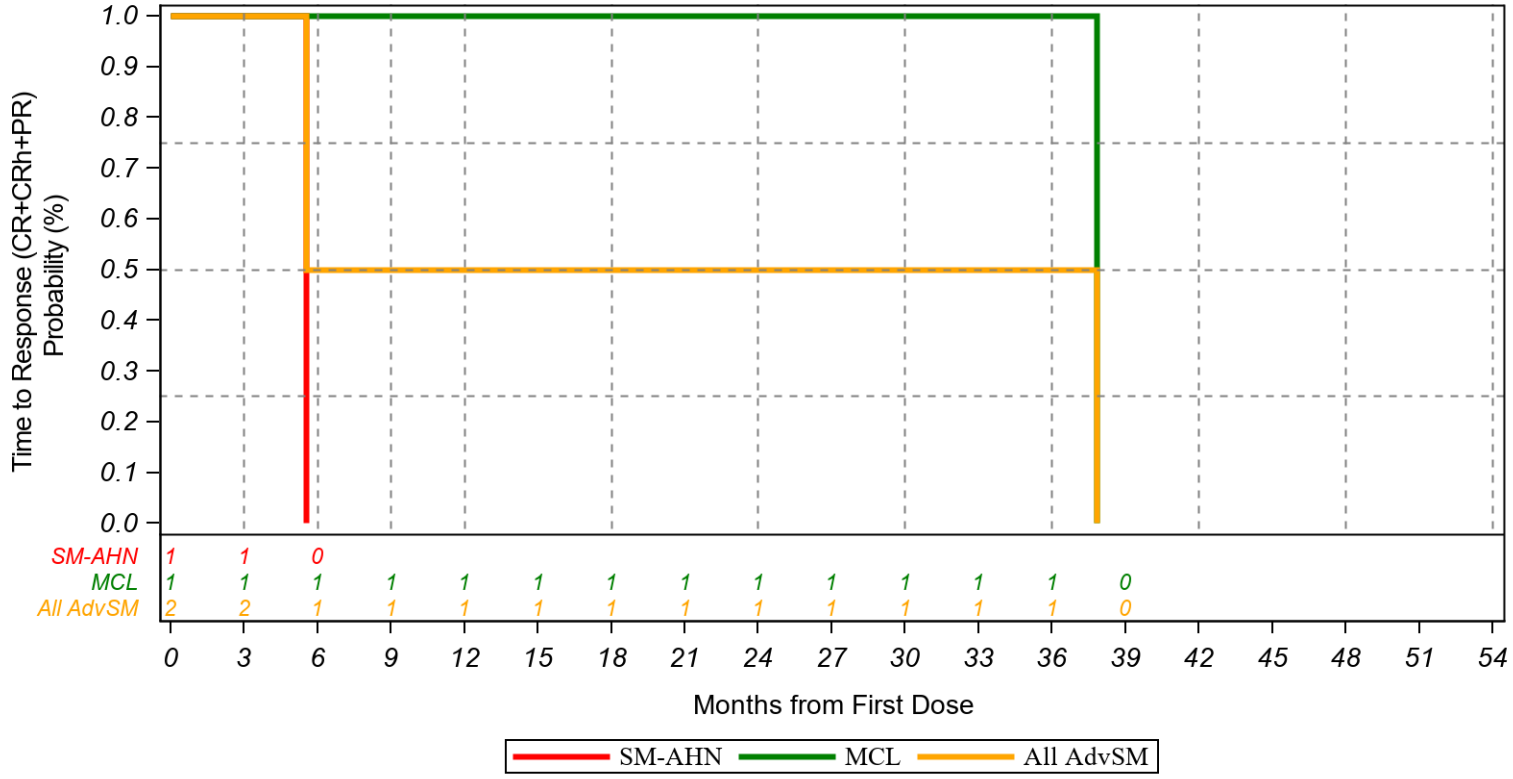

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: < 200 mg

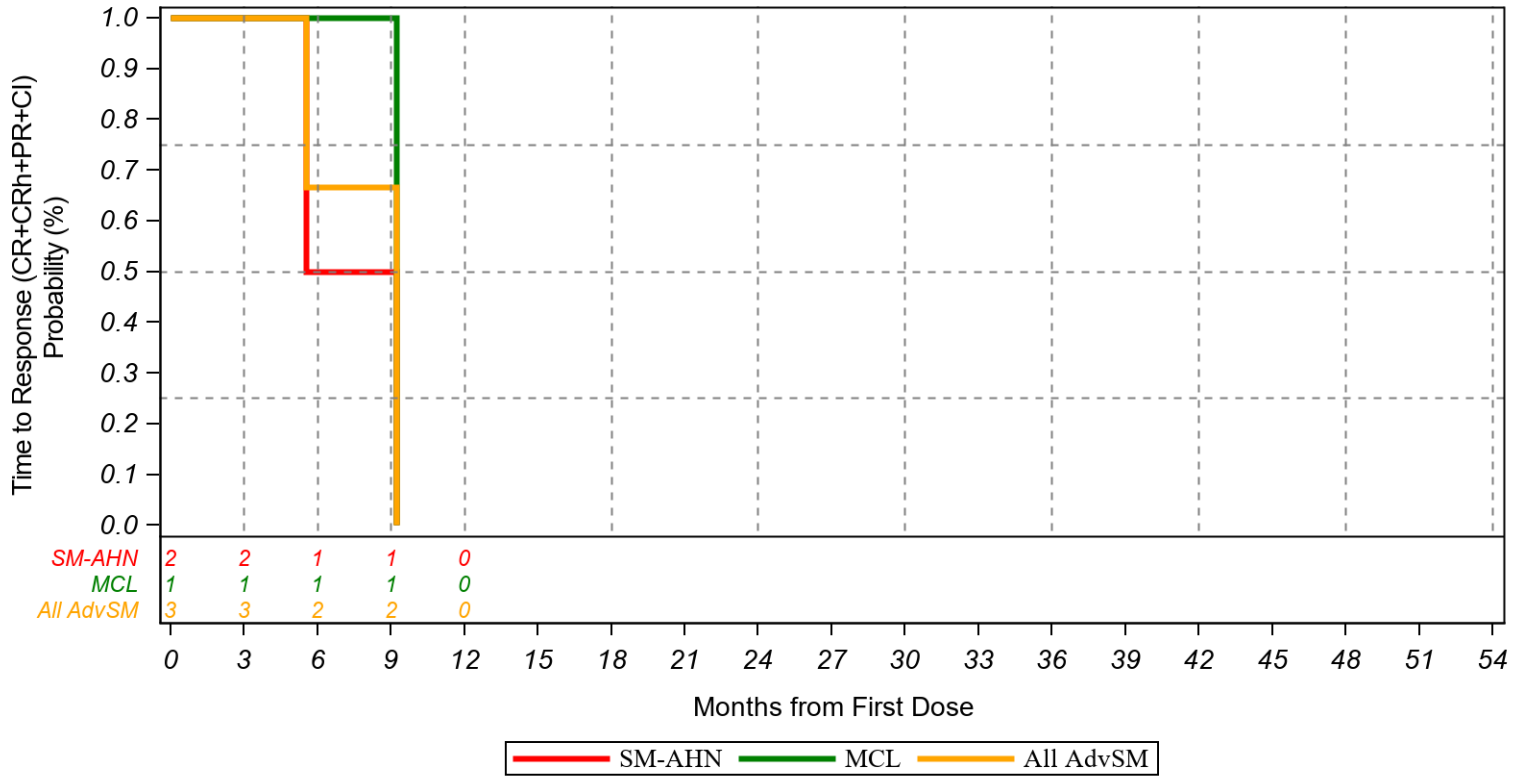

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Study BLU-285-2101
Starting Dose: < 300 mg

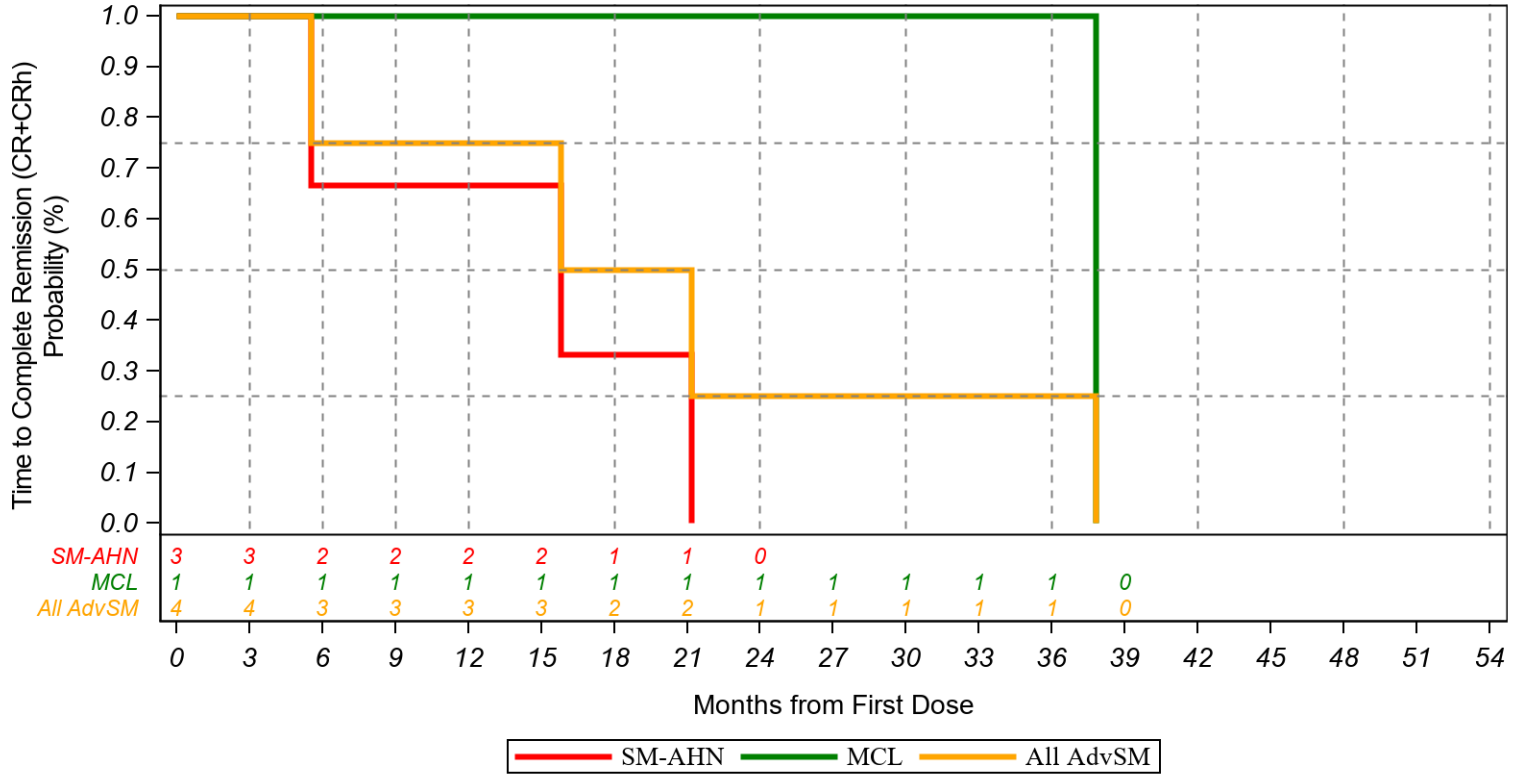

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Study BLU-285-2101
Starting Dose: < 300 mg

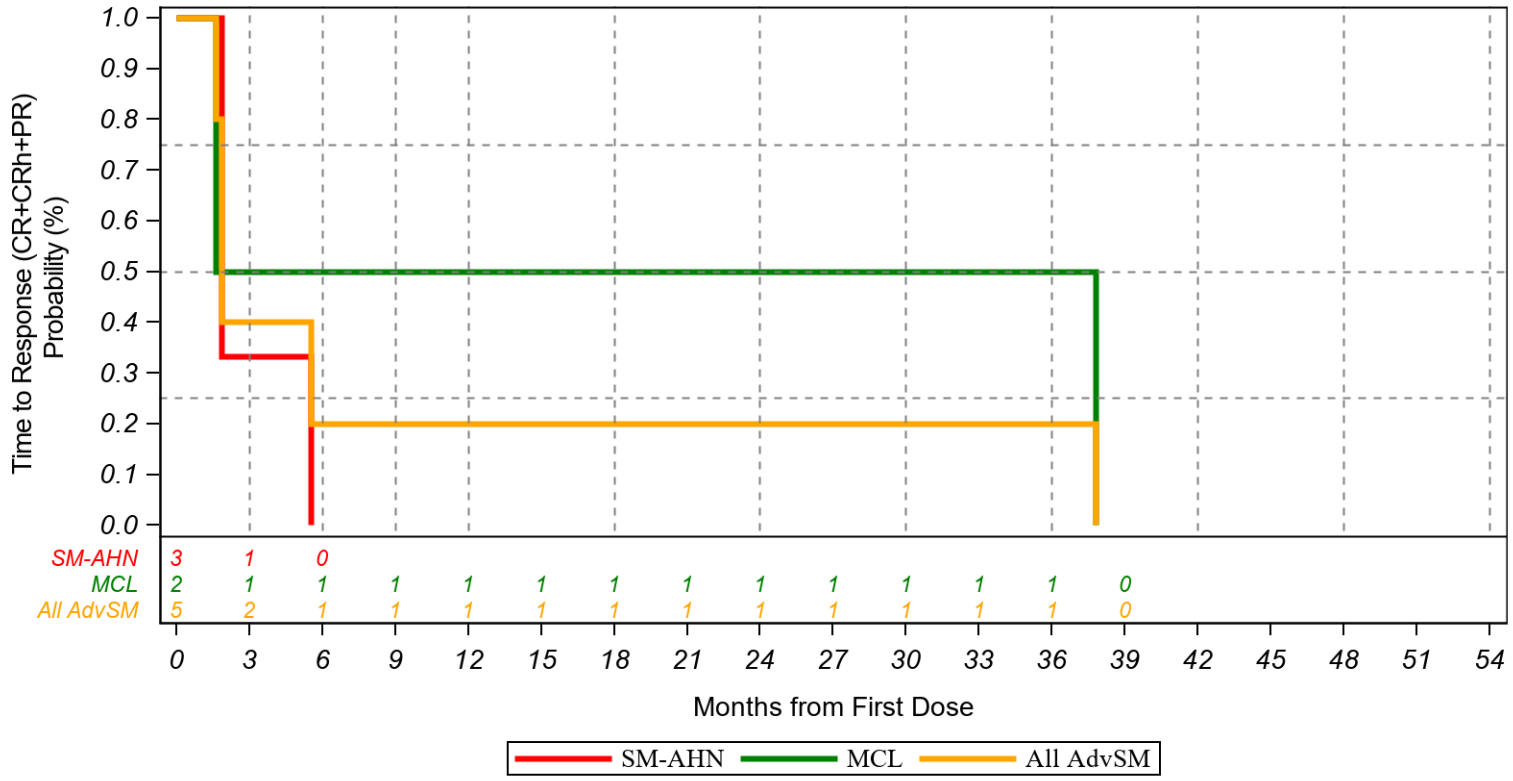

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Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: < 300 mg

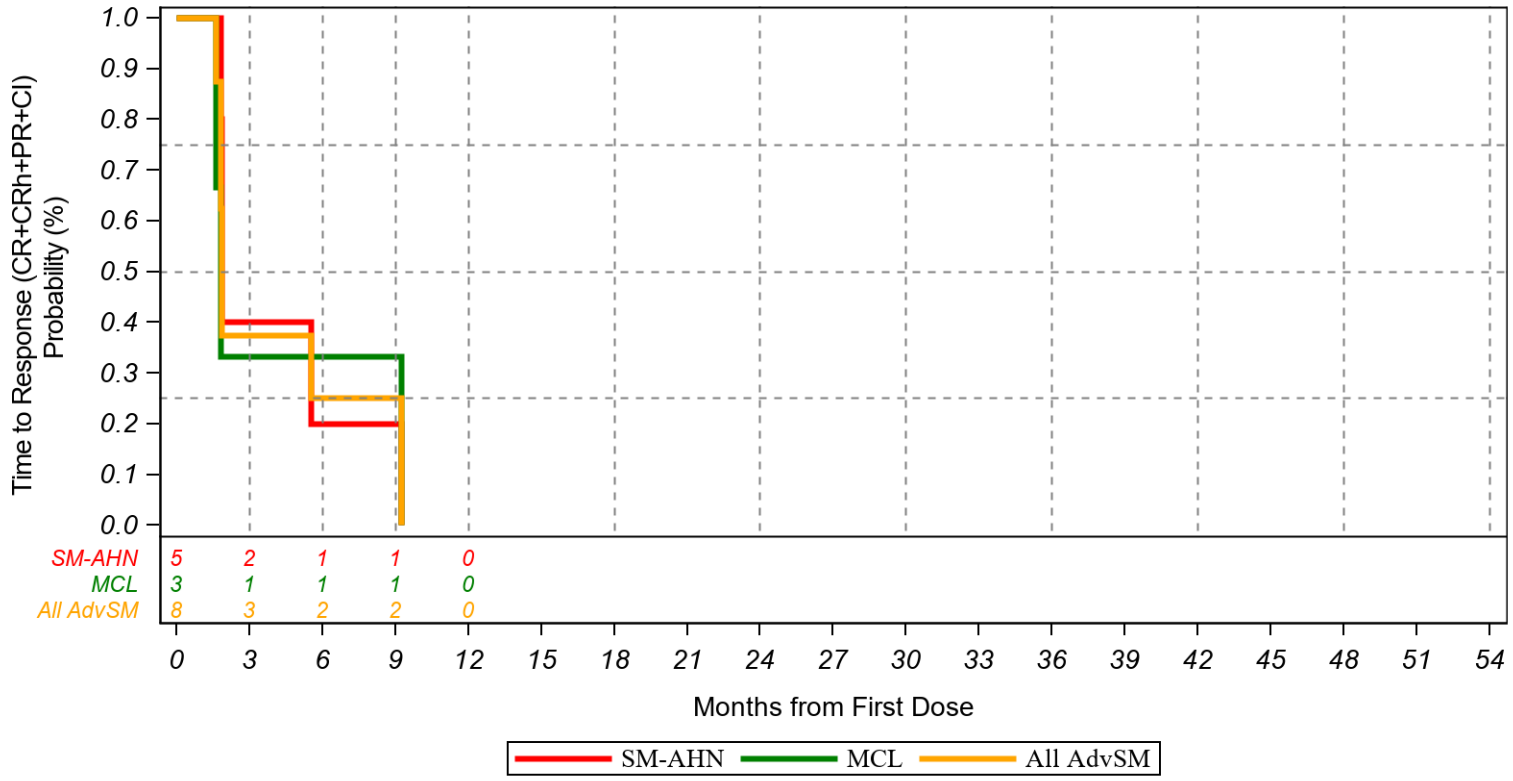

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Study BLU-285-2101
Starting Dose: 200 mg

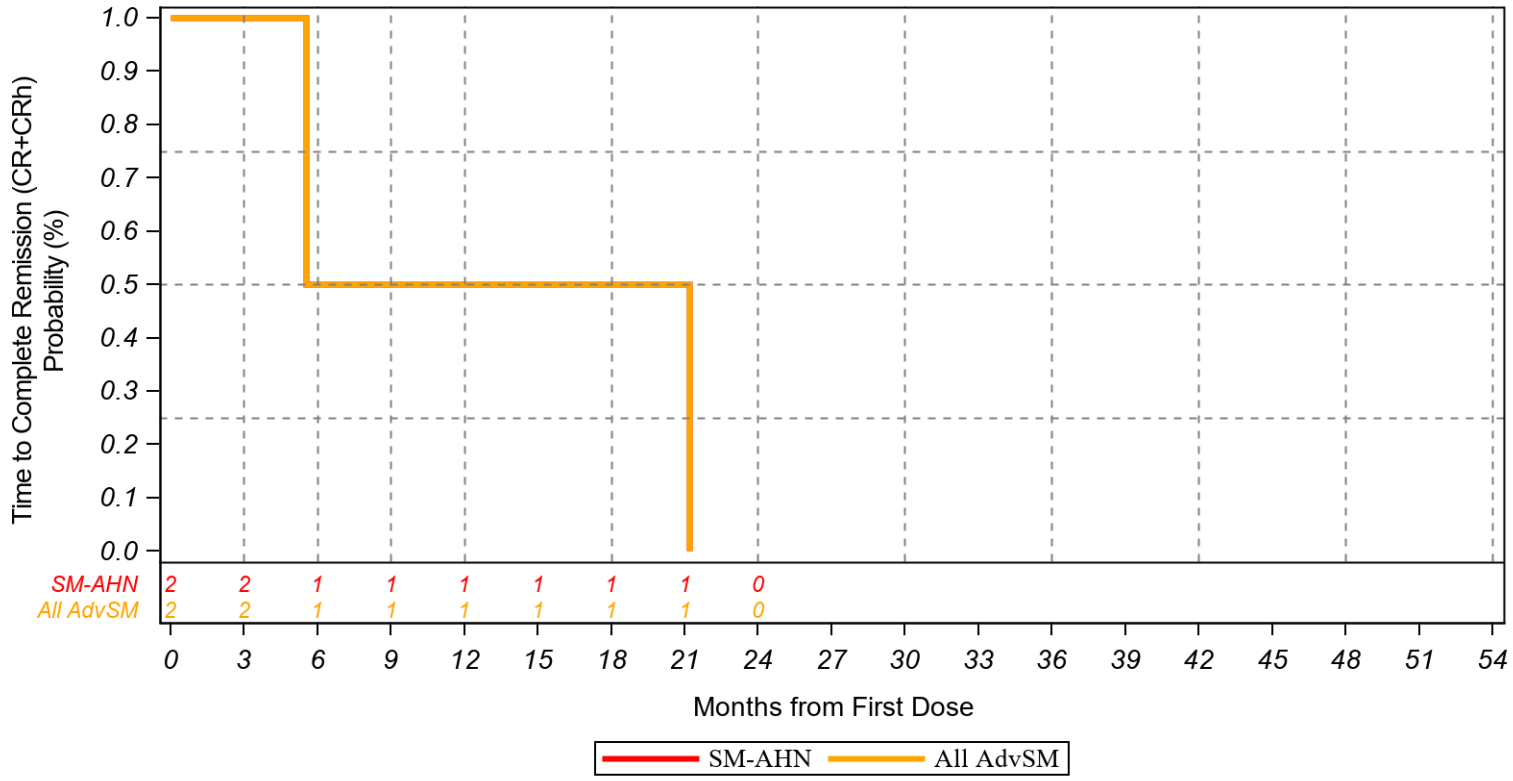

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Study BLU-285-2101
Starting Dose: 200 mg

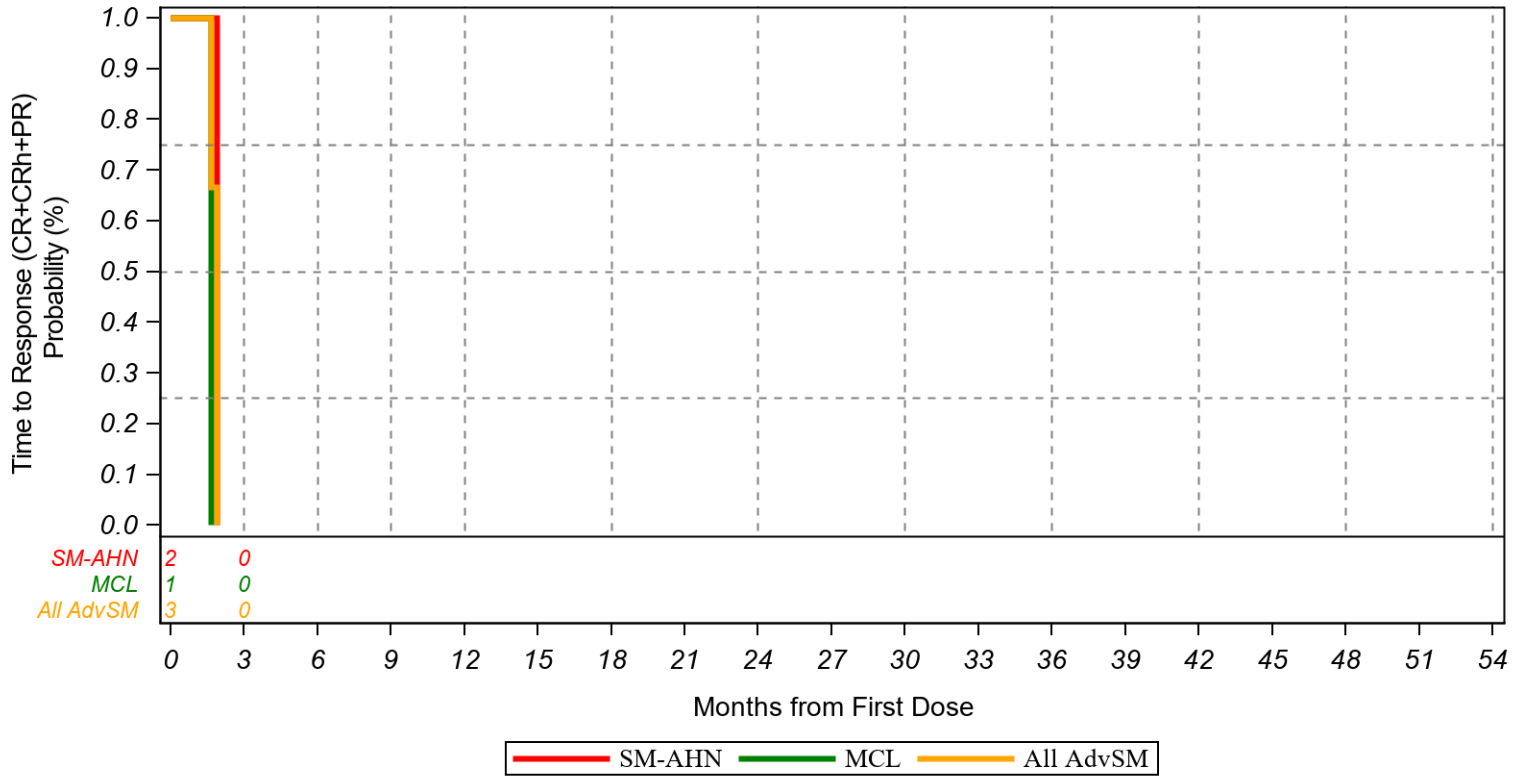

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Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: 200 mg

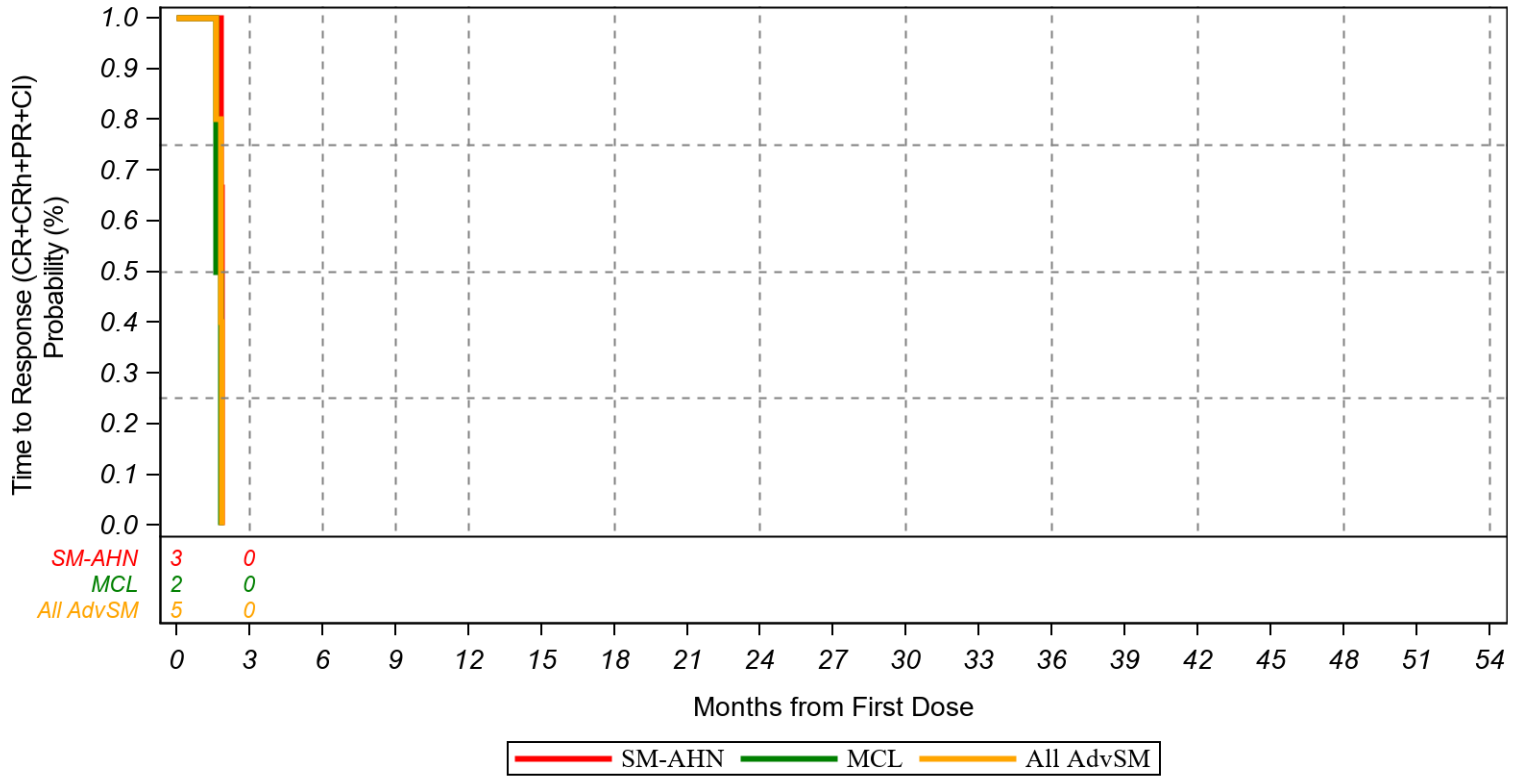

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Study BLU-285-2101
Starting Dose: 300 mg

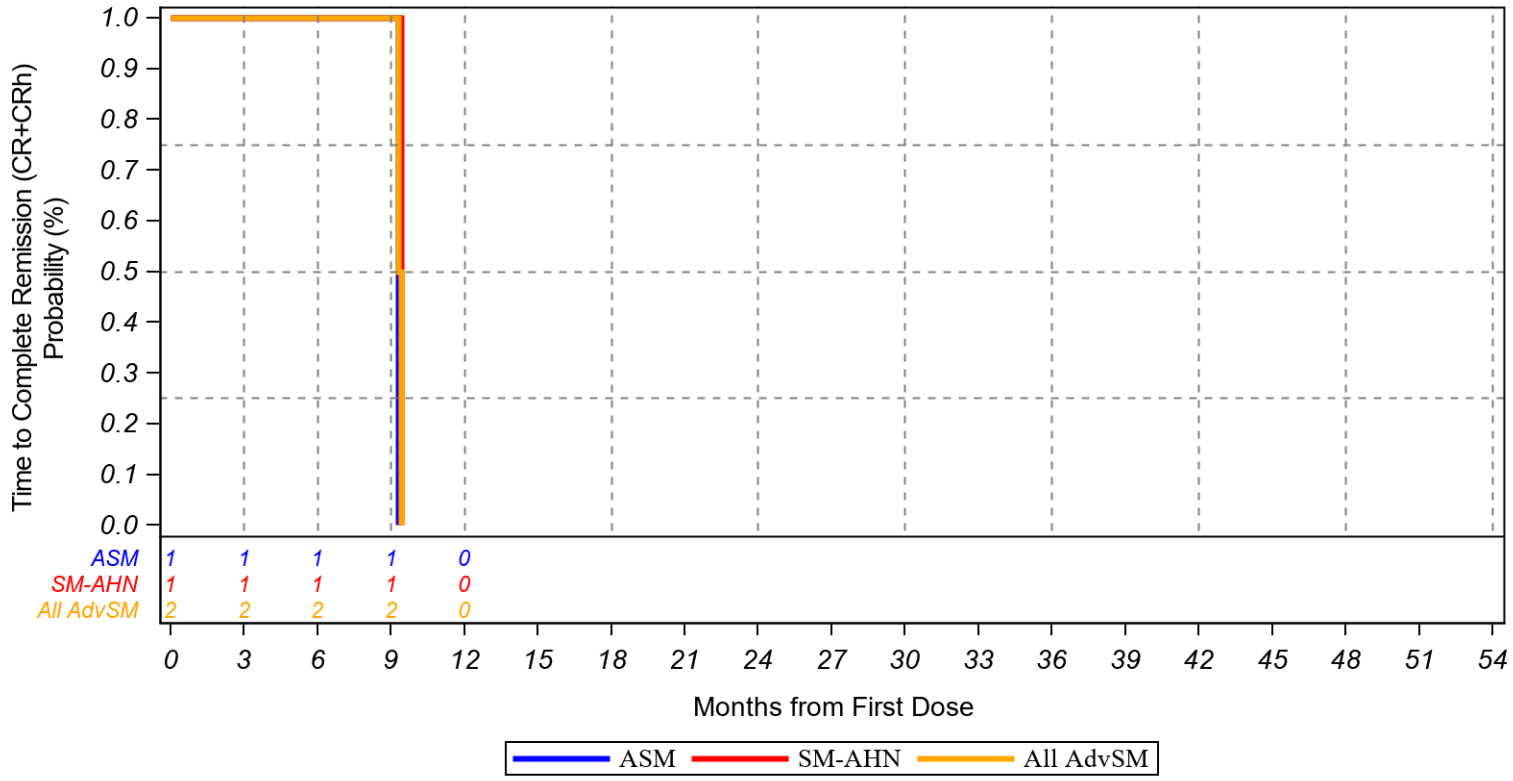

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Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Study BLU-285-2101
Starting Dose: 300 mg

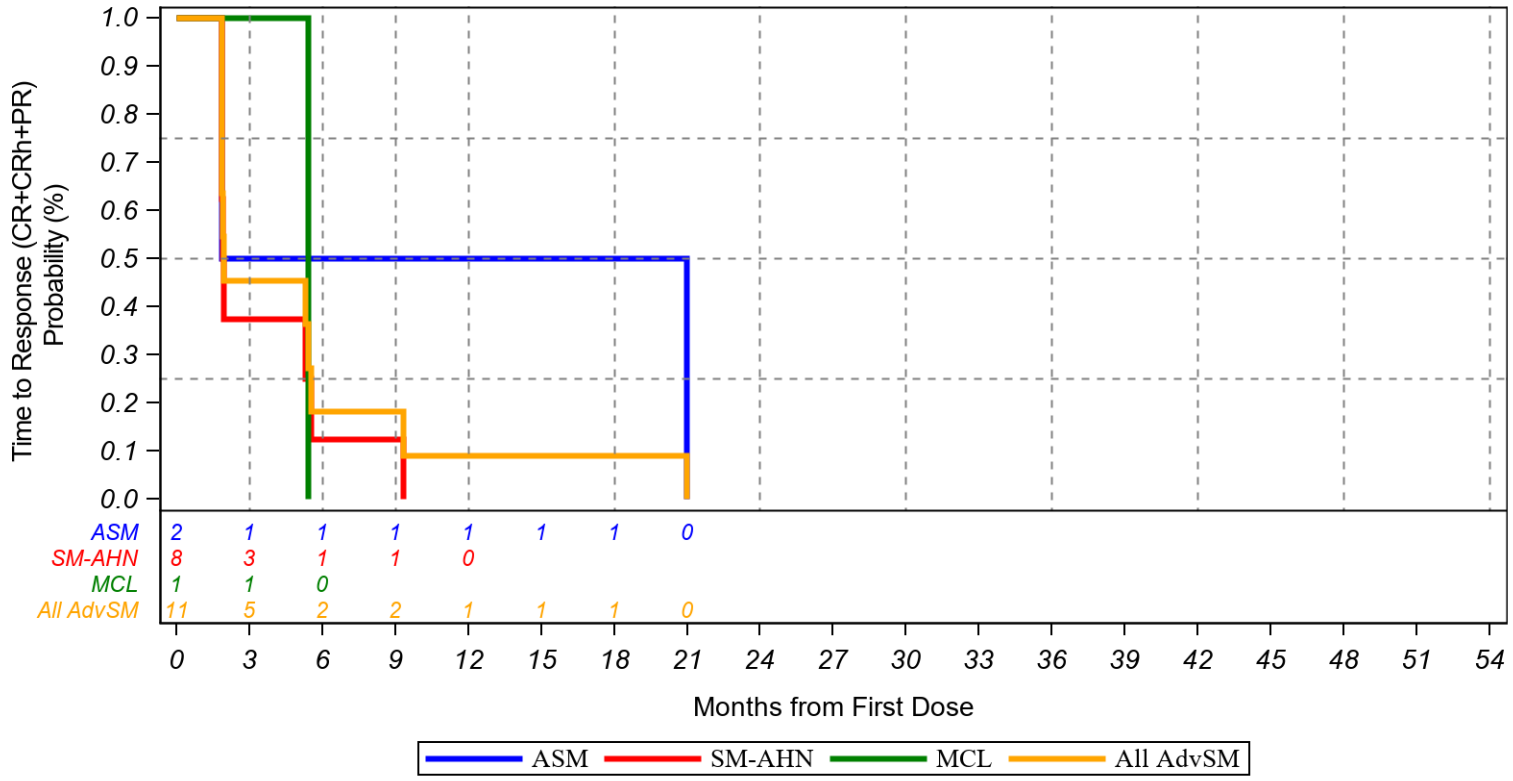

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Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: 300 mg

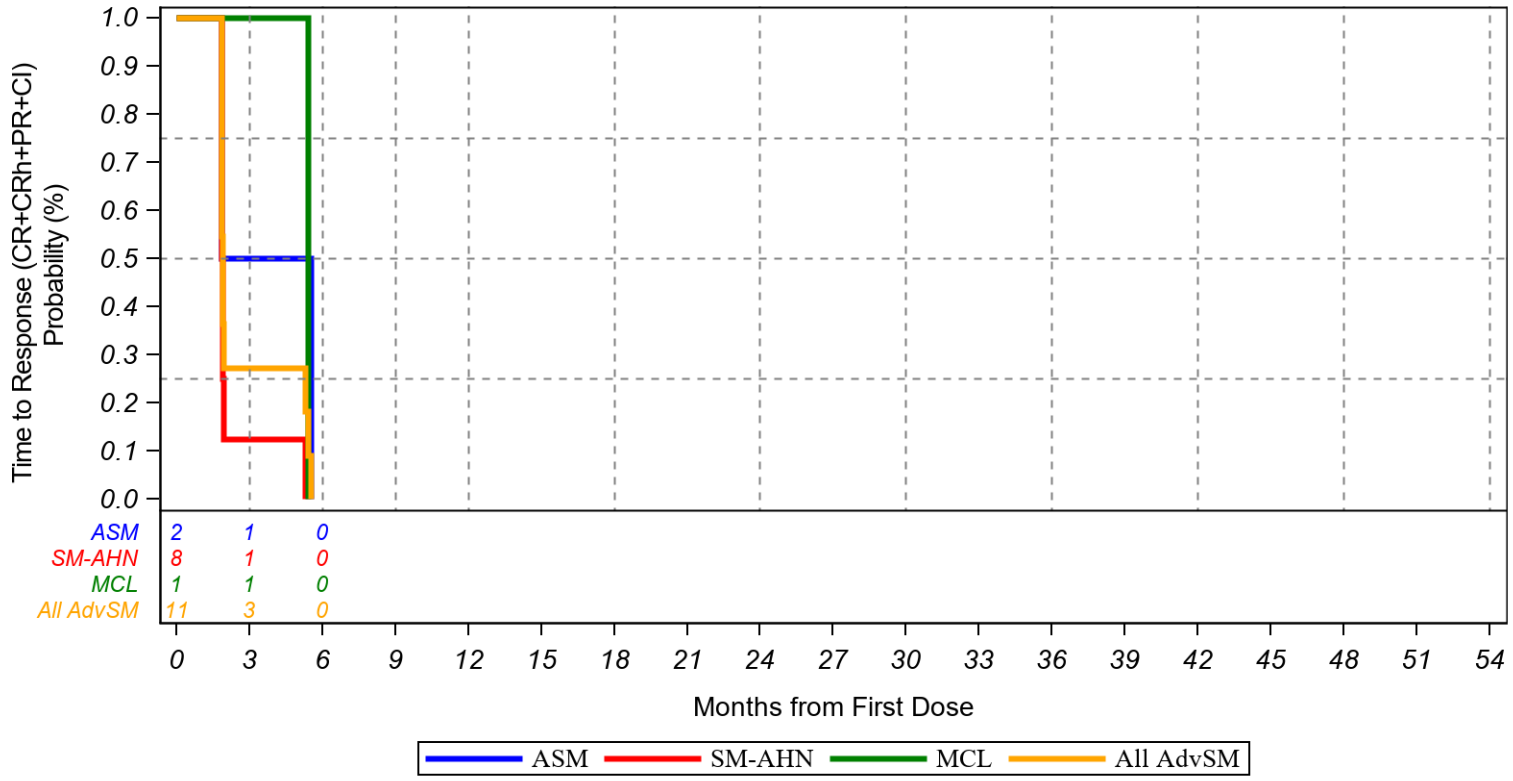

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Study BLU-285-2101
Starting Dose: 200 mg and 300 mg

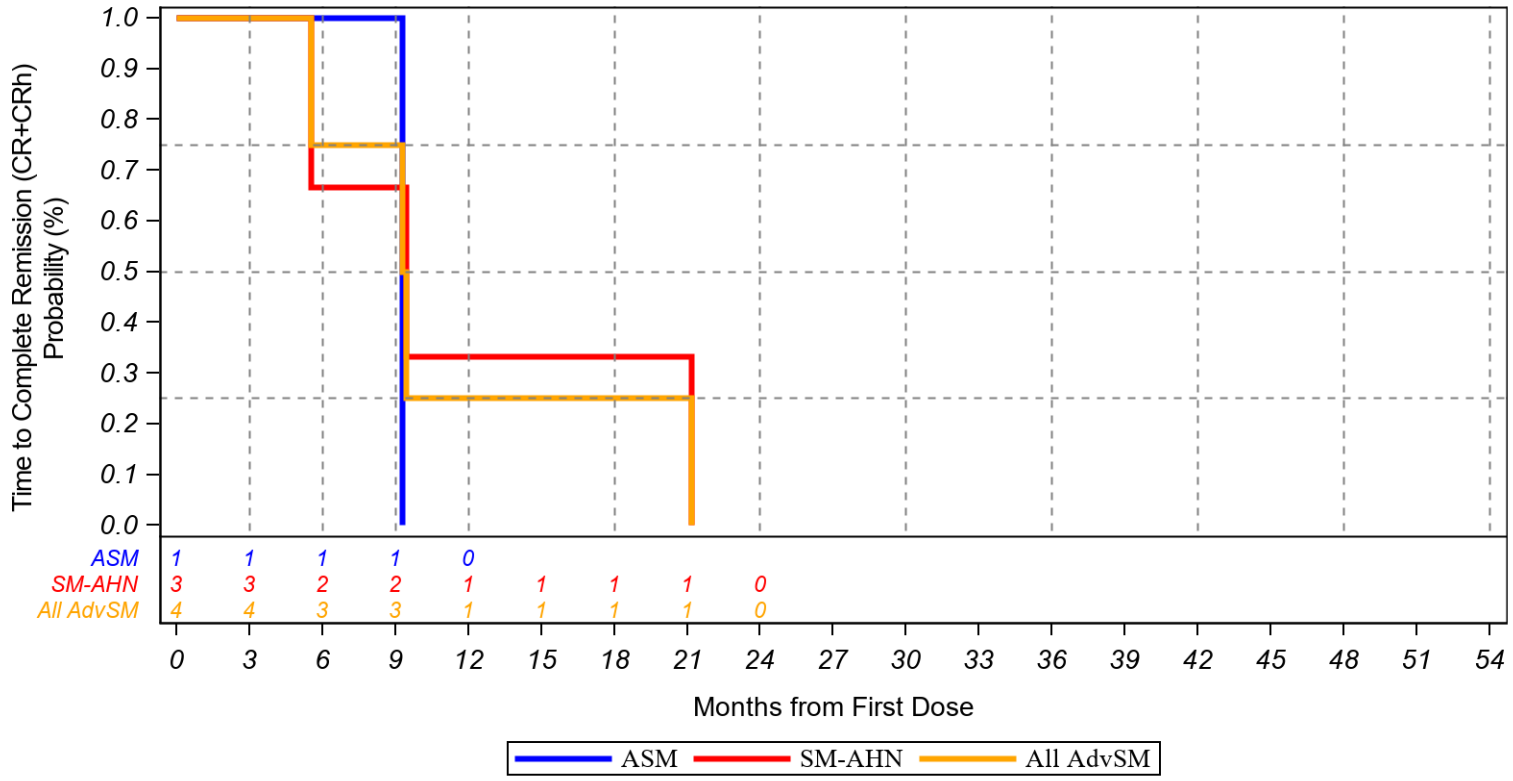

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Study BLU-285-2101
Starting Dose: 200 mg and 300 mg

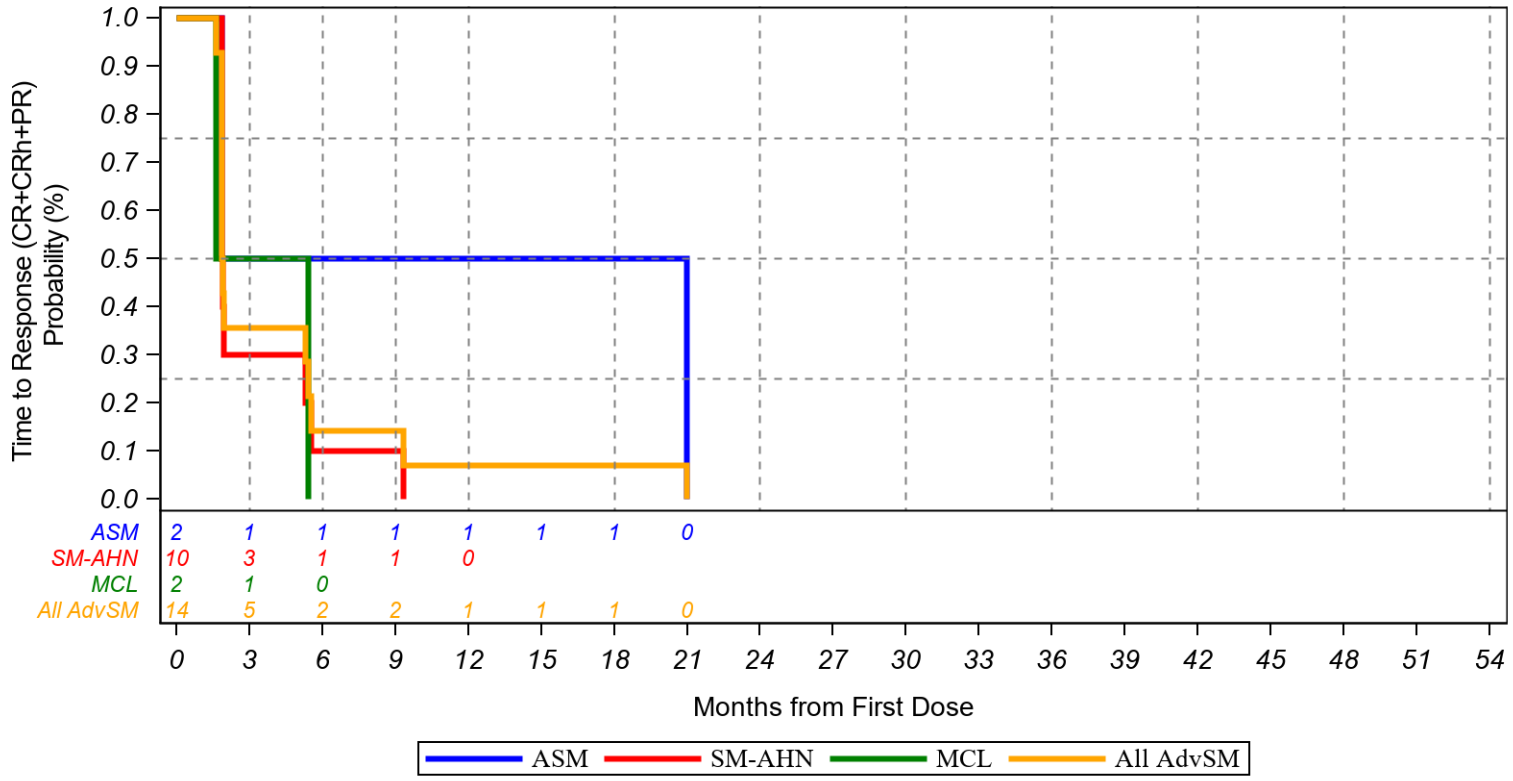

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Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: 200 mg and 300 mg

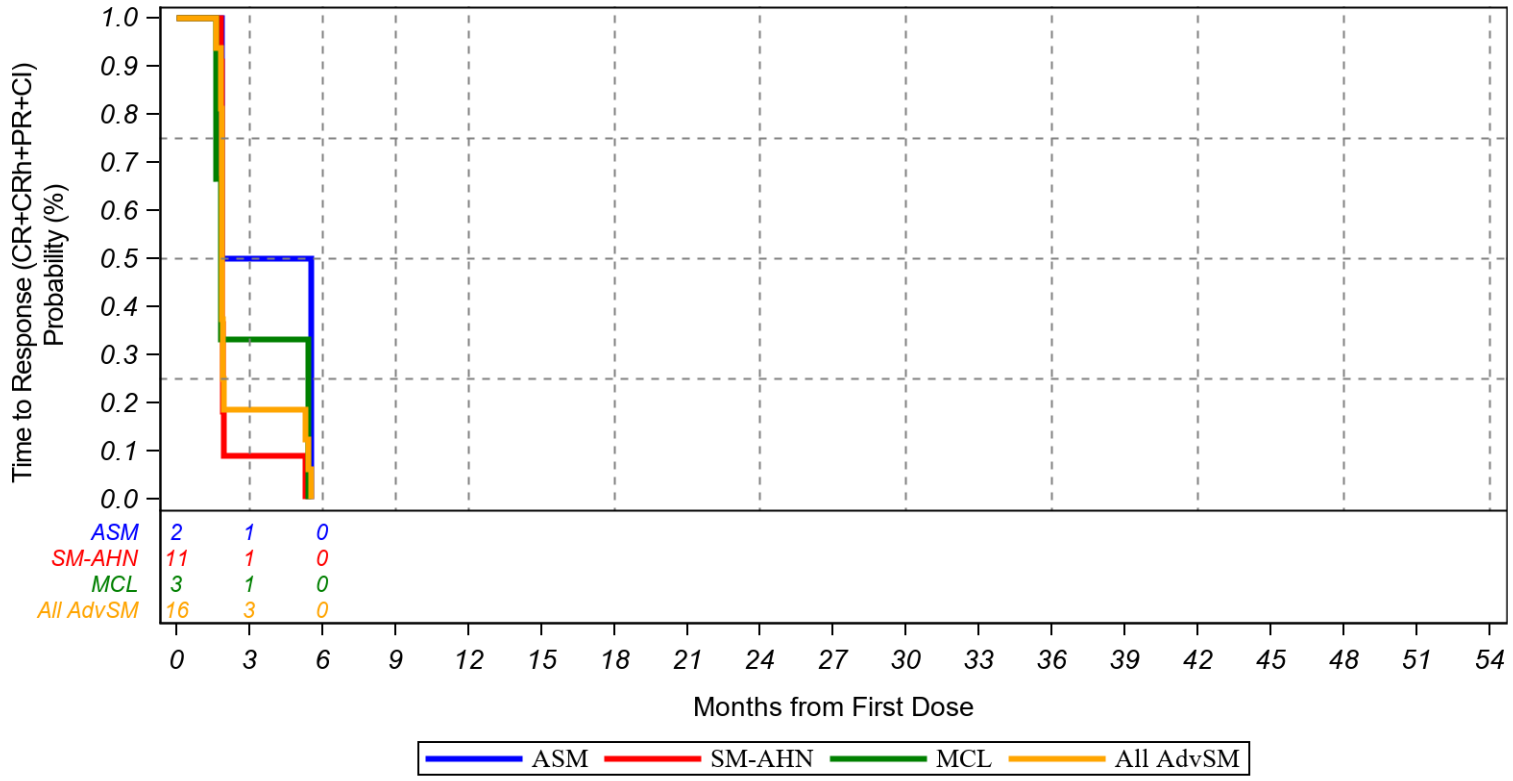

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Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Study BLU-285-2101
Starting Dose: 400 mg

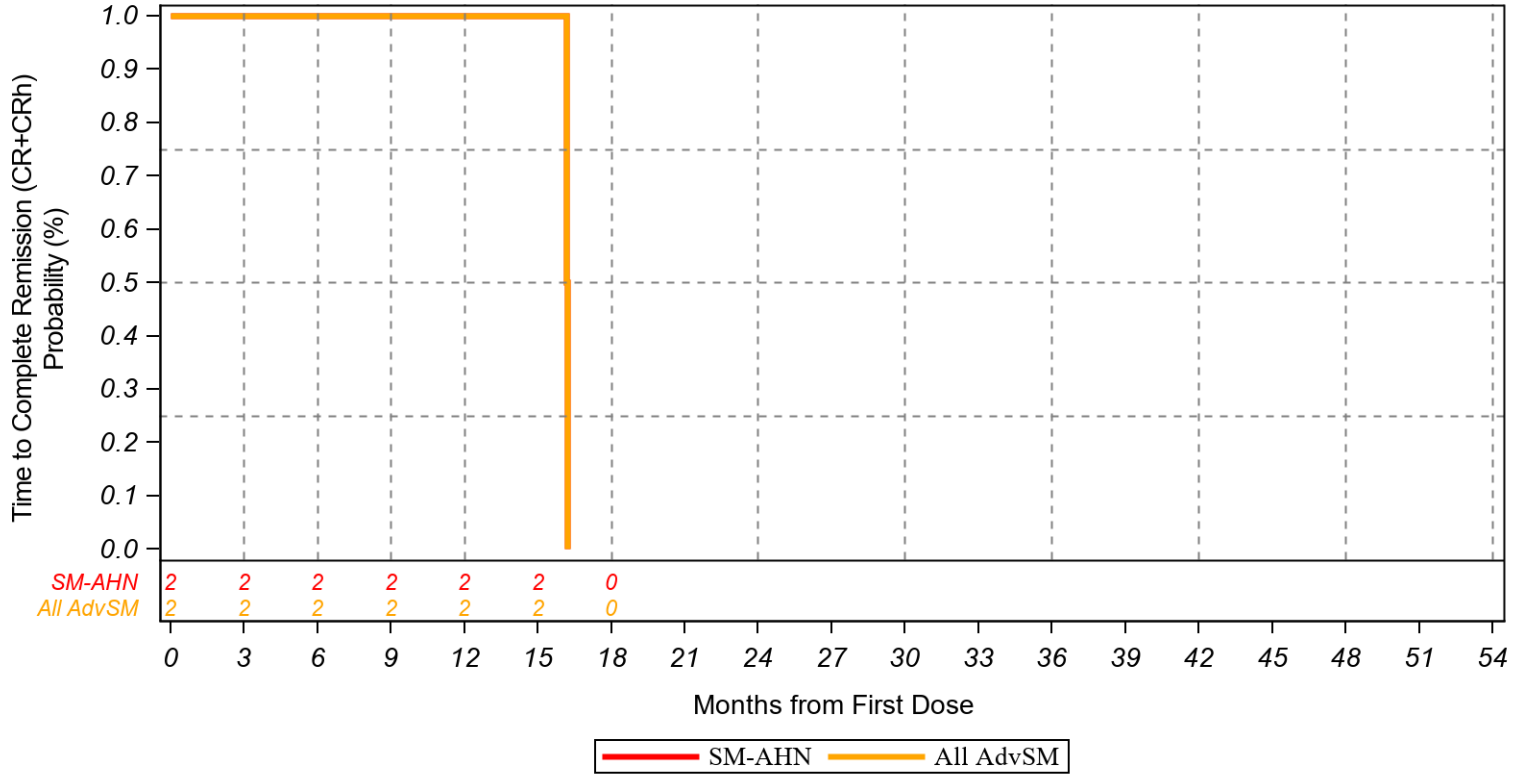

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Study BLU-285-2101
Starting Dose: 400 mg

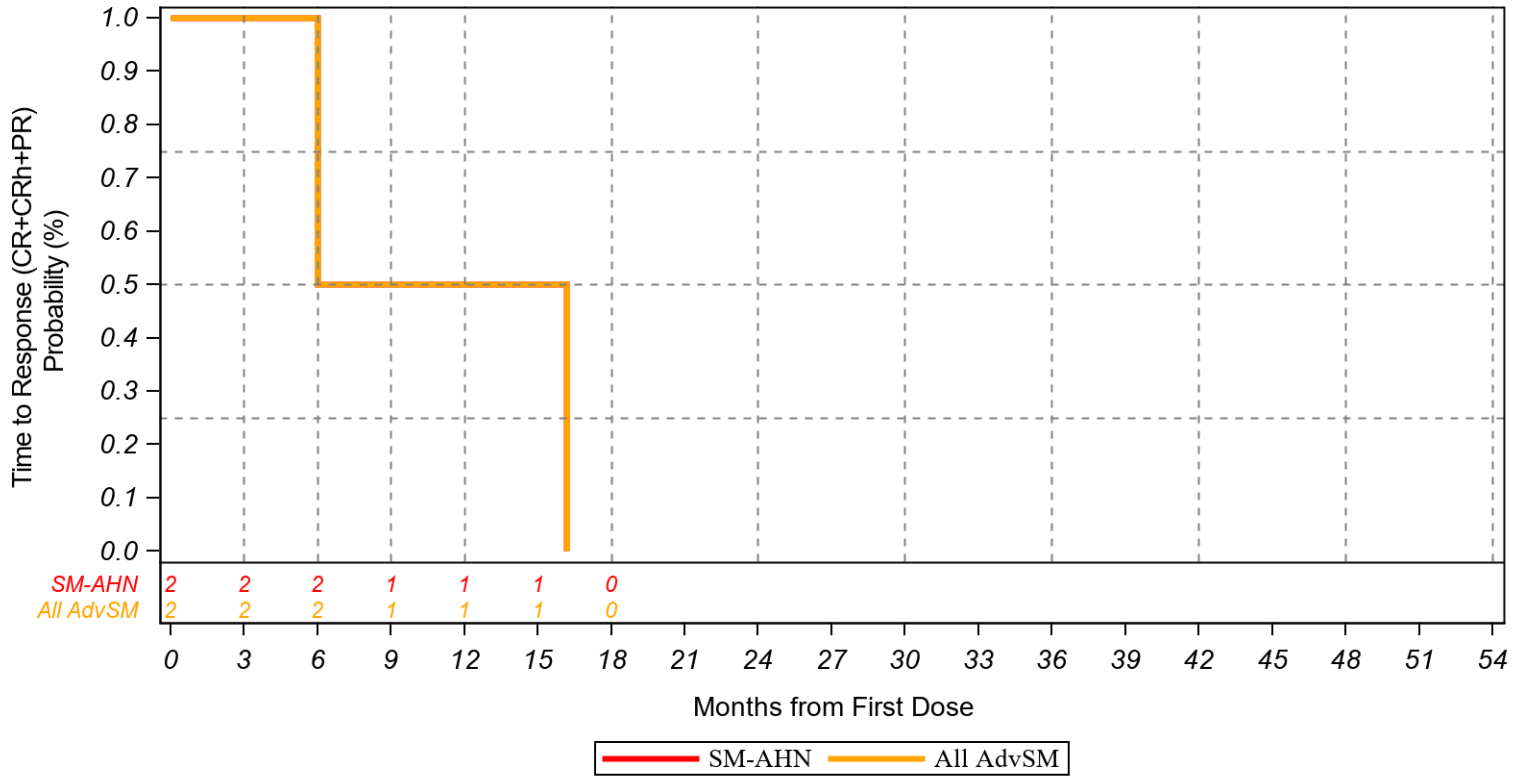

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: 400 mg

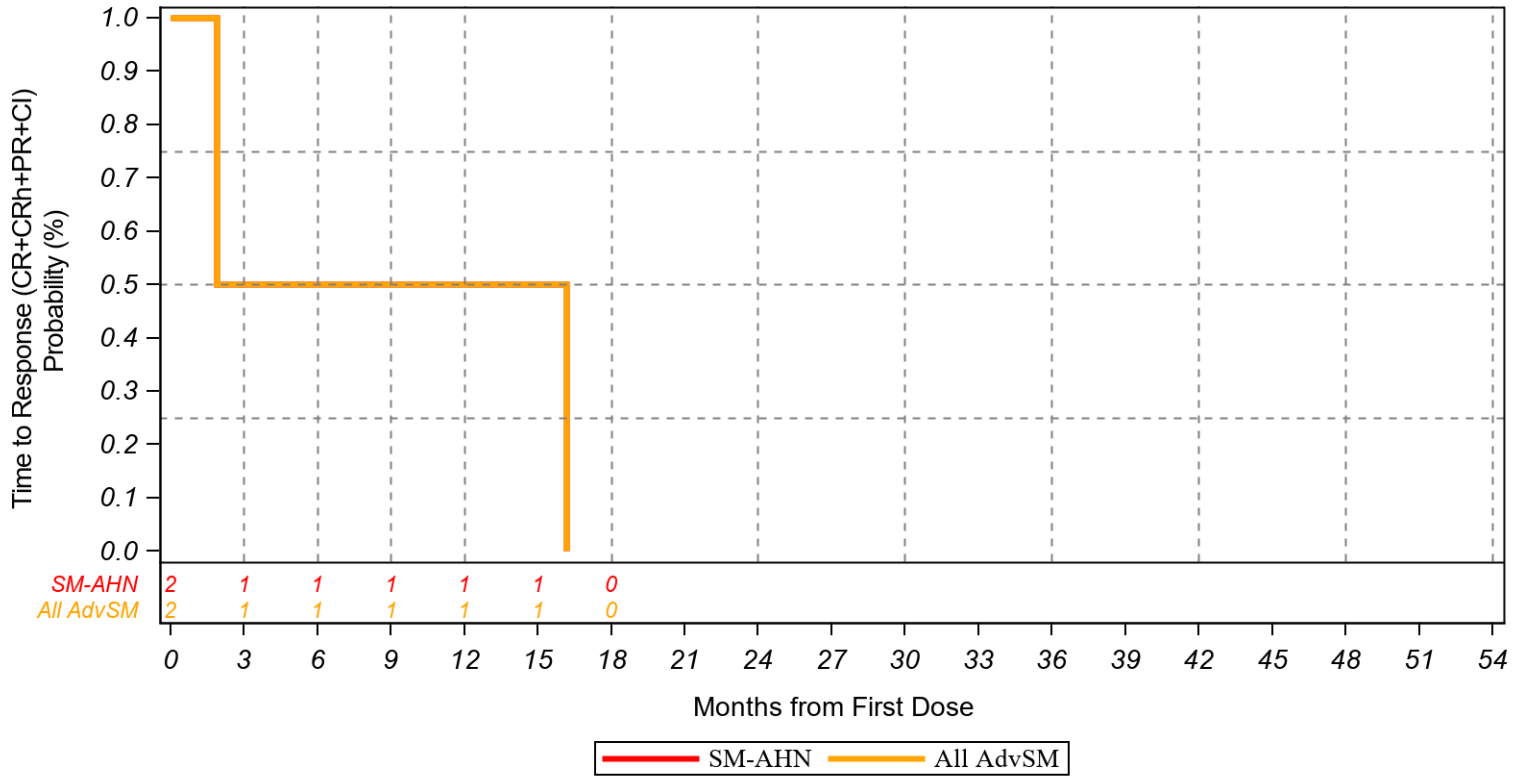

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Study BLU-285-2202
Starting Dose: Overall

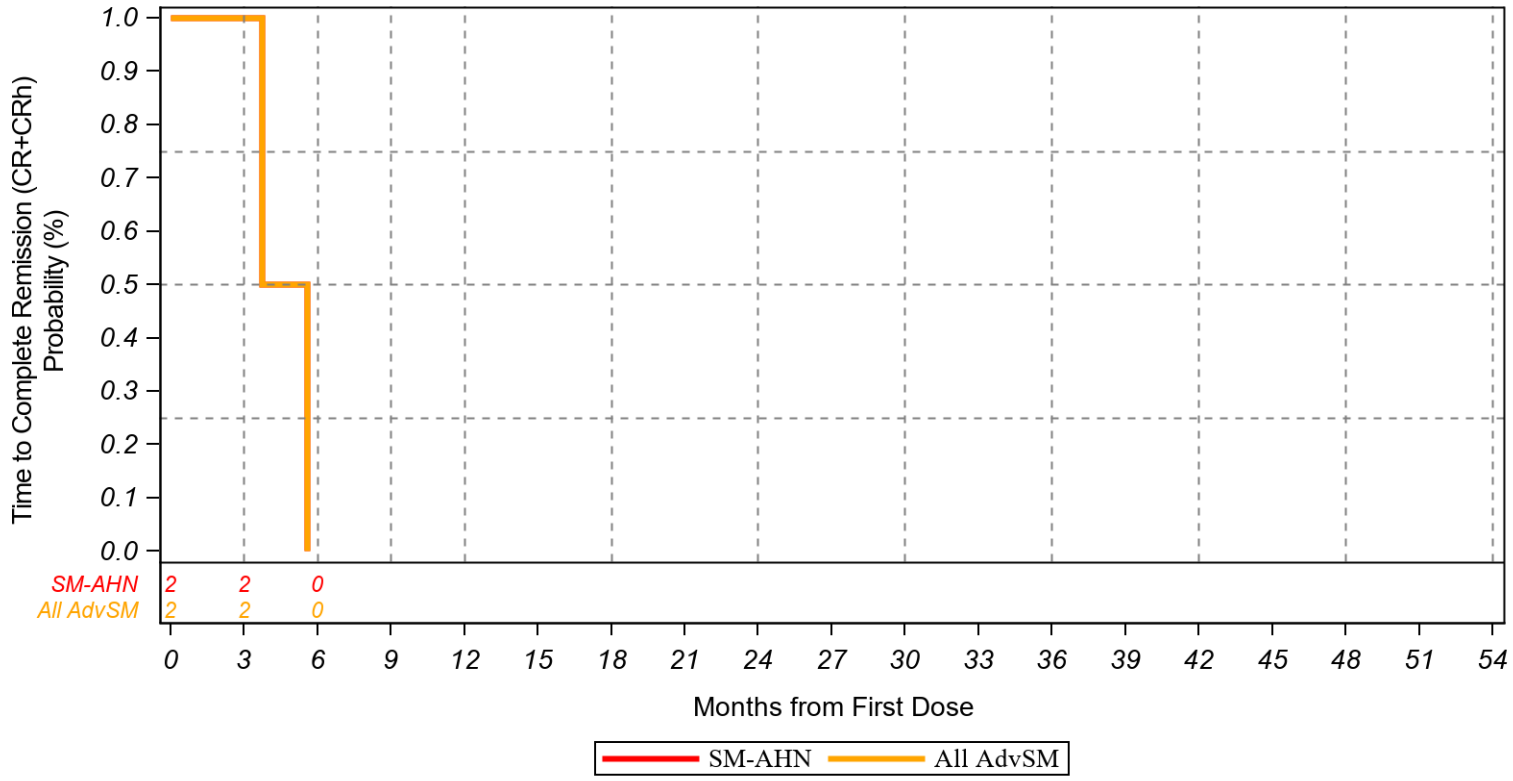

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Study BLU-285-2202
Starting Dose: Overall

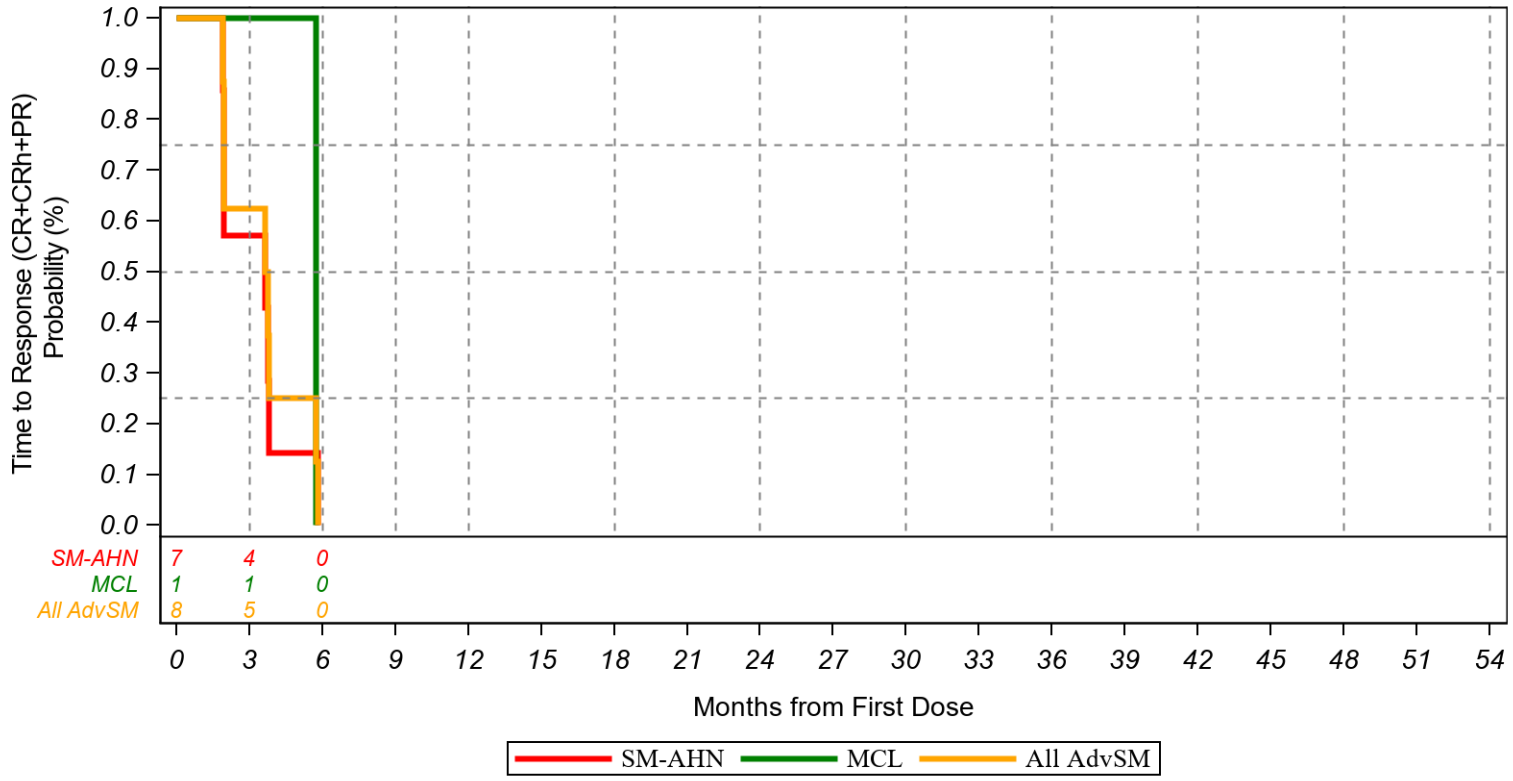

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Study BLU-285-2202
Starting Dose: Overall

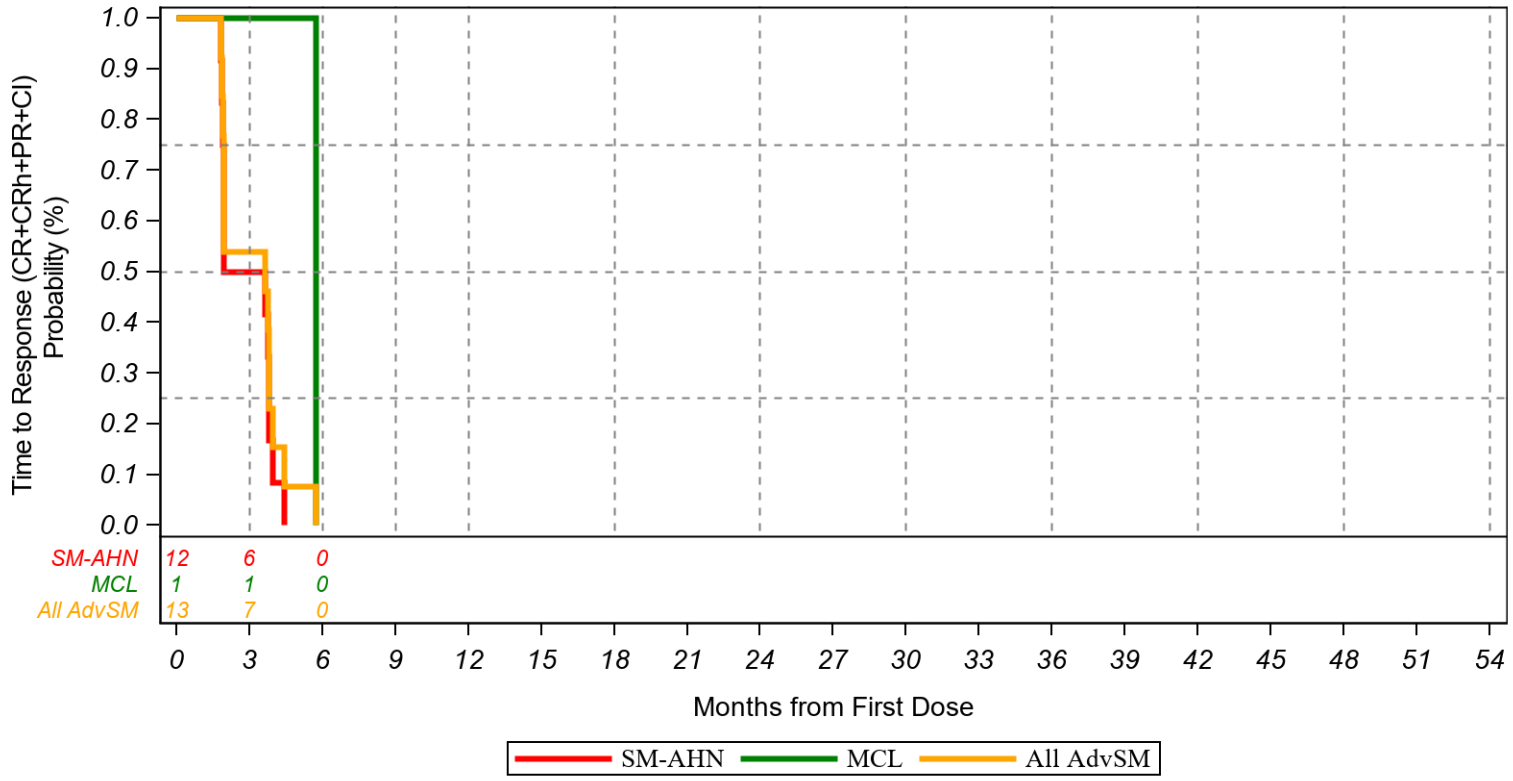

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Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Study BLU-285-2202
Starting Dose: 200 mg

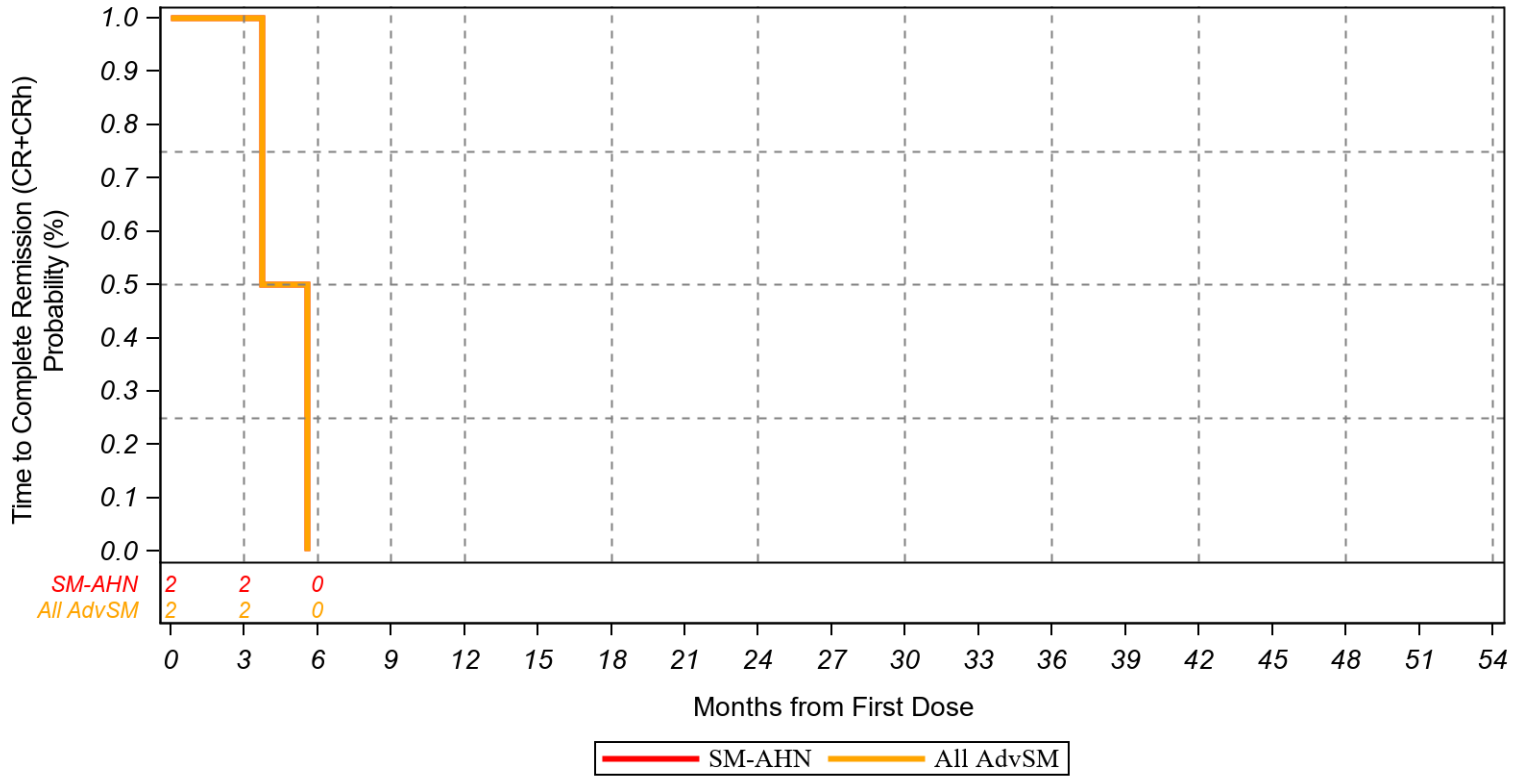

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Study BLU-285-2202
Starting Dose: 200 mg

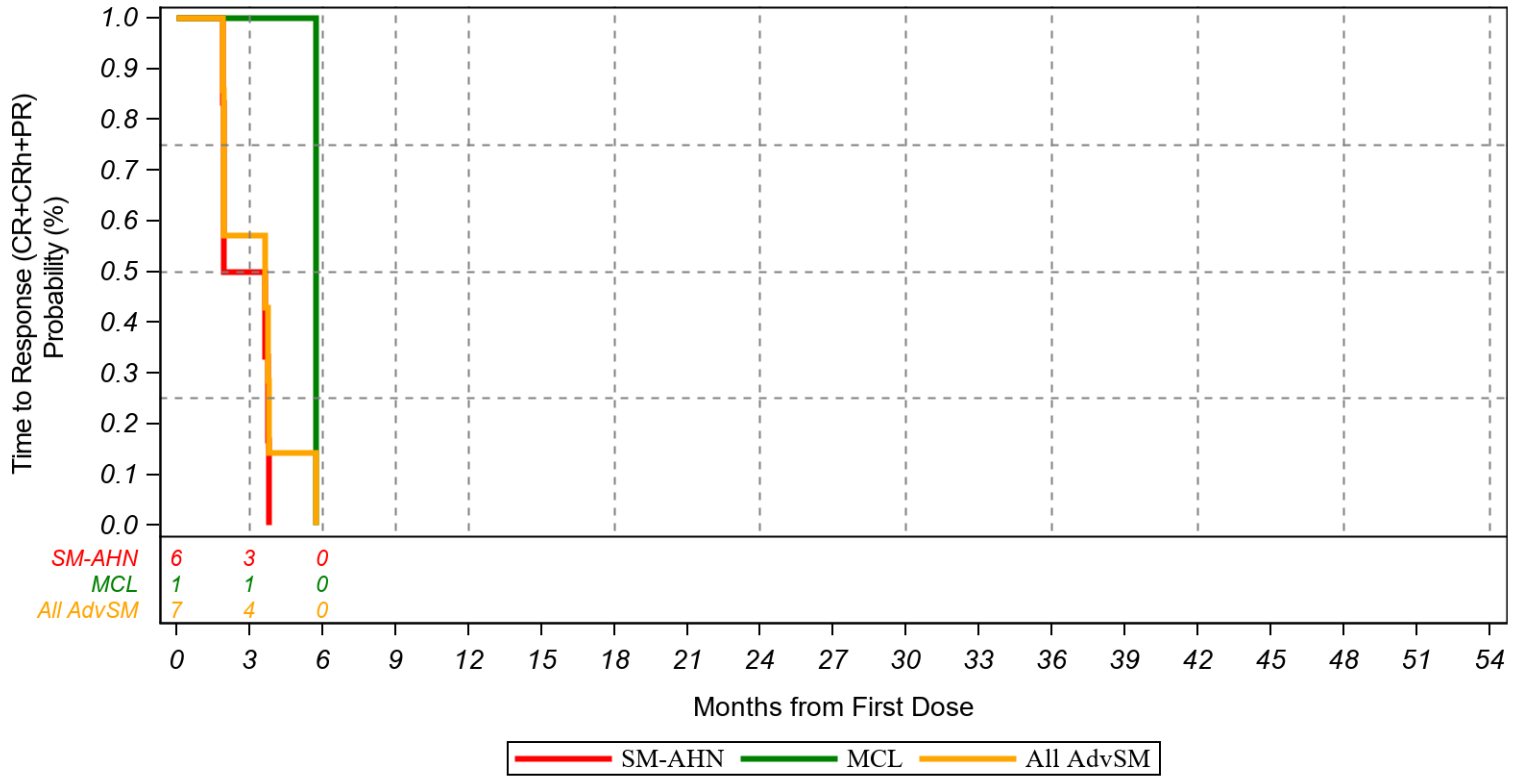

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Study BLU-285-2202
Starting Dose: 200 mg

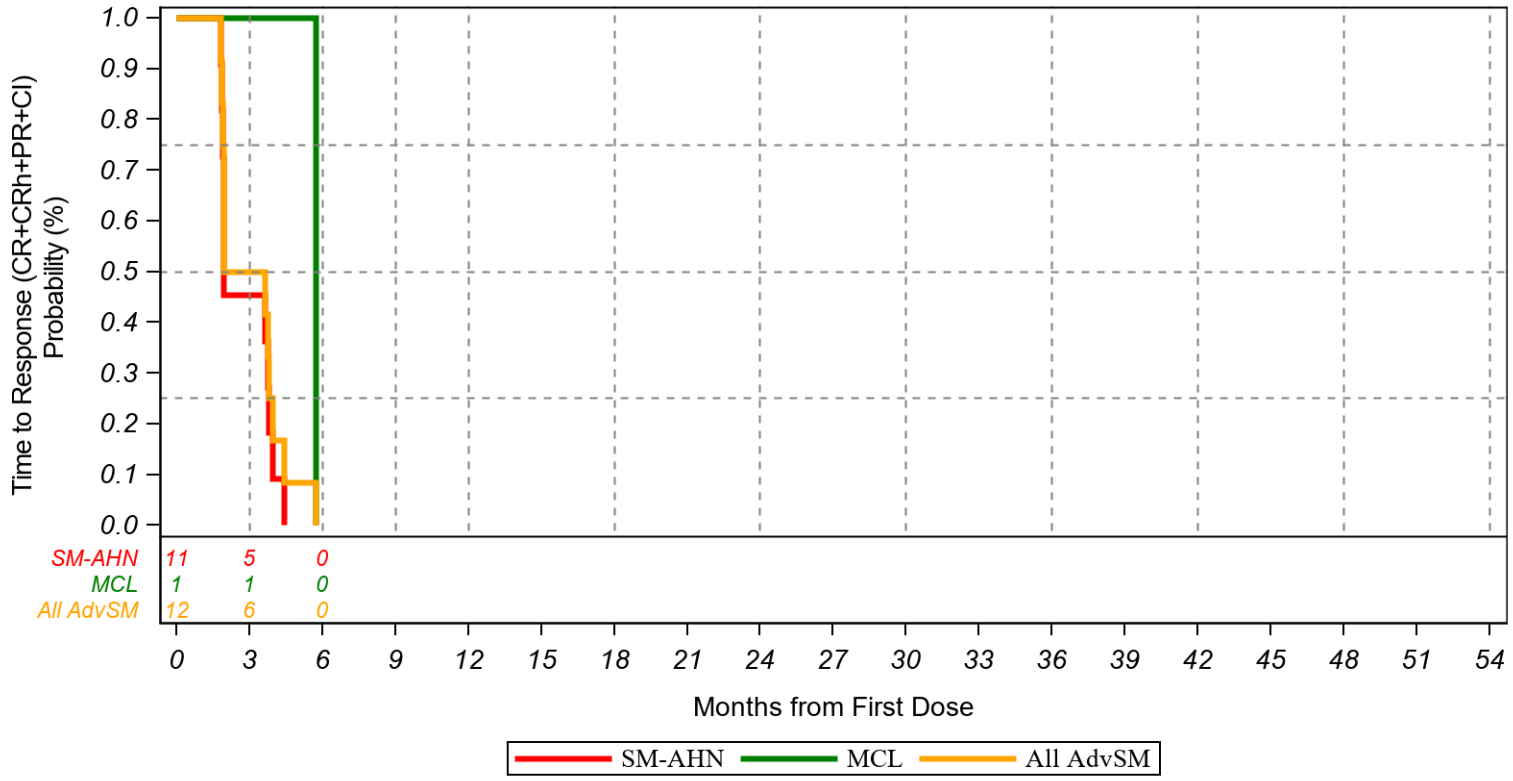

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Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall

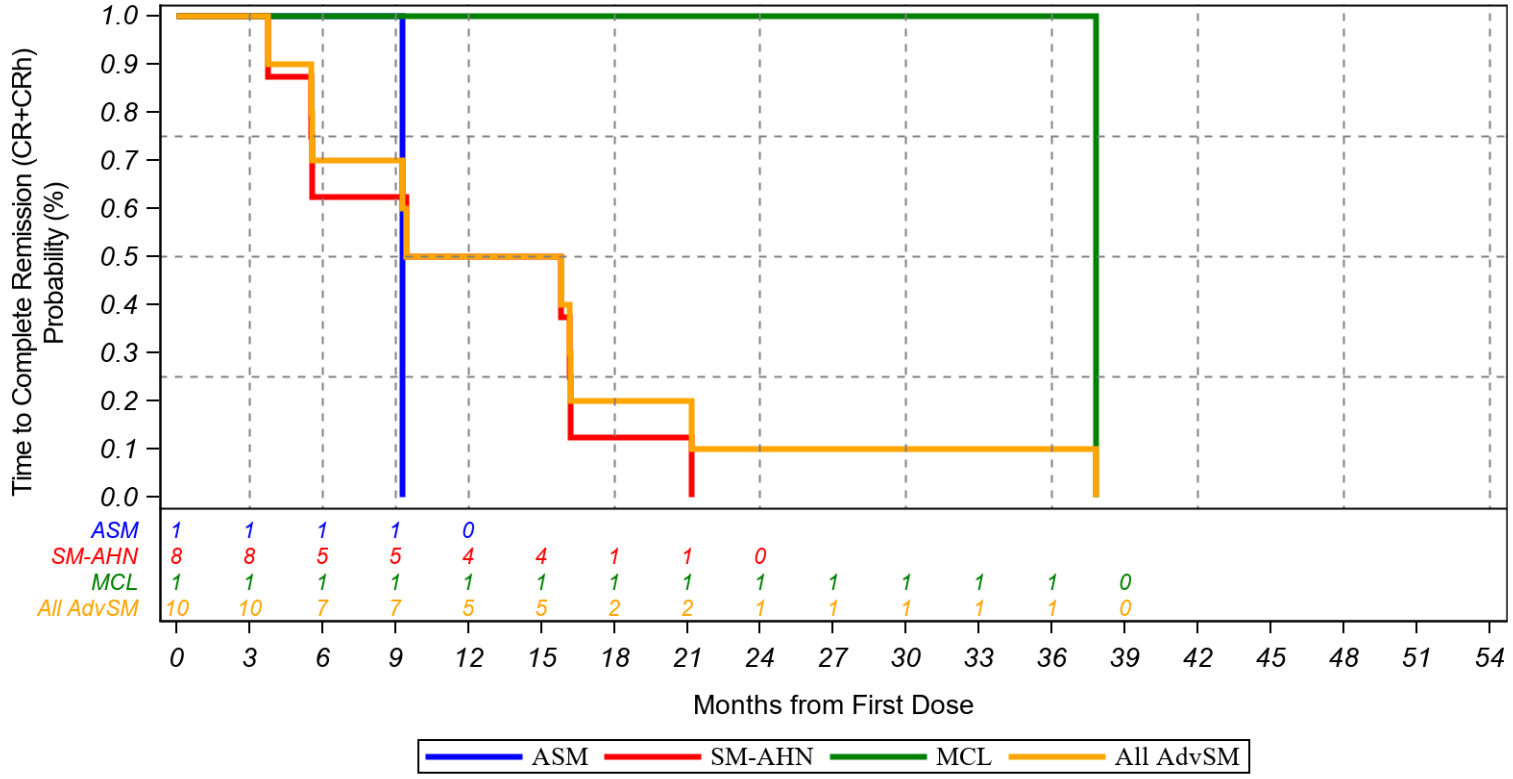

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall

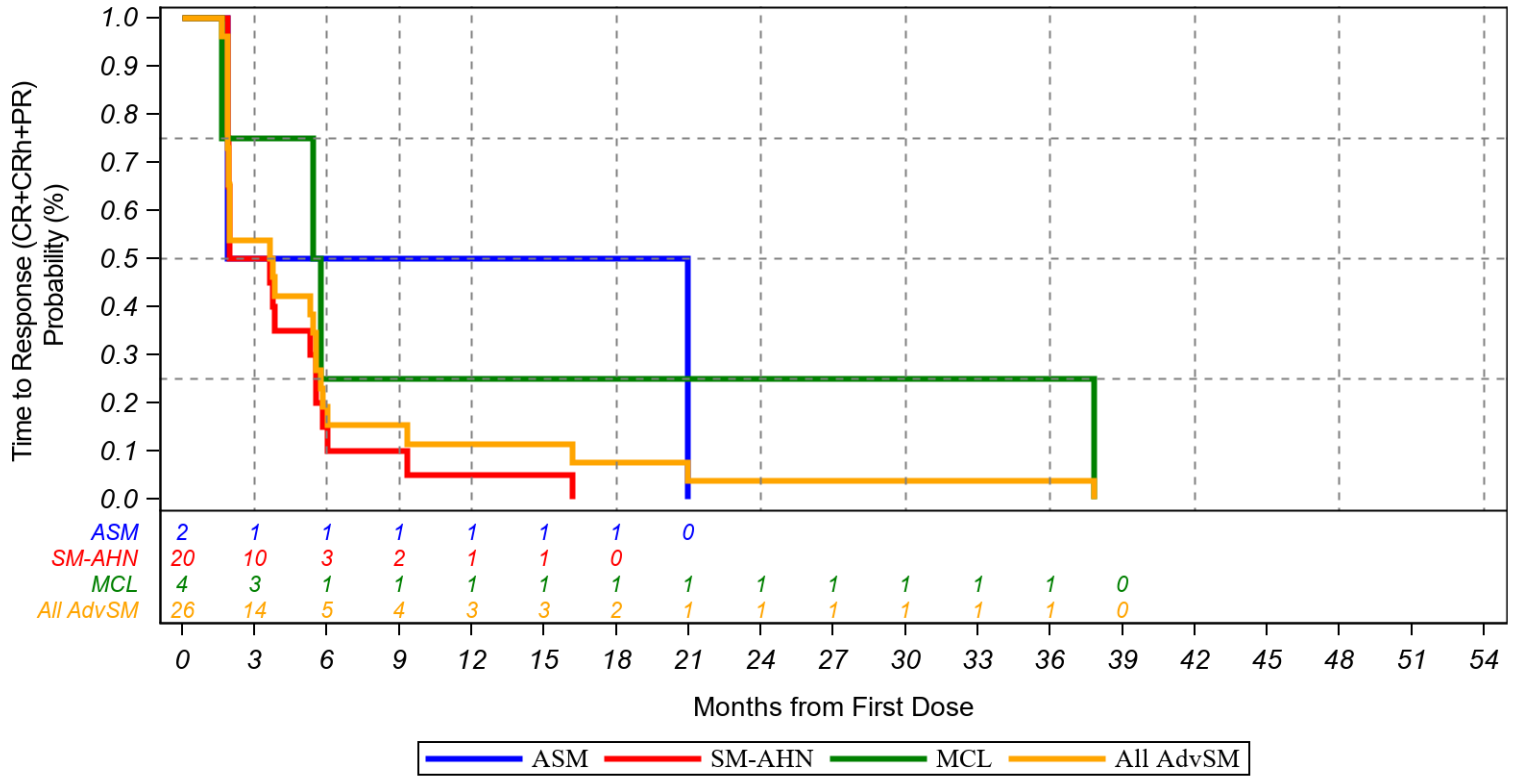

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall

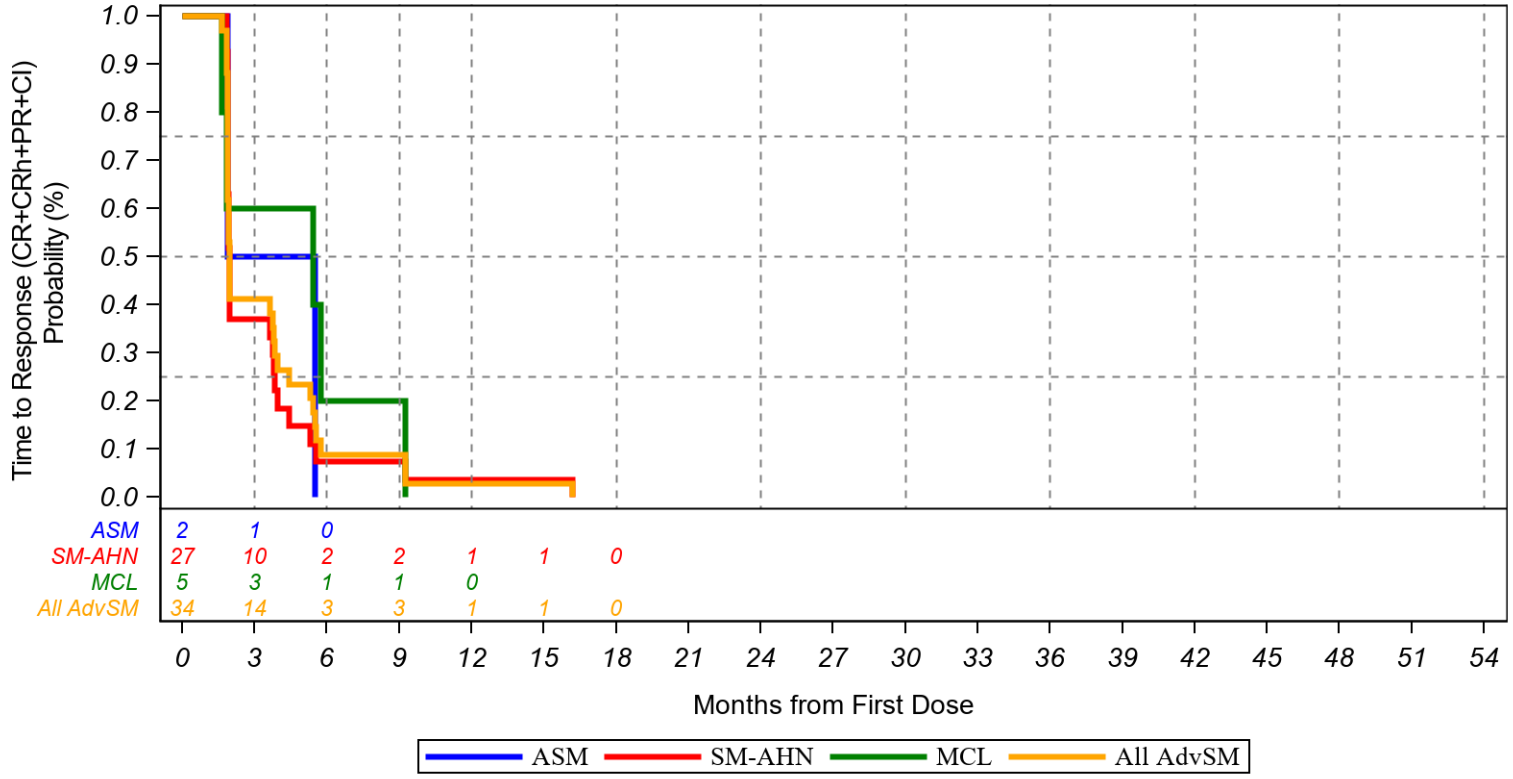

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg

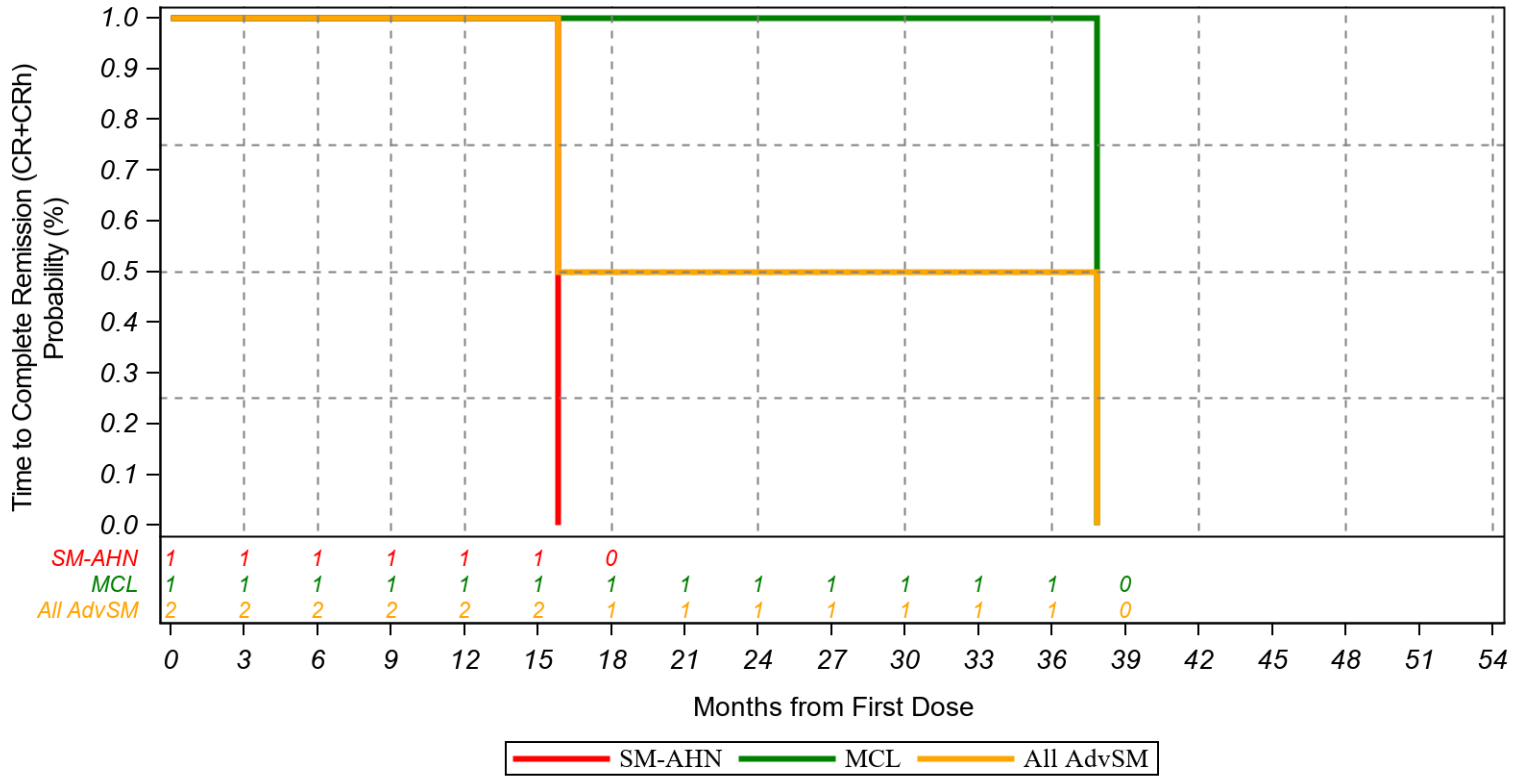

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg

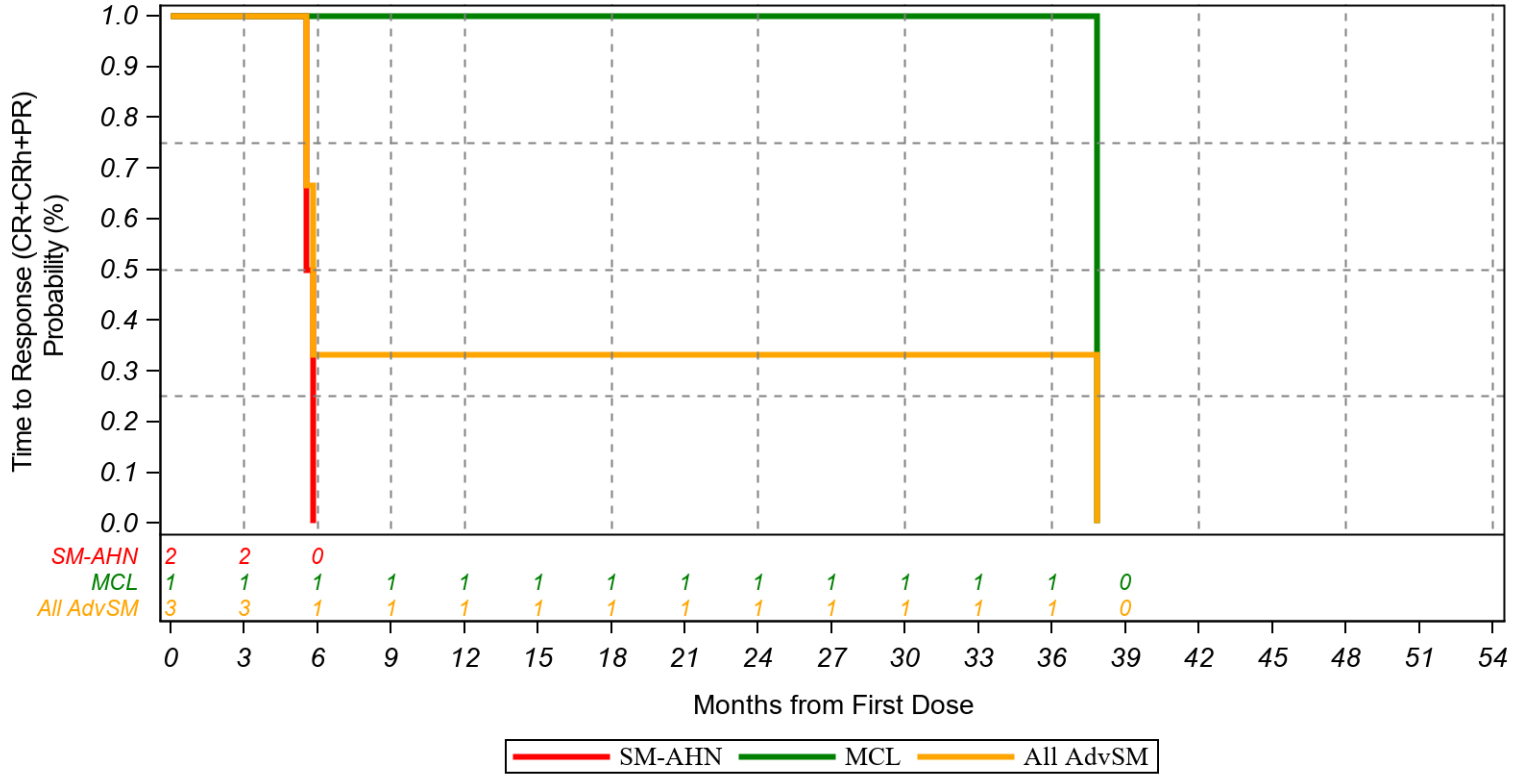

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg

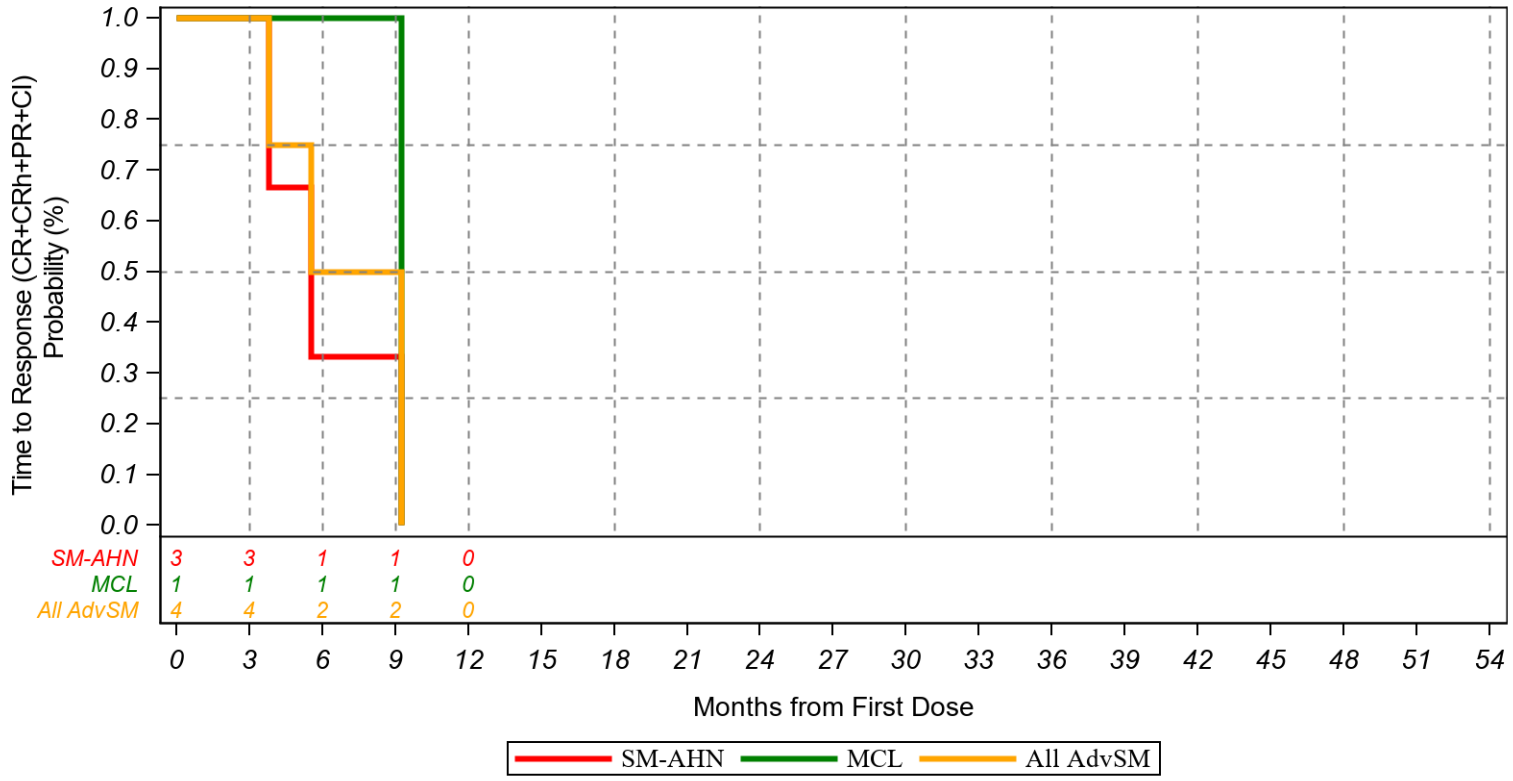

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg

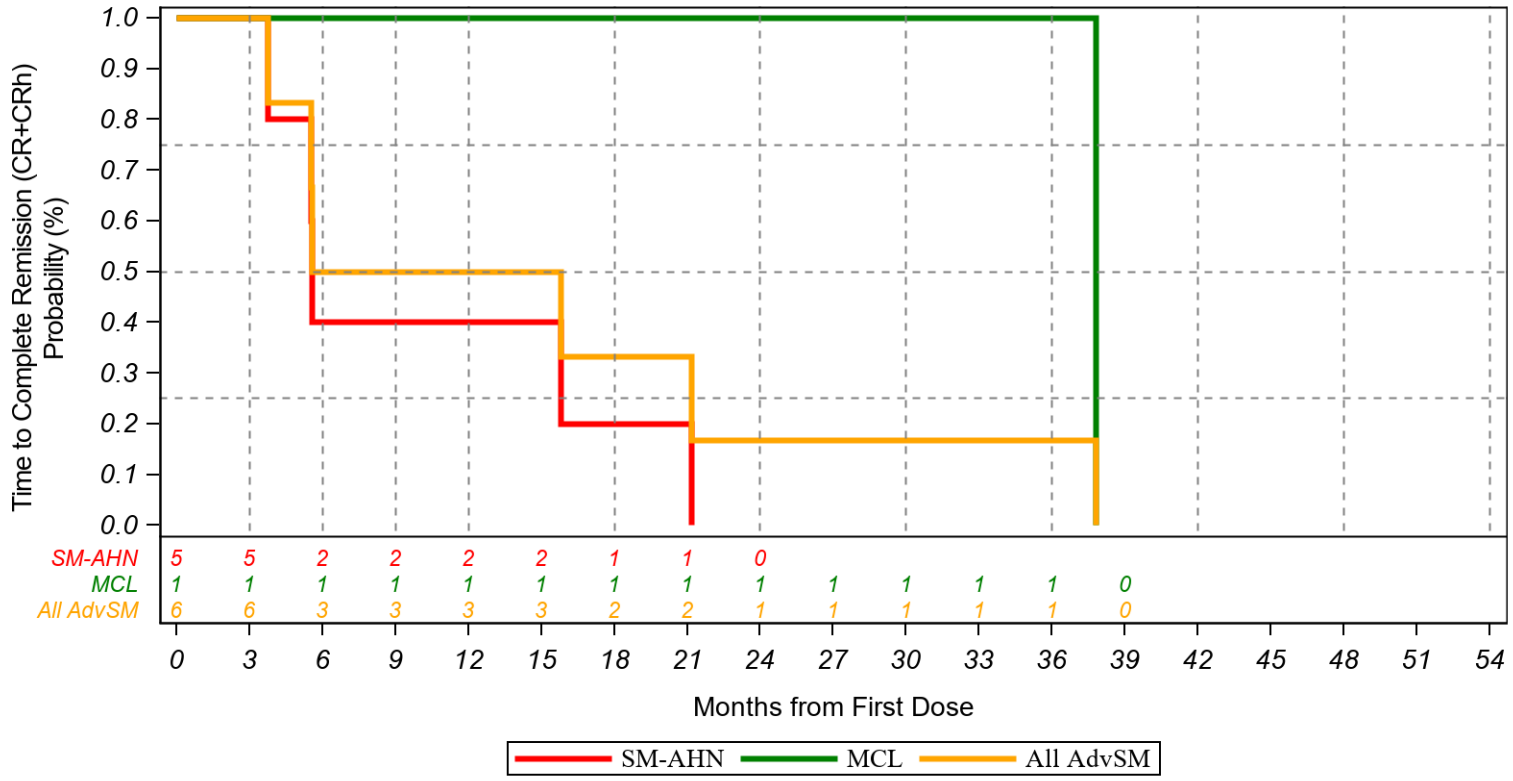

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg

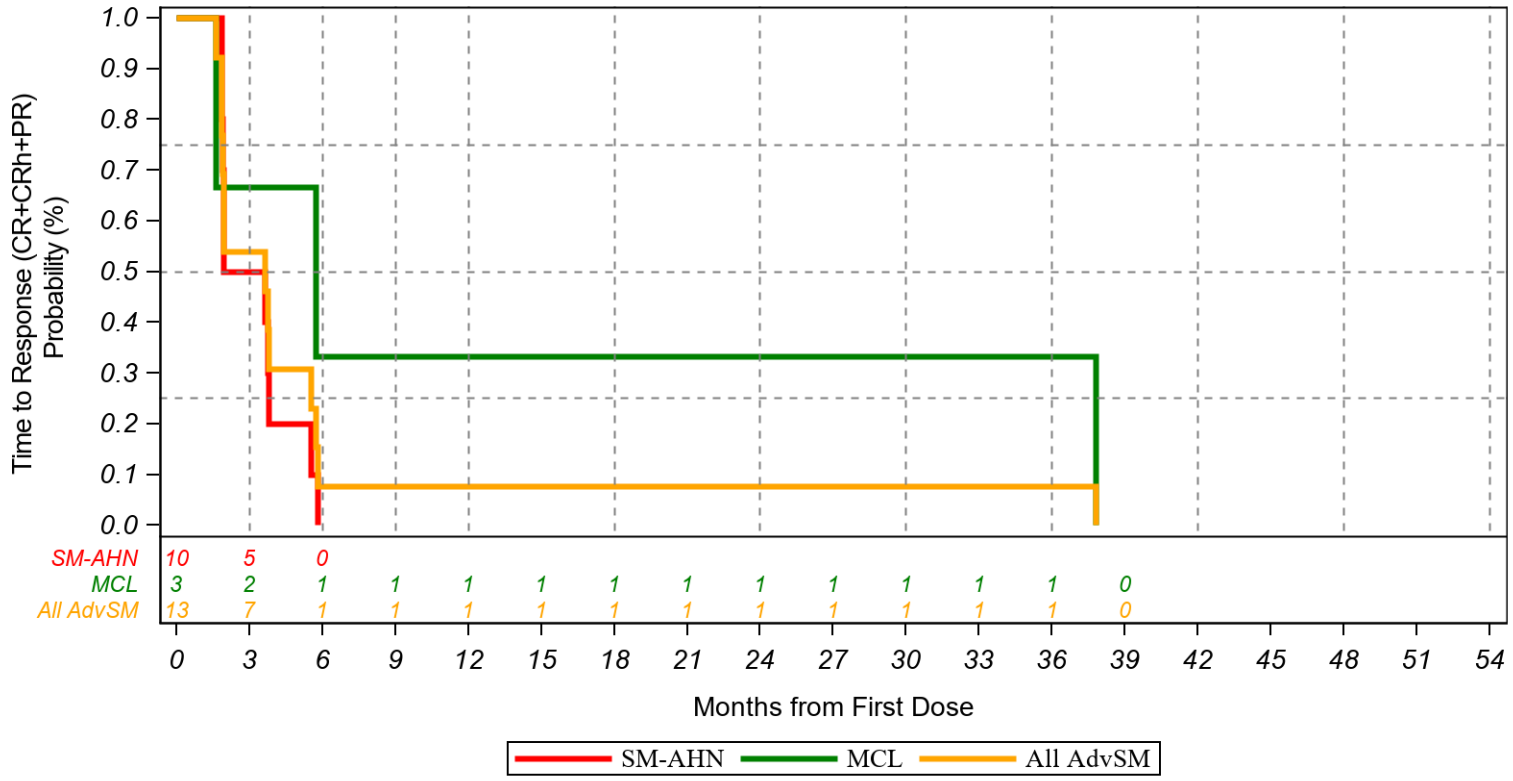

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg

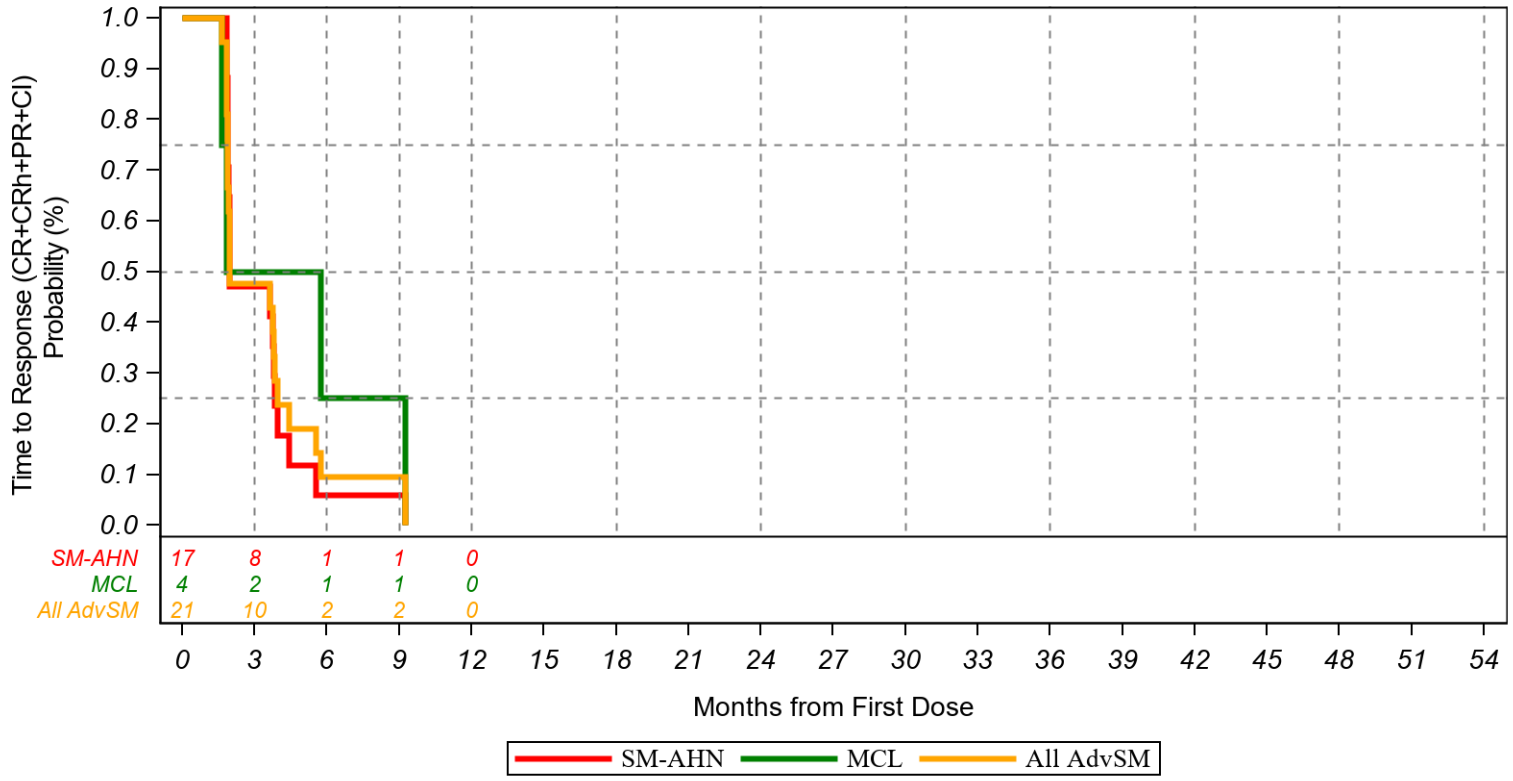

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg

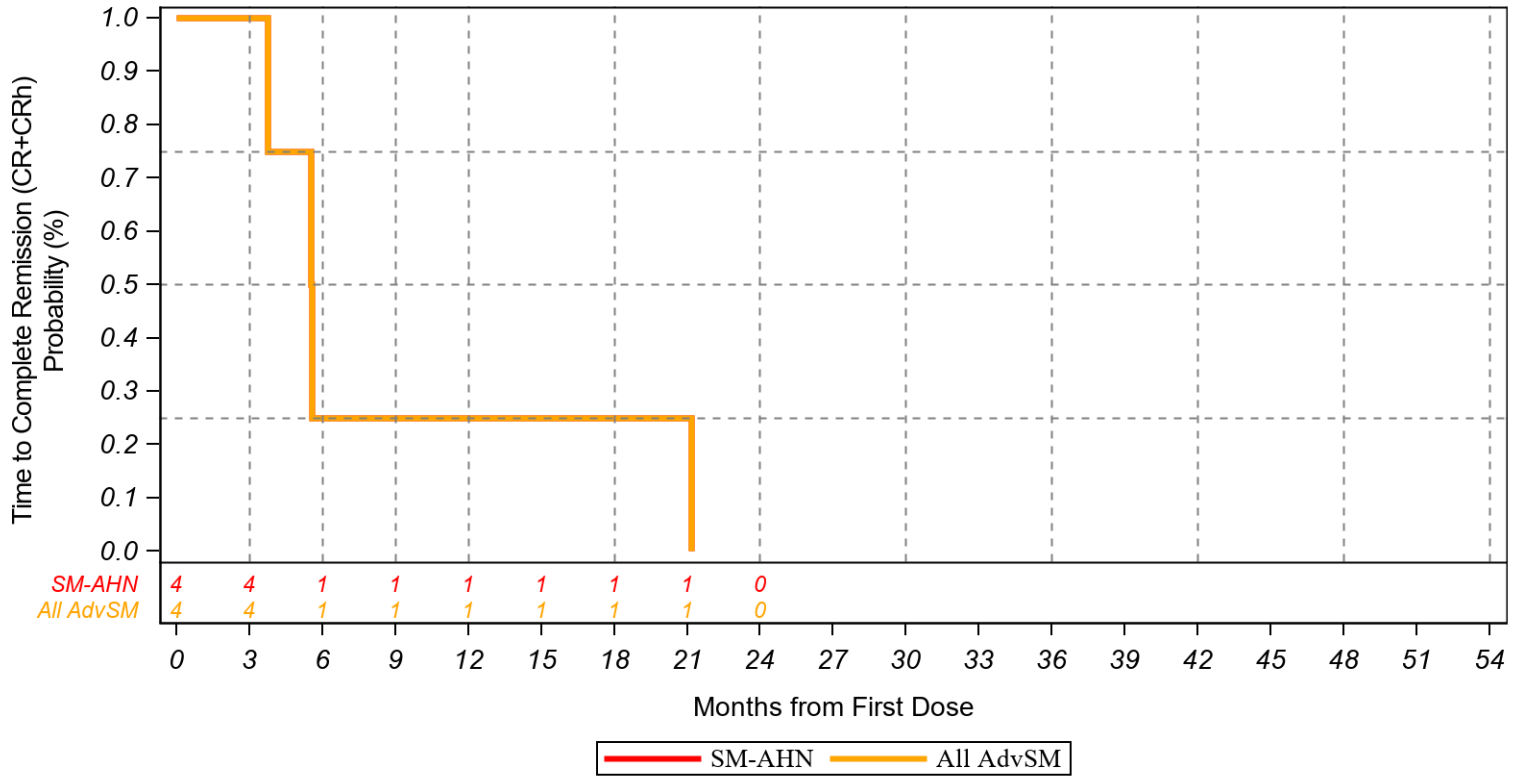

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg

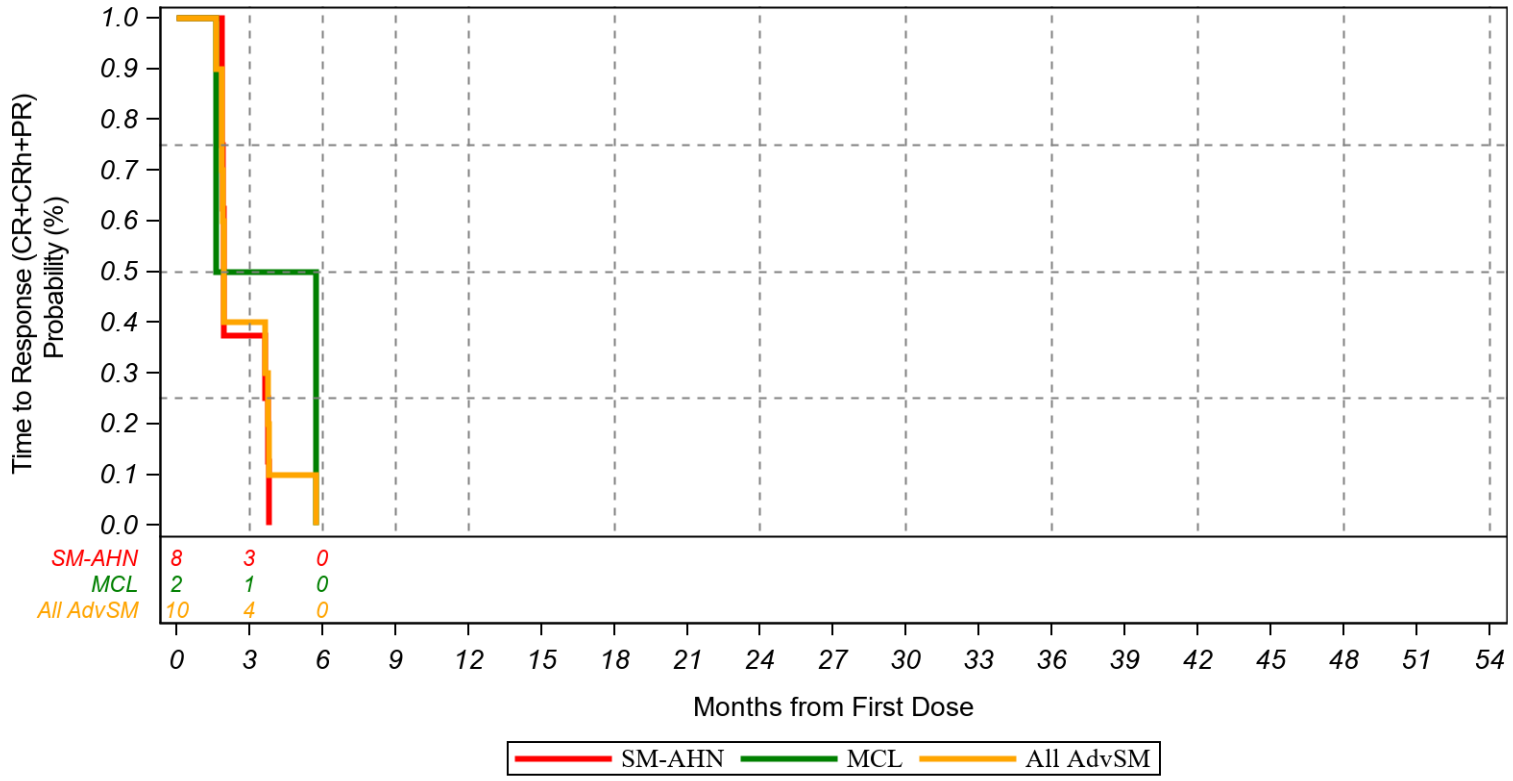

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Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg

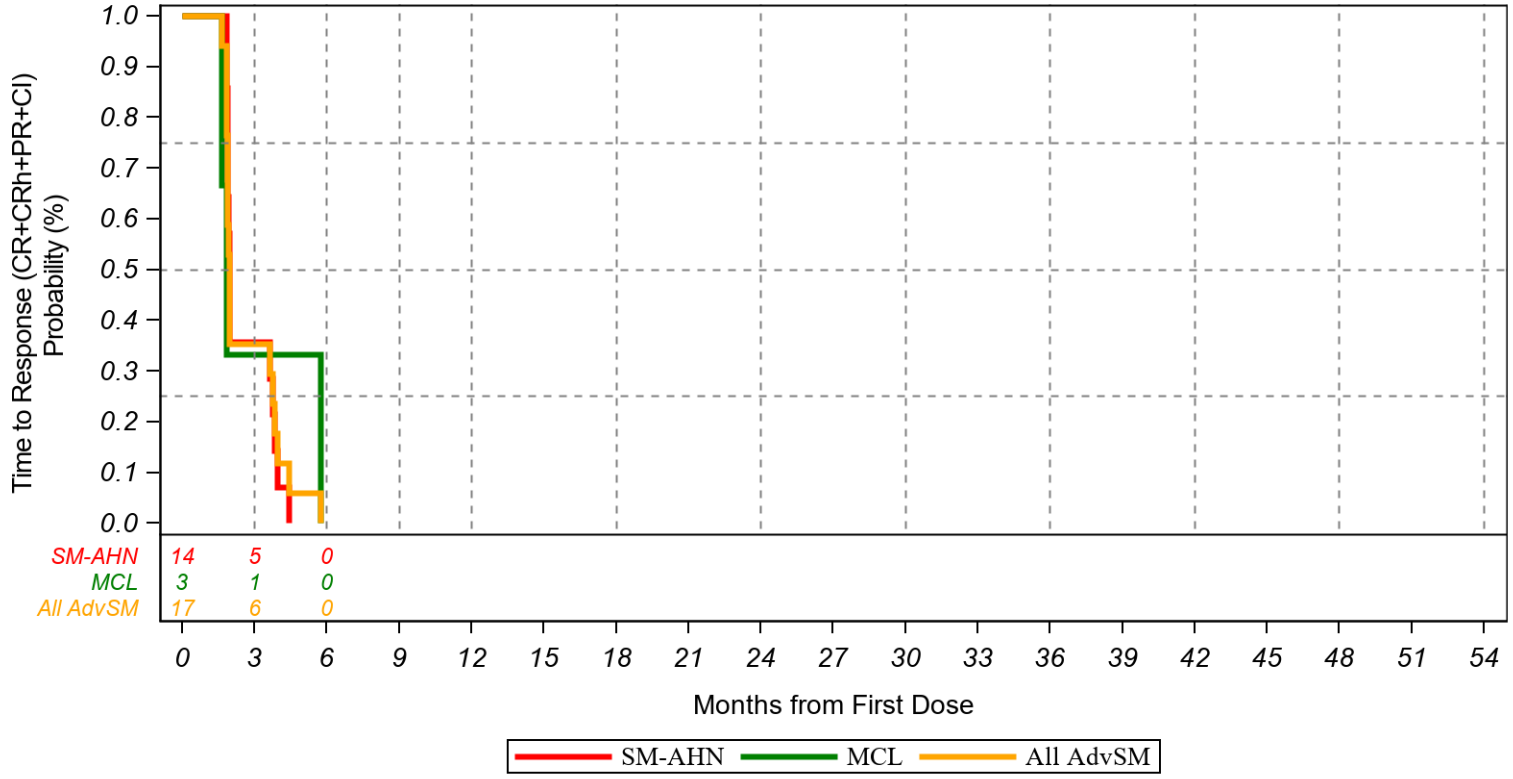

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg

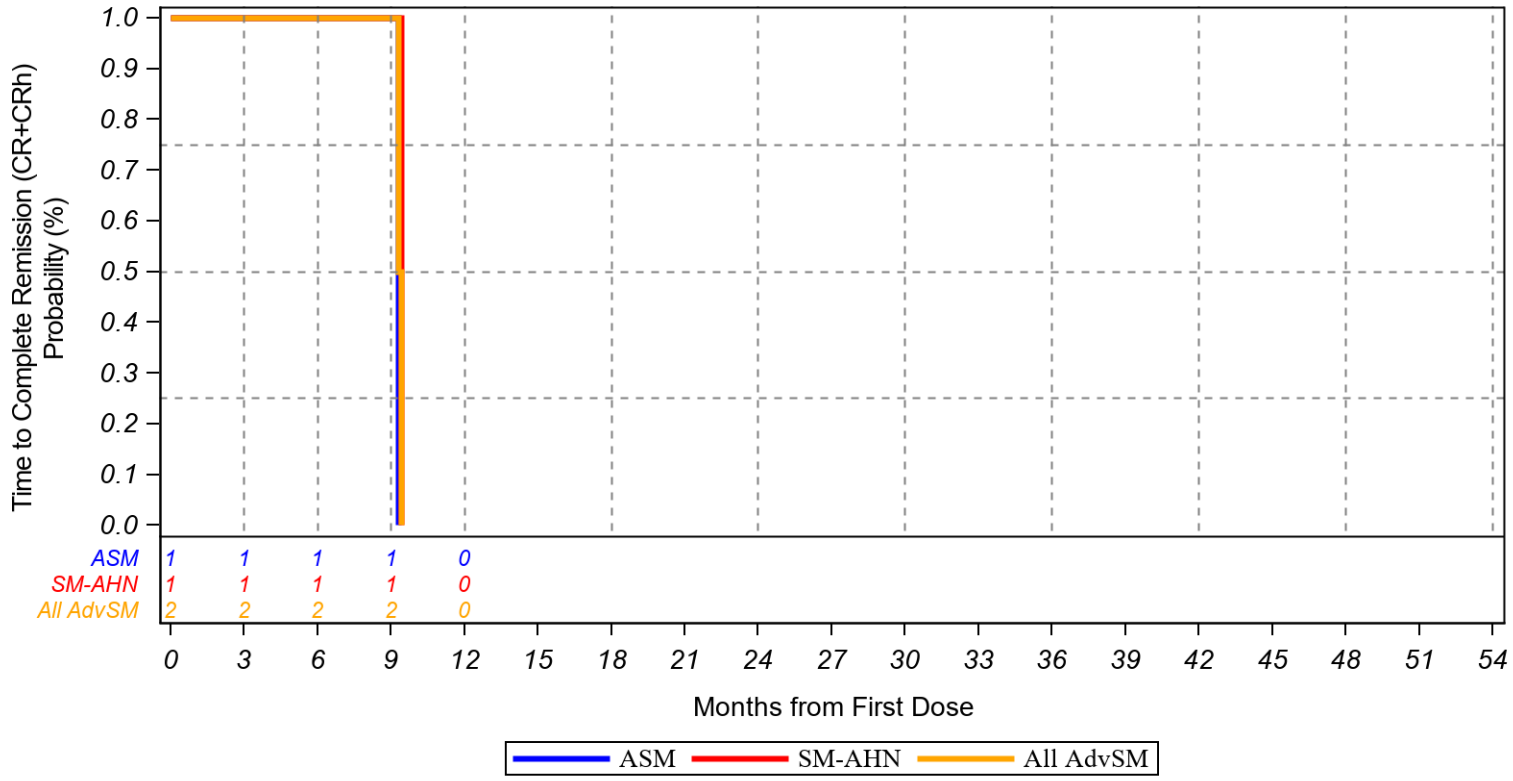

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Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg

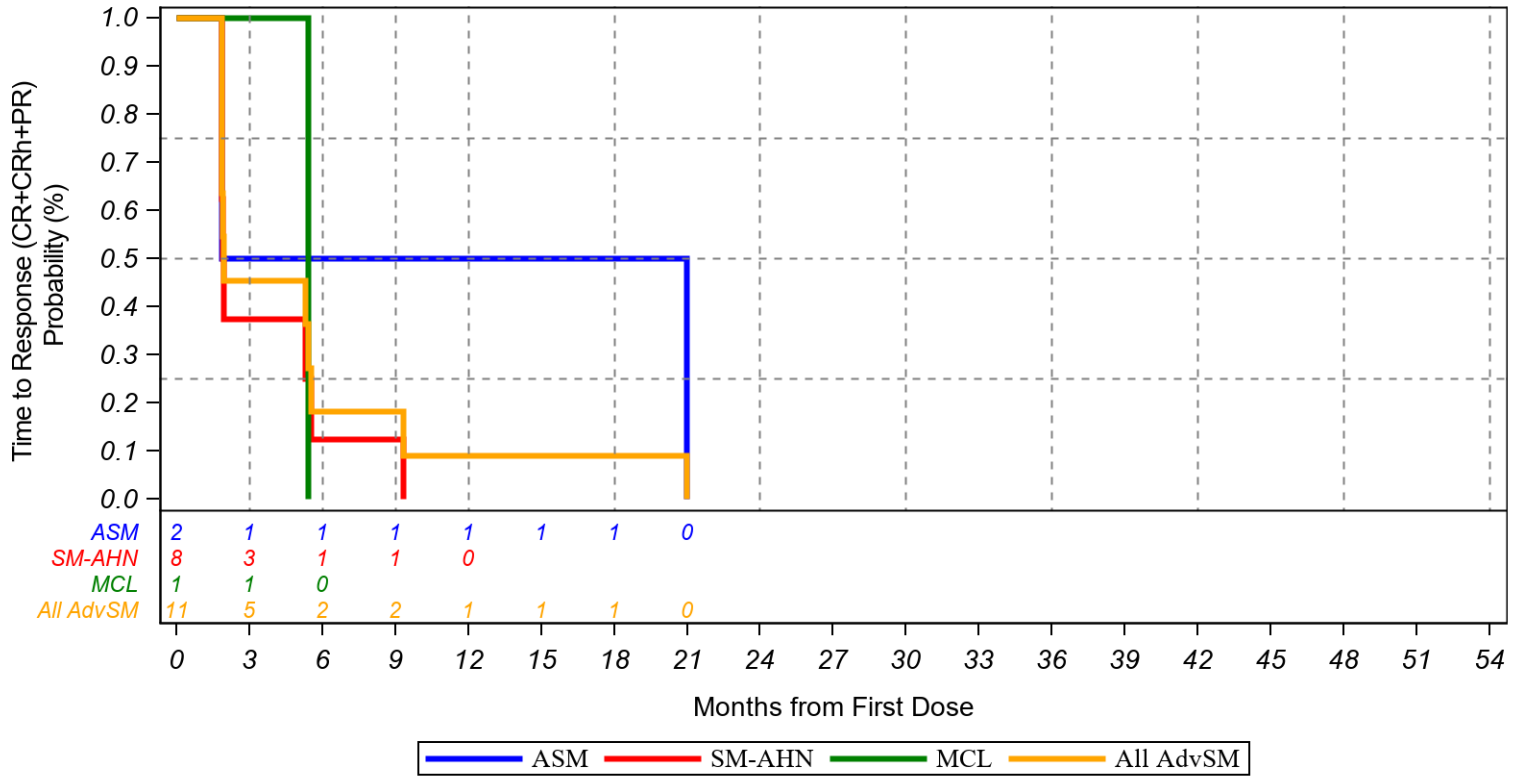

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Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg

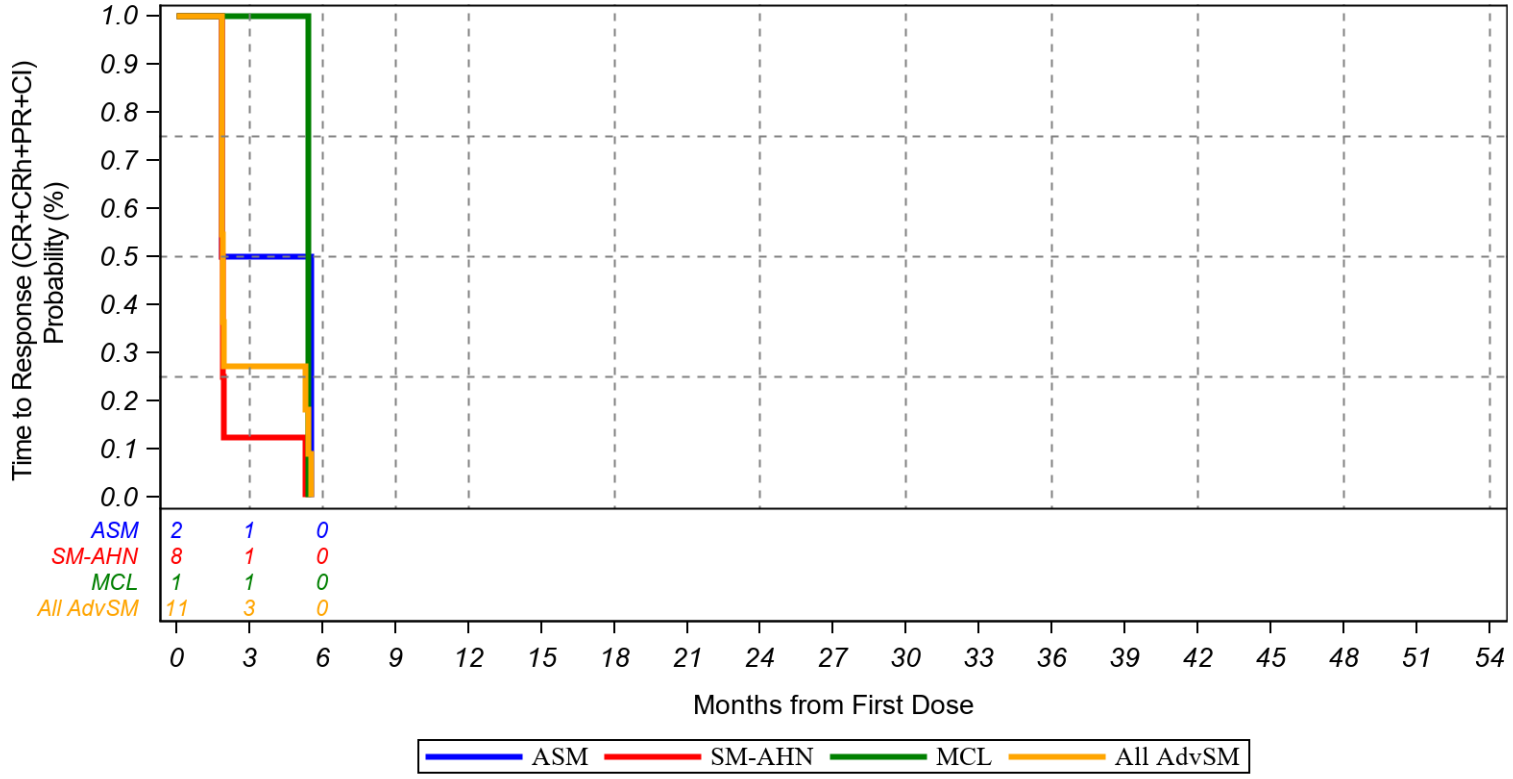


Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg

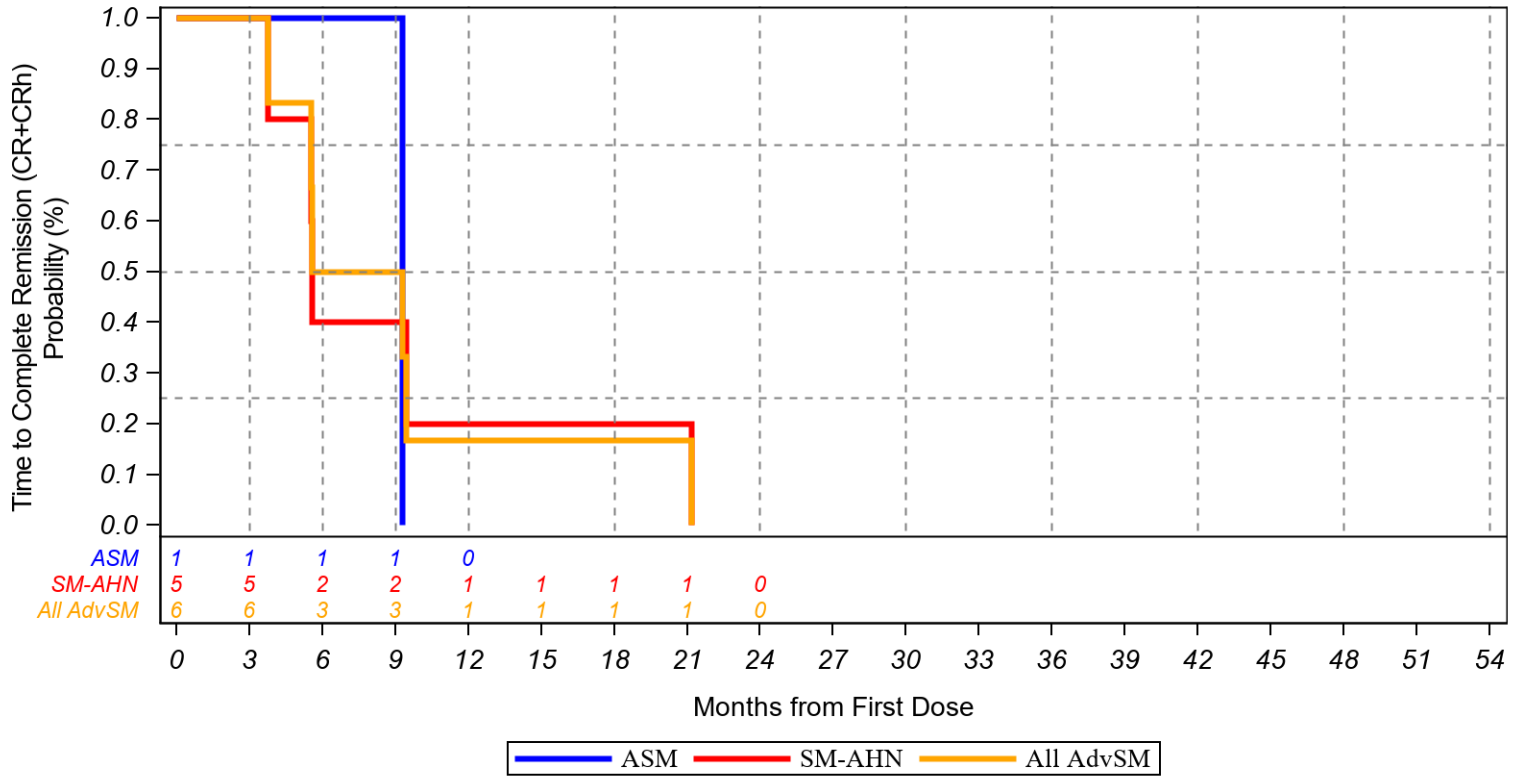
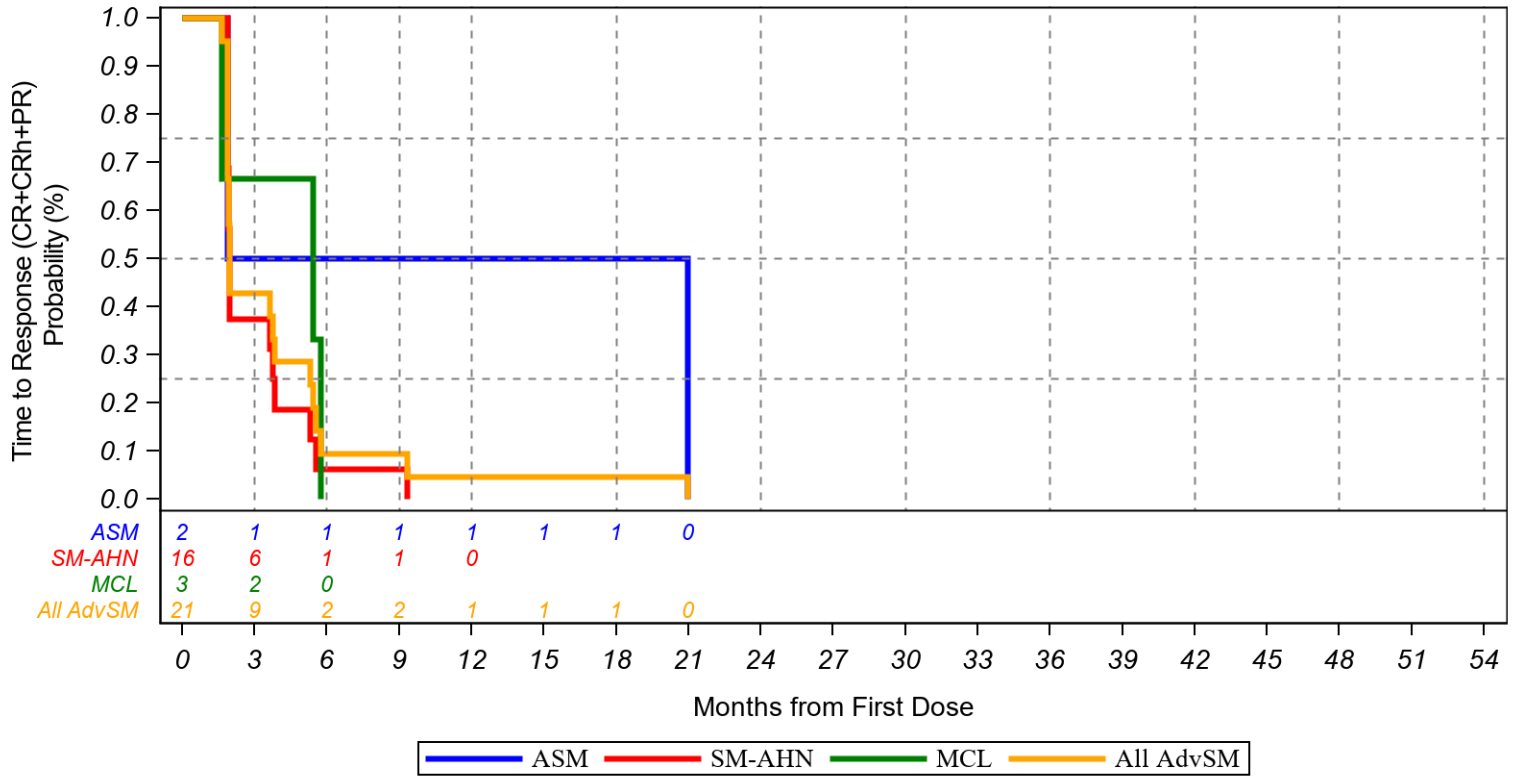


Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg



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Date: 12:21/19OCT2021

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Avapritinib Systemic Mastocytosis Integrated Summary of Efficacy
BLU-285 SM Germany HTA Analysis
Cutoff date: 27may2020 (2101), 23jun2020 (2202)

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg

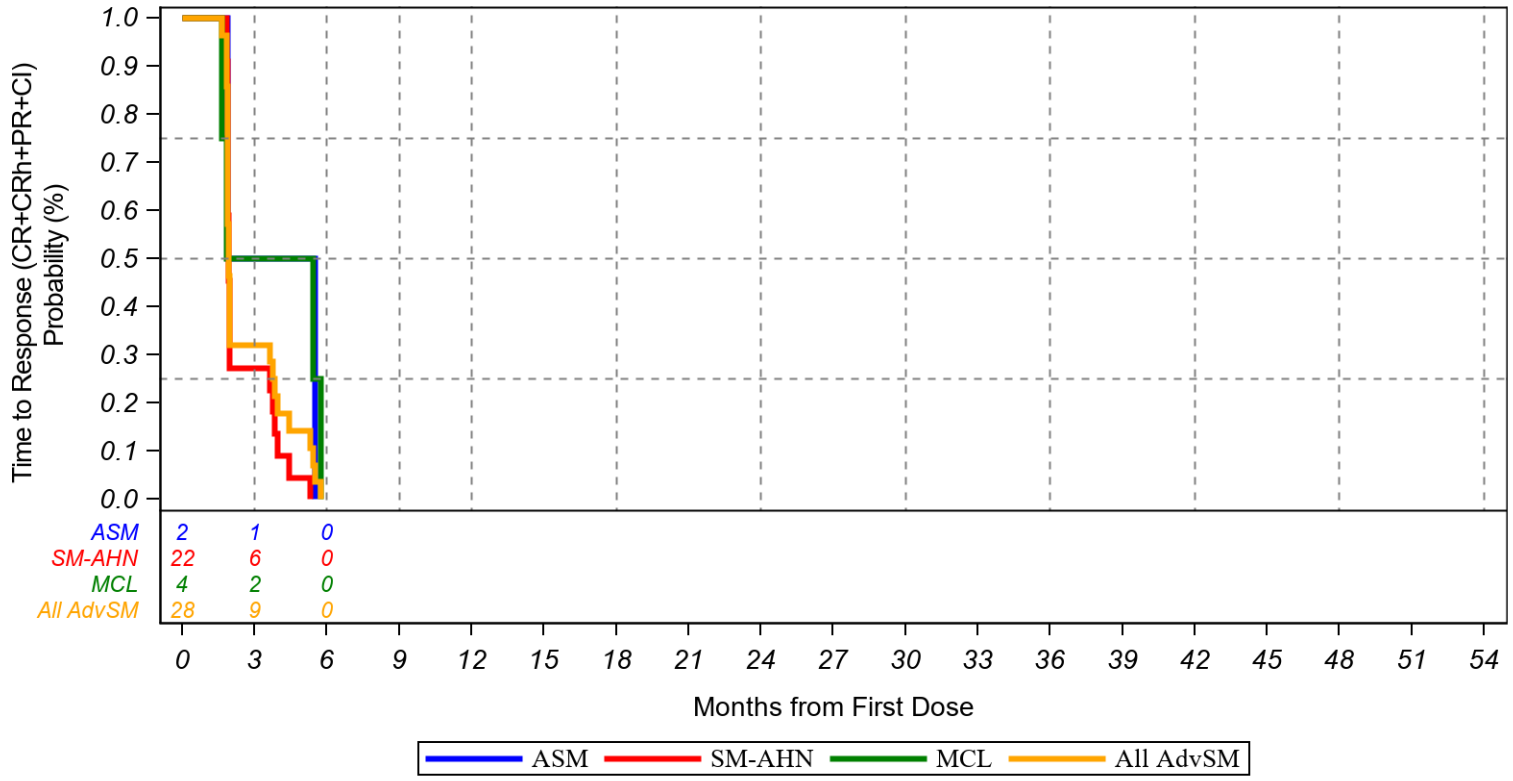

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Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg

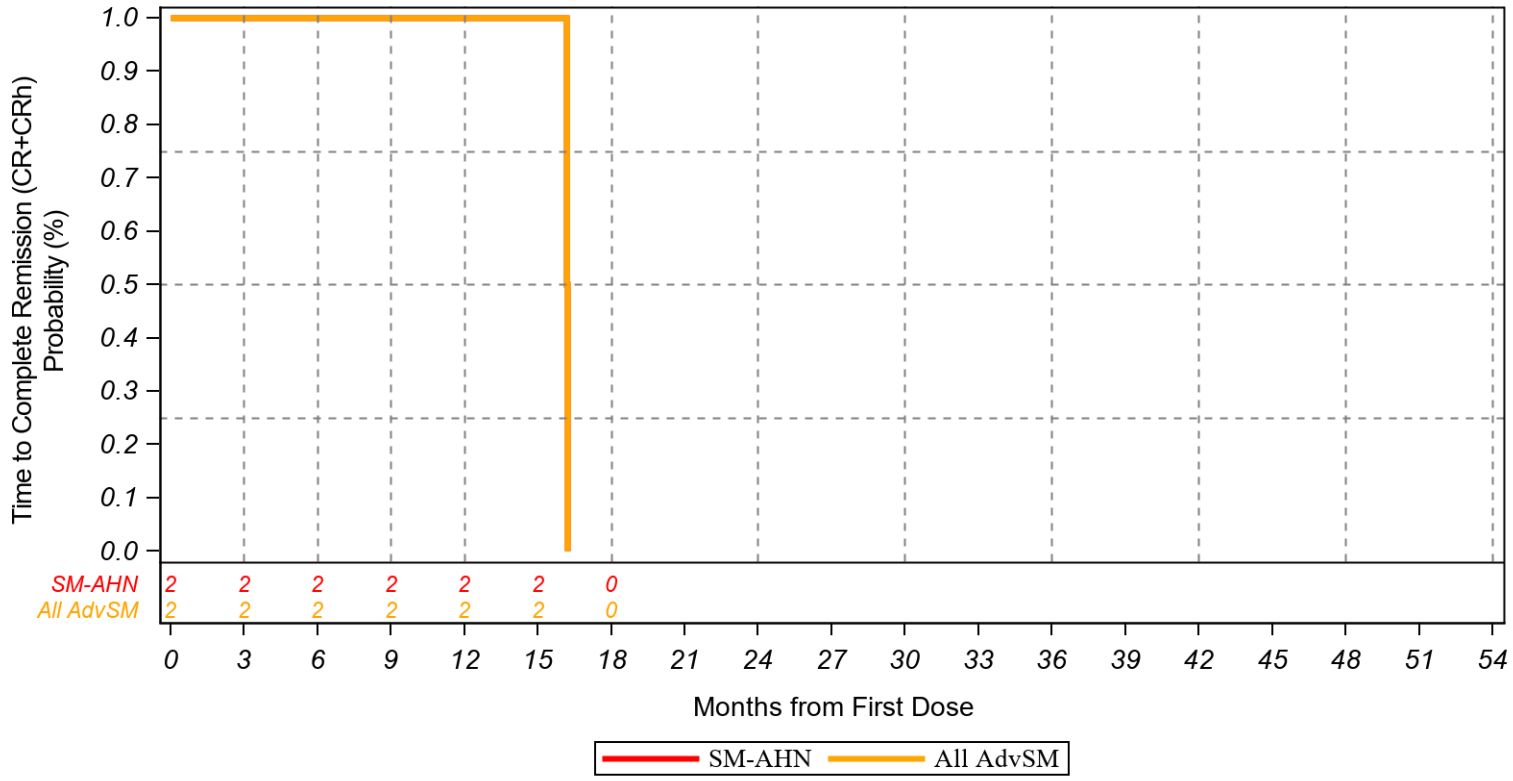

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg

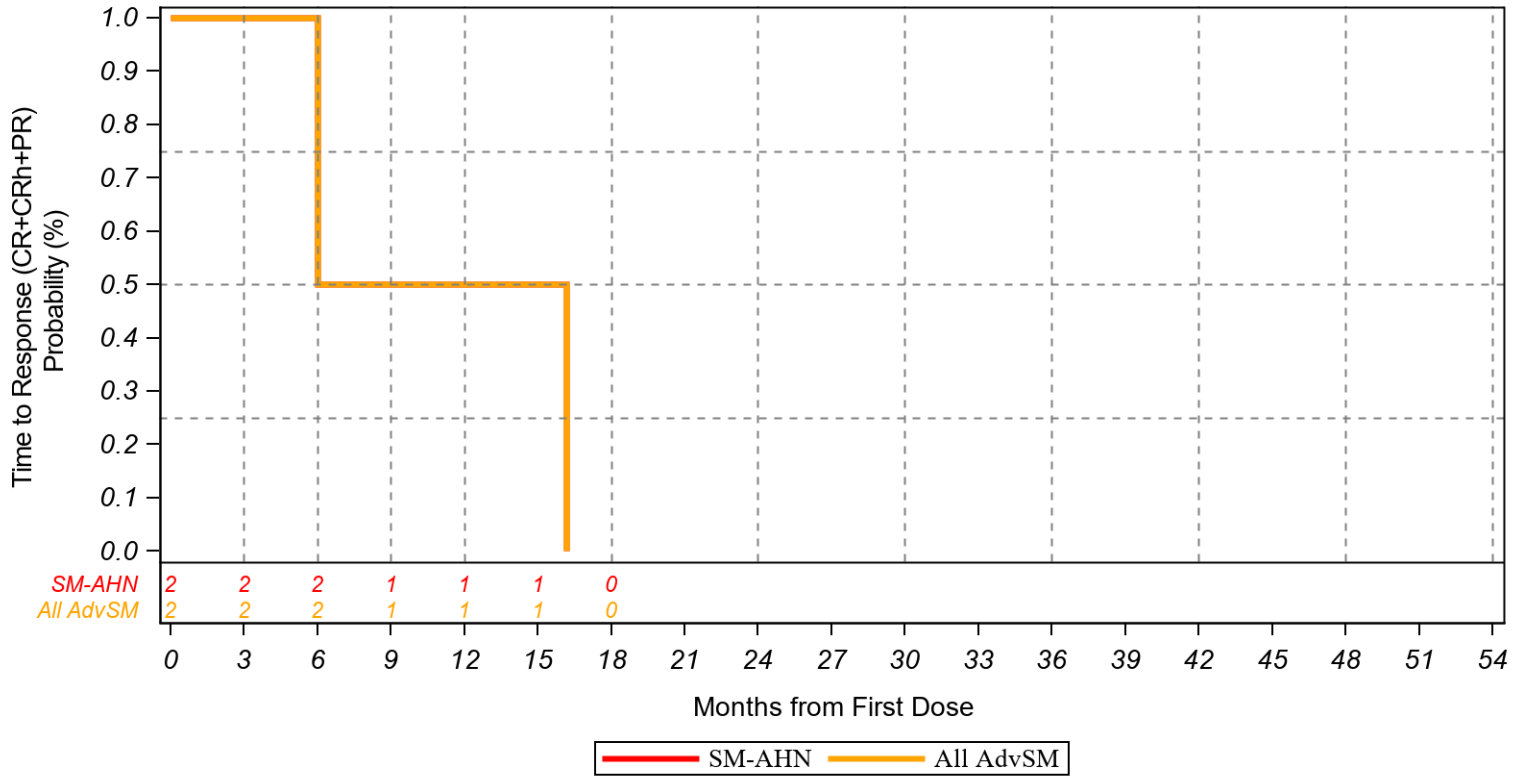

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Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg

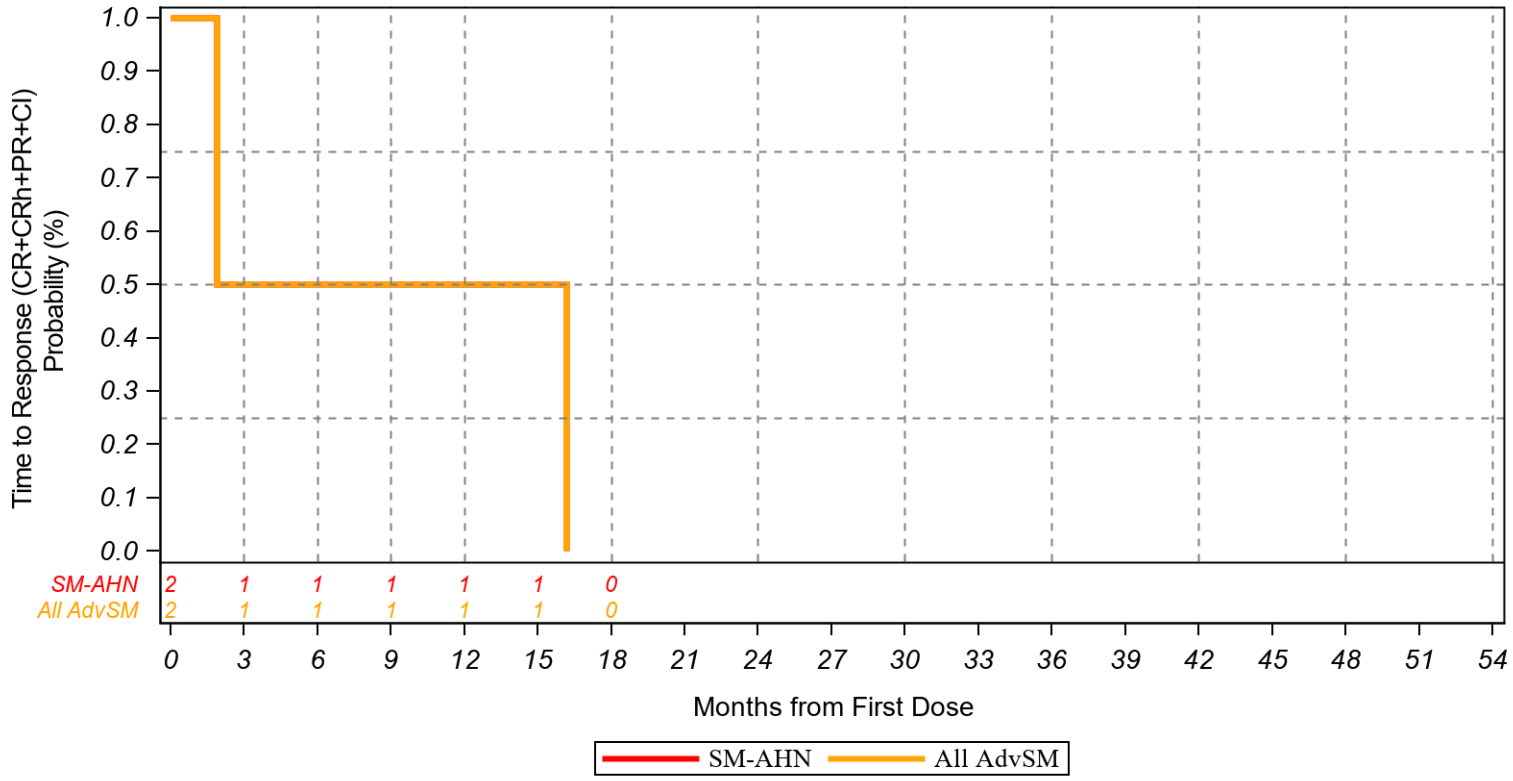

Table 14.2.2.8b
Summary of Algorithm Time to Response and Time to Complete Remission by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+PR+CI)
Study: BLU-285-2101

Overall & Prior antineoplastic therapy = Yes	ASM (N=2) n (%)	SM-AHN (N=12) n (%)	MCL (N=5) n (%)	All AdvSM (N=19) n (%)
Time to Response (Months)				
n	2	12	5	19
Mean (StdDev)	9.94 (11.453)	6.74 (7.760)	8.32 (10.803)	7.49 (8.441)
Median	9.94	4.21	1.91	2.79
Min, Max	1.8, 18.0	0.3, 27.2	1.6, 26.7	0.3, 27.2
Time to CR (Months)				
n	0	4	3	7
Mean (StdDev)		15.70 (4.480)	23.00 (12.833)	18.83 (8.953)
Median		16.92	15.74	16.10
Min, Max		9.3, 19.6	15.4, 37.8	9.3, 37.8
Time to CR+PR (Months)				
n	2	12	4	18
Mean (StdDev)	11.79 (8.828)	7.44 (7.324)	9.92 (11.767)	8.48 (8.140)
Median	11.79	5.63	5.67	5.63
Min, Max	5.6, 18.0	1.9, 27.2	1.6, 26.7	1.6, 27.2

Abbreviations: CR=Complete remission, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to Complete Remission is defined as the time from the start of treatment to the time a CR is first met. Patients without confirmed CR are excluded from this analysis.
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Table 14.2.2.8b
Summary of Algorithm Time to Response and Time to Complete Remission by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+PR+CI)
Study: BLU-285-2101

Starting Dose: <200 mg & Prior antineoplastic therapy = Yes	ASM (N=0) n (%)	SM-AHN (N=1) n (%)	MCL (N=1) n (%)	All AdvSM (N=2) n (%)
Time to Response (Months)				
n		1	1	2
Mean (StdDev)		1.02 (-)	26.71 (-)	13.86 (18.167)
Median		1.02	26.71	13.86
Min, Max		1.0, 1.0	26.7, 26.7	1.0, 26.7
Time to CR (Months)				
n		1	1	2
Mean (StdDev)		17.74 (-)	37.82 (-)	27.78 (14.194)
Median		17.74	37.82	27.78
Min, Max		17.7, 17.7	37.8, 37.8	17.7, 37.8
Time to CR+PR (Months)				
n		1	1	2
Mean (StdDev)		2.00 (-)	26.71 (-)	14.36 (17.470)
Median		2.00	26.71	14.36
Min, Max		2.0, 2.0	26.7, 26.7	2.0, 26.7

Abbreviations: CR=Complete remission, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to Complete Remission is defined as the time from the start of treatment to the time a CR is first met. Patients without confirmed CR are excluded from this analysis.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-tm-rac-tpy.sasDate: 21:09/02NOV2020

Table 14.2.2.8b
Summary of Algorithm Time to Response and Time to Complete Remission by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+PR+CI)
Study: BLU-285-2101

Starting Dose: <300 mg & Prior antineoplastic therapy = Yes	ASM (N=0) n (%)	SM-AHN (N=2) n (%)	MCL (N=3) n (%)	All AdvSM (N=5) n (%)
Time to Response (Months)				
n		2	3	5
Mean (StdDev)		1.91 (1.254)	12.61 (12.826)	8.33 (10.816)
Median		1.91	9.46	2.79
Min, Max		1.0, 2.8	1.6, 26.7	1.0, 26.7
Time to CR (Months)				
n		1	2	3
Mean (StdDev)		17.74 (-)	26.63 (15.821)	23.67 (12.307)
Median		17.74	26.63	17.74
Min, Max		17.7, 17.7	15.4, 37.8	15.4, 37.8
Time to CR+PR (Months)				
n		2	3	5
Mean (StdDev)		2.40 (0.558)	12.61 (12.826)	8.52 (10.658)
Median		2.40	9.46	2.79
Min, Max		2.0, 2.8	1.6, 26.7	1.6, 26.7

Abbreviations: CR=Complete remission, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to Complete Remission is defined as the time from the start of treatment to the time a CR is first met. Patients without confirmed CR are excluded from this analysis.
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Table 14.2.2.8b
Summary of Algorithm Time to Response and Time to Complete Remission by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+PR+CI)
Study: BLU-285-2101

Starting Dose: 200 mg & Prior antineoplastic therapy = Yes	ASM (N=0) n (%)	SM-AHN (N=1) n (%)	MCL (N=2) n (%)	All AdvSM (N=3) n (%)
Time to Response (Months)				
n		1	2	3
Mean (StdDev)		2.79 (-)	5.55 (5.529)	4.63 (4.222)
Median		2.79	5.55	2.79
Min, Max		2.8, 2.8	1.6, 9.5	1.6, 9.5
Time to CR (Months)				
n		0	1	1
Mean (StdDev)			15.44 (-)	15.44 (-)
Median			15.44	15.44
Min, Max			15.4, 15.4	15.4, 15.4
Time to CR+PR (Months)				
n		1	2	3
Mean (StdDev)		2.79 (-)	5.55 (5.529)	4.63 (4.222)
Median		2.79	5.55	2.79
Min, Max		2.8, 2.8	1.6, 9.5	1.6, 9.5

Abbreviations: CR=Complete remission, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to Complete Remission is defined as the time from the start of treatment to the time a CR is first met. Patients without confirmed CR are excluded from this analysis.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-tm-rac-tpy.sasDate: 21:09/02NOV2020

Table 14.2.2.8b
Summary of Algorithm Time to Response and Time to Complete Remission by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+PR+CI)
Study: BLU-285-2101

Starting Dose: 300 mg & Prior antineoplastic therapy = Yes	ASM (N=2) n (%)	SM-AHN (N=7) n (%)	MCL (N=2) n (%)	All AdvSM (N=11) n (%)
Time to Response (Months)				
n	2	7	2	11
Mean (StdDev)	9.94 (11.453)	5.31 (5.453)	1.89 (0.023)	5.53 (6.126)
Median	9.94	1.97	1.89	1.91
Min, Max	1.8, 18.0	0.3, 14.8	1.9, 1.9	0.3, 18.0
Time to CR (Months)				
n	0	2	1	3
Mean (StdDev)		12.71 (4.786)	15.74 (-)	13.72 (3.807)
Median		12.71	15.74	15.74
Min, Max		9.3, 16.1	15.7, 15.7	9.3, 16.1
Time to CR+PR (Months)				
n	2	7	1	10
Mean (StdDev)	11.79 (8.828)	6.39 (4.755)	1.87 (-)	7.02 (5.662)
Median	11.79	5.65	1.87	5.60
Min, Max	5.6, 18.0	1.9, 14.8	1.9, 1.9	1.9, 18.0

Abbreviations: CR=Complete remission, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to Complete Remission is defined as the time from the start of treatment to the time a CR is first met. Patients without confirmed CR are excluded from this analysis.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-tm-rac-tpy.sasDate: 21:09/02NOV2020

Table 14.2.2.8b
Summary of Algorithm Time to Response and Time to Complete Remission by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+PR+CI)
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg & Prior antineoplastic therapy = Yes

	ASM (N=2) n (%)	SM-AHN (N=8) n (%)	MCL (N=4) n (%)	All AdvSM (N=14) n (%)
Time to Response (Months)				
n	2	8	4	14
Mean (StdDev)	9.94 (11.453)	5.00 (5.127)	3.72 (3.829)	5.34 (5.636)
Median	9.94	2.38	1.89	1.94
Min, Max	1.8, 18.0	0.3, 14.8	1.6, 9.5	0.3, 18.0
Time to CR (Months)				
n	0	2	2	4
Mean (StdDev)		12.71 (4.786)	15.59 (0.209)	14.15 (3.225)
Median		12.71	15.59	15.59
Min, Max		9.3, 16.1	15.4, 15.7	9.3, 16.1
Time to CR+PR (Months)				
n	2	8	3	13
Mean (StdDev)	11.79 (8.828)	5.94 (4.582)	4.33 (4.450)	6.47 (5.301)
Median	11.79	4.80	1.87	5.55
Min, Max	5.6, 18.0	1.9, 14.8	1.6, 9.5	1.6, 18.0

Abbreviations: CR=Complete remission, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to Complete Remission is defined as the time from the start of treatment to the time a CR is first met. Patients without confirmed CR are excluded from this analysis.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-tm-rac-tpy.sasDate: 21:09/02NOV2020

Table 14.2.2.8b
Summary of Algorithm Time to Response and Time to Complete Remission by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+PR+CI)
Study: BLU-285-2101

Starting Dose: 400 mg & Prior antineoplastic therapy = Yes	ASM (N=0) n (%)	SM-AHN (N=3) n (%)	MCL (N=0) n (%)	All AdvSM (N=3) n (%)
Time to Response (Months)				
n		3		3
Mean (StdDev)		13.27 (12.111)		13.27 (12.111)
Median		6.97		6.97
Min, Max		5.6, 27.2		5.6, 27.2
Time to CR (Months)				
n		1		1
Mean (StdDev)		19.61 (-)		19.61 (-)
Median		19.61		19.61
Min, Max		19.6, 19.6		19.6, 19.6
Time to CR+PR (Months)				
n		3		3
Mean (StdDev)		13.27 (12.111)		13.27 (12.111)
Median		6.97		6.97
Min, Max		5.6, 27.2		5.6, 27.2

Abbreviations: CR=Complete remission, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to Complete Remission is defined as the time from the start of treatment to the time a CR is first met. Patients without confirmed CR are excluded from this analysis.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-tm-rac-tpy.sasDate: 21:09/02NOV2020

Table 14.2.2.8b
Summary of Algorithm Time to Response and Time to Complete Remission by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+PR+CI)
Study: BLU-285-2101

Overall & Prior antineoplastic therapy = No	ASM (N=1) n (%)	SM-AHN (N=10) n (%)	MCL (N=5) n (%)	All AdvSM (N=16) n (%)
Time to Response (Months)				
n	1	10	5	16
Mean (StdDev)	2.79 (-)	2.10 (0.978)	3.00 (1.695)	2.43 (1.237)
Median	2.79	1.87	2.23	2.02
Min, Max	2.8, 2.8	1.0, 4.4	1.3, 5.6	1.0, 5.6
Time to CR (Months)				
n	0	1	2	3
Mean (StdDev)		12.62 (-)	9.86 (10.965)	10.78 (7.916)
Median		12.62	9.86	12.62
Min, Max		12.6, 12.6	2.1, 17.6	2.1, 17.6
Time to CR+PR (Months)				
n	1	9	4	14
Mean (StdDev)	2.79 (-)	5.38 (4.506)	3.42 (1.639)	4.63 (3.771)
Median	2.79	3.71	2.97	3.71
Min, Max	2.8, 2.8	1.8, 15.7	2.1, 5.6	1.8, 15.7

Abbreviations: CR=Complete remission, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to Complete Remission is defined as the time from the start of treatment to the time a CR is first met. Patients without confirmed CR are excluded from this analysis.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-tm-rac-tpy.sasDate: 21:09/02NOV2020

Table 14.2.2.8b
Summary of Algorithm Time to Response and Time to Complete Remission by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+PR+CI)
Study: BLU-285-2101

Starting Dose: <200 mg & Prior antineoplastic therapy = No

	ASM (N=0) n (%)	SM-AHN (N=3) n (%)	MCL (N=0) n (%)	All AdvSM (N=3) n (%)
Time to Response (Months)				
n		3		3
Mean (StdDev)		1.41 (0.460)		1.41 (0.460)
Median		1.41		1.41
Min, Max		1.0, 1.9		1.0, 1.9
Time to CR (Months)				
n		0		0
Mean (StdDev)				
Median				
Min, Max				
Time to CR+PR (Months)				
n		3		3
Mean (StdDev)		9.53 (5.986)		9.53 (5.986)
Median		9.20		9.20
Min, Max		3.7, 15.7		3.7, 15.7

Abbreviations: CR=Complete remission, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to Complete Remission is defined as the time from the start of treatment to the time a CR is first met. Patients without confirmed CR are excluded from this analysis.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-tm-rac-tpy.sasDate: 21:09/02NOV2020

Table 14.2.2.8b
Summary of Algorithm Time to Response and Time to Complete Remission by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+PR+CI)
Study: BLU-285-2101

Starting Dose: <300 mg & Prior antineoplastic therapy = No

	ASM (N=0) n (%)	SM-AHN (N=3) n (%)	MCL (N=2) n (%)	All AdvSM (N=5) n (%)
Time to Response (Months)				
n		3	2	5
Mean (StdDev)		1.41 (0.460)	2.97 (1.045)	2.04 (1.053)
Median		1.41	2.97	1.87
Min, Max		1.0, 1.9	2.2, 3.7	1.0, 3.7
Time to CR (Months)				
n		0	0	0
Mean (StdDev)				
Median				
Min, Max				
Time to CR+PR (Months)				
n		3	2	5
Mean (StdDev)		9.53 (5.986)	2.97 (1.045)	6.91 (5.575)
Median		9.20	2.97	3.71
Min, Max		3.7, 15.7	2.2, 3.7	2.2, 15.7

Abbreviations: CR=Complete remission, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to Complete Remission is defined as the time from the start of treatment to the time a CR is first met. Patients without confirmed CR are excluded from this analysis.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-tm-rac-tpy.sasDate: 21:09/02NOV2020

Table 14.2.2.8b
Summary of Algorithm Time to Response and Time to Complete Remission by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+PR+CI)
Study: BLU-285-2101

Starting Dose: 200 mg & Prior antineoplastic therapy = No

	ASM (N=0) n (%)	SM-AHN (N=0) n (%)	MCL (N=2) n (%)	All AdvSM (N=2) n (%)
Time to Response (Months)				
n			2	2
Mean (StdDev)			2.97 (1.045)	2.97 (1.045)
Median			2.97	2.97
Min, Max			2.2, 3.7	2.2, 3.7
Time to CR (Months)				
n			0	0
Mean (StdDev)				
Median				
Min, Max				
Time to CR+PR (Months)				
n			2	2
Mean (StdDev)			2.97 (1.045)	2.97 (1.045)
Median			2.97	2.97
Min, Max			2.2, 3.7	2.2, 3.7

Abbreviations: CR=Complete remission, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to Complete Remission is defined as the time from the start of treatment to the time a CR is first met. Patients without confirmed CR are excluded from this analysis.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-tm-rac-tpy.sasDate: 21:09/02NOV2020

Table 14.2.2.8b
Summary of Algorithm Time to Response and Time to Complete Remission by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+PR+CI)
Study: BLU-285-2101

Starting Dose: 300 mg & Prior antineoplastic therapy = No	ASM (N=1) n (%)	SM-AHN (N=7) n (%)	MCL (N=2) n (%)	All AdvSM (N=10) n (%)
Time to Response (Months)				
n	1	7	2	10
Mean (StdDev)	2.79 (-)	2.39 (1.014)	3.48 (3.020)	2.65 (1.381)
Median	2.79	1.94	3.48	2.09
Min, Max	2.8, 2.8	1.4, 4.4	1.3, 5.6	1.3, 5.6
Time to CR (Months)				
n	0	1	1	2
Mean (StdDev)		12.62 (-)	17.61 (-)	15.11 (3.531)
Median		12.62	17.61	15.11
Min, Max		12.6, 12.6	17.6, 17.6	12.6, 17.6
Time to CR+PR (Months)				
n	1	6	1	8
Mean (StdDev)	2.79 (-)	3.31 (1.636)	5.62 (-)	3.53 (1.629)
Median	2.79	2.97	5.62	3.25
Min, Max	2.8, 2.8	1.8, 5.8	5.6, 5.6	1.8, 5.8

Abbreviations: CR=Complete remission, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to Complete Remission is defined as the time from the start of treatment to the time a CR is first met. Patients without confirmed CR are excluded from this analysis.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-tm-rac-tpy.sasDate: 21:09/02NOV2020

Table 14.2.2.8b
Summary of Algorithm Time to Response and Time to Complete Remission by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+PR+CI)
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg & Prior antineoplastic therapy = No	ASM (N=1) n (%)	SM-AHN (N=7) n (%)	MCL (N=4) n (%)	All AdvSM (N=12) n (%)
Time to Response (Months)				
n	1	7	4	12
Mean (StdDev)	2.79 (-)	2.39 (1.014)	3.23 (1.868)	2.70 (1.294)
Median	2.79	1.94	2.97	2.23
Min, Max	2.8, 2.8	1.4, 4.4	1.3, 5.6	1.3, 5.6
Time to CR (Months)				
n	0	1	1	2
Mean (StdDev)		12.62 (-)	17.61 (-)	15.11 (3.531)
Median		12.62	17.61	15.11
Min, Max		12.6, 12.6	17.6, 17.6	12.6, 17.6
Time to CR+PR (Months)				
n	1	6	3	10
Mean (StdDev)	2.79 (-)	3.31 (1.636)	3.85 (1.696)	3.42 (1.497)
Median	2.79	2.97	3.71	3.25
Min, Max	2.8, 2.8	1.8, 5.8	2.2, 5.6	1.8, 5.8

Abbreviations: CR=Complete remission, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to Complete Remission is defined as the time from the start of treatment to the time a CR is first met. Patients without confirmed CR are excluded from this analysis.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-tm-rac-tpy.sasDate: 21:09/02NOV2020

Table 14.2.2.8b
Summary of Algorithm Time to Response and Time to Complete Remission by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+PR+CI)
Study: BLU-285-2101

Starting Dose: 400 mg & Prior antineoplastic therapy = No

	ASM (N=0) n (%)	SM-AHN (N=0) n (%)	MCL (N=1) n (%)	All AdvSM (N=1) n (%)
Time to Response (Months)				
n			1	1
Mean (StdDev)			2.10 (-)	2.10 (-)
Median			2.10	2.10
Min, Max			2.1, 2.1	2.1, 2.1
Time to CR (Months)				
n			1	1
Mean (StdDev)			2.10 (-)	2.10 (-)
Median			2.10	2.10
Min, Max			2.1, 2.1	2.1, 2.1
Time to CR+PR (Months)				
n			1	1
Mean (StdDev)			2.10 (-)	2.10 (-)
Median			2.10	2.10
Min, Max			2.1, 2.1	2.1, 2.1

Abbreviations: CR=Complete remission, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to Complete Remission is defined as the time from the start of treatment to the time a CR is first met. Patients without confirmed CR are excluded from this analysis.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-tm-rac-tpy.sasDate: 21:09/02NOV2020

Table 14.2.2.8b
Summary of Algorithm Time to Response and Time to Complete Remission by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+PR+CI)
Study: BLU-285-2202

Overall & Prior antineoplastic therapy = Yes	ASM (N=1) n (%)	SM-AHN (N=12) n (%)	MCL (N=2) n (%)	All AdvSM (N=15) n (%)
Time to Response (Months)				
n	1	12	2	15
Mean (StdDev)	3.71 (-)	2.66 (1.819)	7.05 (7.271)	3.31 (2.958)
Median	3.71	2.02	7.05	2.10
Min, Max	3.7, 3.7	0.4, 5.8	1.9, 12.2	0.4, 12.2
Time to CR (Months)				
n	0	0	0	0
Mean (StdDev)				
Median				
Min, Max				
Time to CR+PR (Months)				
n	1	6	1	8
Mean (StdDev)	3.71 (-)	2.50 (1.625)	12.19 (-)	3.86 (3.658)
Median	3.71	1.87	12.19	1.92
Min, Max	3.7, 3.7	1.7, 5.8	12.2, 12.2	1.7, 12.2

Abbreviations: CR=Complete remission, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to Complete Remission is defined as the time from the start of treatment to the time a CR is first met. Patients without confirmed CR are excluded from this analysis.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-tm-rac-tpy.sasDate: 21:09/02NOV2020

Table 14.2.2.8b
Summary of Algorithm Time to Response and Time to Complete Remission by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+PR+CI)
Study: BLU-285-2202

Starting Dose: 200 mg & Prior antineoplastic therapy = Yes	ASM (N=1) n (%)	SM-AHN (N=11) n (%)	MCL (N=2) n (%)	All AdvSM (N=14) n (%)
Time to Response (Months)				
n	1	11	2	14
Mean (StdDev)	3.71 (-)	2.37 (1.597)	7.05 (7.271)	3.13 (2.985)
Median	3.71	1.94	7.05	2.02
Min, Max	3.7, 3.7	0.4, 5.6	1.9, 12.2	0.4, 12.2
Time to CR (Months)				
n	0	0	0	0
Mean (StdDev)				
Median				
Min, Max				
Time to CR+PR (Months)				
n	1	5	1	7
Mean (StdDev)	3.71 (-)	1.84 (0.090)	12.19 (-)	3.59 (3.858)
Median	3.71	1.84	12.19	1.91
Min, Max	3.7, 3.7	1.7, 1.9	12.2, 12.2	1.7, 12.2

Abbreviations: CR=Complete remission, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to Complete Remission is defined as the time from the start of treatment to the time a CR is first met. Patients without confirmed CR are excluded from this analysis.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-tm-rac-tpy.sasDate: 21:09/02NOV2020

Table 14.2.2.8b
Summary of Algorithm Time to Response and Time to Complete Remission by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+PR+CI)
Study: BLU-285-2202

Overall & Prior antineoplastic therapy = No	ASM (N=1) n (%)	SM-AHN (N=3) n (%)	MCL (N=0) n (%)	All AdvSM (N=4) n (%)
Time to Response (Months)				
n	1	3		4
Mean (StdDev)	0.26 (-)	1.58 (0.980)		1.25 (1.035)
Median	0.26	1.84		1.17
Min, Max	0.3, 0.3	0.5, 2.4		0.3, 2.4
Time to CR (Months)				
n	0	0		0
Mean (StdDev)				
Median				
Min, Max				
Time to CR+PR (Months)				
n	1	3		4
Mean (StdDev)	5.55 (-)	4.51 (4.543)		4.77 (3.746)
Median	5.55	1.94		3.75
Min, Max	5.6, 5.6	1.8, 9.8		1.8, 9.8

Abbreviations: CR=Complete remission, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to Complete Remission is defined as the time from the start of treatment to the time a CR is first met. Patients without confirmed CR are excluded from this analysis.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-tm-rac-tpy.sasDate: 21:09/02NOV2020

Table 14.2.2.8b
Summary of Algorithm Time to Response and Time to Complete Remission by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+PR+CI)
Study: BLU-285-2202

Starting Dose: 200 mg & Prior antineoplastic therapy = No	ASM (N=1) n (%)	SM-AHN (N=3) n (%)	MCL (N=0) n (%)	All AdvSM (N=4) n (%)
Time to Response (Months)				
n	1	3		4
Mean (StdDev)	0.26 (-)	1.58 (0.980)		1.25 (1.035)
Median	0.26	1.84		1.17
Min, Max	0.3, 0.3	0.5, 2.4		0.3, 2.4
Time to CR (Months)				
n	0	0		0
Mean (StdDev)				
Median				
Min, Max				
Time to CR+PR (Months)				
n	1	3		4
Mean (StdDev)	5.55 (-)	4.51 (4.543)		4.77 (3.746)
Median	5.55	1.94		3.75
Min, Max	5.6, 5.6	1.8, 9.8		1.8, 9.8

Abbreviations: CR=Complete remission, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to Complete Remission is defined as the time from the start of treatment to the time a CR is first met. Patients without confirmed CR are excluded from this analysis.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-tm-rac-tpy.sasDate: 21:09/02NOV2020

Table 14.2.2.8b
Summary of Algorithm Time to Response and Time to Complete Remission by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+PR+CI)
Study: BLU-285-2101 and BLU-285-2202

Overall & Prior antineoplastic therapy = Yes	ASM (N=3) n (%)	SM-AHN (N=24) n (%)	MCL (N=7) n (%)	All AdvSM (N=34) n (%)
Time to Response (Months)				
n	3	24	7	34
Mean (StdDev)	7.86 (8.860)	4.70 (5.893)	7.96 (9.327)	5.65 (6.857)
Median	3.71	2.45	1.91	2.45
Min, Max	1.8, 18.0	0.3, 27.2	1.6, 26.7	0.3, 27.2
Time to CR (Months)				
n	0	4	3	7
Mean (StdDev)		15.70 (4.480)	23.00 (12.833)	18.83 (8.953)
Median		16.92	15.74	16.10
Min, Max		9.3, 19.6	15.4, 37.8	9.3, 37.8
Time to CR+PR (Months)				
n	3	18	5	26
Mean (StdDev)	9.10 (7.794)	5.80 (6.421)	10.38 (10.241)	7.06 (7.316)
Median	5.55	3.37	9.46	4.75
Min, Max	3.7, 18.0	1.7, 27.2	1.6, 26.7	1.6, 27.2

Abbreviations: CR=Complete remission, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to Complete Remission is defined as the time from the start of treatment to the time a CR is first met. Patients without confirmed CR are excluded from this analysis.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-tm-rac-tpy.sasDate: 21:09/02NOV2020

Table 14.2.2.8b
Summary of Algorithm Time to Response and Time to Complete Remission by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+PR+CI)
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg & Prior antineoplastic therapy = Yes

	ASM (N=0) n (%)	SM-AHN (N=2) n (%)	MCL (N=1) n (%)	All AdvSM (N=3) n (%)
Time to Response (Months)				
n		2	1	3
Mean (StdDev)		3.42 (3.392)	26.71 (-)	11.18 (13.661)
Median		3.42	26.71	5.82
Min, Max		1.0, 5.8	26.7, 26.7	1.0, 26.7
Time to CR (Months)				
n		1	1	2
Mean (StdDev)		17.74 (-)	37.82 (-)	27.78 (14.194)
Median		17.74	37.82	27.78
Min, Max		17.7, 17.7	37.8, 37.8	17.7, 37.8
Time to CR+PR (Months)				
n		2	1	3
Mean (StdDev)		3.91 (2.695)	26.71 (-)	11.51 (13.301)
Median		3.91	26.71	5.82
Min, Max		2.0, 5.8	26.7, 26.7	2.0, 26.7

Abbreviations: CR=Complete remission, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to Complete Remission is defined as the time from the start of treatment to the time a CR is first met. Patients without confirmed CR are excluded from this analysis.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-tm-rac-tpy.sasDate: 21:09/02NOV2020

Table 14.2.2.8b
Summary of Algorithm Time to Response and Time to Complete Remission by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+PR+CI)
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg & Prior antineoplastic therapy = Yes	ASM (N=1) n (%)	SM-AHN (N=14) n (%)	MCL (N=5) n (%)	All AdvSM (N=20) n (%)
Time to Response (Months)				
n	1	14	5	20
Mean (StdDev)	3.71 (-)	2.55 (1.731)	10.38 (10.234)	4.57 (6.003)
Median	3.71	2.02	9.46	2.45
Min, Max	3.7, 3.7	0.4, 5.8	1.6, 26.7	0.4, 26.7
Time to CR (Months)				
n	0	1	2	3
Mean (StdDev)		17.74 (-)	26.63 (15.821)	23.67 (12.307)
Median		17.74	26.63	17.74
Min, Max		17.7, 17.7	15.4, 37.8	15.4, 37.8
Time to CR+PR (Months)				
n	1	8	4	13
Mean (StdDev)	3.71 (-)	2.48 (1.390)	12.50 (10.474)	5.66 (7.157)
Median	3.71	1.92	10.83	2.00
Min, Max	3.7, 3.7	1.7, 5.8	1.6, 26.7	1.6, 26.7

Abbreviations: CR=Complete remission, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to Complete Remission is defined as the time from the start of treatment to the time a CR is first met. Patients without confirmed CR are excluded from this analysis.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-tm-rac-tpy.sasDate: 21:09/02NOV2020

Table 14.2.2.8b
Summary of Algorithm Time to Response and Time to Complete Remission by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+PR+CI)
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg & Prior antineoplastic therapy = Yes	ASM (N=1) n (%)	SM-AHN (N=12) n (%)	MCL (N=4) n (%)	All AdvSM (N=17) n (%)
Time to Response (Months)				
n	1	12	4	17
Mean (StdDev)	3.71 (-)	2.40 (1.528)	6.30 (5.344)	3.40 (3.132)
Median	3.71	2.02	5.68	2.10
Min, Max	3.7, 3.7	0.4, 5.6	1.6, 12.2	0.4, 12.2
Time to CR (Months)				
n	0	0	1	1
Mean (StdDev)			15.44 (-)	15.44 (-)
Median			15.44	15.44
Min, Max			15.4, 15.4	15.4, 15.4
Time to CR+PR (Months)				
n	1	6	3	10
Mean (StdDev)	3.71 (-)	2.00 (0.397)	7.76 (5.474)	3.90 (3.760)
Median	3.71	1.87	9.46	1.92
Min, Max	3.7, 3.7	1.7, 2.8	1.6, 12.2	1.6, 12.2

Abbreviations: CR=Complete remission, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to Complete Remission is defined as the time from the start of treatment to the time a CR is first met. Patients without confirmed CR are excluded from this analysis.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-tm-rac-tpy.sasDate: 21:09/02NOV2020

Table 14.2.2.8b
Summary of Algorithm Time to Response and Time to Complete Remission by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+PR+CI)
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg & Prior antineoplastic therapy = Yes	ASM (N=2) n (%)	SM-AHN (N=7) n (%)	MCL (N=2) n (%)	All AdvSM (N=11) n (%)
Time to Response (Months)				
n	2	7	2	11
Mean (StdDev)	9.94 (11.453)	5.31 (5.453)	1.89 (0.023)	5.53 (6.126)
Median	9.94	1.97	1.89	1.91
Min, Max	1.8, 18.0	0.3, 14.8	1.9, 1.9	0.3, 18.0
Time to CR (Months)				
n	0	2	1	3
Mean (StdDev)		12.71 (4.786)	15.74 (-)	13.72 (3.807)
Median		12.71	15.74	15.74
Min, Max		9.3, 16.1	15.7, 15.7	9.3, 16.1
Time to CR+PR (Months)				
n	2	7	1	10
Mean (StdDev)	11.79 (8.828)	6.39 (4.755)	1.87 (-)	7.02 (5.662)
Median	11.79	5.65	1.87	5.60
Min, Max	5.6, 18.0	1.9, 14.8	1.9, 1.9	1.9, 18.0

Abbreviations: CR=Complete remission, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to Complete Remission is defined as the time from the start of treatment to the time a CR is first met. Patients without confirmed CR are excluded from this analysis.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-tm-rac-tpy.sasDate: 21:09/02NOV2020

Table 14.2.2.8b
Summary of Algorithm Time to Response and Time to Complete Remission by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+PR+CI)
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg & Prior antineoplastic therapy = Yes	ASM (N=3) n (%)	SM-AHN (N=19) n (%)	MCL (N=6) n (%)	All AdvSM (N=28) n (%)
Time to Response (Months)				
n	3	19	6	28
Mean (StdDev)	7.86 (8.860)	3.48 (3.663)	4.83 (4.725)	4.24 (4.565)
Median	3.71	1.97	1.91	1.95
Min, Max	1.8, 18.0	0.3, 14.8	1.6, 12.2	0.3, 18.0
Time to CR (Months)				
n	0	2	2	4
Mean (StdDev)		12.71 (4.786)	15.59 (0.209)	14.15 (3.225)
Median		12.71	15.59	15.59
Min, Max		9.3, 16.1	15.4, 15.7	9.3, 16.1
Time to CR+PR (Months)				
n	3	13	4	20
Mean (StdDev)	9.10 (7.794)	4.36 (4.069)	6.29 (5.353)	5.46 (4.944)
Median	5.55	1.97	5.67	3.25
Min, Max	3.7, 18.0	1.7, 14.8	1.6, 12.2	1.6, 18.0

Abbreviations: CR=Complete remission, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to Complete Remission is defined as the time from the start of treatment to the time a CR is first met. Patients without confirmed CR are excluded from this analysis.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-tm-rac-tpy.sasDate: 21:09/02NOV2020

Table 14.2.2.8b
Summary of Algorithm Time to Response and Time to Complete Remission by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+PR+CI)
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg & Prior antineoplastic therapy = Yes	ASM (N=0) n (%)	SM-AHN (N=3) n (%)	MCL (N=0) n (%)	All AdvSM (N=3) n (%)
Time to Response (Months)				
n		3		3
Mean (StdDev)		13.27 (12.111)		13.27 (12.111)
Median		6.97		6.97
Min, Max		5.6, 27.2		5.6, 27.2
Time to CR (Months)				
n		1		1
Mean (StdDev)		19.61 (-)		19.61 (-)
Median		19.61		19.61
Min, Max		19.6, 19.6		19.6, 19.6
Time to CR+PR (Months)				
n		3		3
Mean (StdDev)		13.27 (12.111)		13.27 (12.111)
Median		6.97		6.97
Min, Max		5.6, 27.2		5.6, 27.2

Abbreviations: CR=Complete remission, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to Complete Remission is defined as the time from the start of treatment to the time a CR is first met. Patients without confirmed CR are excluded from this analysis.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-tm-rac-tpy.sasDate: 21:09/02NOV2020

Table 14.2.2.8b
Summary of Algorithm Time to Response and Time to Complete Remission by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+PR+CI)
Study: BLU-285-2101 and BLU-285-2202

Overall & Prior antineoplastic therapy = No	ASM (N=2) n (%)	SM-AHN (N=13) n (%)	MCL (N=5) n (%)	All AdvSM (N=20) n (%)
Time to Response (Months)				
n	2	13	5	20
Mean (StdDev)	1.53 (1.789)	1.98 (0.964)	3.00 (1.695)	2.19 (1.269)
Median	1.53	1.87	2.23	1.91
Min, Max	0.3, 2.8	0.5, 4.4	1.3, 5.6	0.3, 5.6
Time to CR (Months)				
n	0	1	2	3
Mean (StdDev)		12.62 (-)	9.86 (10.965)	10.78 (7.916)
Median		12.62	9.86	12.62
Min, Max		12.6, 12.6	2.1, 17.6	2.1, 17.6
Time to CR+PR (Months)				
n	2	12	4	18
Mean (StdDev)	4.17 (1.951)	5.16 (4.321)	3.42 (1.639)	4.67 (3.654)
Median	4.17	3.71	2.97	3.71
Min, Max	2.8, 5.6	1.8, 15.7	2.1, 5.6	1.8, 15.7

Abbreviations: CR=Complete remission, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to Complete Remission is defined as the time from the start of treatment to the time a CR is first met. Patients without confirmed CR are excluded from this analysis.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-tm-rac-tpy.sasDate: 21:09/02NOV2020

Table 14.2.2.8b
Summary of Algorithm Time to Response and Time to Complete Remission by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+PR+CI)
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg & Prior antineoplastic therapy = No	ASM (N=0) n (%)	SM-AHN (N=3) n (%)	MCL (N=0) n (%)	All AdvSM (N=3) n (%)
Time to Response (Months)				
n		3		3
Mean (StdDev)		1.41 (0.460)		1.41 (0.460)
Median		1.41		1.41
Min, Max		1.0, 1.9		1.0, 1.9
Time to CR (Months)				
n		0		0
Mean (StdDev)				
Median				
Min, Max				
Time to CR+PR (Months)				
n		3		3
Mean (StdDev)		9.53 (5.986)		9.53 (5.986)
Median		9.20		9.20
Min, Max		3.7, 15.7		3.7, 15.7

Abbreviations: CR=Complete remission, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to Complete Remission is defined as the time from the start of treatment to the time a CR is first met. Patients without confirmed CR are excluded from this analysis.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-tm-rac-tpy.sasDate: 21:09/02NOV2020

Table 14.2.2.8b
Summary of Algorithm Time to Response and Time to Complete Remission by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+PR+CI)
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg & Prior antineoplastic therapy = No	ASM (N=1) n (%)	SM-AHN (N=6) n (%)	MCL (N=2) n (%)	All AdvSM (N=9) n (%)
Time to Response (Months)				
n	1	6	2	9
Mean (StdDev)	0.26 (-)	1.49 (0.690)	2.97 (1.045)	1.69 (1.063)
Median	0.26	1.63	2.97	1.84
Min, Max	0.3, 0.3	0.5, 2.4	2.2, 3.7	0.3, 3.7
Time to CR (Months)				
n	0	0	0	0
Mean (StdDev)				
Median				
Min, Max				
Time to CR+PR (Months)				
n	1	6	2	9
Mean (StdDev)	5.55 (-)	7.02 (5.490)	2.97 (1.045)	5.96 (4.697)
Median	5.55	6.46	2.97	3.71
Min, Max	5.6, 5.6	1.8, 15.7	2.2, 3.7	1.8, 15.7

Abbreviations: CR=Complete remission, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to Complete Remission is defined as the time from the start of treatment to the time a CR is first met. Patients without confirmed CR are excluded from this analysis.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-tm-rac-tpy.sasDate: 21:09/02NOV2020

Table 14.2.2.8b
Summary of Algorithm Time to Response and Time to Complete Remission by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+PR+CI)
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg & Prior antineoplastic therapy = No	ASM (N=1) n (%)	SM-AHN (N=3) n (%)	MCL (N=2) n (%)	All AdvSM (N=6) n (%)
Time to Response (Months)				
n	1	3	2	6
Mean (StdDev)	0.26 (-)	1.58 (0.980)	2.97 (1.045)	1.82 (1.286)
Median	0.26	1.84	2.97	2.04
Min, Max	0.3, 0.3	0.5, 2.4	2.2, 3.7	0.3, 3.7
Time to CR (Months)				
n	0	0	0	0
Mean (StdDev)				
Median				
Min, Max				
Time to CR+PR (Months)				
n	1	3	2	6
Mean (StdDev)	5.55 (-)	4.51 (4.543)	2.97 (1.045)	4.17 (3.082)
Median	5.55	1.94	2.97	2.97
Min, Max	5.6, 5.6	1.8, 9.8	2.2, 3.7	1.8, 9.8

Abbreviations: CR=Complete remission, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to Complete Remission is defined as the time from the start of treatment to the time a CR is first met. Patients without confirmed CR are excluded from this analysis.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-tm-rac-tpy.sasDate: 21:09/02NOV2020

Table 14.2.2.8b
Summary of Algorithm Time to Response and Time to Complete Remission by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+PR+CI)
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg & Prior antineoplastic therapy = No	ASM (N=1) n (%)	SM-AHN (N=7) n (%)	MCL (N=2) n (%)	All AdvSM (N=10) n (%)
Time to Response (Months)				
n	1	7	2	10
Mean (StdDev)	2.79 (-)	2.39 (1.014)	3.48 (3.020)	2.65 (1.381)
Median	2.79	1.94	3.48	2.09
Min, Max	2.8, 2.8	1.4, 4.4	1.3, 5.6	1.3, 5.6
Time to CR (Months)				
n	0	1	1	2
Mean (StdDev)		12.62 (-)	17.61 (-)	15.11 (3.531)
Median		12.62	17.61	15.11
Min, Max		12.6, 12.6	17.6, 17.6	12.6, 17.6
Time to CR+PR (Months)				
n	1	6	1	8
Mean (StdDev)	2.79 (-)	3.31 (1.636)	5.62 (-)	3.53 (1.629)
Median	2.79	2.97	5.62	3.25
Min, Max	2.8, 2.8	1.8, 5.8	5.6, 5.6	1.8, 5.8

Abbreviations: CR=Complete remission, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to Complete Remission is defined as the time from the start of treatment to the time a CR is first met. Patients without confirmed CR are excluded from this analysis.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-tm-rac-tpy.sasDate: 21:09/02NOV2020

Table 14.2.2.8b
Summary of Algorithm Time to Response and Time to Complete Remission by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+PR+CI)
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg & Prior antineoplastic therapy = No	ASM (N=2) n (%)	SM-AHN (N=10) n (%)	MCL (N=4) n (%)	All AdvSM (N=16) n (%)
Time to Response (Months)				
n	2	10	4	16
Mean (StdDev)	1.53 (1.789)	2.15 (1.027)	3.23 (1.868)	2.34 (1.366)
Median	1.53	1.91	2.97	2.09
Min, Max	0.3, 2.8	0.5, 4.4	1.3, 5.6	0.3, 5.6
Time to CR (Months)				
n	0	1	1	2
Mean (StdDev)		12.62 (-)	17.61 (-)	15.11 (3.531)
Median		12.62	17.61	15.11
Min, Max		12.6, 12.6	17.6, 17.6	12.6, 17.6
Time to CR+PR (Months)				
n	2	9	3	14
Mean (StdDev)	4.17 (1.951)	3.71 (2.682)	3.85 (1.696)	3.81 (2.278)
Median	4.17	2.23	3.71	3.25
Min, Max	2.8, 5.6	1.8, 9.8	2.2, 5.6	1.8, 9.8

Abbreviations: CR=Complete remission, PR=Partial remission
Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to Complete Remission is defined as the time from the start of treatment to the time a CR is first met. Patients without confirmed CR are excluded from this analysis.
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-tm-rac-tpy.sasDate: 21:09/02NOV2020

Table 14.2.2.8b

Summary of Algorithm Time to Response and Time to Complete Remission by IWG Criteria by Prior Antineoplastic Therapy

RAC-RE Population - Responders (CR+PR+CI)

Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg & Prior antineoplastic therapy = No	ASM (N=0) n (%)	SM-AHN (N=0) n (%)	MCL (N=1) n (%)	All AdvSM (N=1) n (%)
Time to Response (Months)				
n			1	1
Mean (StdDev)			2.10 (-)	2.10 (-)
Median			2.10	2.10
Min, Max			2.1, 2.1	2.1, 2.1
Time to CR (Months)				
n			1	1
Mean (StdDev)			2.10 (-)	2.10 (-)
Median			2.10	2.10
Min, Max			2.1, 2.1	2.1, 2.1
Time to CR+PR (Months)				
n			1	1
Mean (StdDev)			2.10 (-)	2.10 (-)
Median			2.10	2.10
Min, Max			2.1, 2.1	2.1, 2.1

Abbreviations: CR=Complete remission, PR=Partial remission

Notes: Time to response is defined as the time in months from the start of treatment to the time a response (CR/PR) is first met. Patients without confirmed response are excluded from this analysis. Time to Complete Remission is defined as the time from the start of treatment to the time a CR is first met. Patients without confirmed CR are excluded from this analysis.

Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_sNDA/Final_biopier/programs/prod/Tables/t-alg-tm-rac-tpy.sasDate: 21:09/02NOV2020

Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR)
Study BLU-285-2101
Starting Dose: Overall

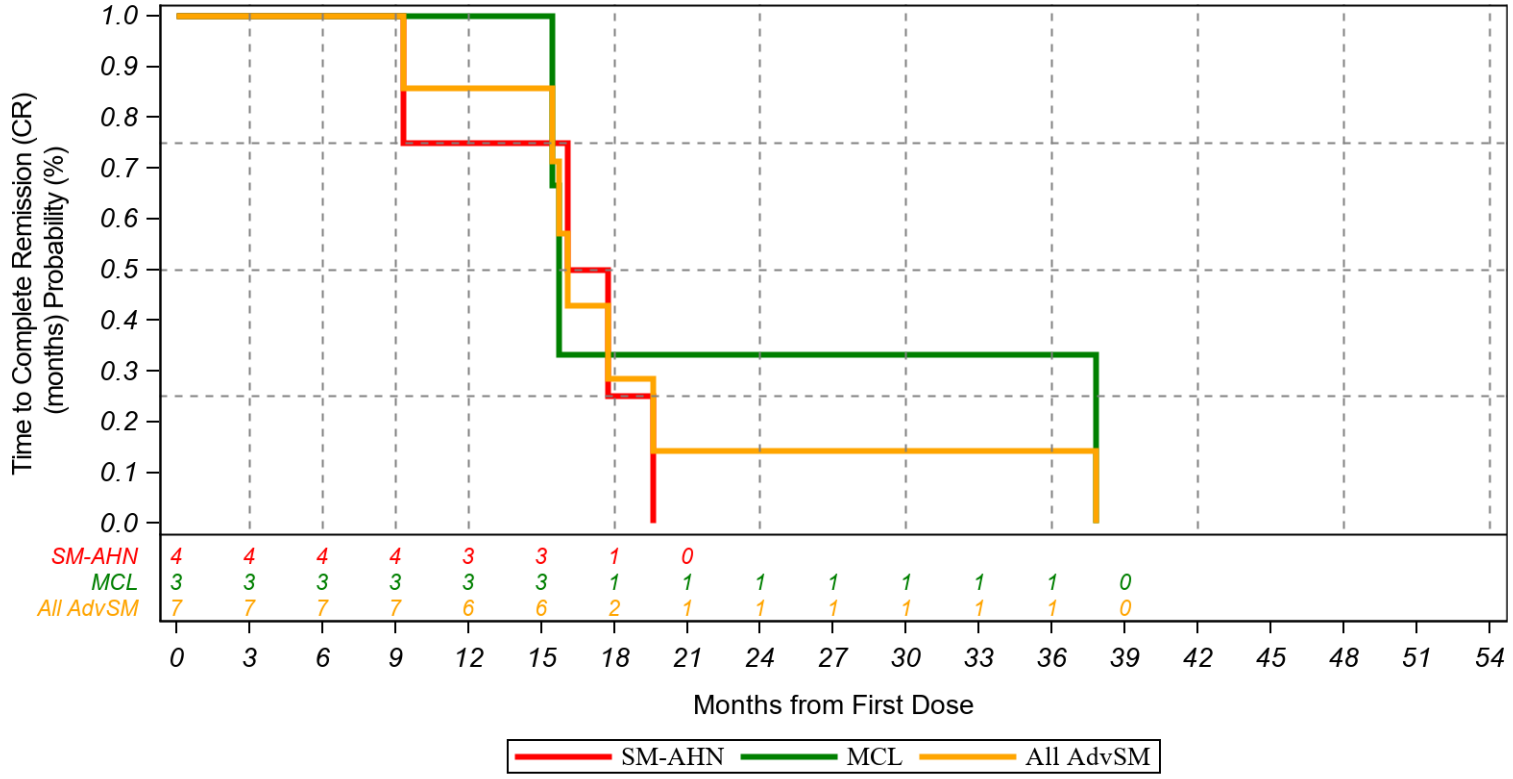

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Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR)
Study BLU-285-2101
Starting Dose: Overall

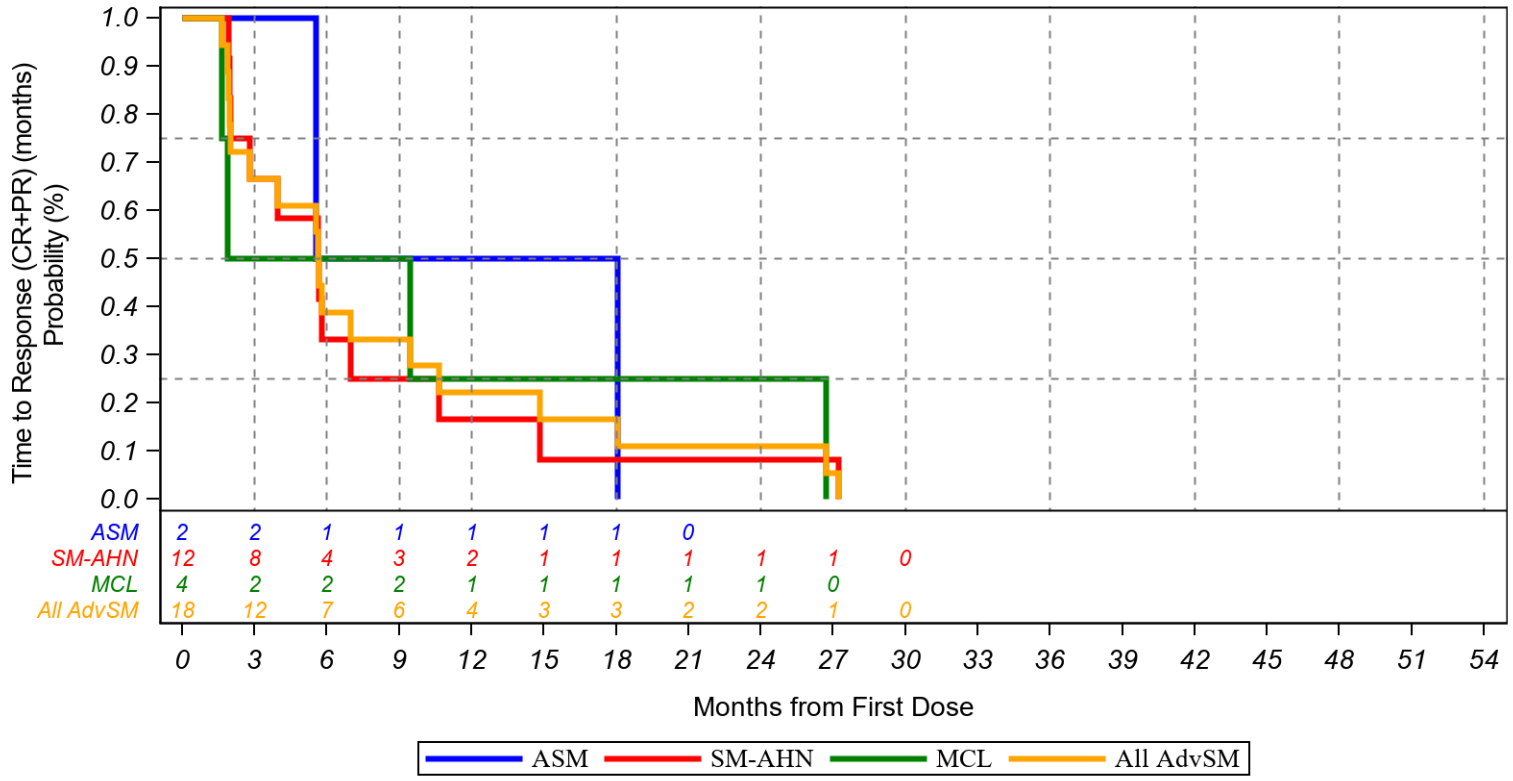

Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR+CI)
Study BLU-285-2101
Starting Dose: Overall

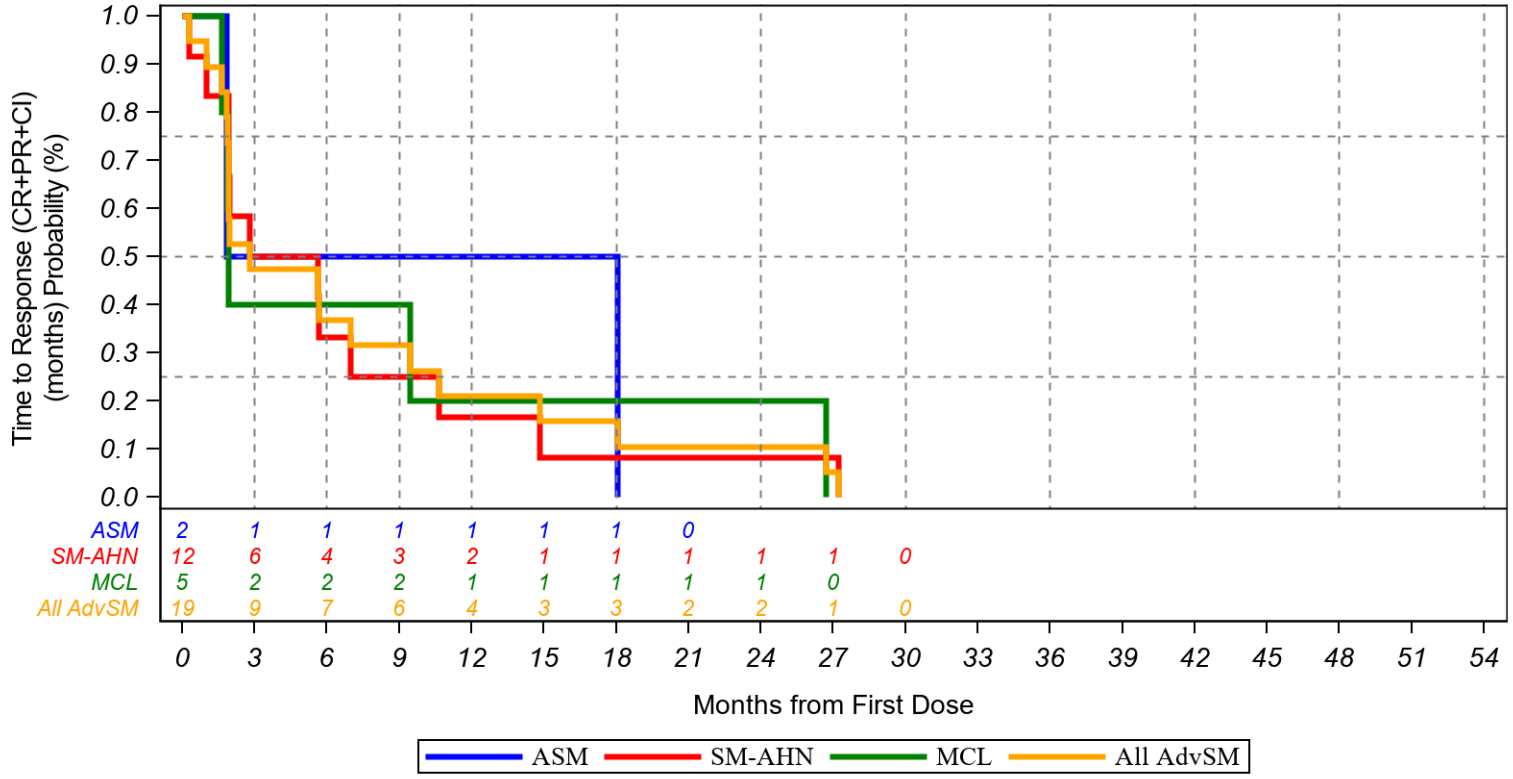

Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR)
Study BLU-285-2101
Starting Dose: < 200 mg

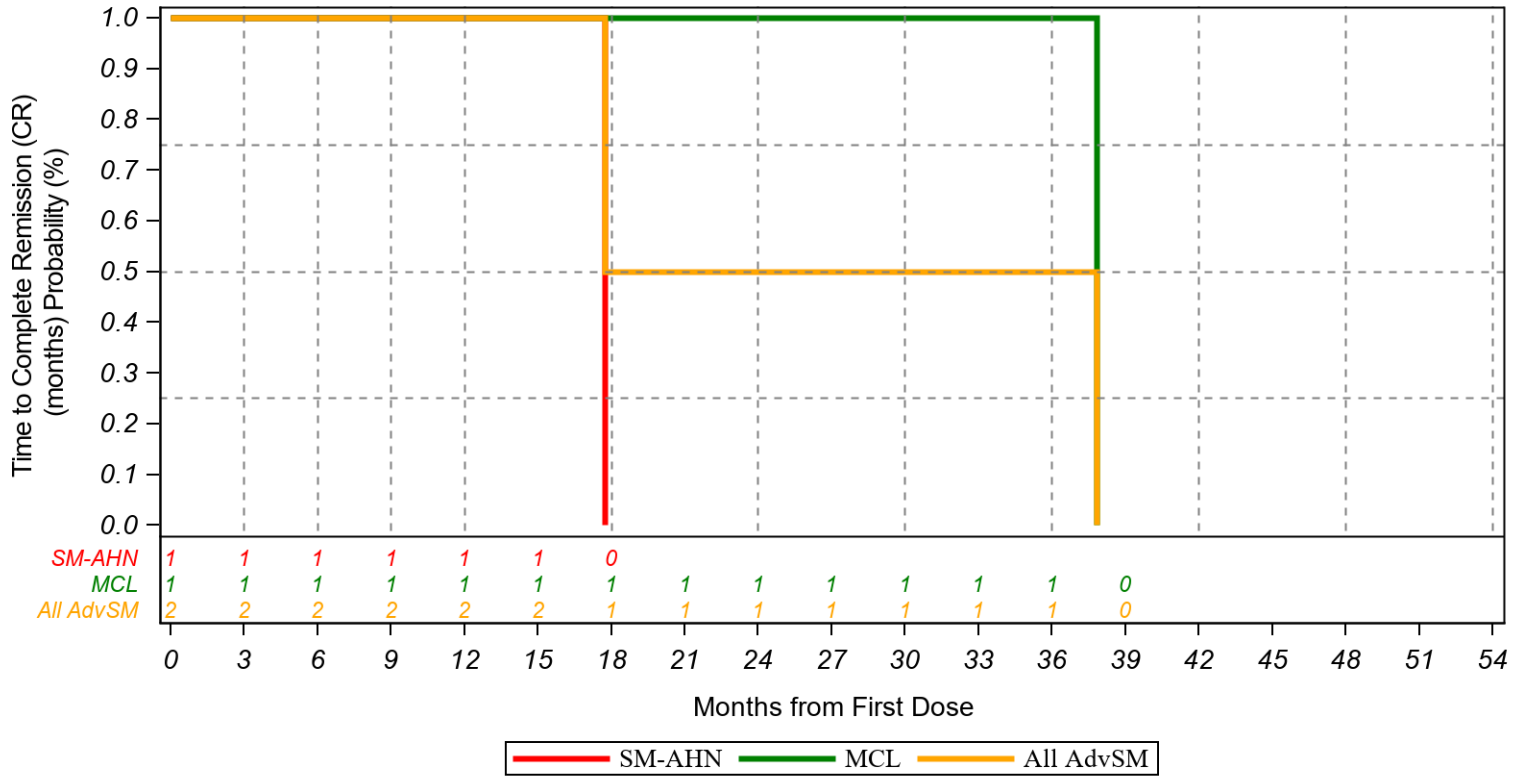

Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR)
Study BLU-285-2101
Starting Dose: < 200 mg

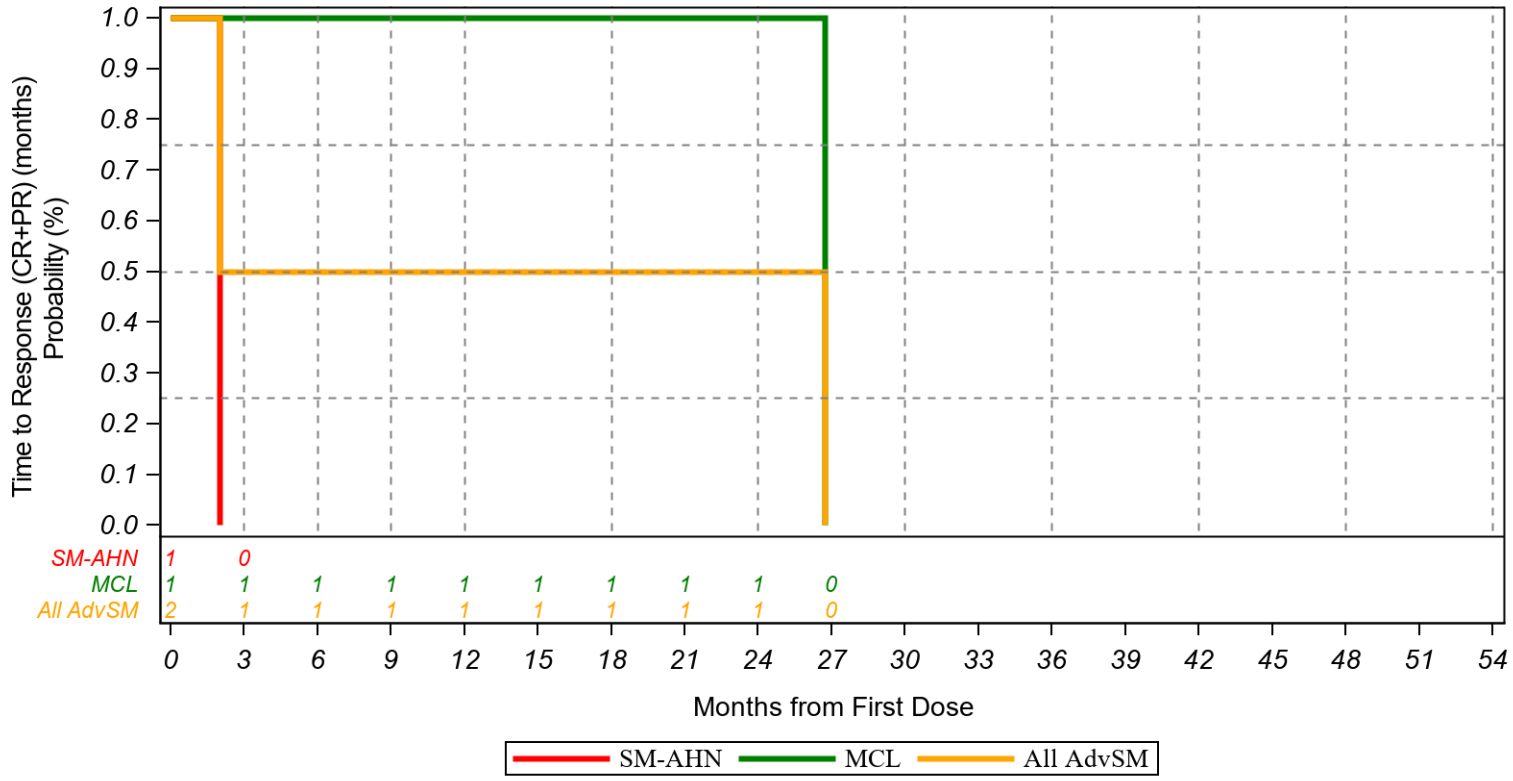

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Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR+CI)
Study BLU-285-2101
Starting Dose: < 200 mg

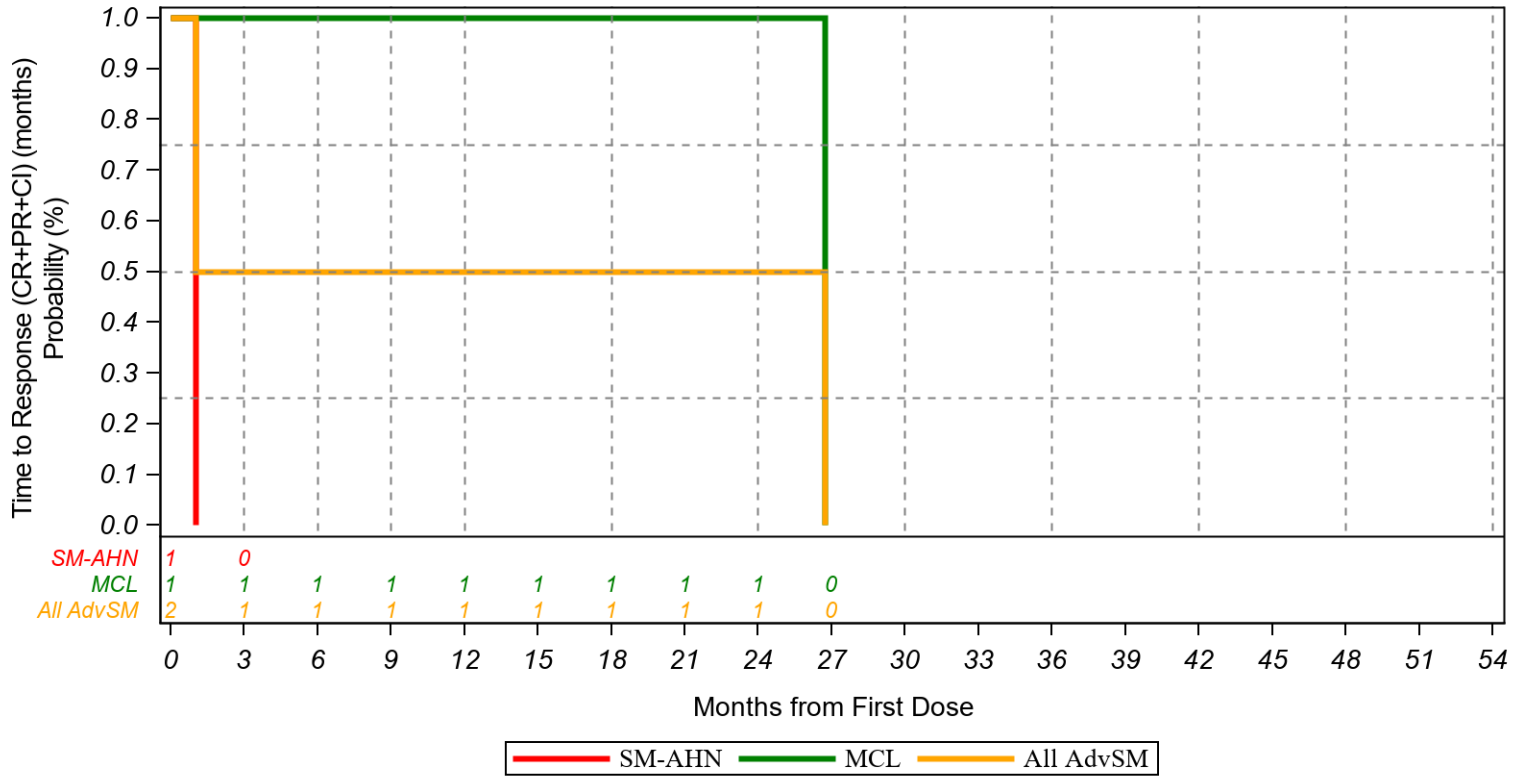

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Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR)
Study BLU-285-2101
Starting Dose: < 300 mg

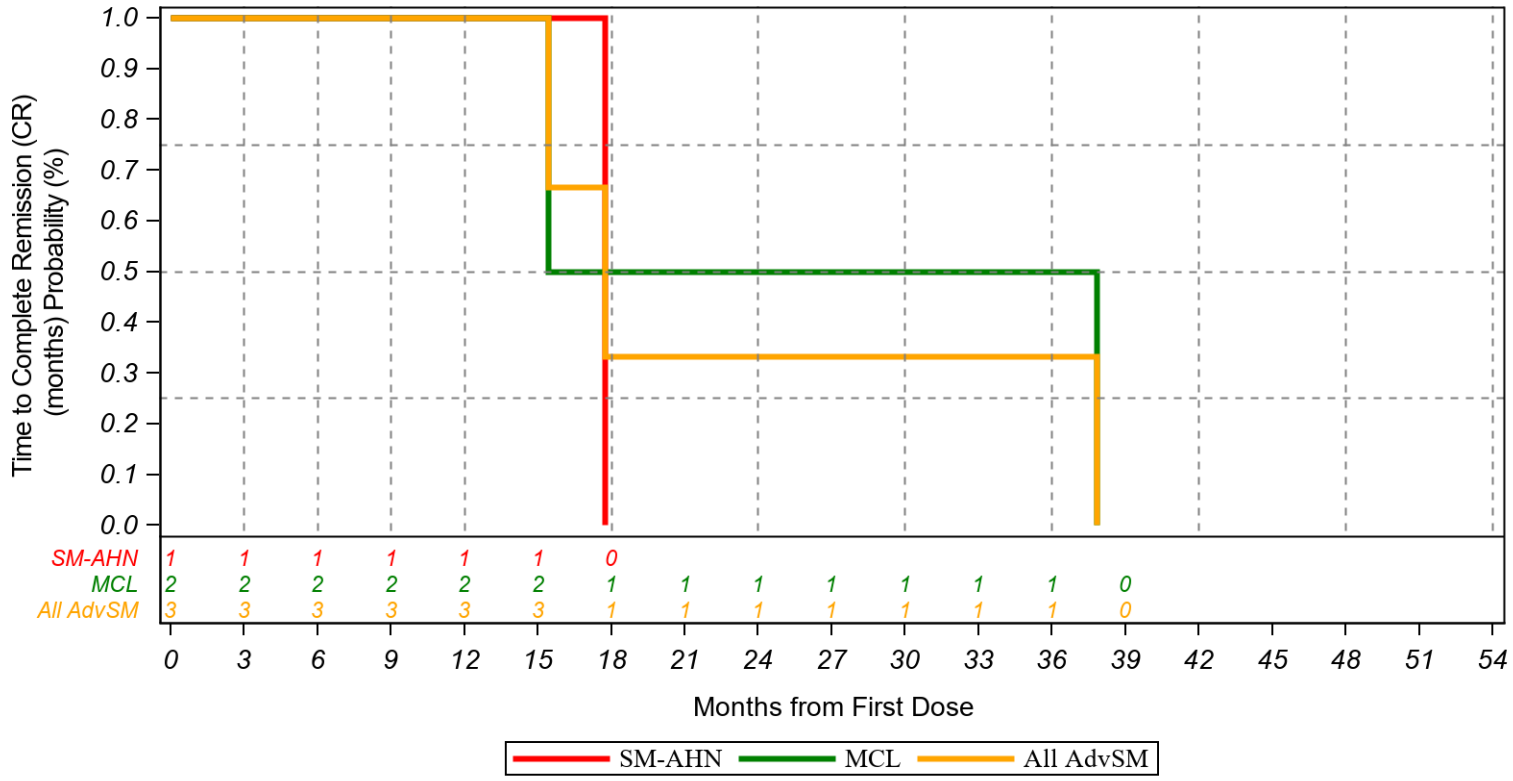

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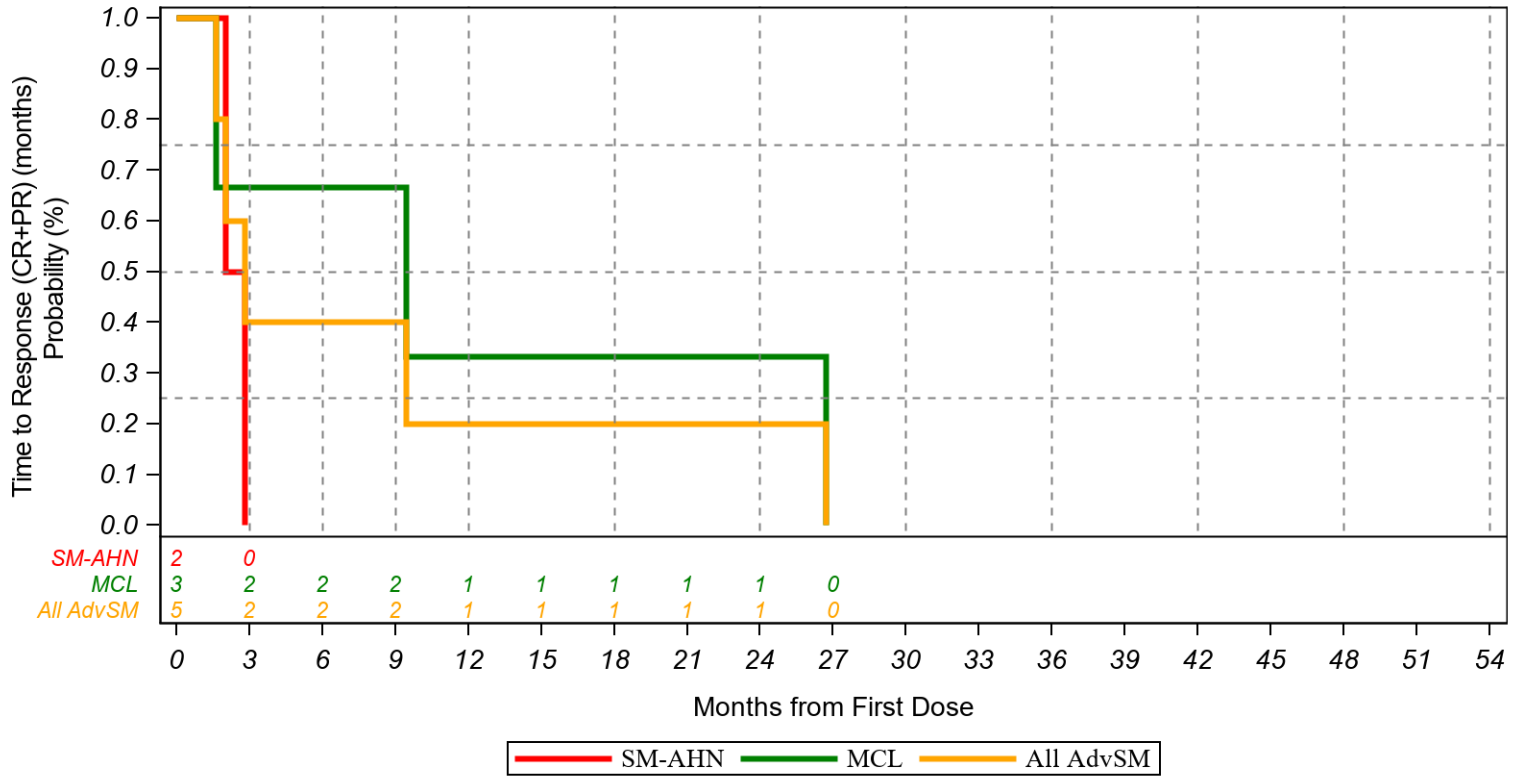
Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR)
Study BLU-285-2101
Starting Dose: < 300 mg



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Date: 7:56/14OCT2021

Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR+CI)
Study BLU-285-2101
Starting Dose: < 300 mg

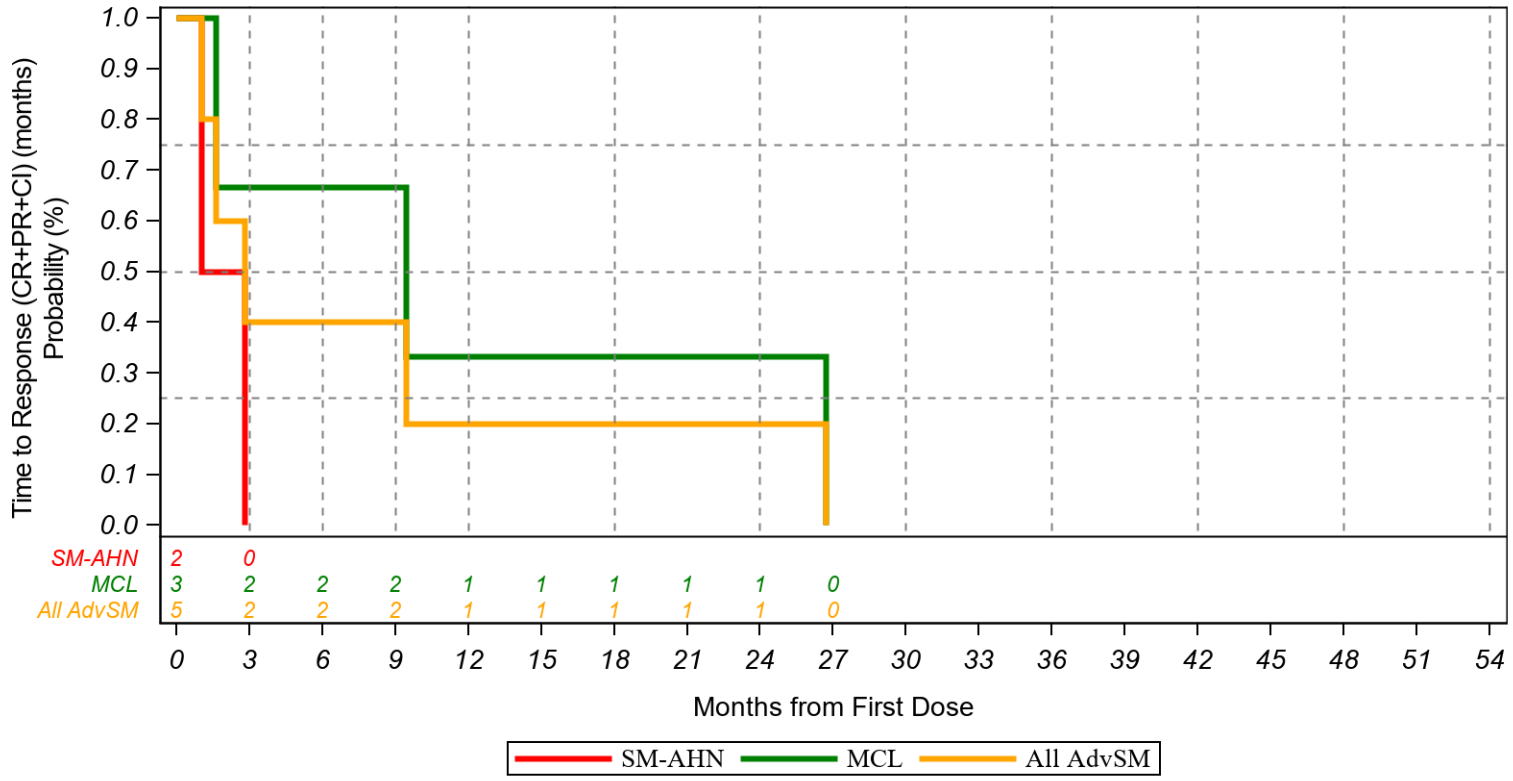

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Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR)
Study BLU-285-2101
Starting Dose: 200 mg

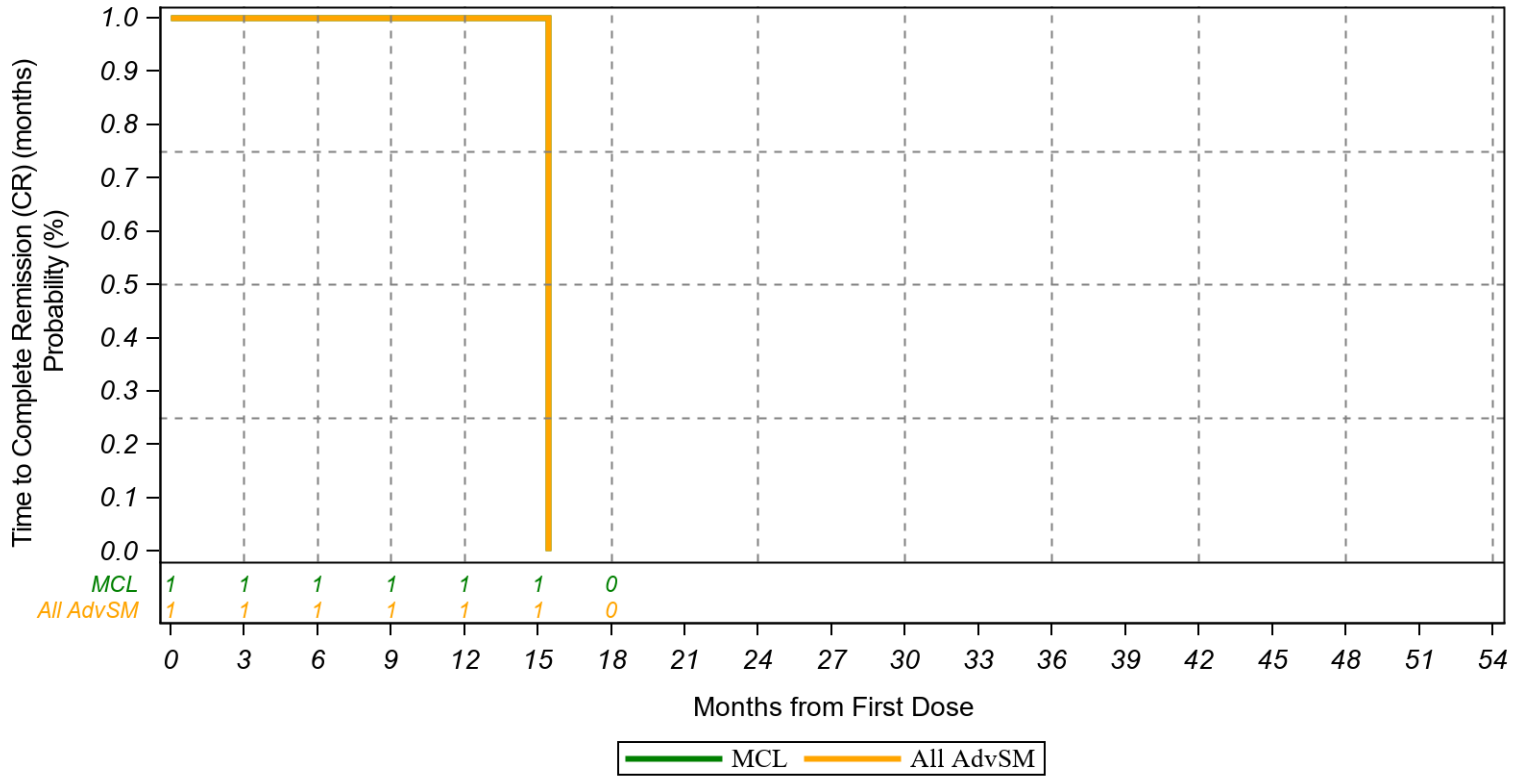

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Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR)
Study BLU-285-2101
Starting Dose: 200 mg

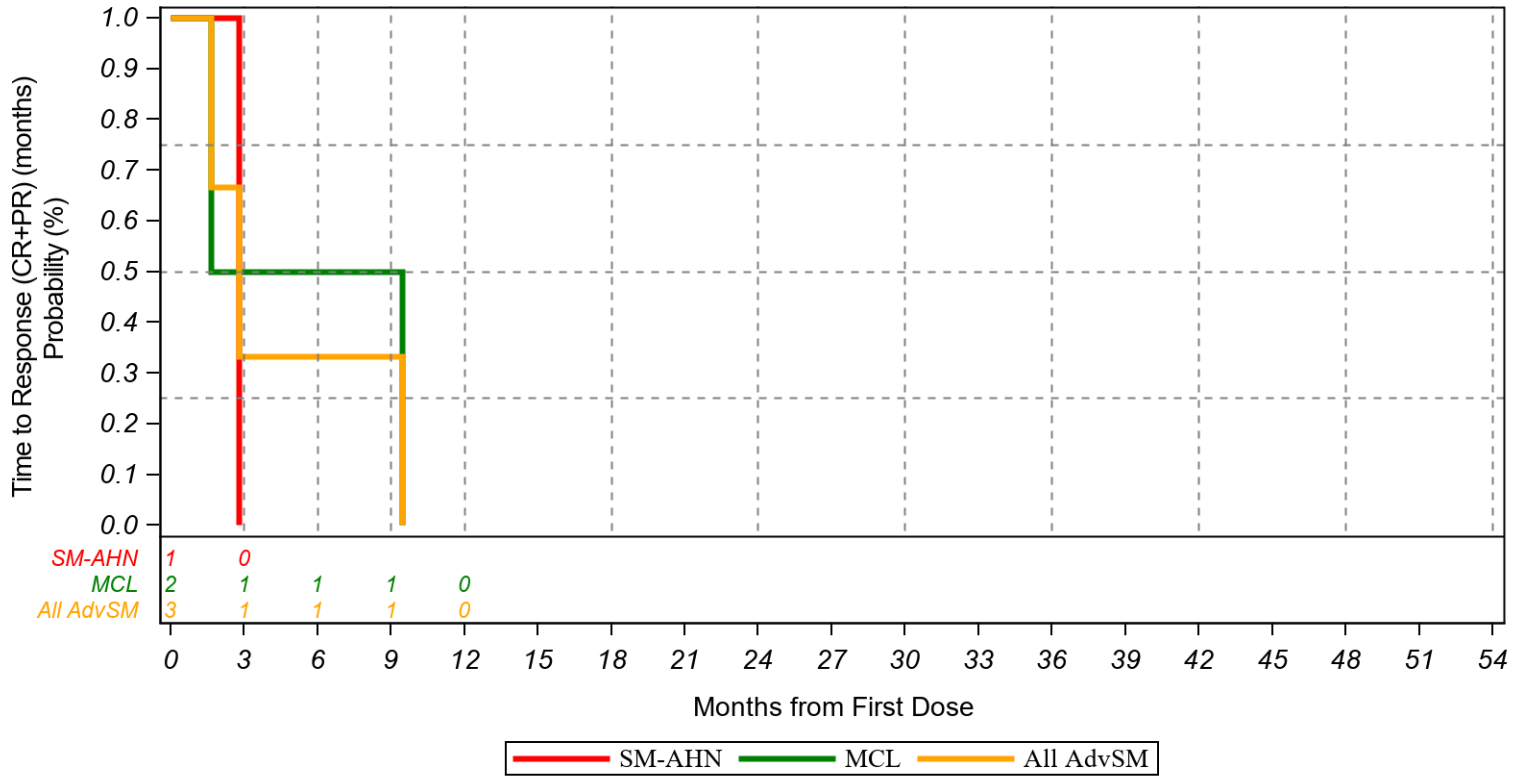

Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR+CI)
Study BLU-285-2101
Starting Dose: 200 mg

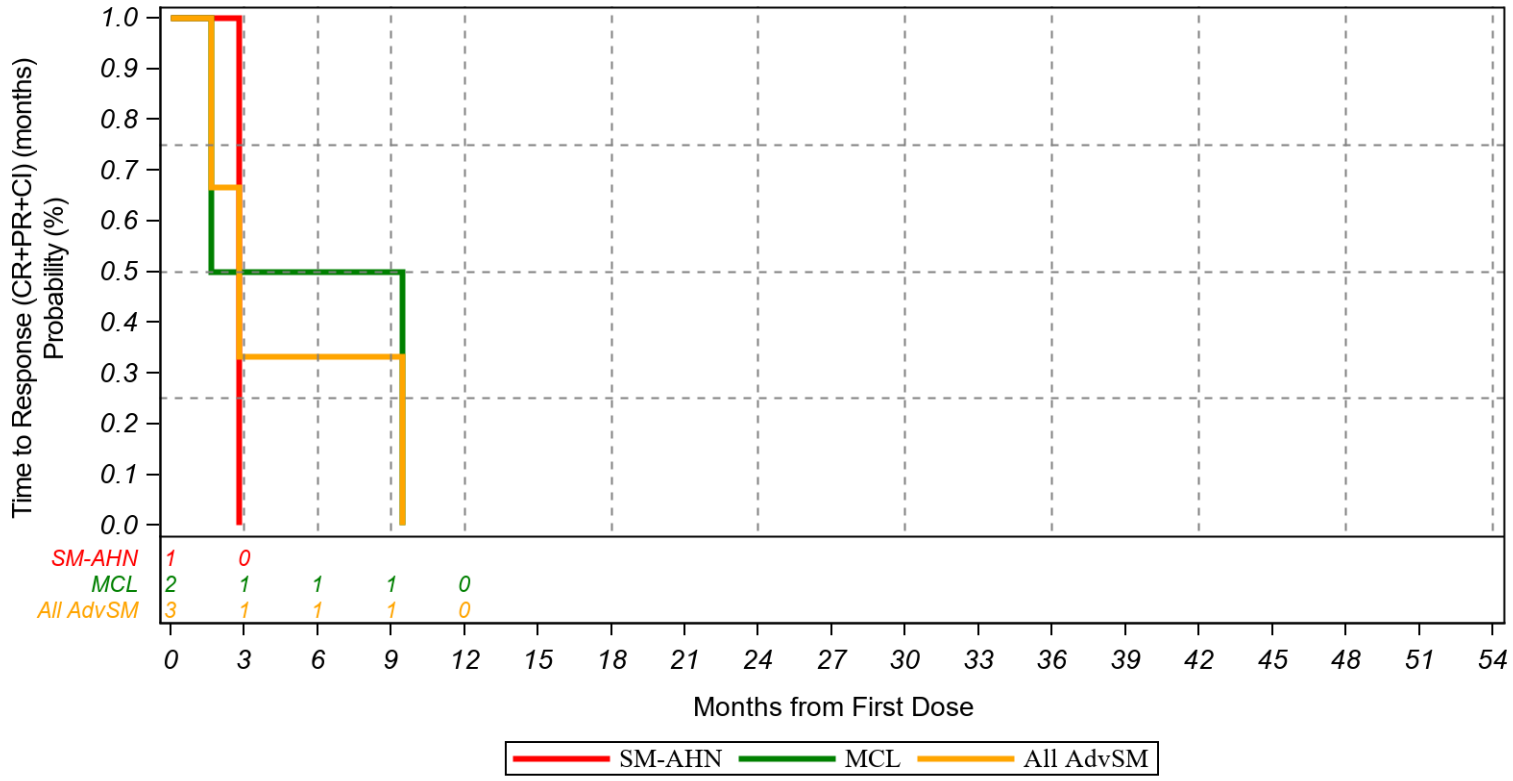

Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR)
Study BLU-285-2101
Starting Dose: 300 mg

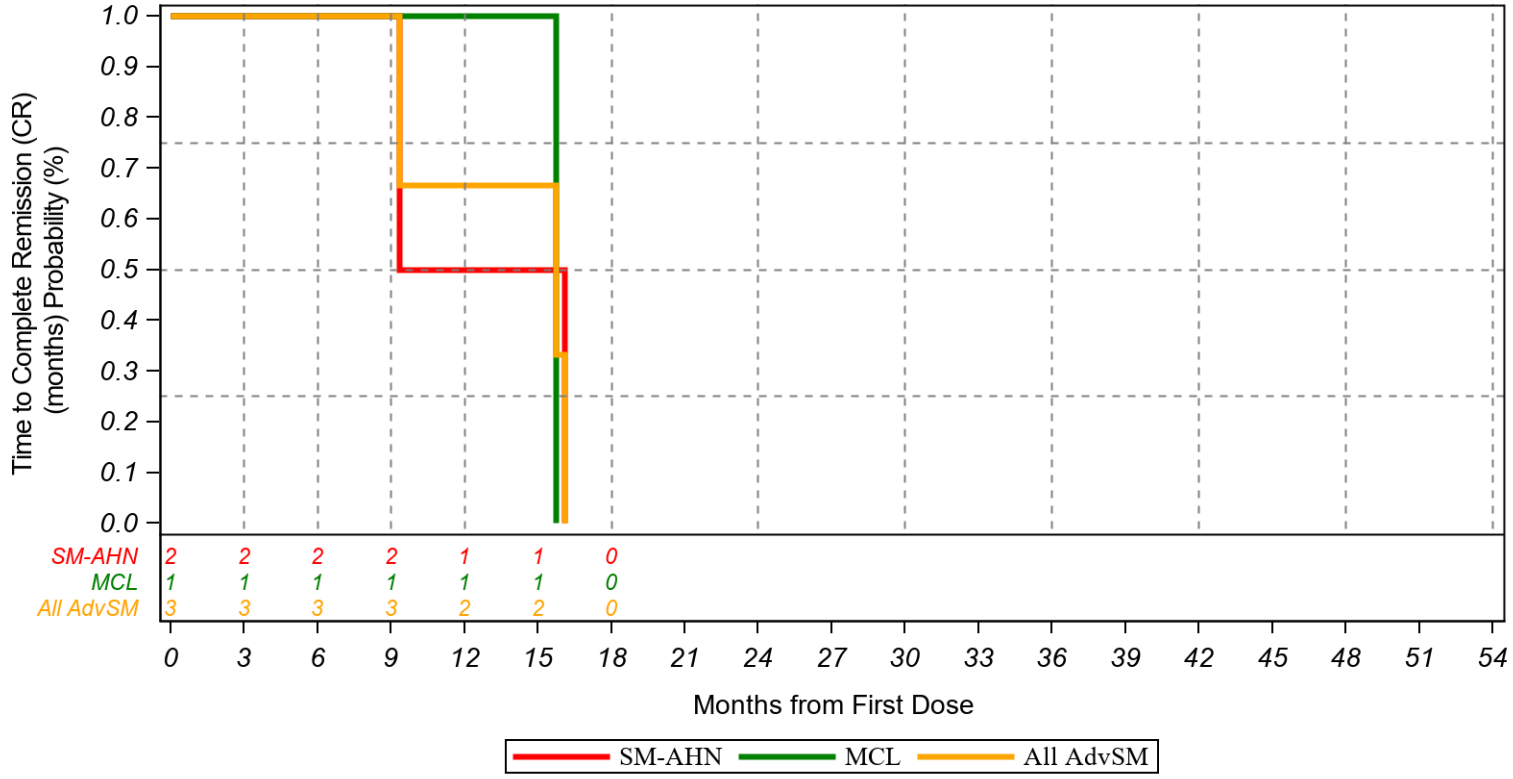

Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR)
Study BLU-285-2101
Starting Dose: 300 mg

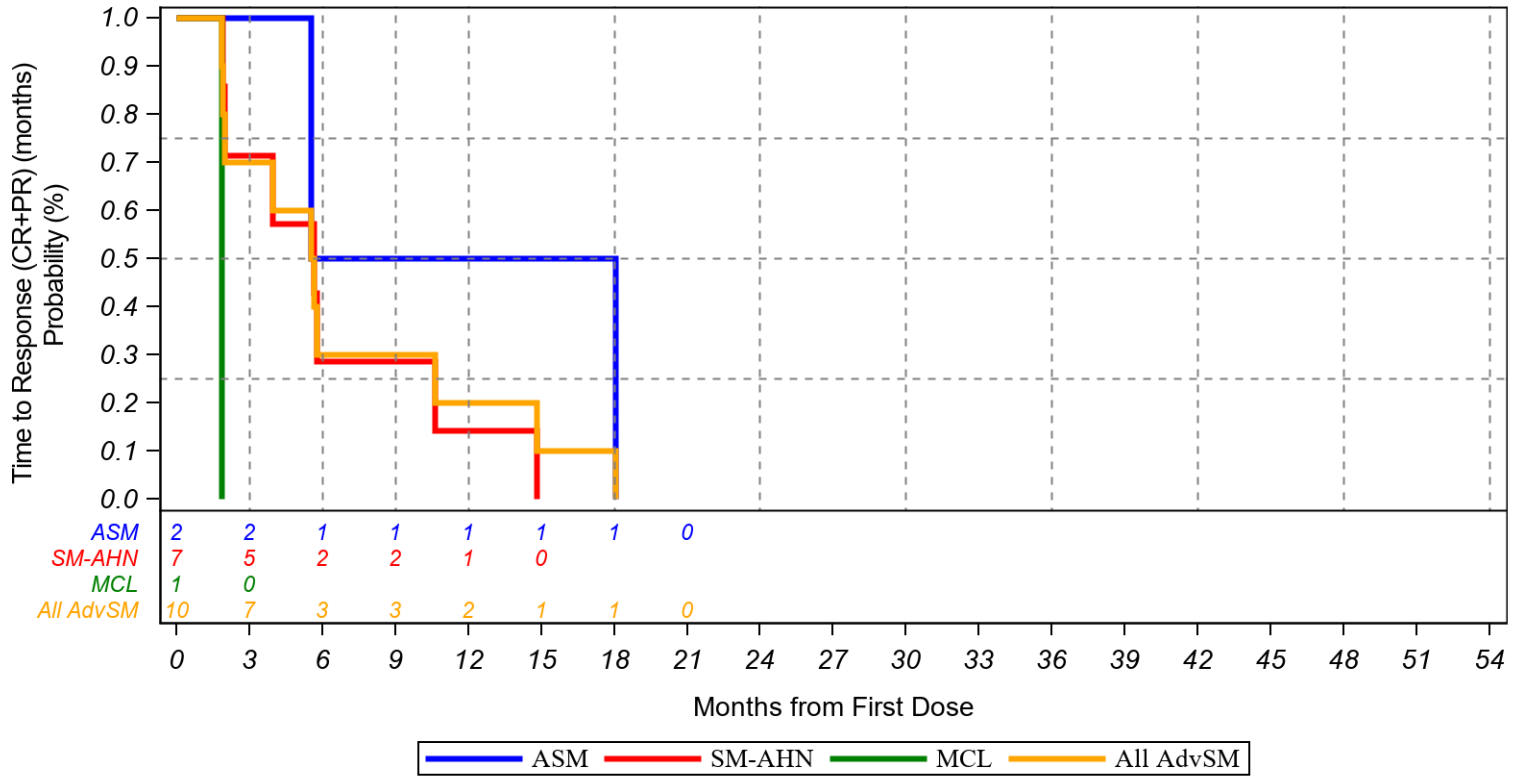

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Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR+CI)
Study BLU-285-2101
Starting Dose: 300 mg

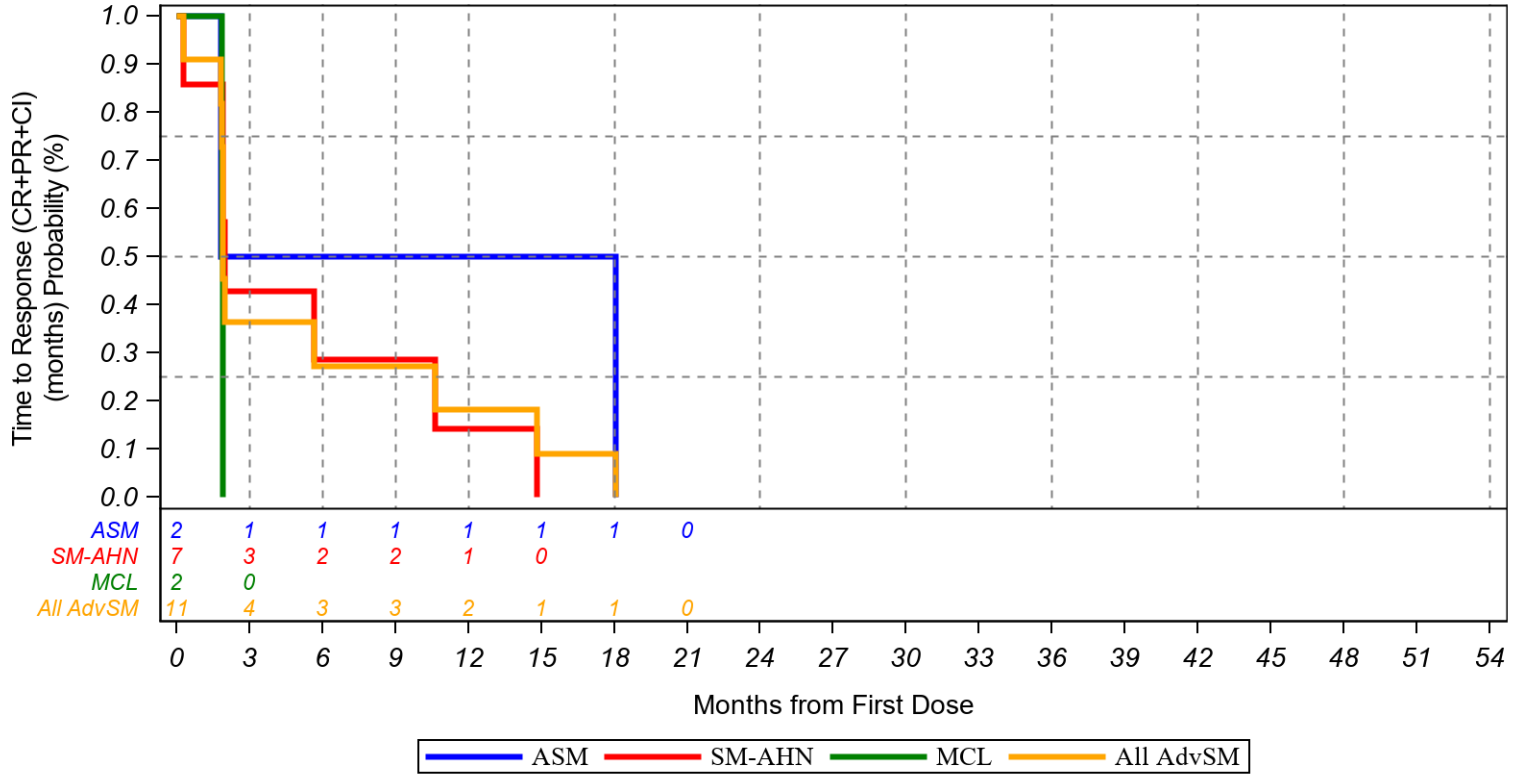

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Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR)
Study BLU-285-2101
Starting Dose: 200 mg and 300 mg

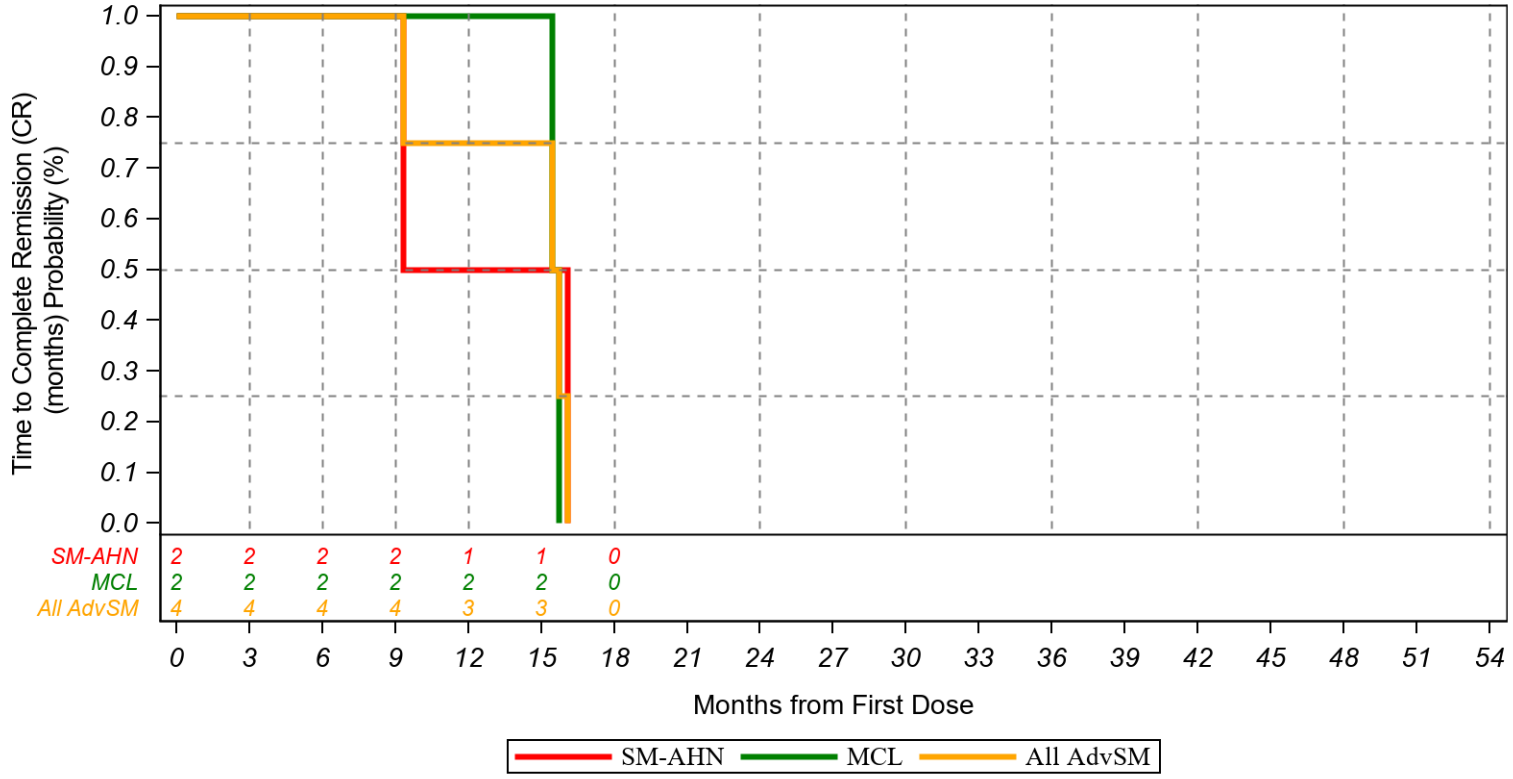

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Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR)
Study BLU-285-2101
Starting Dose: 200 mg and 300 mg

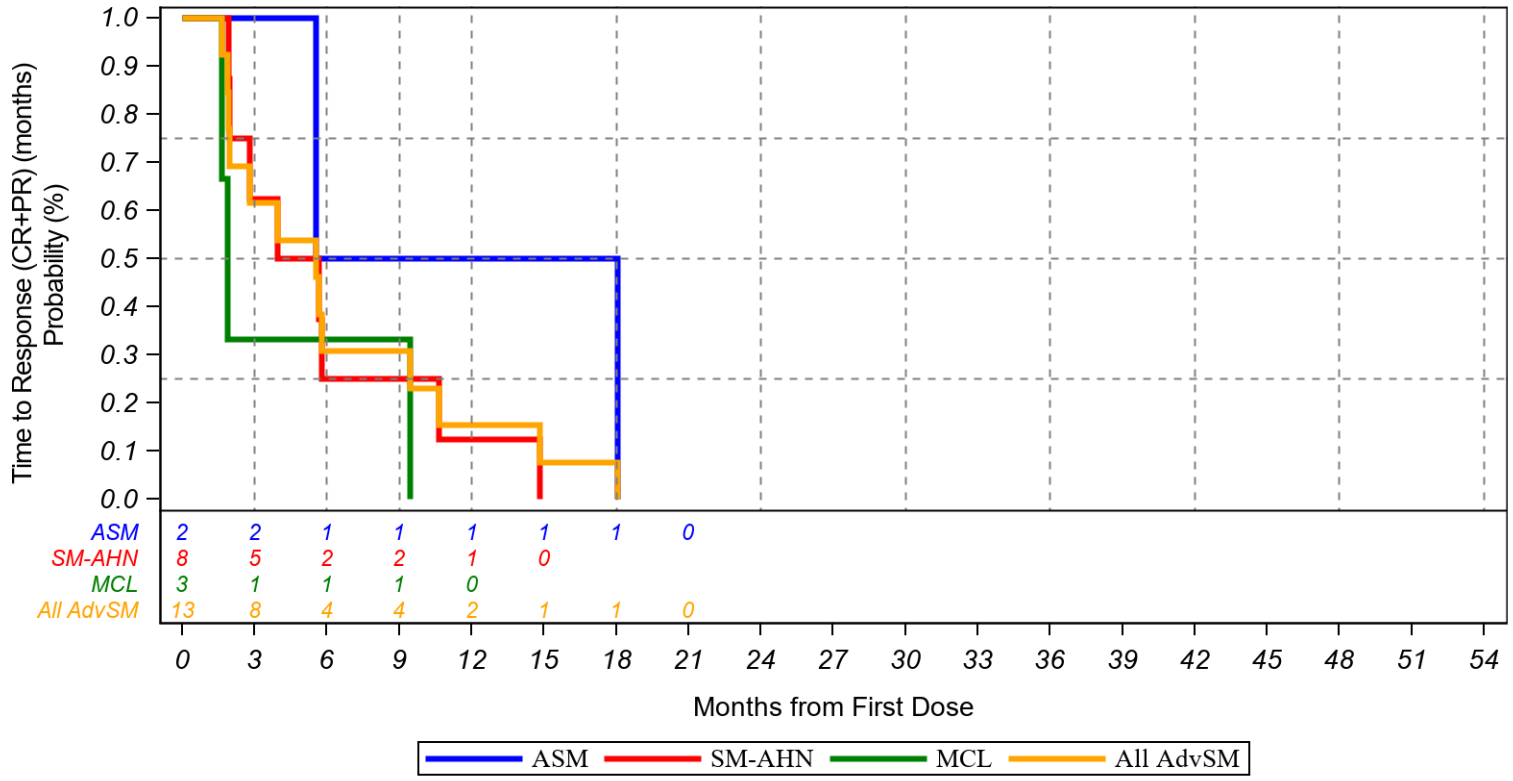

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Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR+CI)
Study BLU-285-2101
Starting Dose: 200 mg and 300 mg

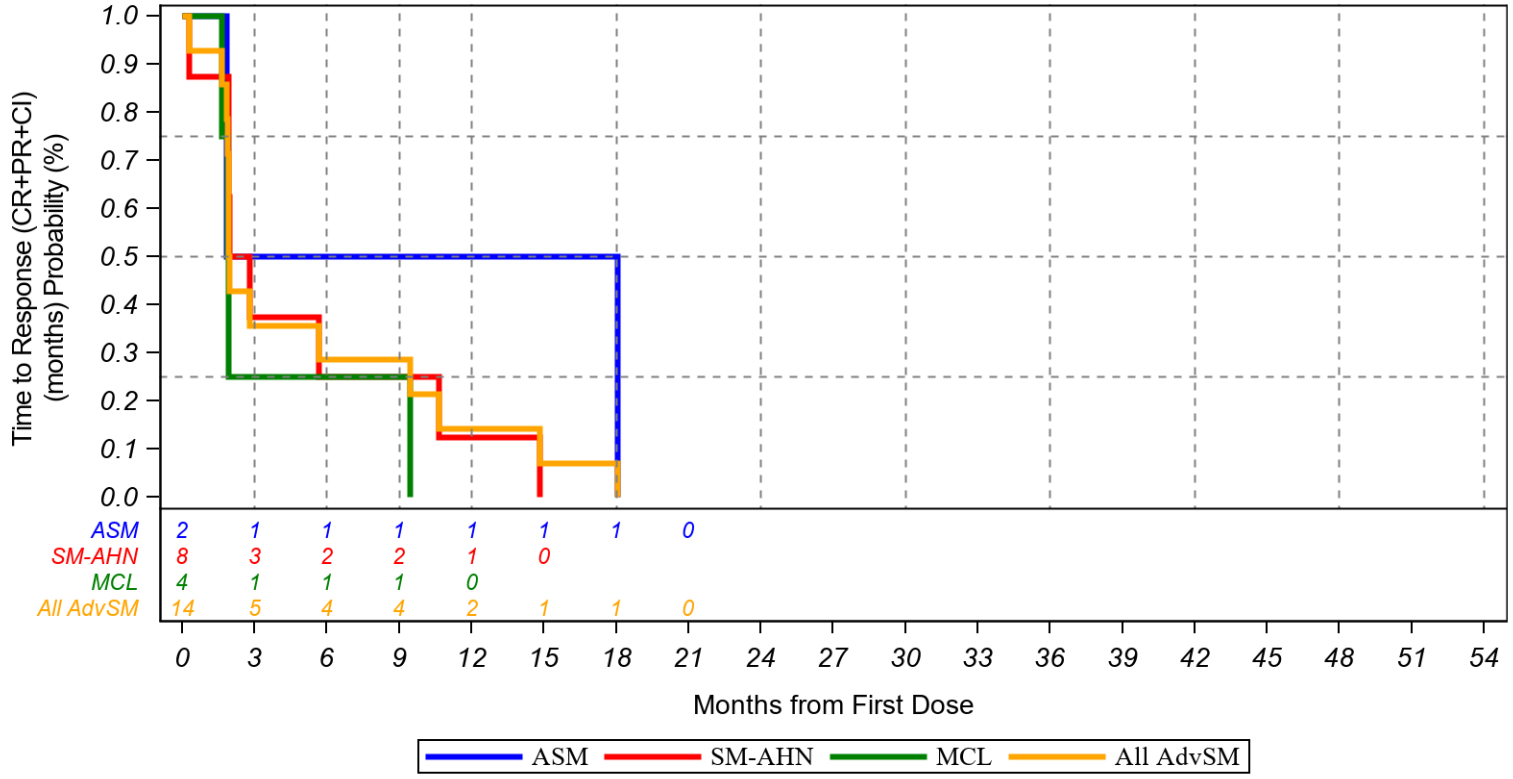

Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR)
Study BLU-285-2101
Starting Dose: 400 mg

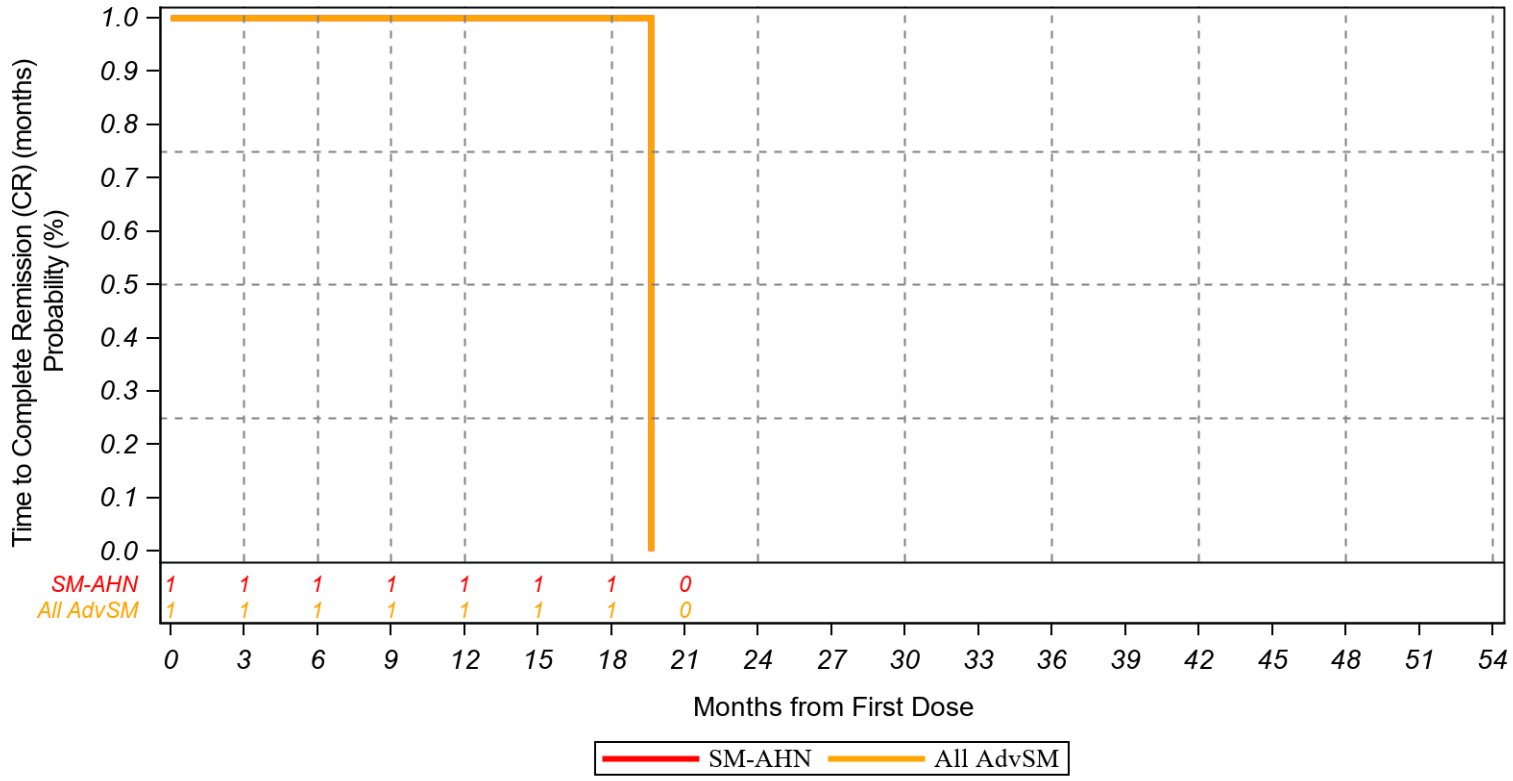

Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR)
Study BLU-285-2101
Starting Dose: 400 mg

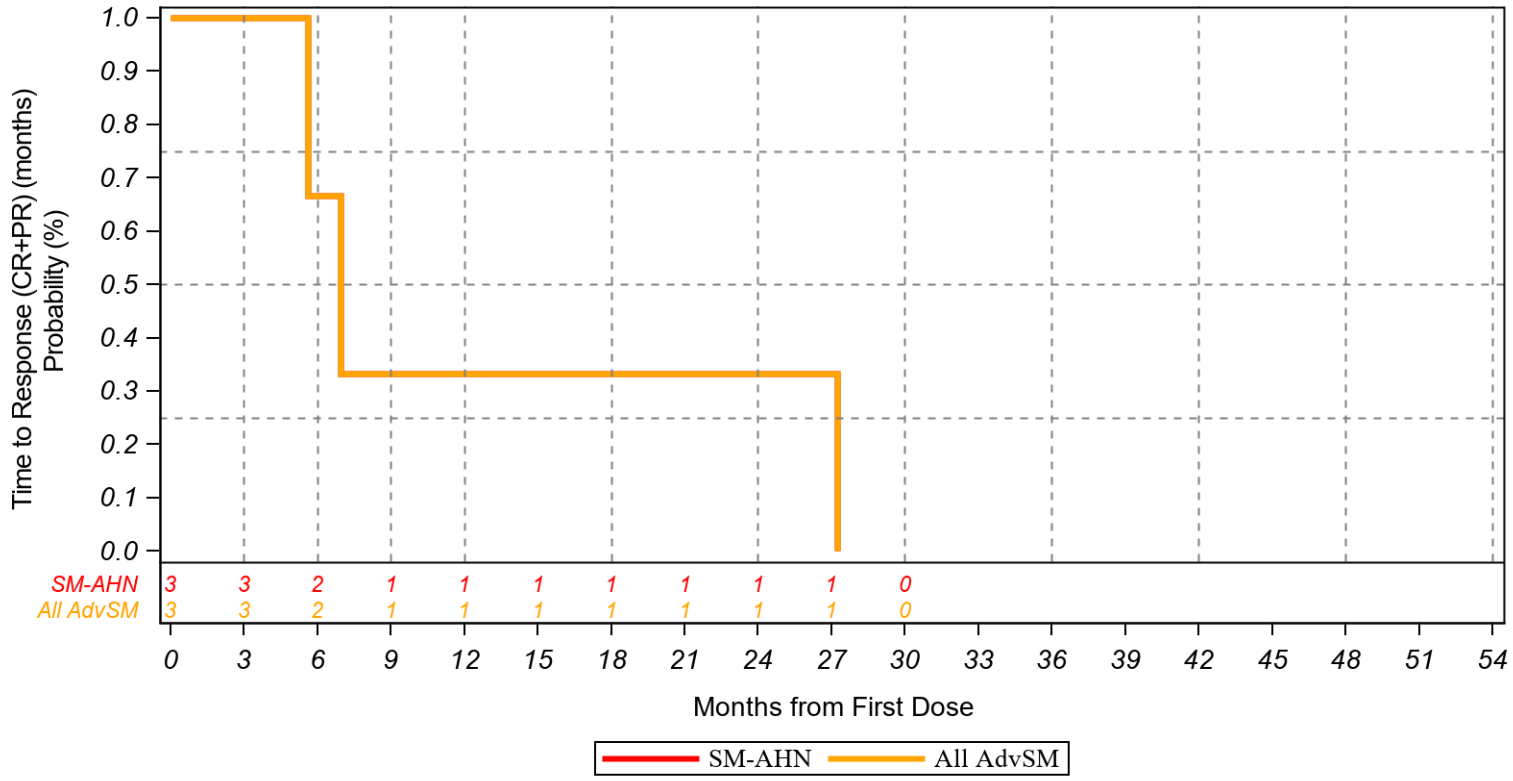

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Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR+CI)
Study BLU-285-2101
Starting Dose: 400 mg

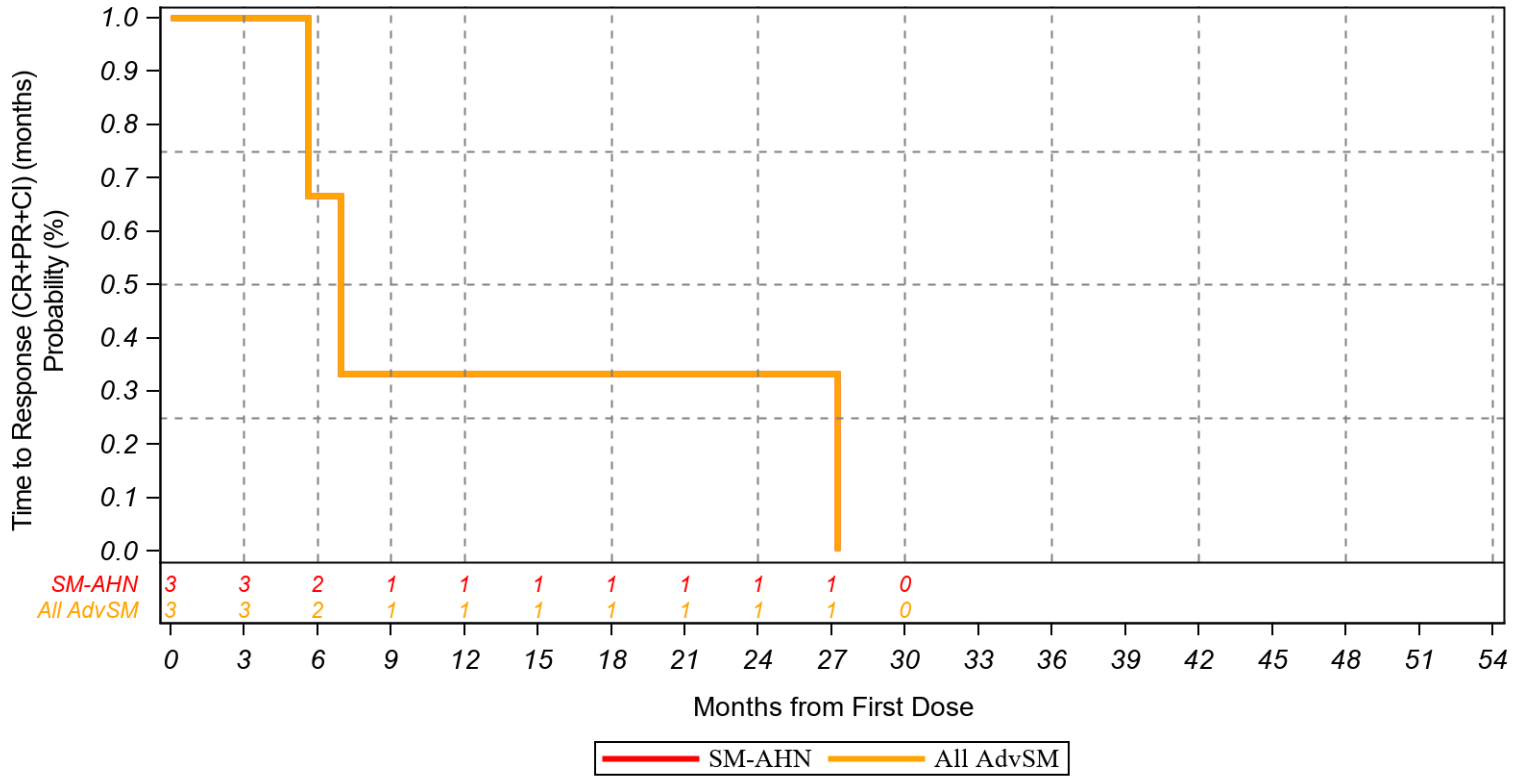

Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR)
Study BLU-285-2202
Starting Dose: Overall

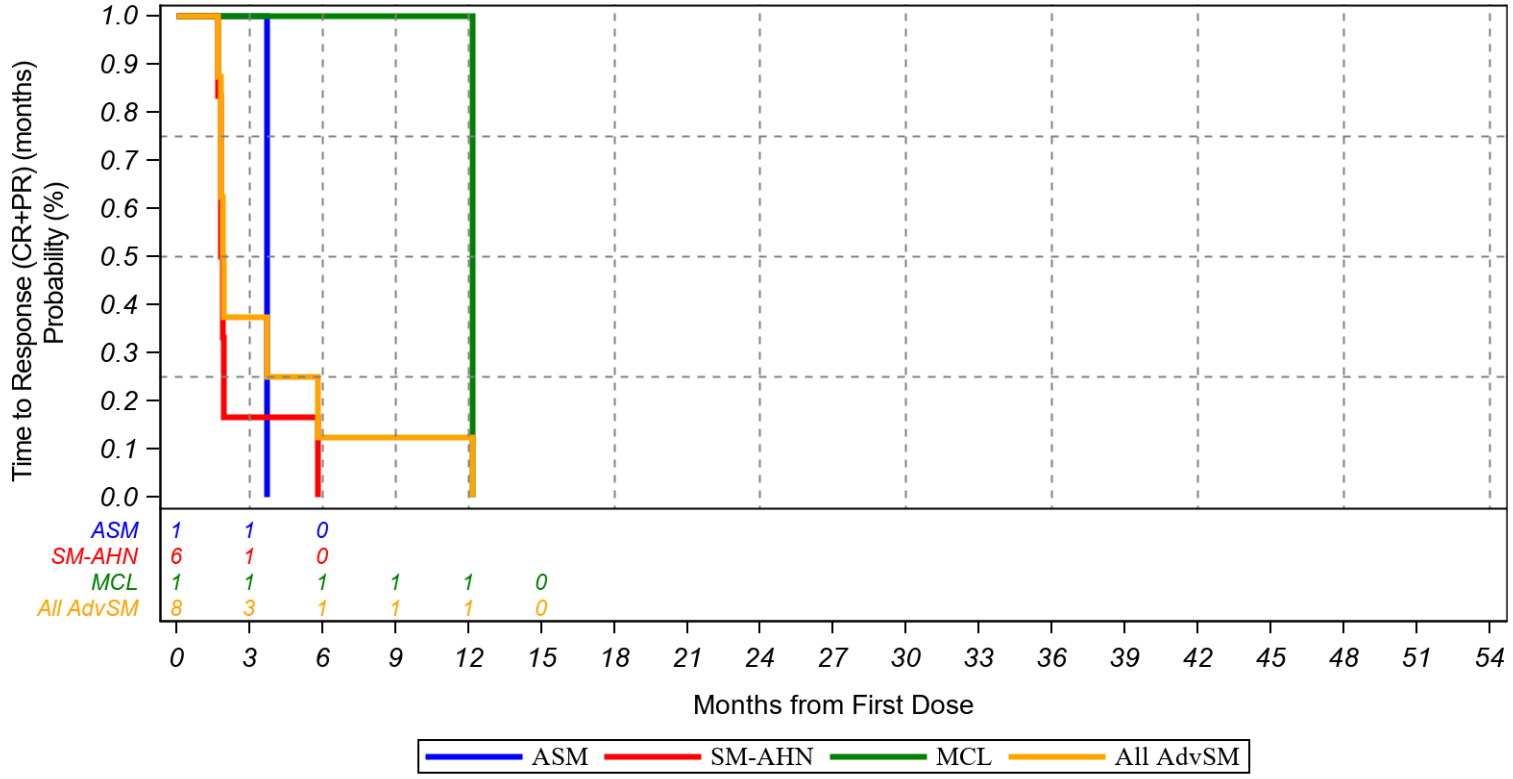

Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR+CI)
Study BLU-285-2202
Starting Dose: Overall

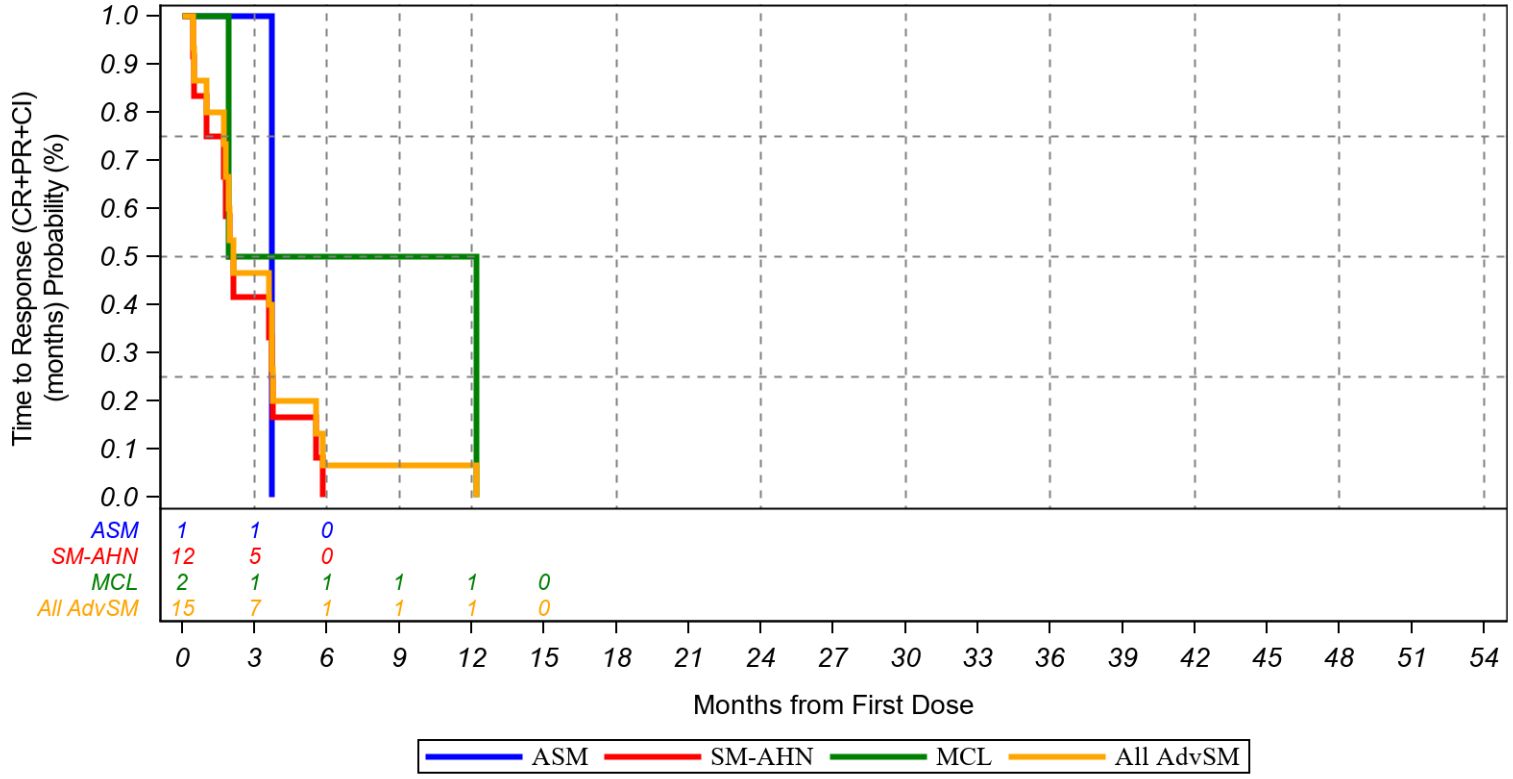

Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR)
Study BLU-285-2202
Starting Dose: 200 mg

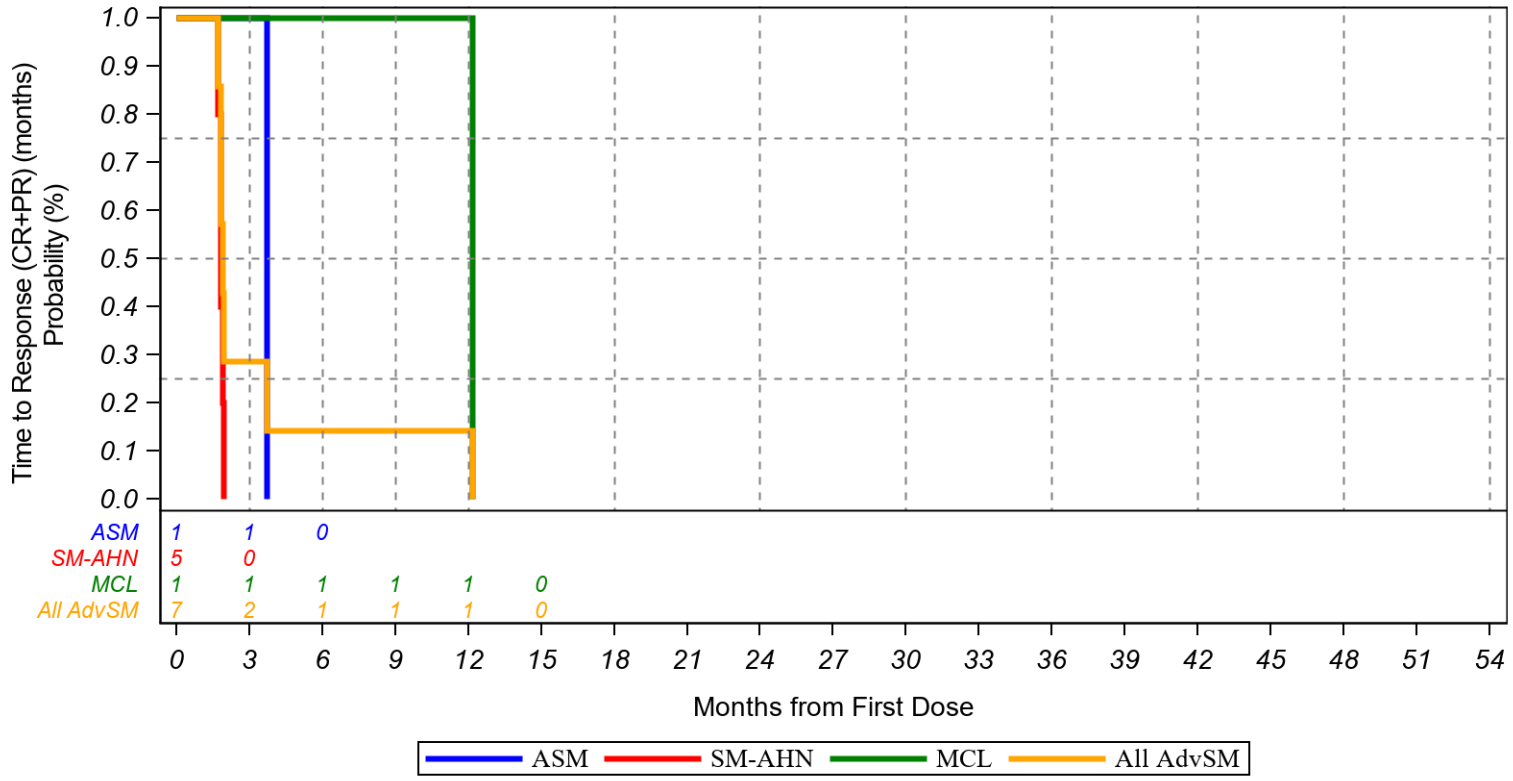

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Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR+CI)
Study BLU-285-2202
Starting Dose: 200 mg

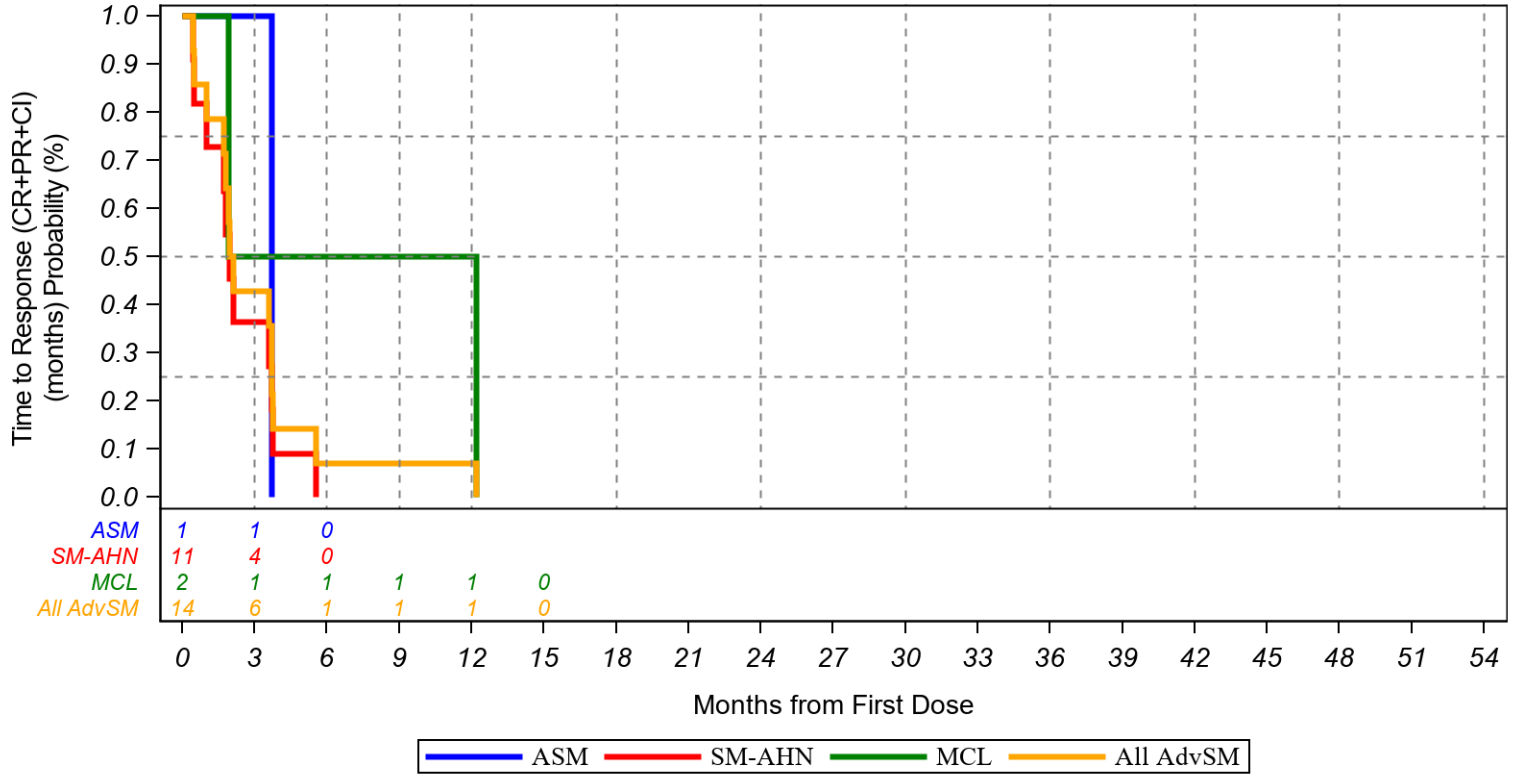

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Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall

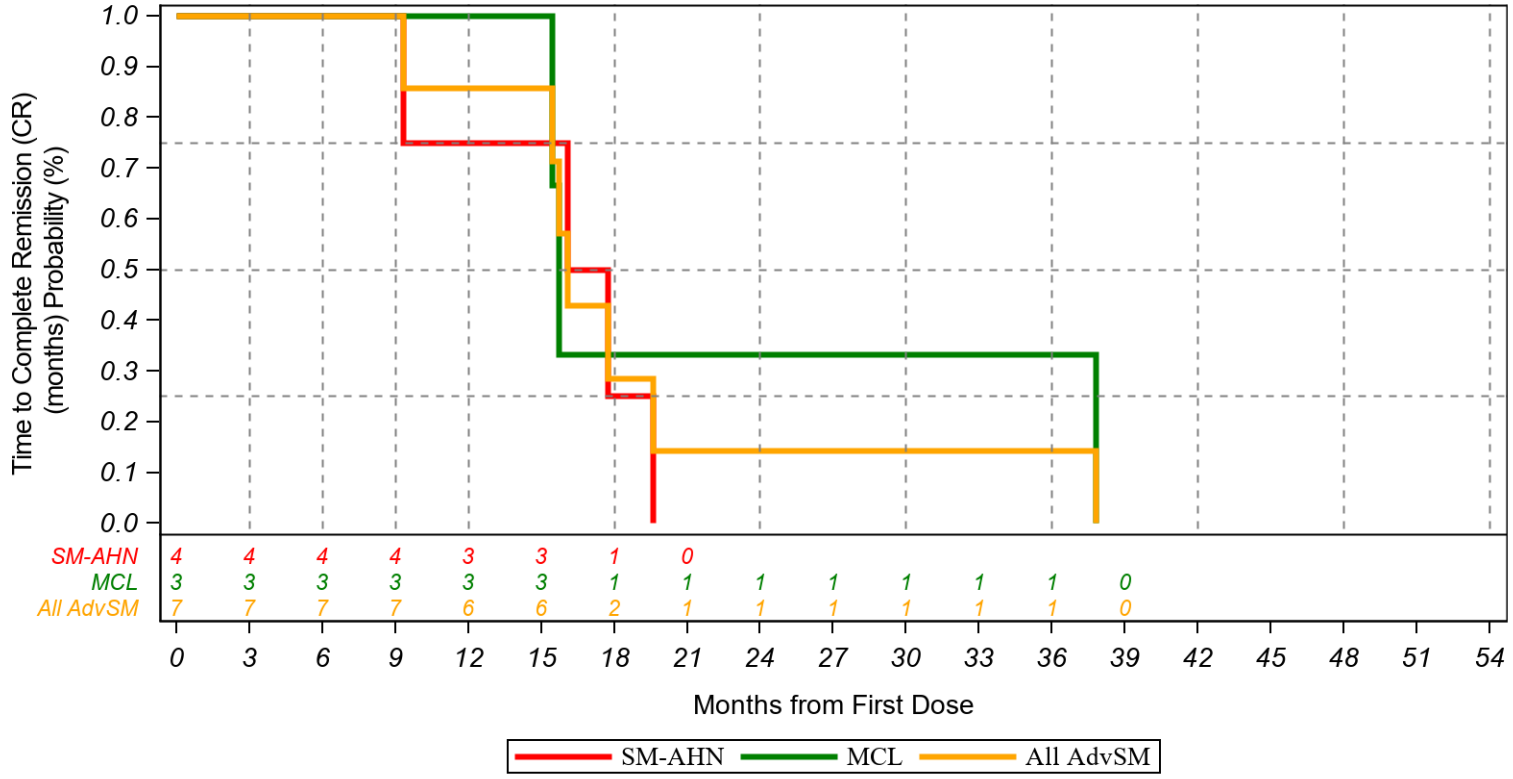

Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall

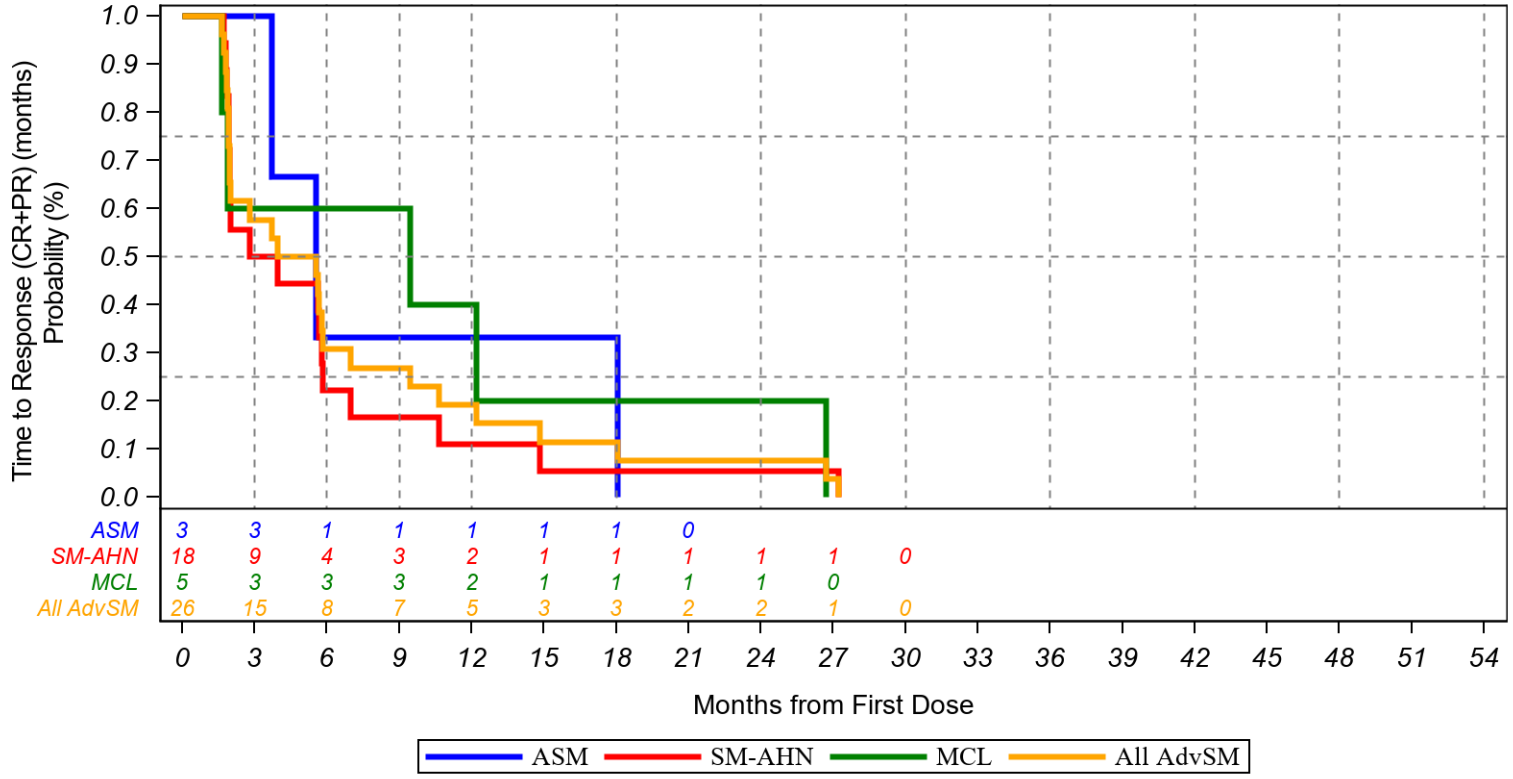

Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall

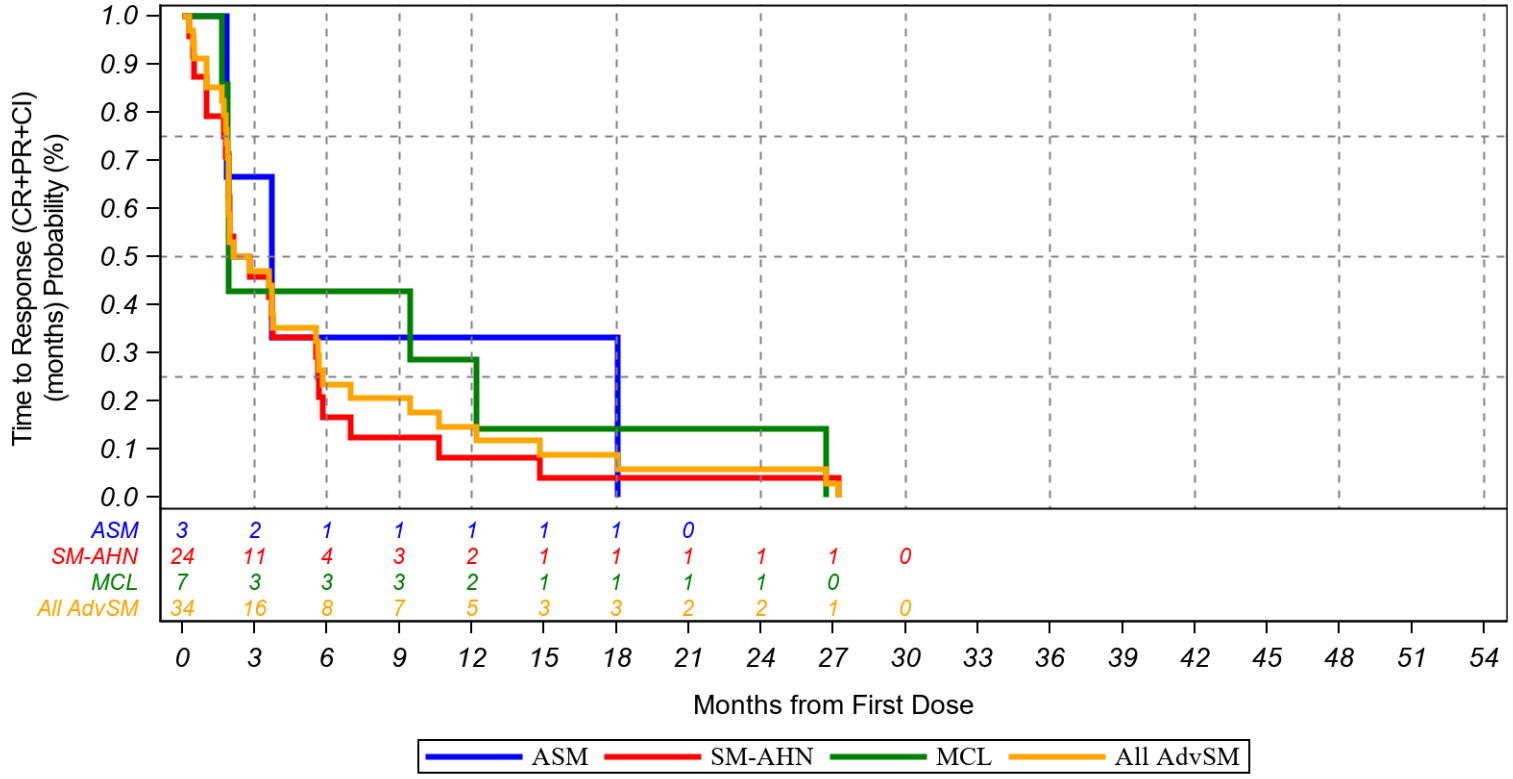

Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg

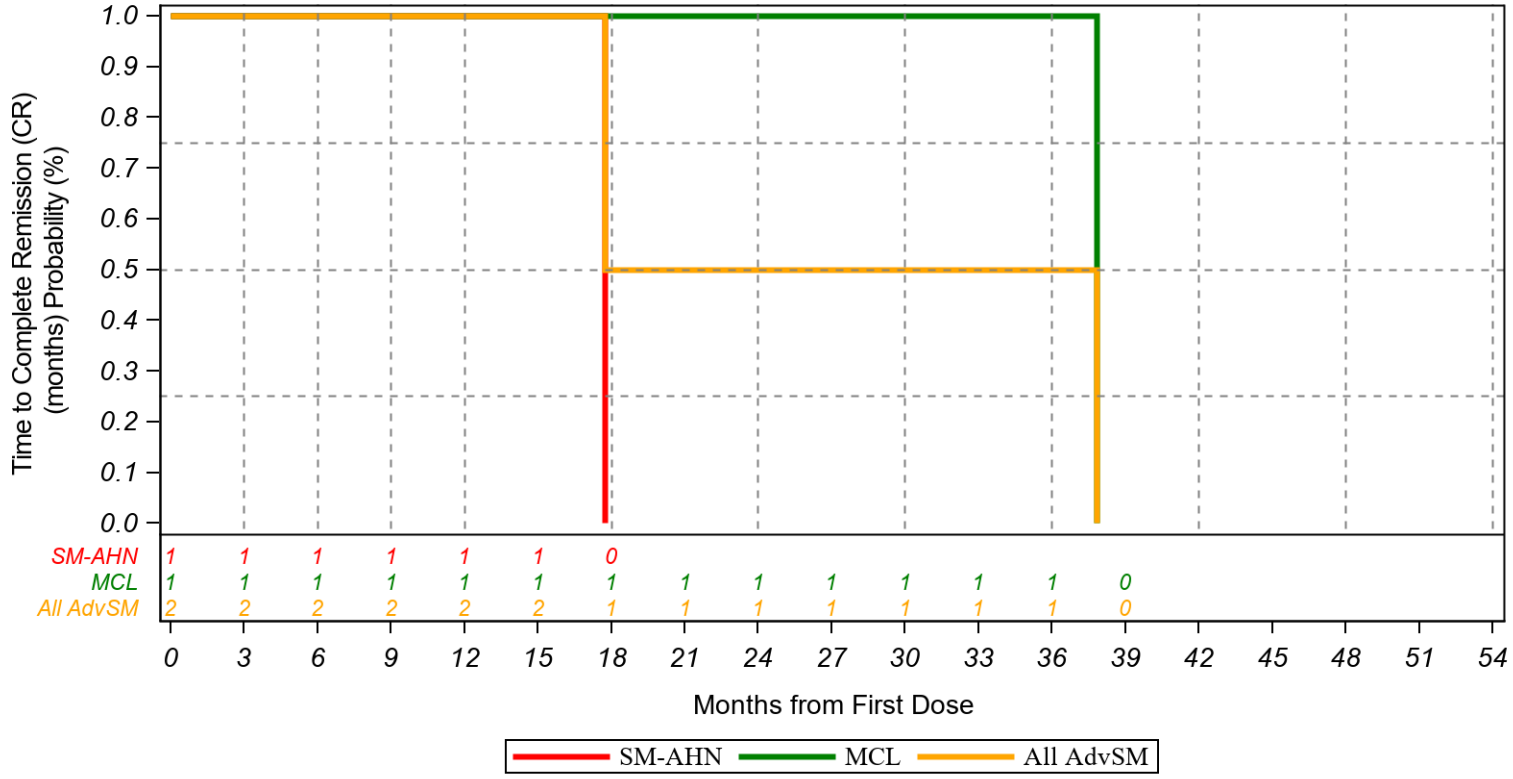

Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg

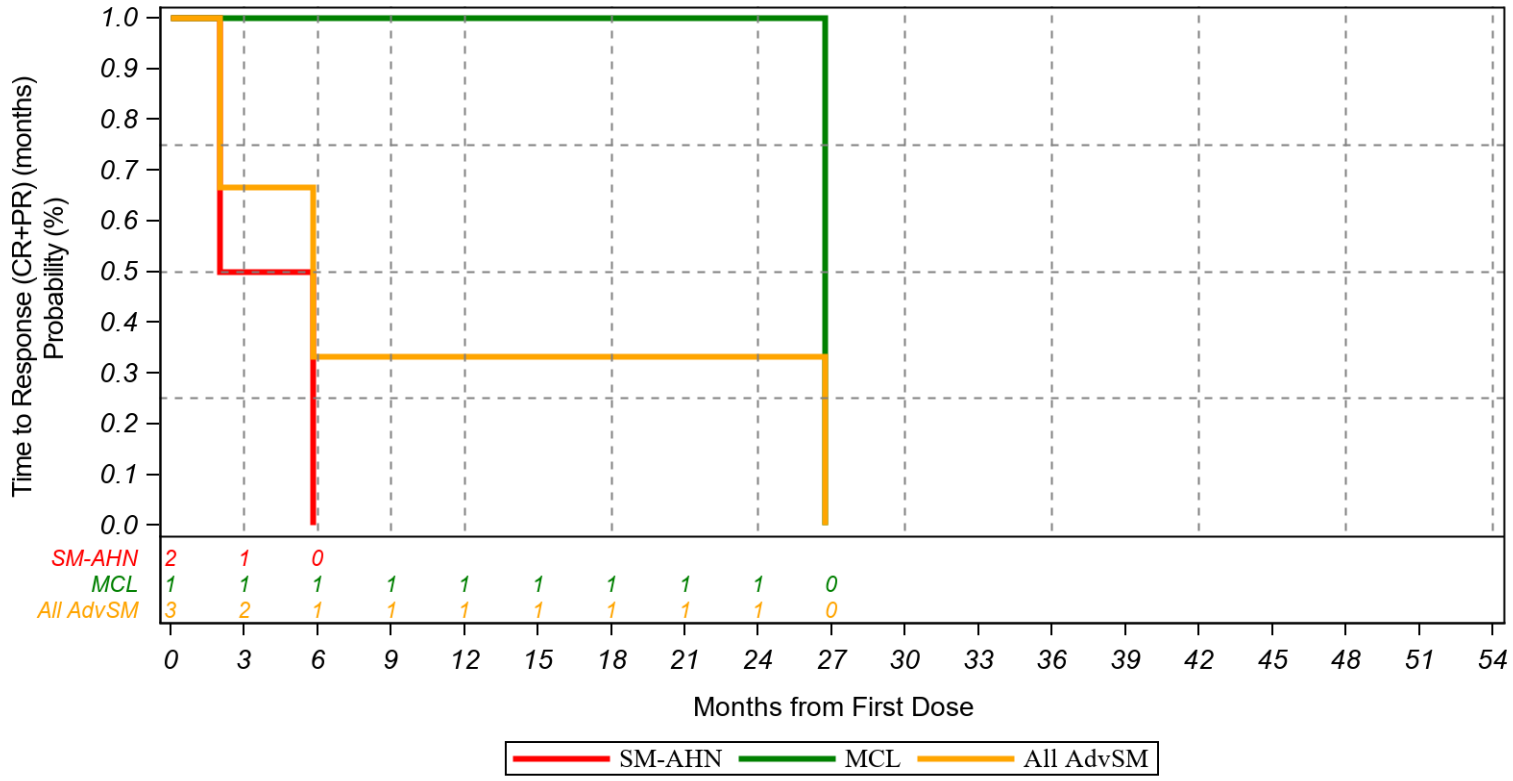

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Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg

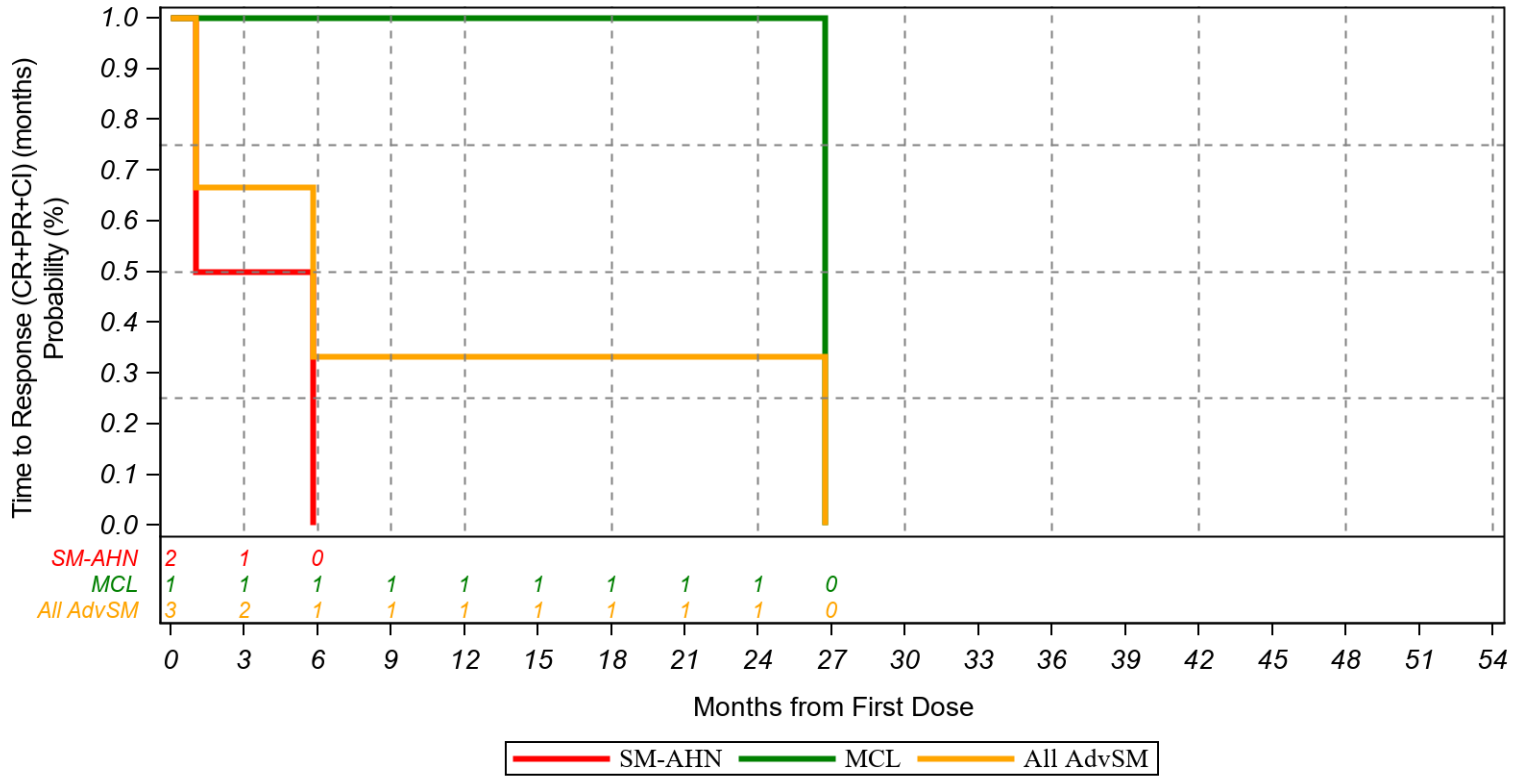

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Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg

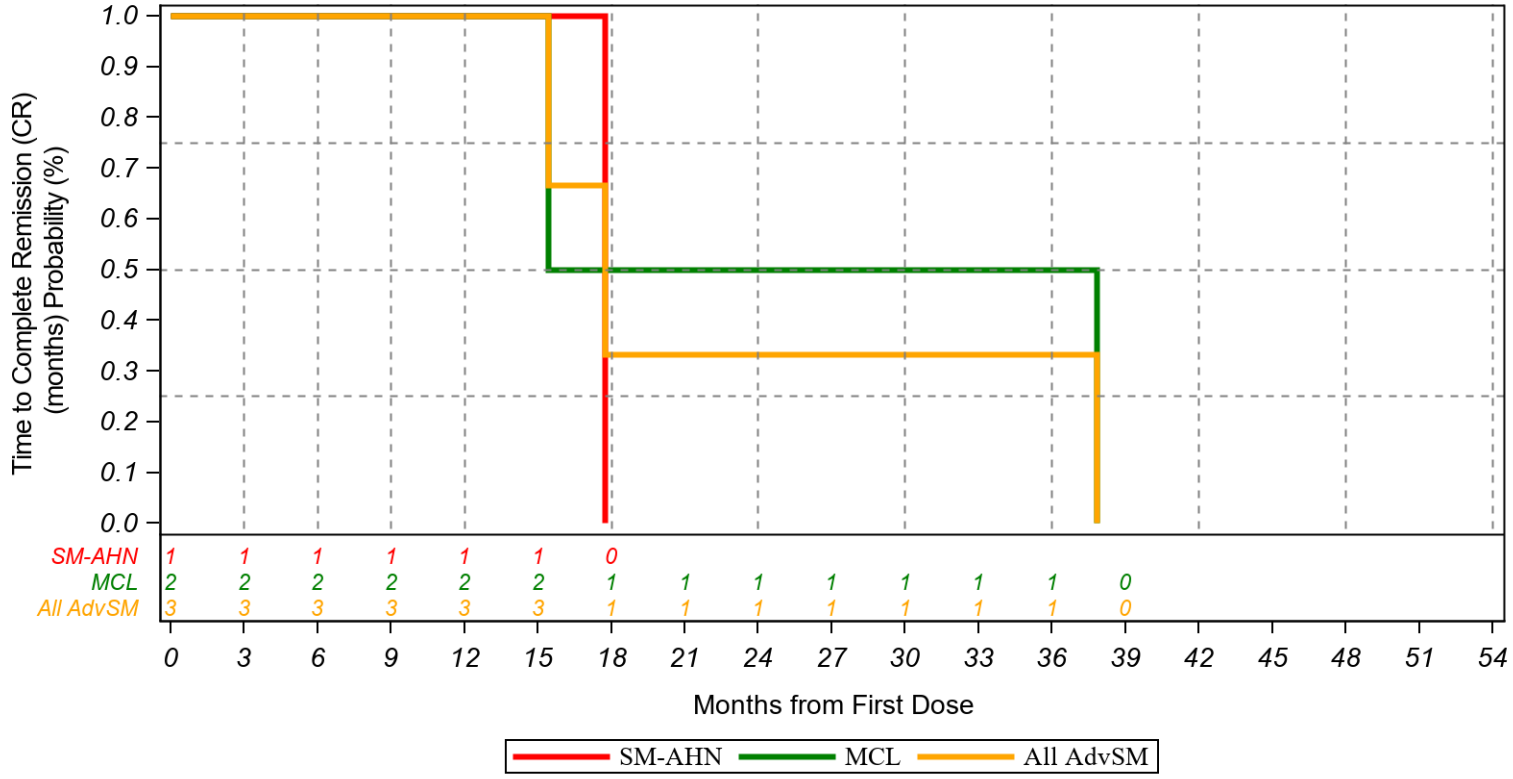

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Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg

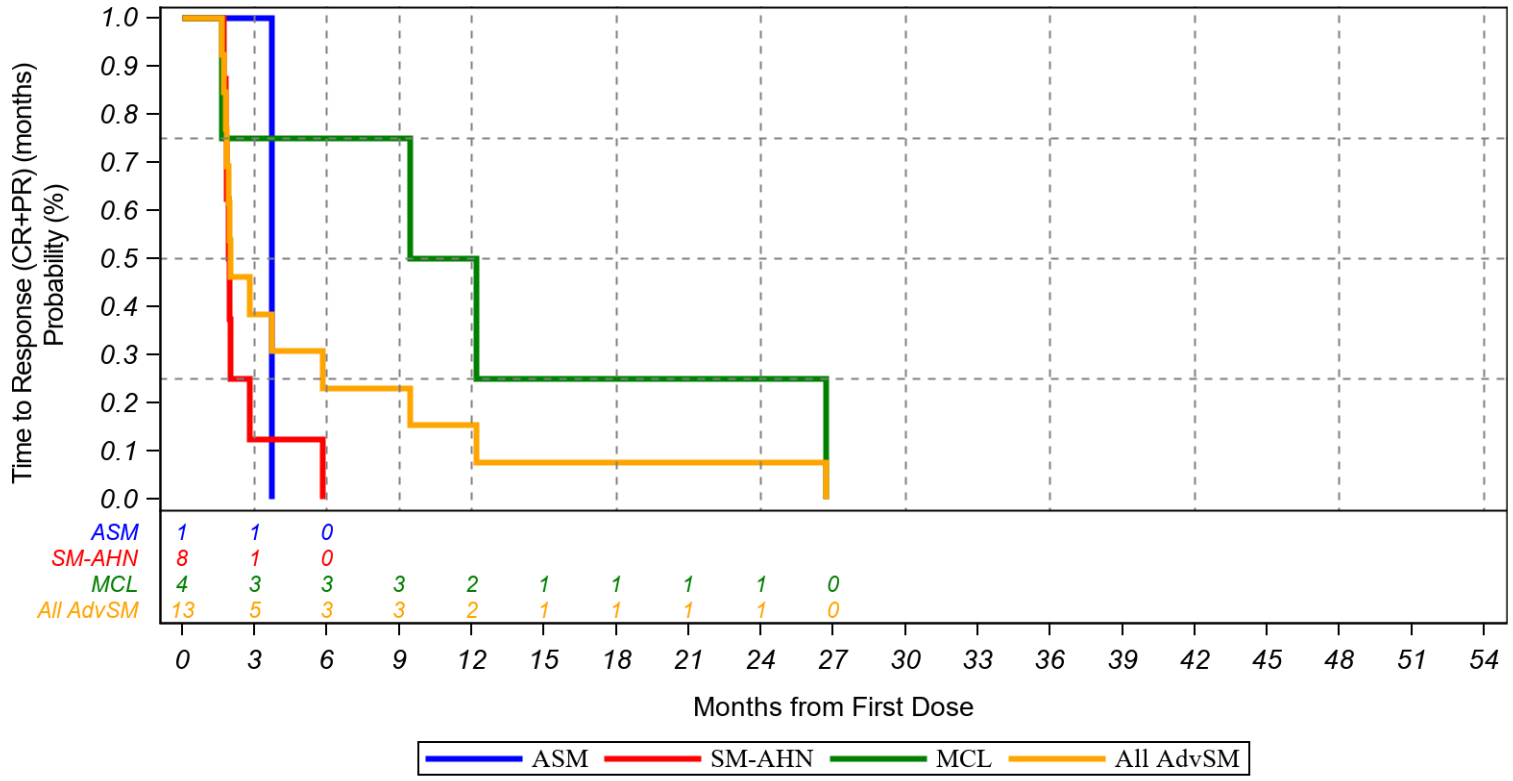

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Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg

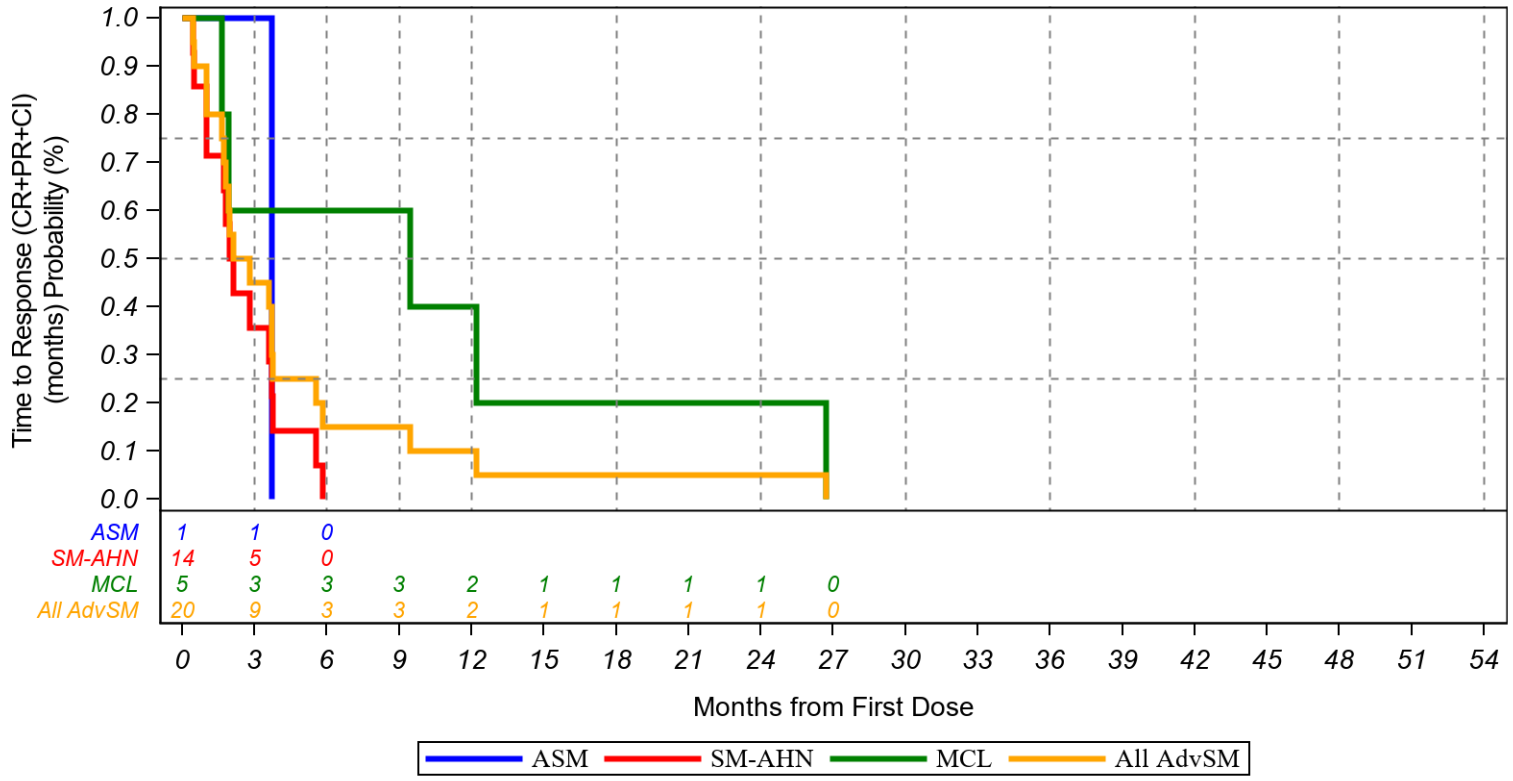
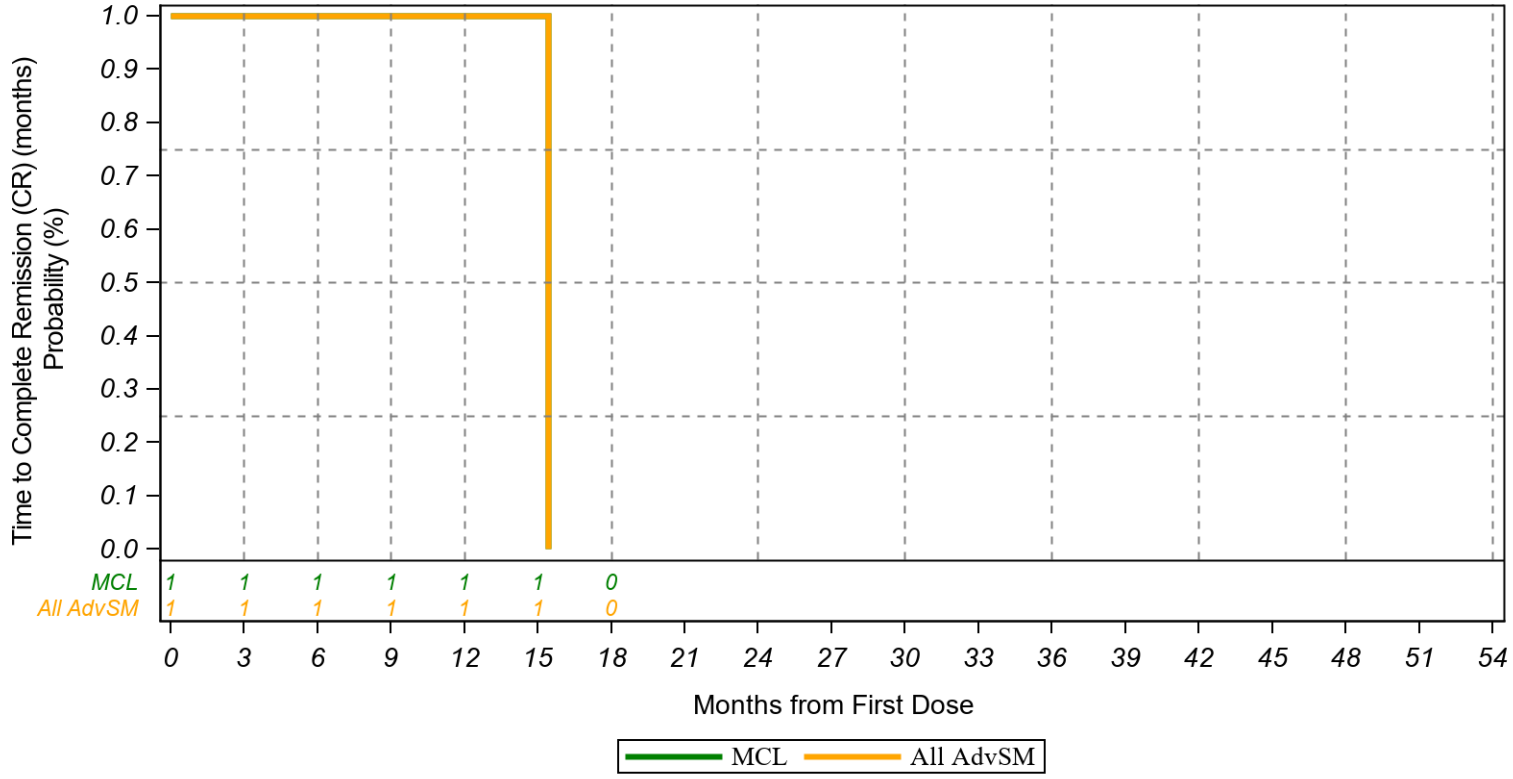
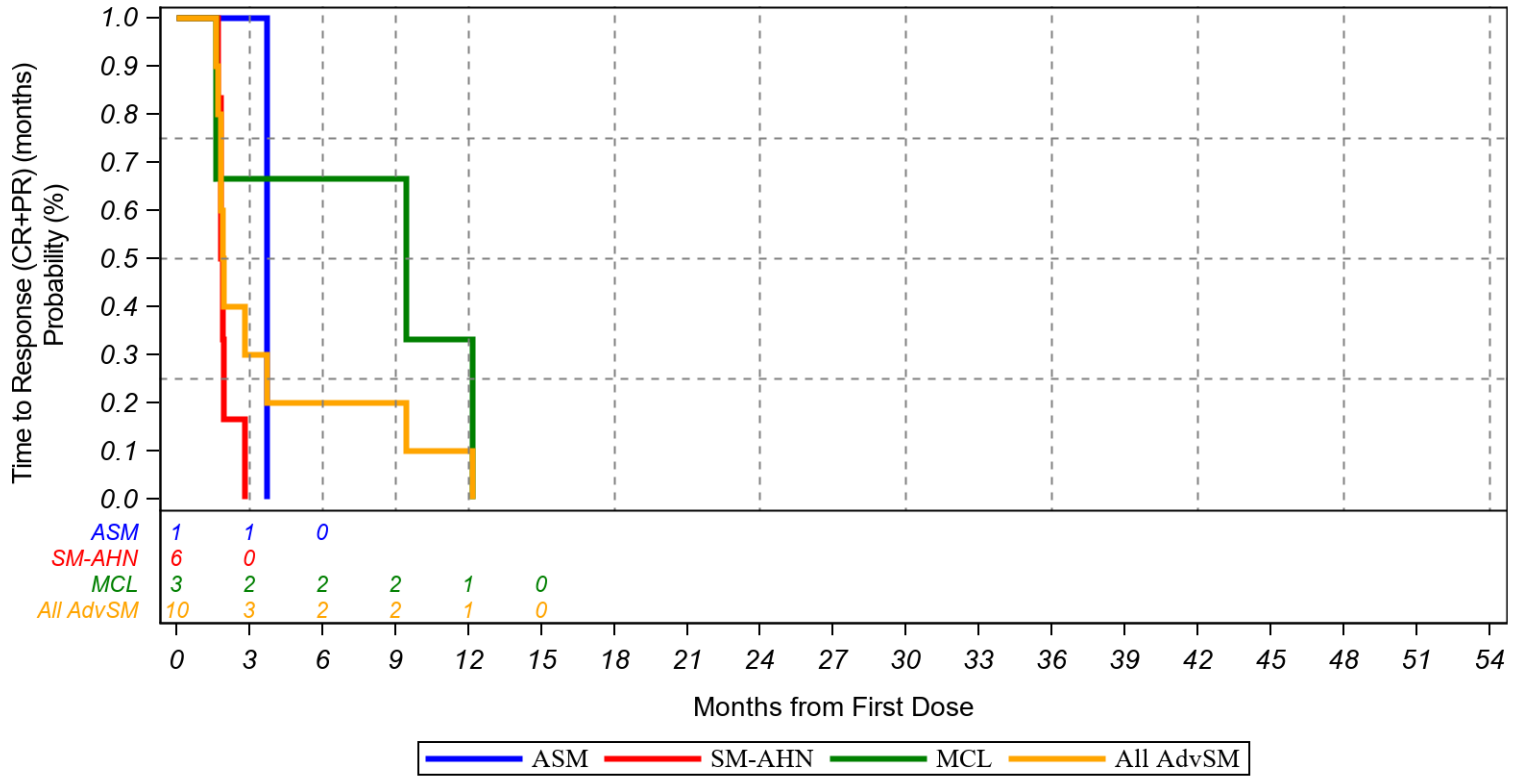


Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg



Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/f-alg-t2rs-rac.sas
Date: 7:56/14OCT2021

Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg



Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/f-alg-t2rs-rac.sas
Date: 7:56/14OCT2021

Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg

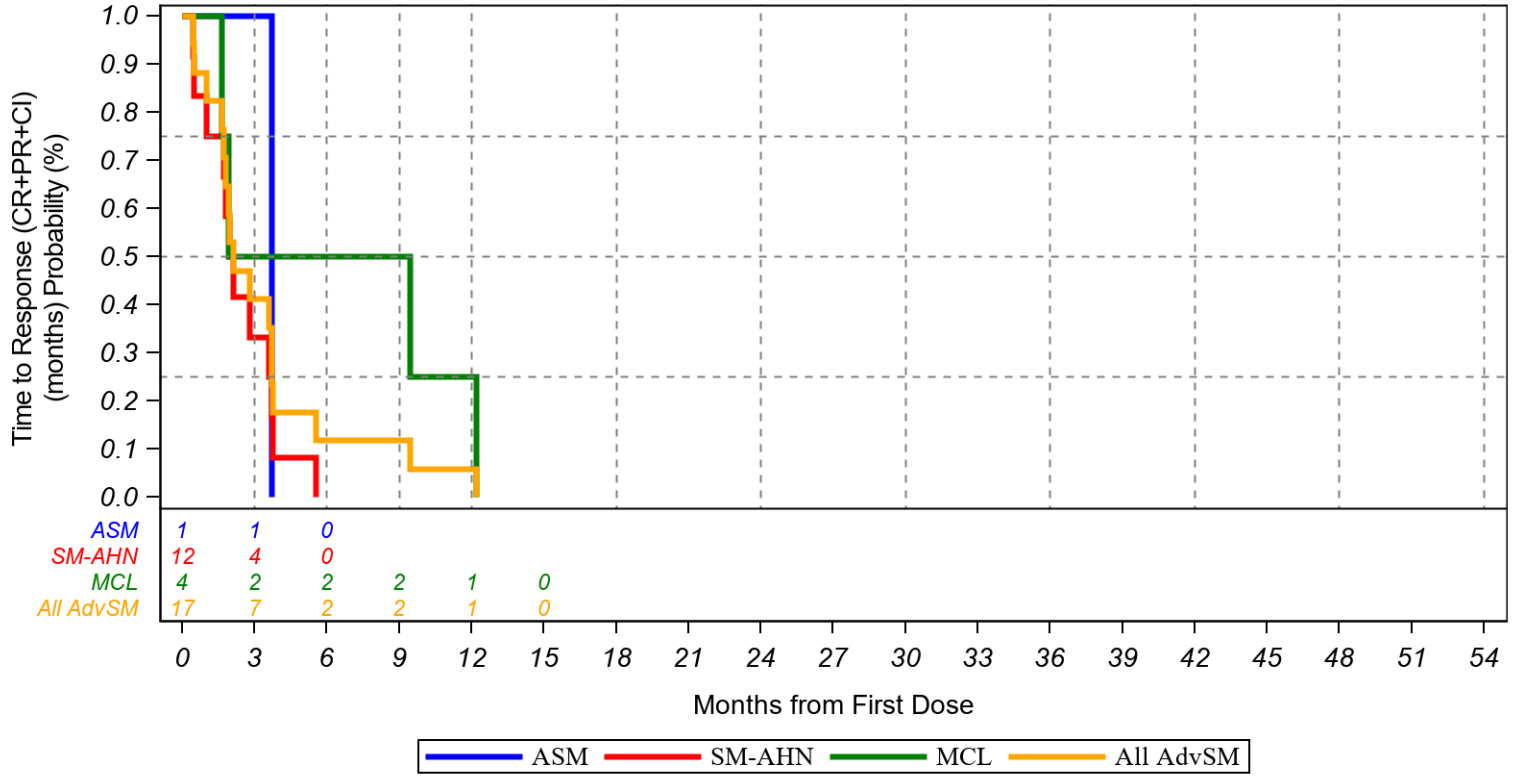
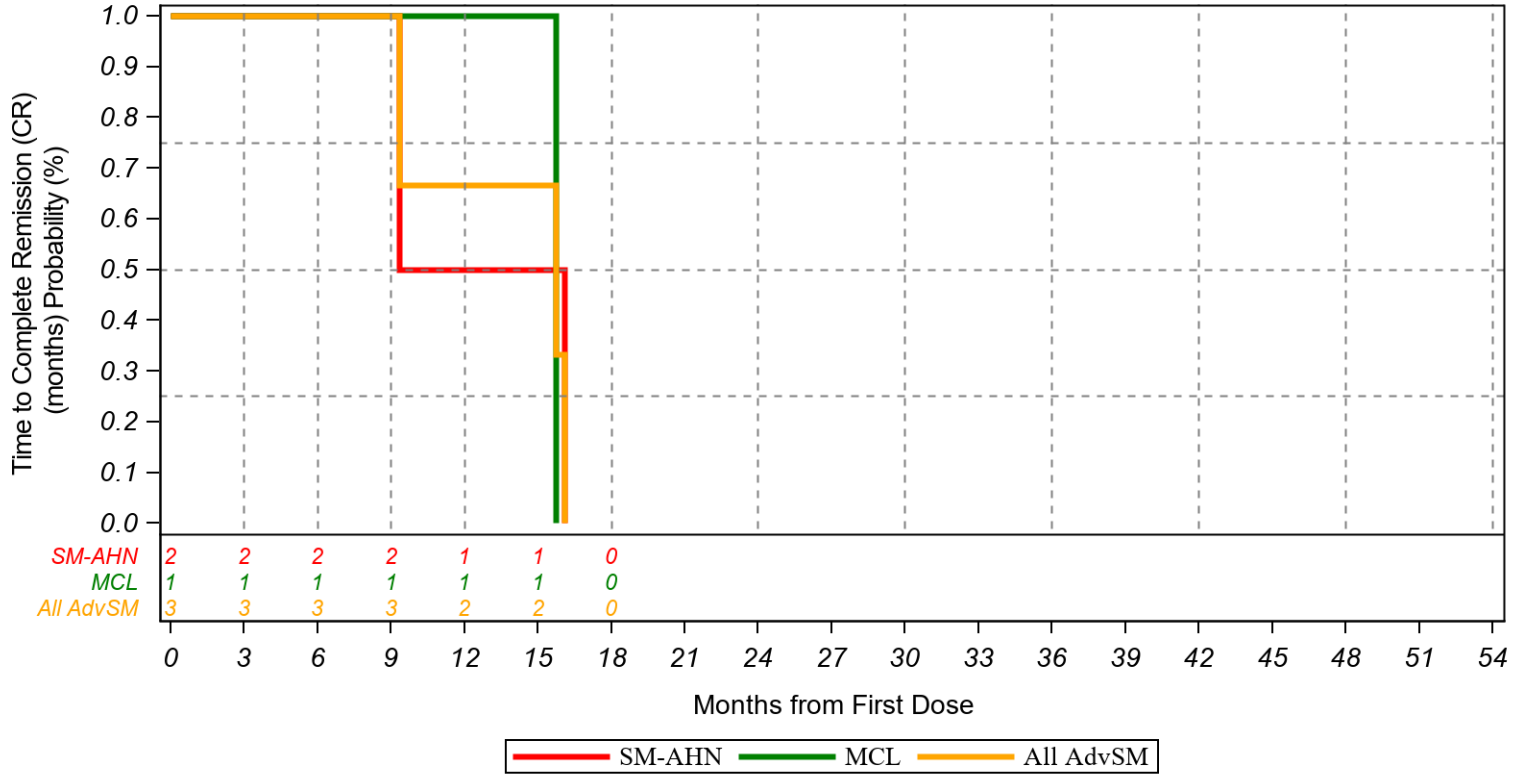
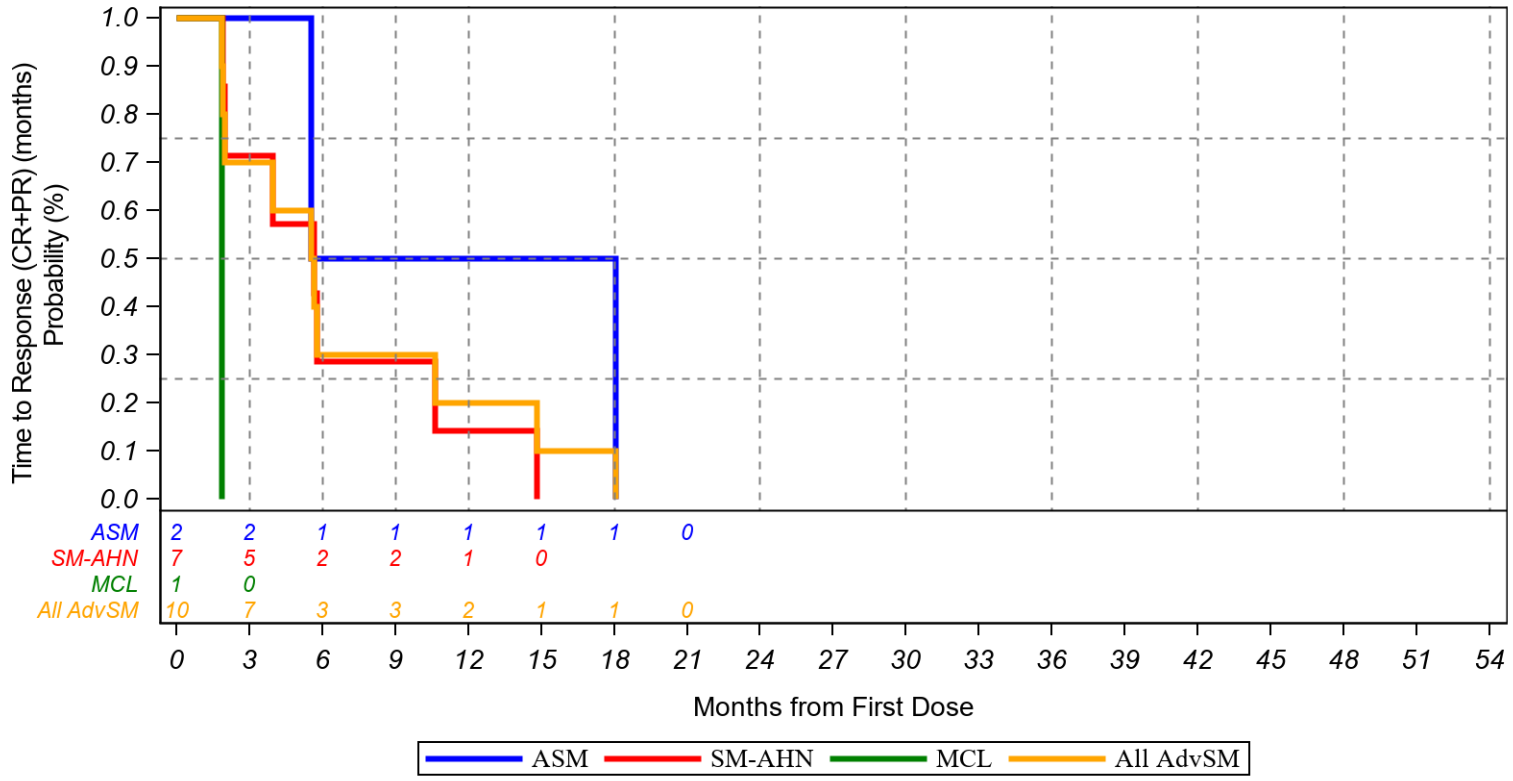


Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg



Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/f-alg-t2rs-rac.sas
Date: 7:56/14OCT2021

Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg



Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/f-alg-t2rs-rac.sas
Date: 7:56/14OCT2021

Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg

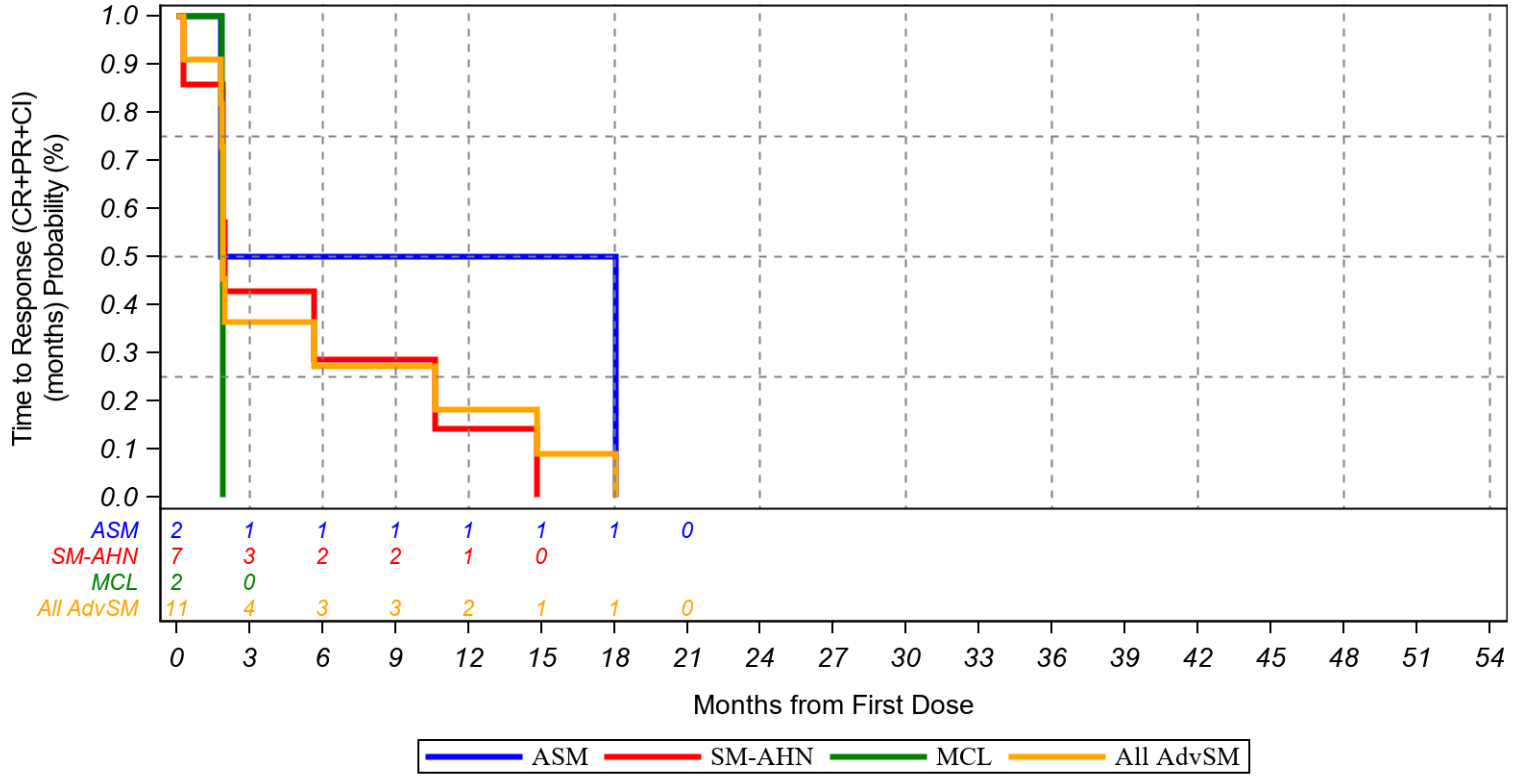
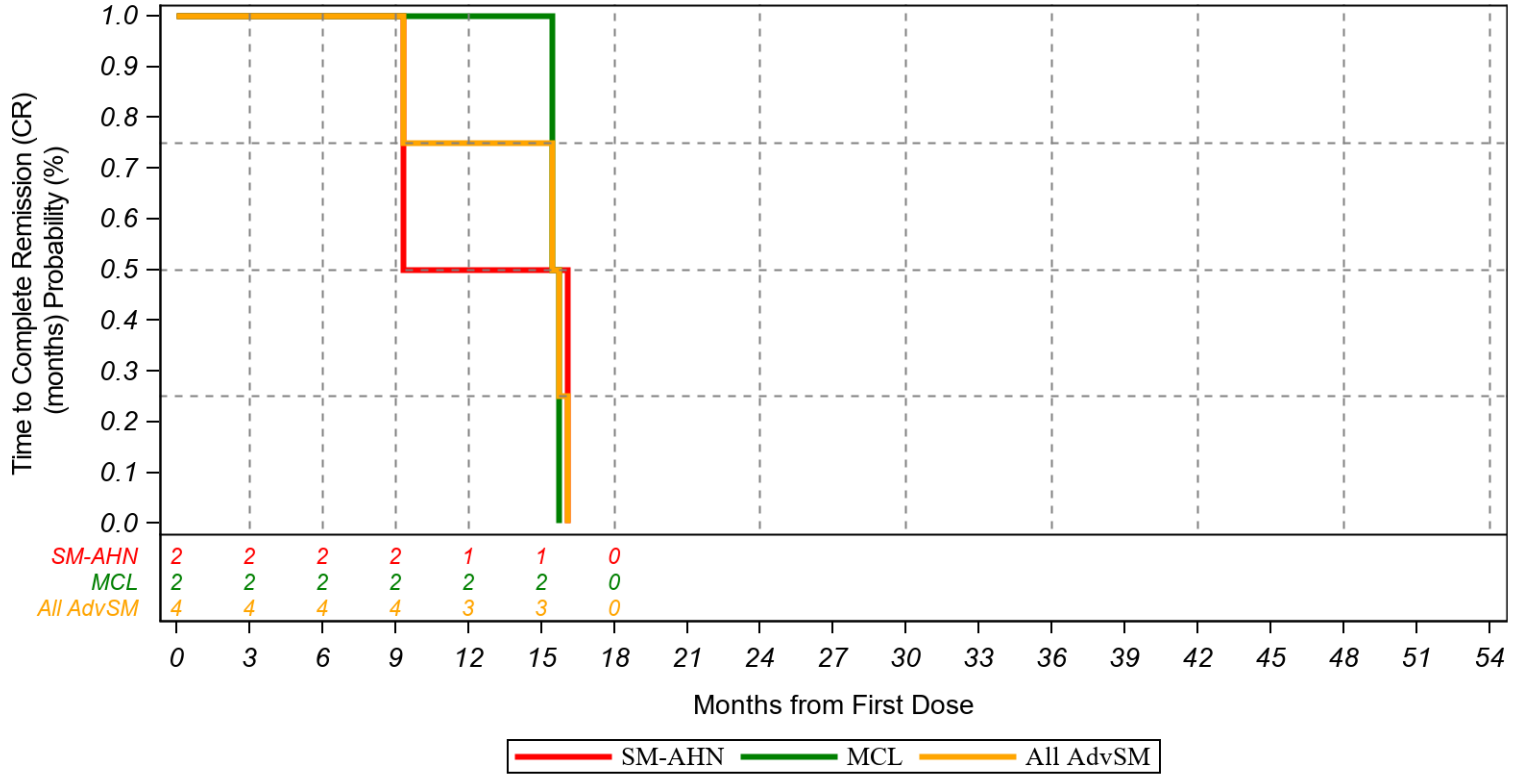


Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg



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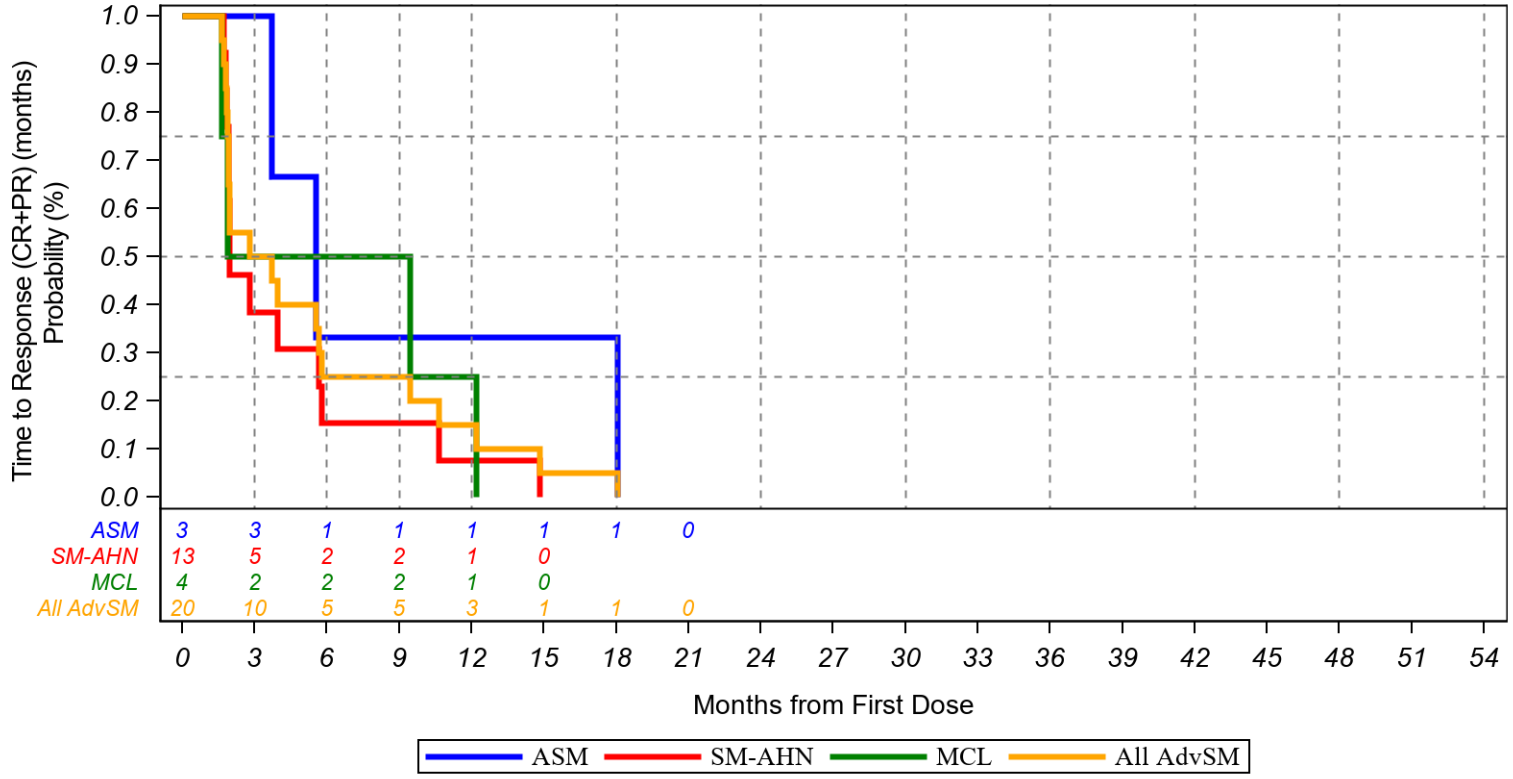
Date: 7:56/14OCT2021

Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg



Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/f-alg-t2rs-rac.sas
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Blueprint Medicines Corporation
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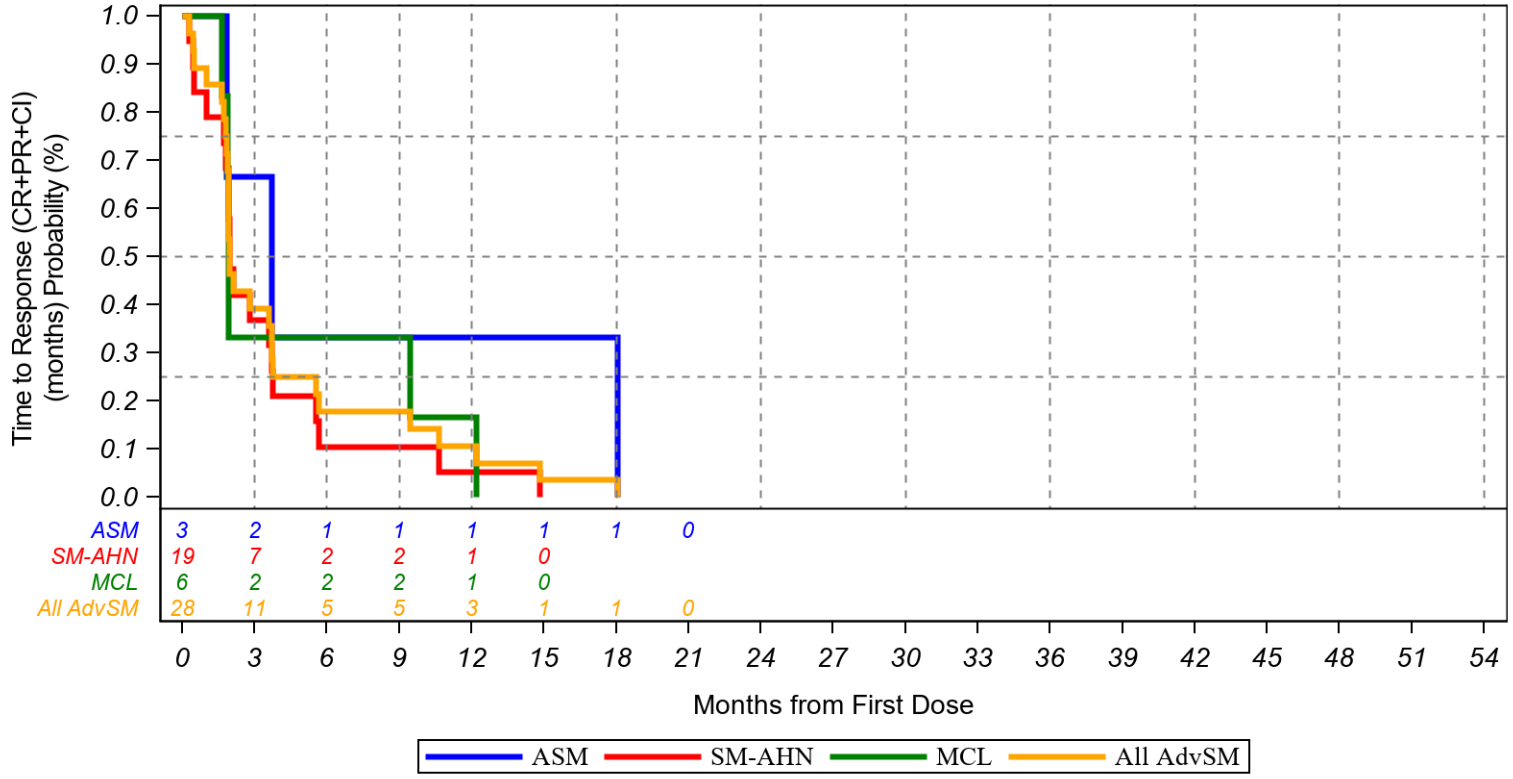
Avapritinib Systemic Mastocytosis Integrated Summary of Efficacy
BLU-285 SM Germany HTA Analysis
Cutoff date: 27may2020 (2101), 23jun2020 (2202)

Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg



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Date: 7:56/14OCT2021

Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg

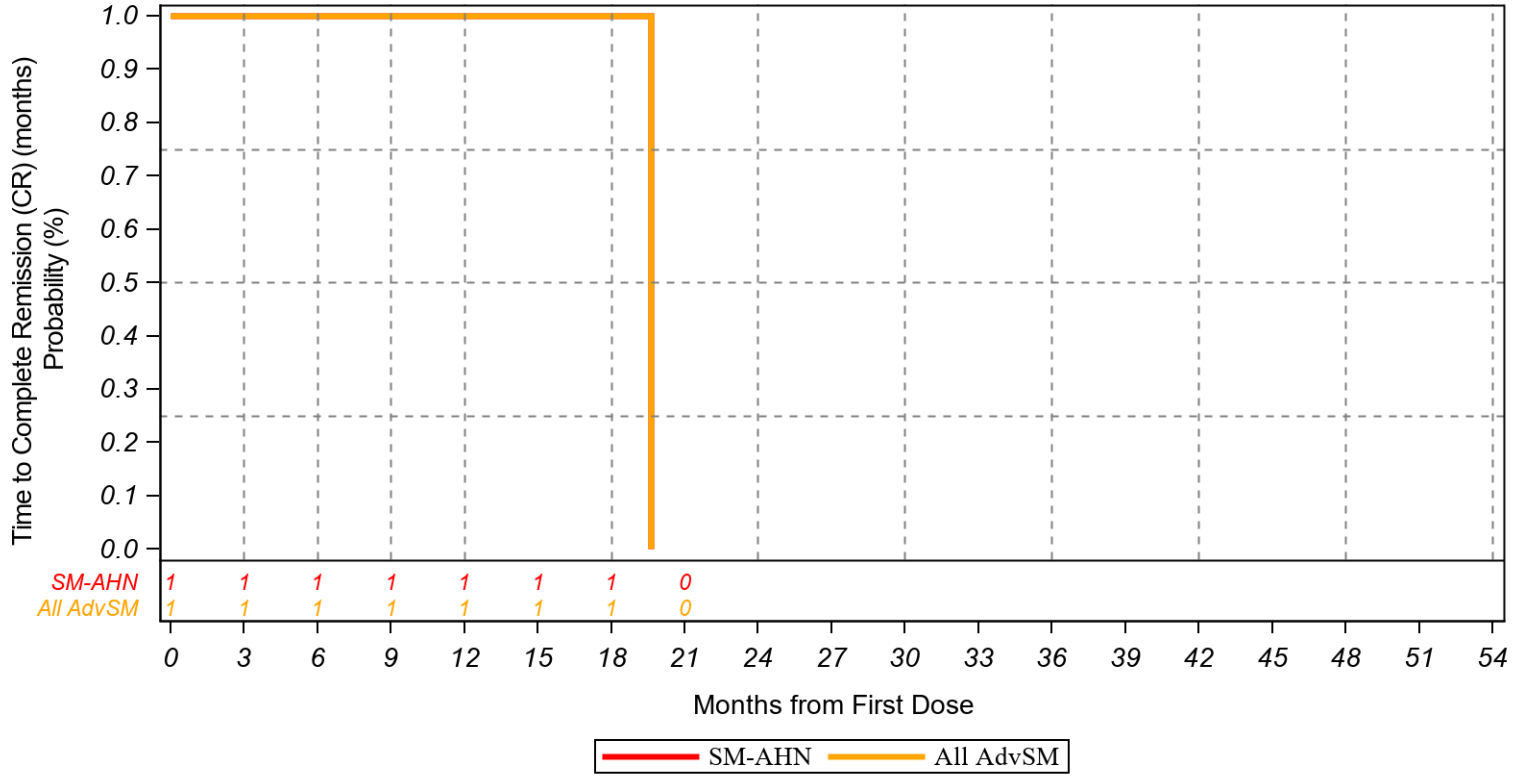
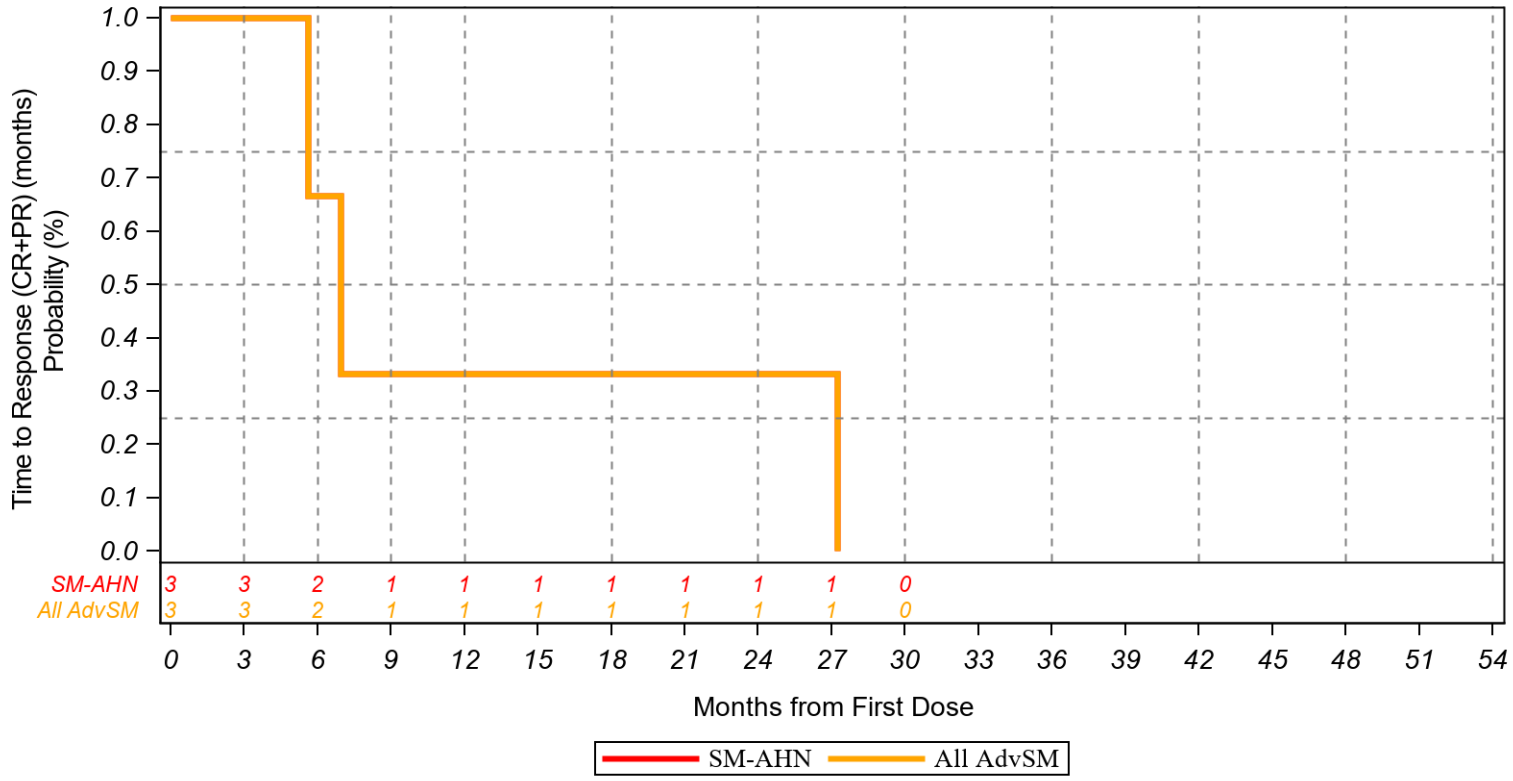


Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg



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Date: 7:56/14OCT2021

Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg

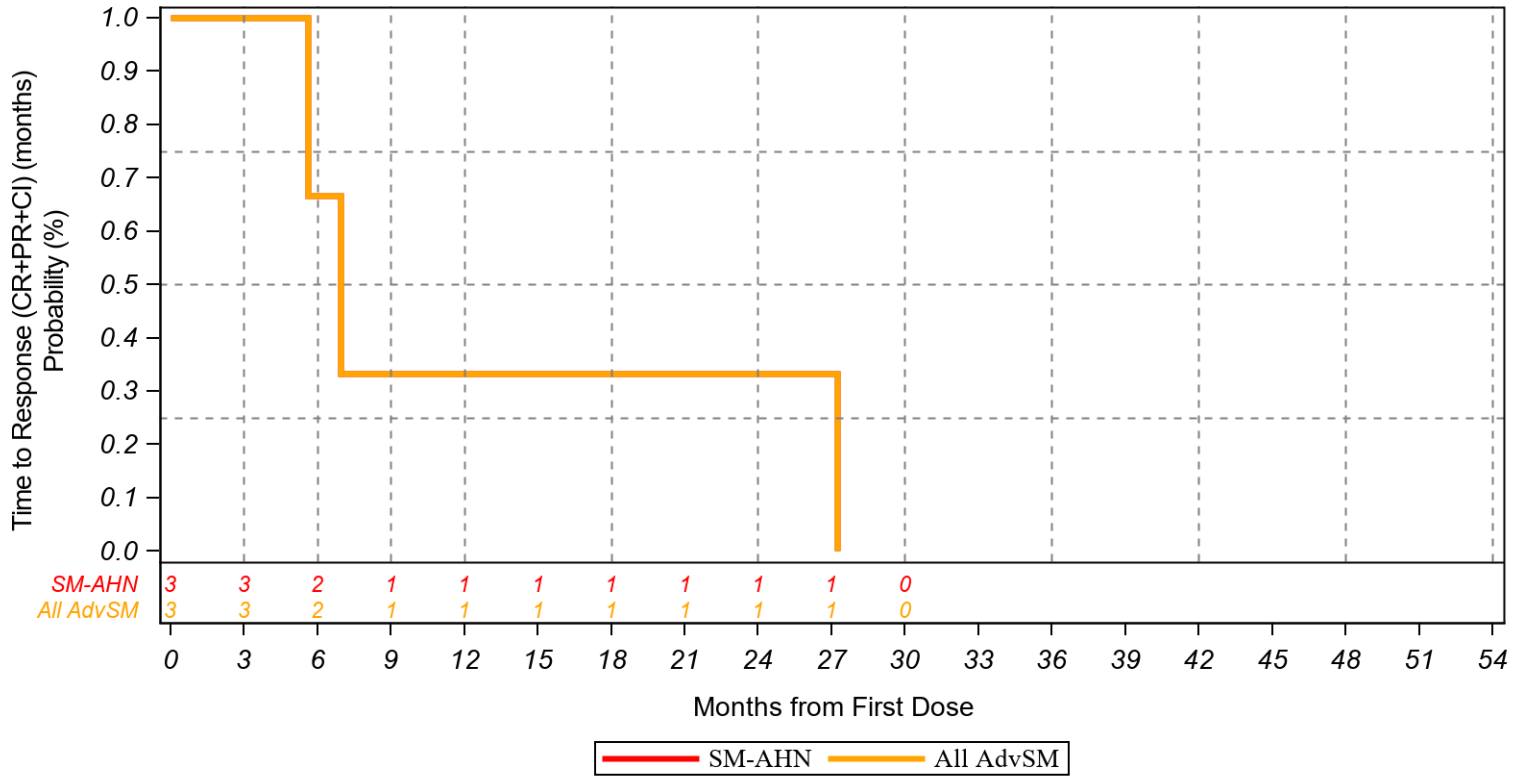


Table 35.2.3.1
Summary of Adjudicated Progression Free Survival by Modified IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Progression Free Survival	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=22) n (%) (95% CIs)	MCL (N=8) n (%) (95% CIs)	All AdvSM (N=32) n (%) (95% CIs)
Events	0	6 (27.3)	1 (12.5)	7 (21.9)
Censors	2 (100.0)	16 (72.7)	7 (87.5)	25 (78.1)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (NE -NE)	NE (31.2 -NE)	NE (31.2 -NE)
25th, 75th percentiles	NE, NE	13.5, NE	31.2, NE	31.2, NE
Min, Max	27.4*, 29.6*	2.7, 50.3*	7.4*, 45.4*	2.7, 50.3*
3 Months (95% CIs)	100.0 (100.0 -100.0)	95.5 (86.8 -100.0)	100.0 (100.0 -100.0)	96.9 (90.8 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	90.7 (78.4 -100.0)	100.0 (100.0 -100.0)	93.6 (85.1 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	85.9 (71.1 -100.0)	100.0 (100.0 -100.0)	90.3 (79.9 -100.0)
12 Months (95% CIs)	100.0 (100.0 -100.0)	81.1 (64.5 - 97.8)	100.0 (100.0 -100.0)	86.7 (74.5 - 98.9)
18 Months (95% CIs)	100.0 (100.0 -100.0)	71.0 (51.4 - 90.6)	100.0 (100.0 -100.0)	79.2 (64.2 - 94.1)
24 Months (95% CIs)	100.0 (100.0 -100.0)	71.0 (51.4 - 90.6)	100.0 (100.0 -100.0)	79.2 (64.2 - 94.1)
30 Months (95% CIs)		71.0 (51.4 - 90.6)	100.0 (100.0 -100.0)	79.2 (64.2 - 94.1)
36 Months (95% CIs)		71.0 (51.4 - 90.6)	50.0 (0.0 -100.0)	67.8 (43.7 - 92.0)
42 Months (95% CIs)		71.0 (51.4 - 90.6)	50.0 (0.0 -100.0)	67.8 (43.7 - 92.0)
48 Months (95% CIs)		71.0 (51.4 - 90.6)		67.8 (43.7 - 92.0)
Median PFS Follow-up[a] (months) (95% CI)	28.5 (27.4 - 29.6)	24.1 (15.4 - 34.6)	16.8 (8.2 - 45.4)	24.1 (15.4 - 29.6)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-adj-m-pfs-rac.sas Date: 16:26/27SEP2021

Table 35.2.3.1
Summary of Adjudicated Progression Free Survival by Modified IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: < 200 mg

Progression Free Survival	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=2) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=3) n (%) (95% CIs)
Events		0	0	0
Censors		2 (100.0)	1 (100.0)	3 (100.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE -NE)	NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles		NE, NE	NE, NE	NE, NE
Min, Max		41.8*, 50.3*	45.4*, 45.4*	41.8*, 50.3*
3 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
12 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
18 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
24 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
30 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
36 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
42 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
48 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
Median PFS Follow-up[a] (months) (95% CI)		46.0 (41.8 - 50.3)	45.4 (NE -NE)	45.4 (41.8 - 50.3)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-adj-m-pfs-rac.sas Date: 16:26/27SEP2021

Table 35.2.3.1
Summary of Adjudicated Progression Free Survival by Modified IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: < 300 mg

Progression Free Survival	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=7) n (%) (95% CIs)	MCL (N=5) n (%) (95% CIs)	All AdvSM (N=12) n (%) (95% CIs)
Events		3 (42.9)	0	3 (25.0)
Censors		4 (57.1)	5 (100.0)	9 (75.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (8.0 -NE)	NE (NE -NE)	NE (13.0 -NE)
25th, 75th percentiles		8.0, NE	NE, NE	13.0, NE
Min, Max		2.7, 50.3*	8.2*, 45.4*	2.7, 50.3*
3 Months (95% CIs)		85.7 (59.8 -100.0)	100.0 (100.0 -100.0)	91.7 (76.0 -100.0)
6 Months (95% CIs)		85.7 (59.8 -100.0)	100.0 (100.0 -100.0)	91.7 (76.0 -100.0)
9 Months (95% CIs)		71.4 (38.0 -100.0)	100.0 (100.0 -100.0)	83.3 (62.2 -100.0)
12 Months (95% CIs)		71.4 (38.0 -100.0)	100.0 (100.0 -100.0)	83.3 (62.2 -100.0)
18 Months (95% CIs)		57.1 (20.5 - 93.8)	100.0 (100.0 -100.0)	72.9 (46.4 - 99.5)
24 Months (95% CIs)		57.1 (20.5 - 93.8)	100.0 (100.0 -100.0)	72.9 (46.4 - 99.5)
30 Months (95% CIs)		57.1 (20.5 - 93.8)	100.0 (100.0 -100.0)	72.9 (46.4 - 99.5)
36 Months (95% CIs)		57.1 (20.5 - 93.8)	100.0 (100.0 -100.0)	72.9 (46.4 - 99.5)
42 Months (95% CIs)		57.1 (20.5 - 93.8)	100.0 (100.0 -100.0)	72.9 (46.4 - 99.5)
48 Months (95% CIs)		57.1 (20.5 - 93.8)		72.9 (46.4 - 99.5)
Median PFS Follow-up[a] (months) (95% CI)		39.8 (15.4 - 50.3)	14.7 (8.2 - 45.4)	19.0 (14.7 - 45.4)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-adj-m-pfs-rac.sas Date: 16:26/27SEP2021

Table 35.2.3.1
Summary of Adjudicated Progression Free Survival by Modified IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Progression Free Survival	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=5) n (%) (95% CIs)	MCL (N=4) n (%) (95% CIs)	All AdvSM (N=9) n (%) (95% CIs)
Events		3 (60.0)	0	3 (33.3)
Censors		2 (40.0)	4 (100.0)	6 (66.7)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		13.0 (2.7 -NE)	NE (NE -NE)	NE (13.0 -NE)
25th, 75th percentiles		8.0, NE	NE, NE	13.0, NE
Min, Max		2.7, 37.7*	8.2*, 19.0*	2.7, 37.7*
3 Months (95% CIs)		80.0 (44.9 -100.0)	100.0 (100.0 -100.0)	88.9 (68.4 -100.0)
6 Months (95% CIs)		80.0 (44.9 -100.0)	100.0 (100.0 -100.0)	88.9 (68.4 -100.0)
9 Months (95% CIs)		60.0 (17.1 -100.0)	100.0 (100.0 -100.0)	77.8 (50.6 -100.0)
12 Months (95% CIs)		60.0 (17.1 -100.0)	100.0 (100.0 -100.0)	77.8 (50.6 -100.0)
18 Months (95% CIs)		40.0 (0.0 - 82.9)	100.0 (100.0 -100.0)	62.2 (27.4 - 97.1)
24 Months (95% CIs)		40.0 (0.0 - 82.9)		62.2 (27.4 - 97.1)
30 Months (95% CIs)		40.0 (0.0 - 82.9)		62.2 (27.4 - 97.1)
36 Months (95% CIs)		40.0 (0.0 - 82.9)		62.2 (27.4 - 97.1)
42 Months (95% CIs)				
48 Months (95% CIs)				
Median PFS Follow-up[a] (months) (95% CI)		26.6 (15.4 - 37.7)	11.6 (8.2 - 19.0)	15.4 (8.5 - 19.0)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-adj-m-pfs-rac.sas Date: 16:26/27SEP2021

Table 35.2.3.1
Summary of Adjudicated Progression Free Survival by Modified IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 300 mg

Progression Free Survival	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=11) n (%) (95% CIs)	MCL (N=3) n (%) (95% CIs)	All AdvSM (N=16) n (%) (95% CIs)
Events	0	3 (27.3)	1 (33.3)	4 (25.0)
Censors	2 (100.0)	8 (72.7)	2 (66.7)	12 (75.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (13.5 -NE)	31.2 (NE -NE)	31.2 (NE -NE)
25th, 75th percentiles	NE, NE	13.5, NE	31.2, 31.2	31.2, 31.2
Min, Max	27.4*, 29.6*	4.8, 29.5*	7.4*, 31.2	4.8, 31.2
3 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	90.9 (73.9 -100.0)	100.0 (100.0 -100.0)	93.8 (81.9 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	90.9 (73.9 -100.0)	100.0 (100.0 -100.0)	93.8 (81.9 -100.0)
12 Months (95% CIs)	100.0 (100.0 -100.0)	81.8 (59.0 -100.0)	100.0 (100.0 -100.0)	87.1 (70.3 -100.0)
18 Months (95% CIs)	100.0 (100.0 -100.0)	71.6 (44.2 - 99.0)	100.0 (100.0 -100.0)	79.8 (59.3 -100.0)
24 Months (95% CIs)	100.0 (100.0 -100.0)	71.6 (44.2 - 99.0)	100.0 (100.0 -100.0)	79.8 (59.3 -100.0)
30 Months (95% CIs)			100.0 (100.0 -100.0)	79.8 (59.3 -100.0)
36 Months (95% CIs)			0.0 (0.0 - 0.0)	0.0 (0.0 - 0.0)
42 Months (95% CIs)			0.0 (0.0 - 0.0)	0.0 (0.0 - 0.0)
48 Months (95% CIs)			0.0 (0.0 - 0.0)	0.0 (0.0 - 0.0)
Median PFS Follow-up[a] (months) (95% CI)	28.5 (27.4 - 29.6)	22.3 (15.0 - 27.0)	30.2 (7.4 -NE)	24.1 (17.6 - 29.5)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-adj-m-pfs-rac.sas Date: 16:26/27SEP2021

Table 35.2.3.1
Summary of Adjudicated Progression Free Survival by Modified IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg and 300 mg

Progression Free Survival	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=16) n (%) (95% CIs)	MCL (N=7) n (%) (95% CIs)	All AdvSM (N=25) n (%) (95% CIs)
Events	0	6 (37.5)	1 (14.3)	7 (28.0)
Censors	2 (100.0)	10 (62.5)	6 (85.7)	18 (72.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (13.0 -NE)	31.2 (NE -NE)	31.2 (31.2 -NE)
25th, 75th percentiles	NE, NE	11.2, NE	31.2, 31.2	13.5, NE
Min, Max	27.4*, 29.6*	2.7, 37.7*	7.4*, 31.2	2.7, 37.7*
3 Months (95% CIs)	100.0 (100.0 -100.0)	93.8 (81.9 -100.0)	100.0 (100.0 -100.0)	96.0 (88.3 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	87.5 (71.3 -100.0)	100.0 (100.0 -100.0)	92.0 (81.4 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	81.3 (62.1 -100.0)	100.0 (100.0 -100.0)	87.8 (74.9 -100.0)
12 Months (95% CIs)	100.0 (100.0 -100.0)	75.0 (53.8 - 96.2)	100.0 (100.0 -100.0)	83.2 (68.1 - 98.3)
18 Months (95% CIs)	100.0 (100.0 -100.0)	61.4 (37.0 - 85.7)	100.0 (100.0 -100.0)	73.4 (55.0 - 91.8)
24 Months (95% CIs)	100.0 (100.0 -100.0)	61.4 (37.0 - 85.7)	100.0 (100.0 -100.0)	73.4 (55.0 - 91.8)
30 Months (95% CIs)		61.4 (37.0 - 85.7)	100.0 (100.0 -100.0)	73.4 (55.0 - 91.8)
36 Months (95% CIs)		61.4 (37.0 - 85.7)	0.0 (0.0 - 0.0)	36.7 (0.0 - 88.4)
42 Months (95% CIs)			0.0 (0.0 - 0.0)	
48 Months (95% CIs)			0.0 (0.0 - 0.0)	
Median PFS Follow-up[a] (months) (95% CI)	28.5 (27.4 - 29.6)	22.3 (15.4 - 27.0)	14.7 (8.2 - 30.2)	21.4 (15.4 - 27.4)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-adj-m-pfs-rac.sas Date: 16:26/27SEP2021

Table 35.2.3.1
Summary of Adjudicated Progression Free Survival by Modified IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 400 mg

Progression Free Survival	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=4) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=4) n (%) (95% CIs)
Events		0		0
Censors		4 (100.0)		4 (100.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE -NE)		NE (NE -NE)
25th, 75th percentiles		NE, NE		NE, NE
Min, Max		4.3*, 37.8*		4.3*, 37.8*
3 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
6 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
9 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
12 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
18 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
24 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
30 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
36 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
42 Months (95% CIs)				
48 Months (95% CIs)				
Median PFS Follow-up[a] (months) (95% CI)		24.9 (4.3 - 37.8)		24.9 (4.3 - 37.8)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-adj-m-pfs-rac.sas Date: 16:26/27SEP2021

Table 35.2.3.1
Summary of Adjudicated Progression Free Survival by Modified IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Progression Free Survival	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=18) n (%) (95% CIs)	MCL (N=4) n (%) (95% CIs)	All AdvSM (N=23) n (%) (95% CIs)
Events	0	3 (16.7)	2 (50.0)	5 (21.7)
Censors	1 (100.0)	15 (83.3)	2 (50.0)	18 (78.3)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (NE -NE)	10.5 (2.1 -NE)	NE (10.5 -NE)
25th, 75th percentiles	NE, NE	NE, NE	6.3, NE	10.5, NE
Min, Max	8.7*, 8.7*	0.3, 17.6*	2.1, 16.1*	0.3, 17.6*
3 Months (95% CIs)	100.0 (100.0 -100.0)	94.4 (83.9 -100.0)	75.0 (32.6 -100.0)	91.3 (79.8 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	88.9 (74.4 -100.0)	75.0 (32.6 -100.0)	87.0 (73.2 -100.0)
9 Months (95% CIs)		83.0 (65.4 -100.0)	75.0 (32.6 -100.0)	82.1 (66.2 - 98.1)
12 Months (95% CIs)		83.0 (65.4 -100.0)	37.5 (0.0 - 93.6)	70.4 (45.1 - 95.7)
18 Months (95% CIs)				
24 Months (95% CIs)				
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				
Median PFS Follow-up[a] (months) (95% CI)	8.7 (NE -NE)	10.2 (7.9 - 11.8)	16.1 (4.4 - 16.1)	10.2 (7.9 - 13.7)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-adj-m-pfs-rac.sas Date: 16:26/27SEP2021

Table 35.2.3.1
Summary of Adjudicated Progression Free Survival by Modified IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Progression Free Survival	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=17) n (%) (95% CIs)	MCL (N=4) n (%) (95% CIs)	All AdvSM (N=22) n (%) (95% CIs)
Events	0	3 (17.6)	2 (50.0)	5 (22.7)
Censors	1 (100.0)	14 (82.4)	2 (50.0)	17 (77.3)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (NE -NE)	10.5 (2.1 -NE)	NE (10.5 -NE)
25th, 75th percentiles	NE, NE	NE, NE	6.3, NE	10.5, NE
Min, Max	8.7*, 8.7*	0.3, 17.6*	2.1, 16.1*	0.3, 17.6*
3 Months (95% CIs)	100.0 (100.0 -100.0)	94.1 (82.9 -100.0)	75.0 (32.6 -100.0)	90.9 (78.9 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	88.2 (72.9 -100.0)	75.0 (32.6 -100.0)	86.4 (72.0 -100.0)
9 Months (95% CIs)		81.9 (63.4 -100.0)	75.0 (32.6 -100.0)	81.3 (64.7 - 97.9)
12 Months (95% CIs)		81.9 (63.4 -100.0)	37.5 (0.0 - 93.6)	67.7 (39.8 - 95.6)
18 Months (95% CIs)				
24 Months (95% CIs)				
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				
Median PFS Follow-up[a] (months) (95% CI)	8.7 (NE -NE)	10.2 (7.4 - 13.7)	16.1 (4.4 - 16.1)	10.2 (7.9 - 13.7)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-adj-m-pfs-rac.sas Date: 16:26/27SEP2021

Table 35.2.3.1
Summary of Adjudicated Progression Free Survival by Modified IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Progression Free Survival	ASM (N=3) n (%) (95% CIs)	SM-AHN (N=40) n (%) (95% CIs)	MCL (N=12) n (%) (95% CIs)	All AdvSM (N=55) n (%) (95% CIs)
Events	0	9 (22.5)	3 (25.0)	12 (21.8)
Censors	3 (100.0)	31 (77.5)	9 (75.0)	43 (78.2)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (NE -NE)	31.2 (31.2 -NE)	NE (31.2 -NE)
25th, 75th percentiles	NE, NE	13.5, NE	31.2, NE	31.2, NE
Min, Max	8.7*, 29.6*	0.3, 50.3*	2.1, 45.4*	0.3, 50.3*
3 Months (95% CIs)	100.0 (100.0 -100.0)	95.0 (88.2 -100.0)	91.7 (76.0 -100.0)	94.5 (88.5 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	89.9 (80.6 - 99.3)	91.7 (76.0 -100.0)	90.8 (83.2 - 98.5)
9 Months (95% CIs)	100.0 (100.0 -100.0)	84.3 (72.7 - 95.9)	91.7 (76.0 -100.0)	86.7 (77.5 - 95.9)
12 Months (95% CIs)	100.0 (100.0 -100.0)	81.2 (68.5 - 93.8)	78.6 (51.3 -100.0)	81.6 (70.5 - 92.7)
18 Months (95% CIs)	100.0 (100.0 -100.0)	73.0 (57.4 - 88.7)	78.6 (51.3 -100.0)	75.8 (62.9 - 88.7)
24 Months (95% CIs)	100.0 (100.0 -100.0)	73.0 (57.4 - 88.7)	78.6 (51.3 -100.0)	75.8 (62.9 - 88.7)
30 Months (95% CIs)		73.0 (57.4 - 88.7)	78.6 (51.3 -100.0)	75.8 (62.9 - 88.7)
36 Months (95% CIs)		73.0 (57.4 - 88.7)	39.3 (0.0 - 95.4)	65.0 (42.4 - 87.5)
42 Months (95% CIs)		73.0 (57.4 - 88.7)	39.3 (0.0 - 95.4)	65.0 (42.4 - 87.5)
48 Months (95% CIs)		73.0 (57.4 - 88.7)		65.0 (42.4 - 87.5)
Median PFS Follow-up[a] (months) (95% CI)	27.4 (8.7 - 29.6)	15.4 (10.6 - 21.4)	16.1 (8.2 - 30.2)	15.7 (11.8 - 21.4)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-adj-m-pfs-rac.sas Date: 16:26/27SEP2021

Table 35.2.3.1
Summary of Adjudicated Progression Free Survival by Modified IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: < 200 mg

Progression Free Survival	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=3) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=4) n (%) (95% CIs)
Events		0	0	0
Censors		3 (100.0)	1 (100.0)	4 (100.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE -NE)	NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles		NE, NE	NE, NE	NE, NE
Min, Max		11.8*, 50.3*	45.4*, 45.4*	11.8*, 50.3*
3 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
12 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
18 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
24 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
30 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
36 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
42 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
48 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
Median PFS Follow-up[a] (months) (95% CI)		41.8 (11.8 - 50.3)	45.4 (NE -NE)	43.6 (11.8 - 50.3)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-adj-m-pfs-rac.sas Date: 16:26/27SEP2021

Table 35.2.3.1
Summary of Adjudicated Progression Free Survival by Modified IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: < 300 mg

Progression Free Survival	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=25) n (%) (95% CIs)	MCL (N=9) n (%) (95% CIs)	All AdvSM (N=35) n (%) (95% CIs)
Events	0	6 (24.0)	2 (22.2)	8 (22.9)
Censors	1 (100.0)	19 (76.0)	7 (77.8)	27 (77.1)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (13.0 -NE)	NE (10.5 -NE)	NE (NE -NE)
25th, 75th percentiles	NE, NE	13.0, NE	10.5, NE	13.0, NE
Min, Max	8.7*, 8.7*	0.3, 50.3*	2.1, 45.4*	0.3, 50.3*
3 Months (95% CIs)	100.0 (100.0 -100.0)	92.0 (81.4 -100.0)	88.9 (68.4 -100.0)	91.4 (82.2 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	88.0 (75.3 -100.0)	88.9 (68.4 -100.0)	88.6 (78.0 - 99.1)
9 Months (95% CIs)		78.6 (61.7 - 95.4)	88.9 (68.4 -100.0)	82.0 (68.8 - 95.1)
12 Months (95% CIs)		78.6 (61.7 - 95.4)	71.1 (35.9 -100.0)	76.5 (60.4 - 92.6)
18 Months (95% CIs)		69.8 (47.8 - 91.9)	71.1 (35.9 -100.0)	70.6 (52.1 - 89.1)
24 Months (95% CIs)		69.8 (47.8 - 91.9)	71.1 (35.9 -100.0)	70.6 (52.1 - 89.1)
30 Months (95% CIs)		69.8 (47.8 - 91.9)	71.1 (35.9 -100.0)	70.6 (52.1 - 89.1)
36 Months (95% CIs)		69.8 (47.8 - 91.9)	71.1 (35.9 -100.0)	70.6 (52.1 - 89.1)
42 Months (95% CIs)		69.8 (47.8 - 91.9)	71.1 (35.9 -100.0)	70.6 (52.1 - 89.1)
48 Months (95% CIs)		69.8 (47.8 - 91.9)		70.6 (52.1 - 89.1)
Median PFS Follow-up[a] (months) (95% CI)	8.7 (NE -NE)	11.8 (9.7 - 15.7)	14.7 (8.2 - 19.0)	11.8 (8.7 - 15.8)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-adj-m-pfs-rac.sas Date: 16:26/27SEP2021

Table 35.2.3.1
Summary of Adjudicated Progression Free Survival by Modified IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Progression Free Survival	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=22) n (%) (95% CIs)	MCL (N=8) n (%) (95% CIs)	All AdvSM (N=31) n (%) (95% CIs)
Events	0	6 (27.3)	2 (25.0)	8 (25.8)
Censors	1 (100.0)	16 (72.7)	6 (75.0)	23 (74.2)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (13.0 -NE)	NE (10.5 -NE)	NE (13.0 -NE)
25th, 75th percentiles	NE, NE	13.0, NE	10.5, NE	10.5, NE
Min, Max	8.7*, 8.7*	0.3, 37.7*	2.1, 19.0*	0.3, 37.7*
3 Months (95% CIs)	100.0 (100.0 -100.0)	90.9 (78.9 -100.0)	87.5 (64.6 -100.0)	90.3 (79.9 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	86.4 (72.0 -100.0)	87.5 (64.6 -100.0)	87.1 (75.3 - 98.9)
9 Months (95% CIs)		75.3 (56.1 - 94.4)	87.5 (64.6 -100.0)	79.4 (64.6 - 94.3)
12 Months (95% CIs)		75.3 (56.1 - 94.4)	65.6 (24.7 -100.0)	72.2 (53.1 - 91.3)
18 Months (95% CIs)		64.5 (39.0 - 90.0)	65.6 (24.7 -100.0)	65.0 (43.2 - 86.8)
24 Months (95% CIs)		64.5 (39.0 - 90.0)		65.0 (43.2 - 86.8)
30 Months (95% CIs)		64.5 (39.0 - 90.0)		65.0 (43.2 - 86.8)
36 Months (95% CIs)		64.5 (39.0 - 90.0)		65.0 (43.2 - 86.8)
42 Months (95% CIs)				
48 Months (95% CIs)				
Median PFS Follow-up[a] (months) (95% CI)	8.7 (NE -NE)	10.2 (8.0 - 15.7)	14.7 (8.2 - 19.0)	10.2 (8.5 - 15.4)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-adj-m-pfs-rac.sas Date: 16:26/27SEP2021

Table 35.2.3.1
Summary of Adjudicated Progression Free Survival by Modified IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg

Progression Free Survival	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=11) n (%) (95% CIs)	MCL (N=3) n (%) (95% CIs)	All AdvSM (N=16) n (%) (95% CIs)
Events	0	3 (27.3)	1 (33.3)	4 (25.0)
Censors	2 (100.0)	8 (72.7)	2 (66.7)	12 (75.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (13.5 -NE)	31.2 (NE -NE)	31.2 (NE -NE)
25th, 75th percentiles	NE, NE	13.5, NE	31.2, 31.2	31.2, 31.2
Min, Max	27.4*, 29.6*	4.8, 29.5*	7.4*, 31.2	4.8, 31.2
3 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	90.9 (73.9 -100.0)	100.0 (100.0 -100.0)	93.8 (81.9 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	90.9 (73.9 -100.0)	100.0 (100.0 -100.0)	93.8 (81.9 -100.0)
12 Months (95% CIs)	100.0 (100.0 -100.0)	81.8 (59.0 -100.0)	100.0 (100.0 -100.0)	87.1 (70.3 -100.0)
18 Months (95% CIs)	100.0 (100.0 -100.0)	71.6 (44.2 - 99.0)	100.0 (100.0 -100.0)	79.8 (59.3 -100.0)
24 Months (95% CIs)	100.0 (100.0 -100.0)	71.6 (44.2 - 99.0)	100.0 (100.0 -100.0)	79.8 (59.3 -100.0)
30 Months (95% CIs)			100.0 (100.0 -100.0)	79.8 (59.3 -100.0)
36 Months (95% CIs)			0.0 (0.0 - 0.0)	0.0 (0.0 - 0.0)
42 Months (95% CIs)			0.0 (0.0 - 0.0)	0.0 (0.0 - 0.0)
48 Months (95% CIs)			0.0 (0.0 - 0.0)	0.0 (0.0 - 0.0)
Median PFS Follow-up[a] (months) (95% CI)	28.5 (27.4 - 29.6)	22.3 (15.0 - 27.0)	30.2 (7.4 -NE)	24.1 (17.6 - 29.5)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-adj-m-pfs-rac.sas Date: 16:26/27SEP2021

Table 35.2.3.1
Summary of Adjudicated Progression Free Survival by Modified IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg

Progression Free Survival	ASM (N=3) n (%) (95% CIs)	SM-AHN (N=33) n (%) (95% CIs)	MCL (N=11) n (%) (95% CIs)	All AdvSM (N=47) n (%) (95% CIs)
Events	0	9 (27.3)	3 (27.3)	12 (25.5)
Censors	3 (100.0)	24 (72.7)	8 (72.7)	35 (74.5)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (13.5 -NE)	31.2 (10.5 - 31.2)	31.2 (31.2 -NE)
25th, 75th percentiles	NE, NE	13.0, NE	31.2, 31.2	13.0, NE
Min, Max	8.7*, 29.6*	0.3, 37.7*	2.1, 31.2	0.3, 37.7*
3 Months (95% CIs)	100.0 (100.0 -100.0)	93.9 (85.8 -100.0)	90.9 (73.9 -100.0)	93.6 (86.6 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	87.9 (76.7 - 99.0)	90.9 (73.9 -100.0)	89.3 (80.5 - 98.2)
9 Months (95% CIs)	100.0 (100.0 -100.0)	81.1 (67.3 - 94.8)	90.9 (73.9 -100.0)	84.5 (73.9 - 95.1)
12 Months (95% CIs)	100.0 (100.0 -100.0)	77.2 (62.2 - 92.2)	75.8 (45.2 -100.0)	78.2 (65.3 - 91.1)
18 Months (95% CIs)	100.0 (100.0 -100.0)	66.9 (48.3 - 85.5)	75.8 (45.2 -100.0)	71.1 (56.0 - 86.2)
24 Months (95% CIs)	100.0 (100.0 -100.0)	66.9 (48.3 - 85.5)	75.8 (45.2 -100.0)	71.1 (56.0 - 86.2)
30 Months (95% CIs)		66.9 (48.3 - 85.5)	75.8 (45.2 -100.0)	71.1 (56.0 - 86.2)
36 Months (95% CIs)		66.9 (48.3 - 85.5)	0.0 (0.0 - 0.0)	35.5 (0.0 - 85.4)
42 Months (95% CIs)			0.0 (0.0 - 0.0)	
48 Months (95% CIs)			0.0 (0.0 - 0.0)	
Median PFS Follow-up[a] (months) (95% CI)	27.4 (8.7 - 29.6)	15.0 (10.2 - 17.6)	14.7 (8.2 - 30.2)	15.4 (10.3 - 17.6)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-adj-m-pfs-rac.sas Date: 16:26/27SEP2021

Table 35.2.3.1
Summary of Adjudicated Progression Free Survival by Modified IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg

Progression Free Survival	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=4) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=4) n (%) (95% CIs)
Events		0		0
Censors		4 (100.0)		4 (100.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE -NE)		NE (NE -NE)
25th, 75th percentiles		NE, NE		NE, NE
Min, Max		4.3*, 37.8*		4.3*, 37.8*
3 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
6 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
9 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
12 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
18 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
24 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
30 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
36 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
42 Months (95% CIs)				
48 Months (95% CIs)				
Median PFS Follow-up[a] (months) (95% CI)		24.9 (4.3 - 37.8)		24.9 (4.3 - 37.8)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-adj-m-pfs-rac.sas Date: 16:26/27SEP2021

Figure 35.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101
Starting Dose: Overall

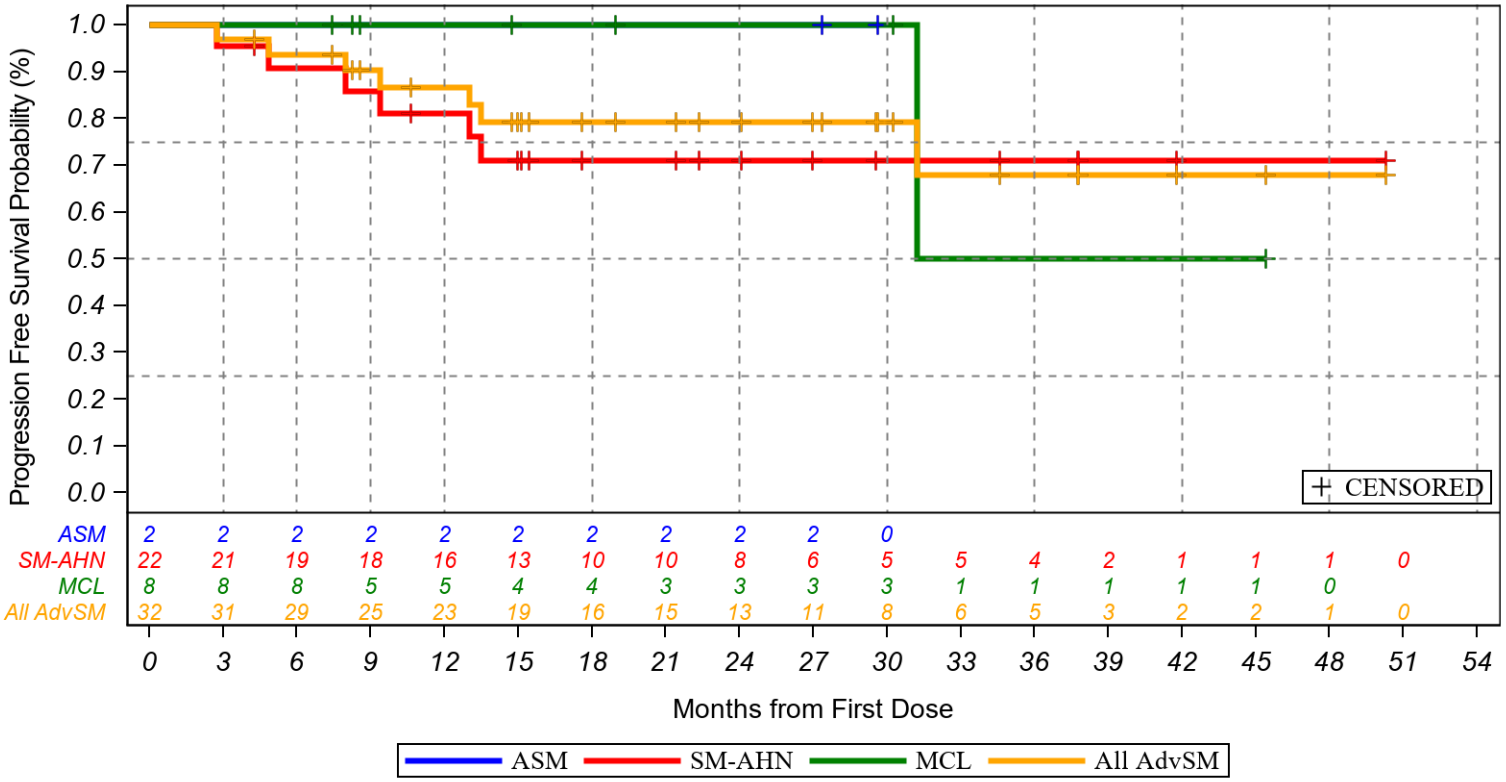


Figure 35.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101
Starting Dose: < 200 mg

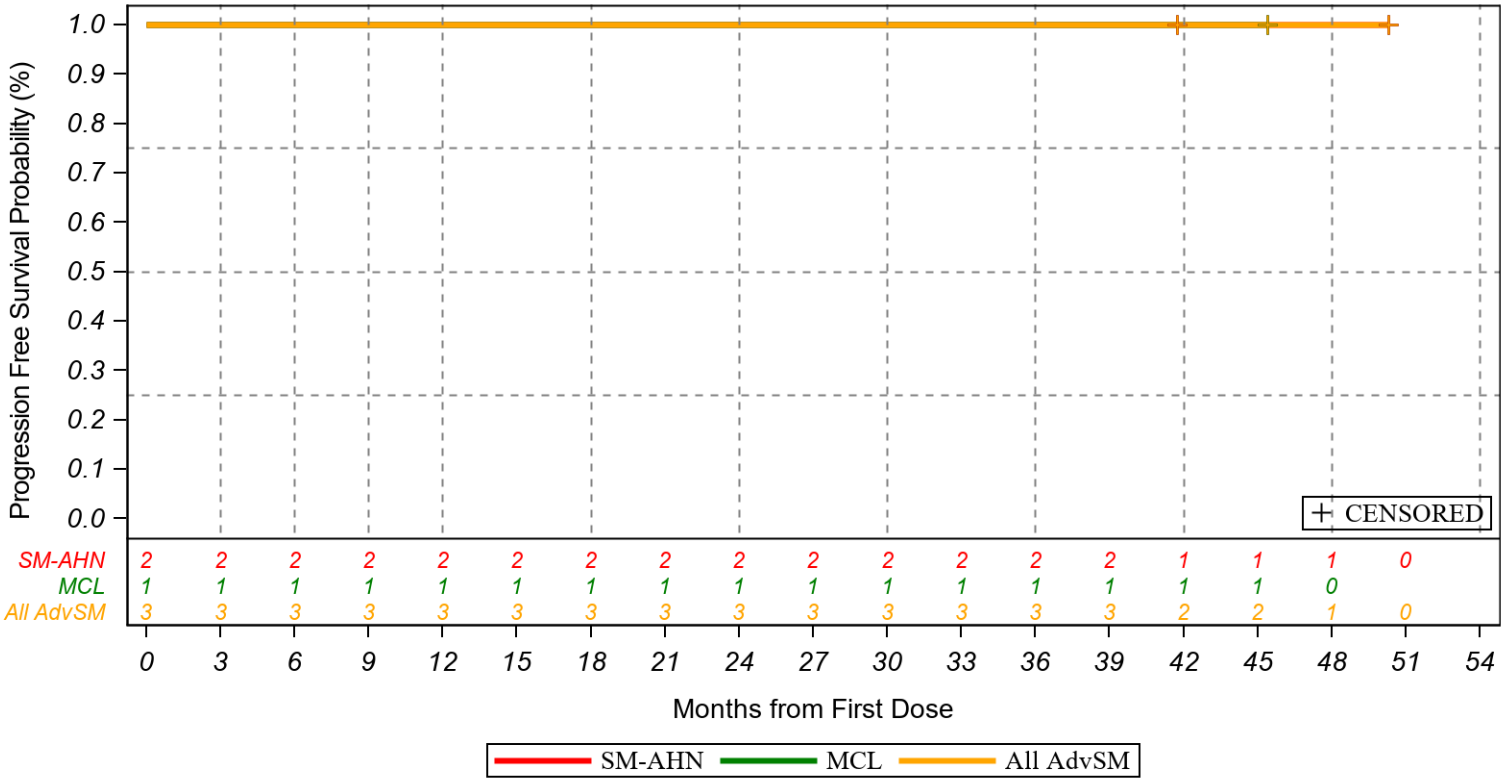


Figure 35.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101
Starting Dose: < 300 mg

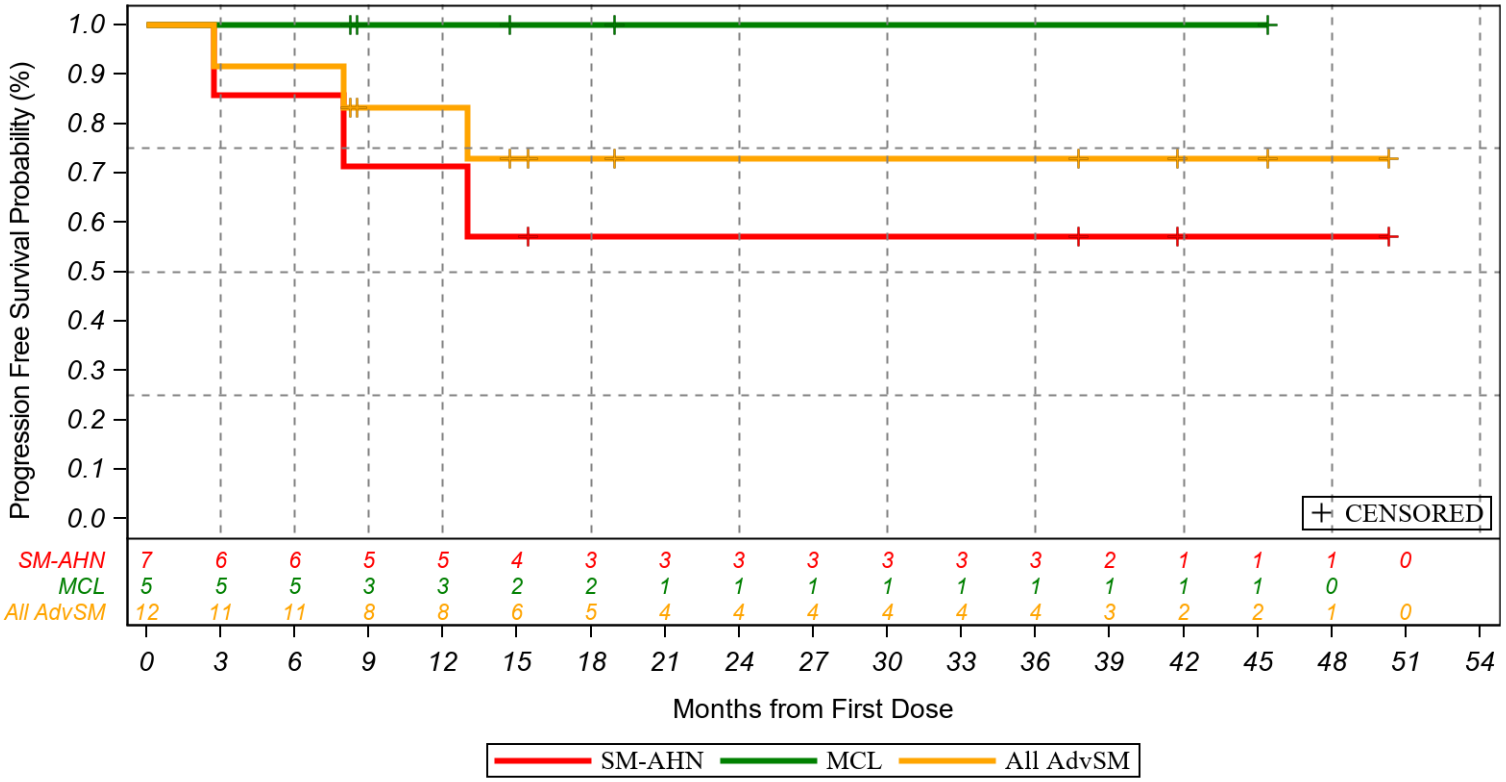


Figure 35.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101
Starting Dose: 200 mg

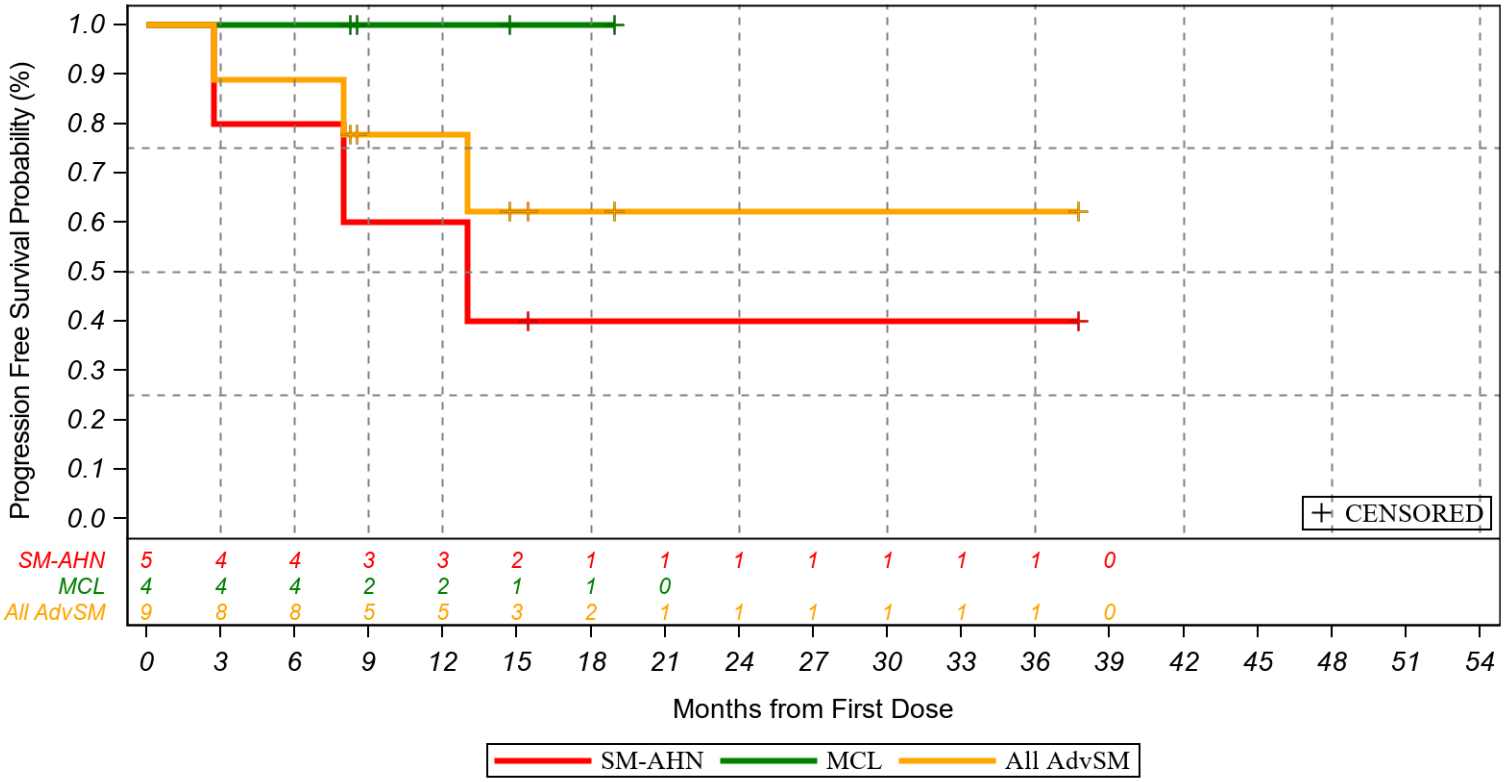


Figure 35.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101
Starting Dose: 300 mg

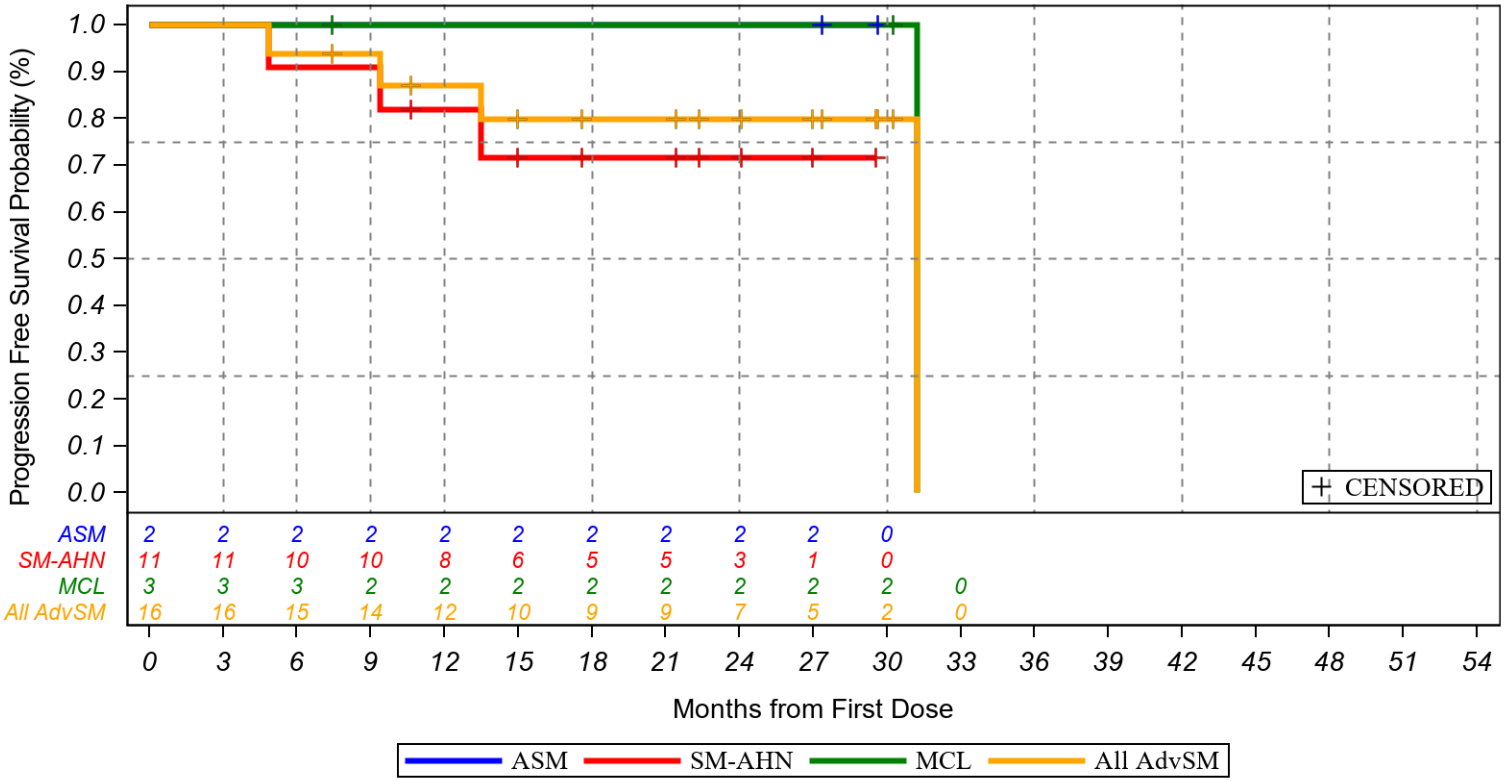


Figure 35.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101
Starting Dose: 200 mg and 300 mg

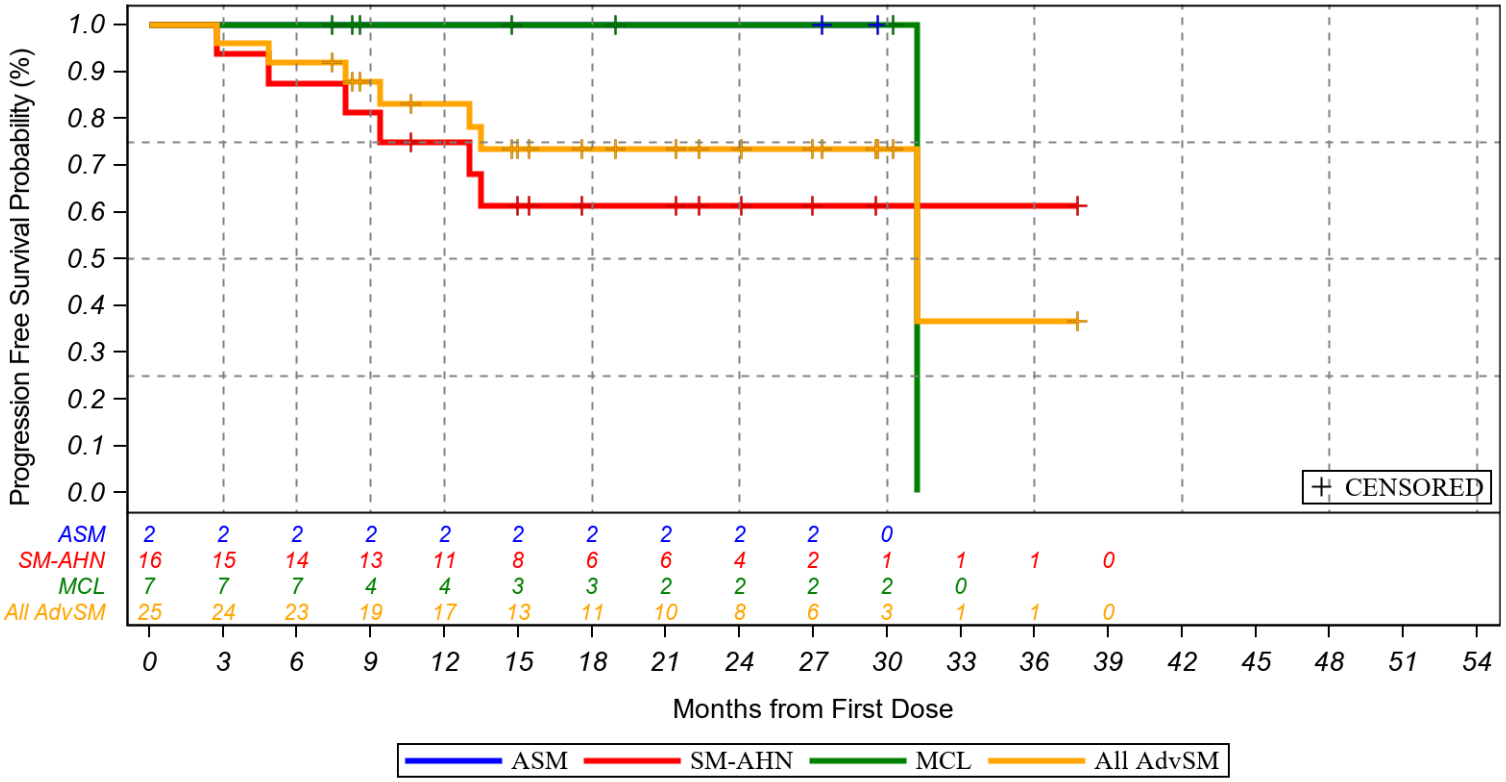
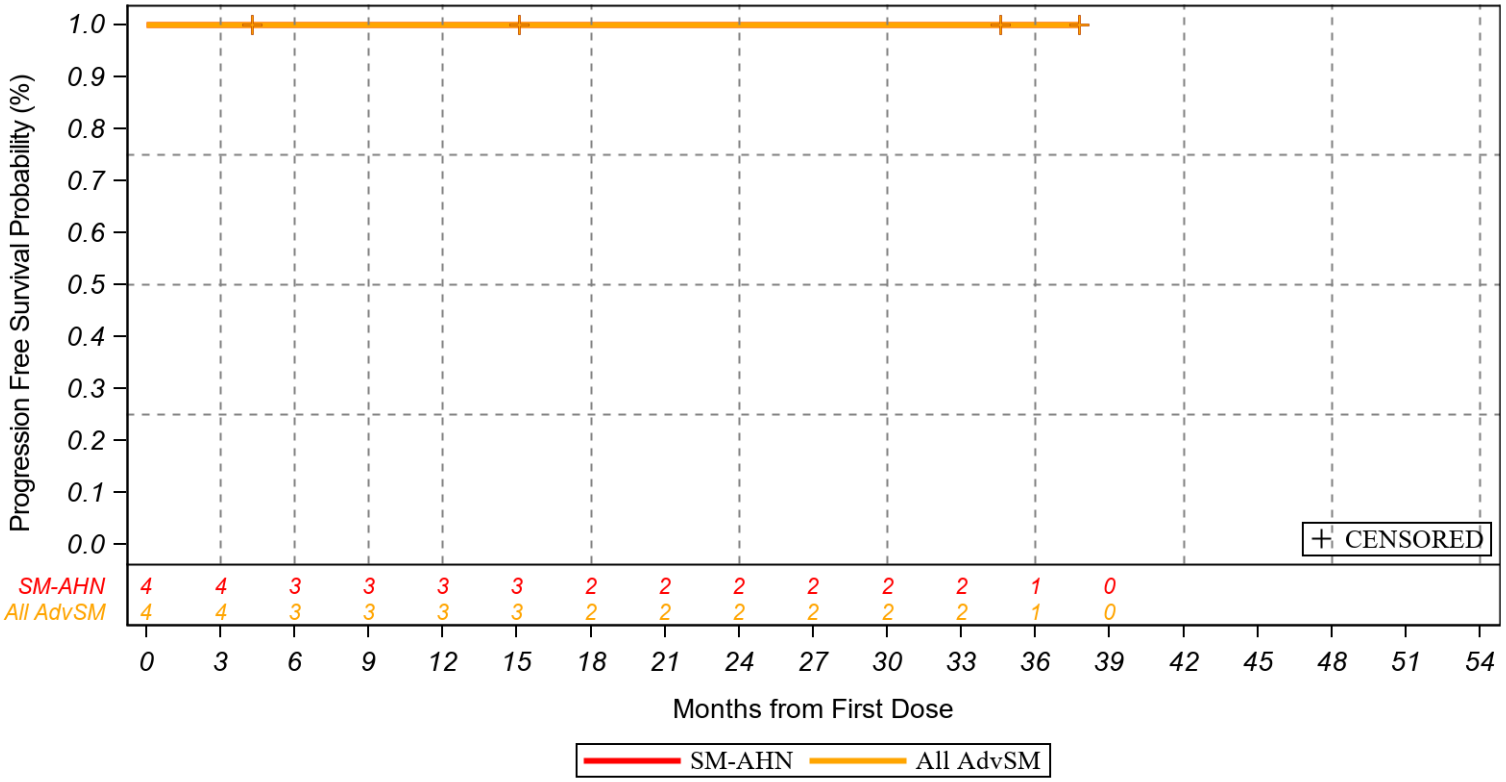


Figure 35.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101
Starting Dose: 400 mg



Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/f-adj-m-pfs-rac.sas
Date: 12:50/13OCT2021

Figure 35.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2202
Starting Dose: Overall

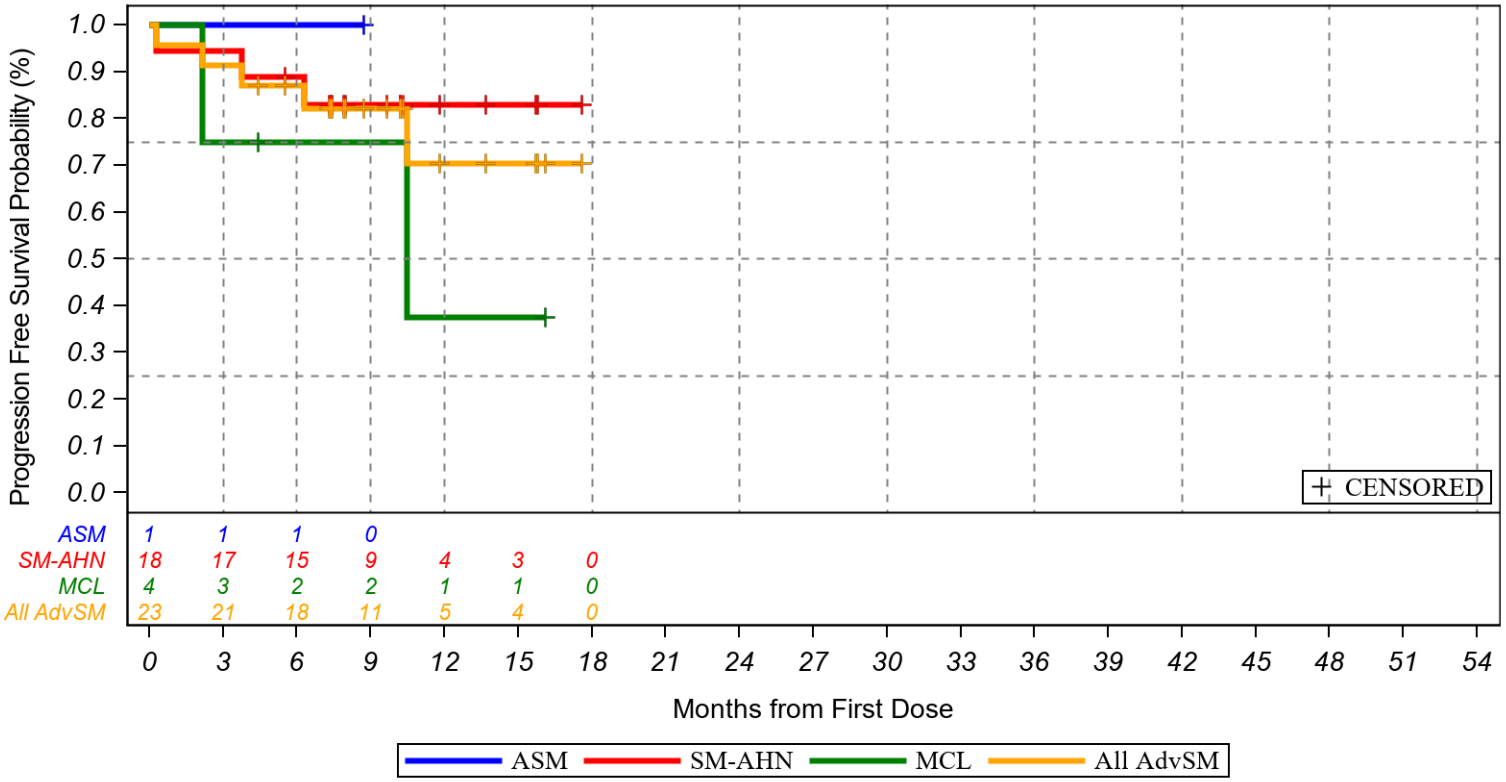


Figure 35.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2202
Starting Dose: 200 mg

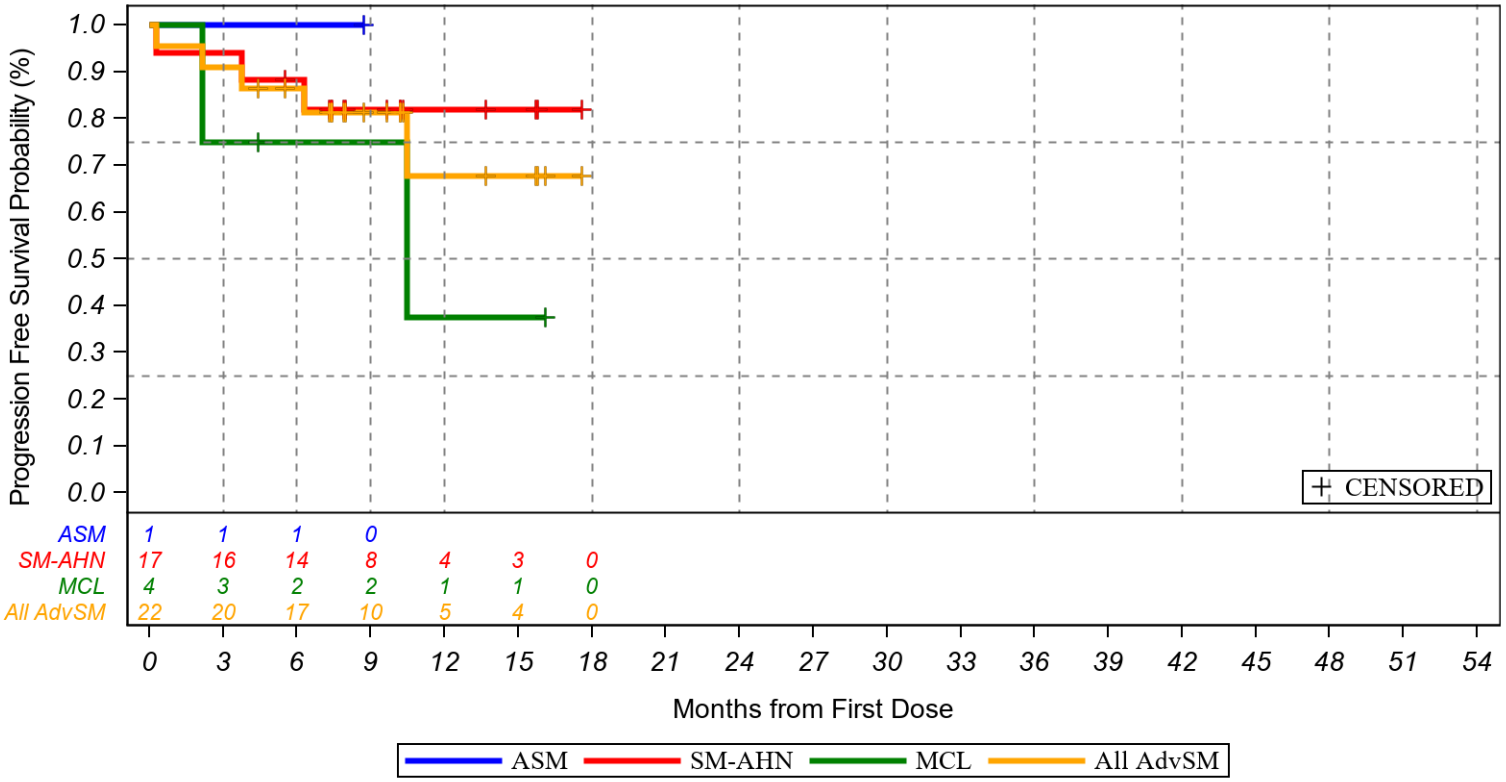


Figure 35.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall

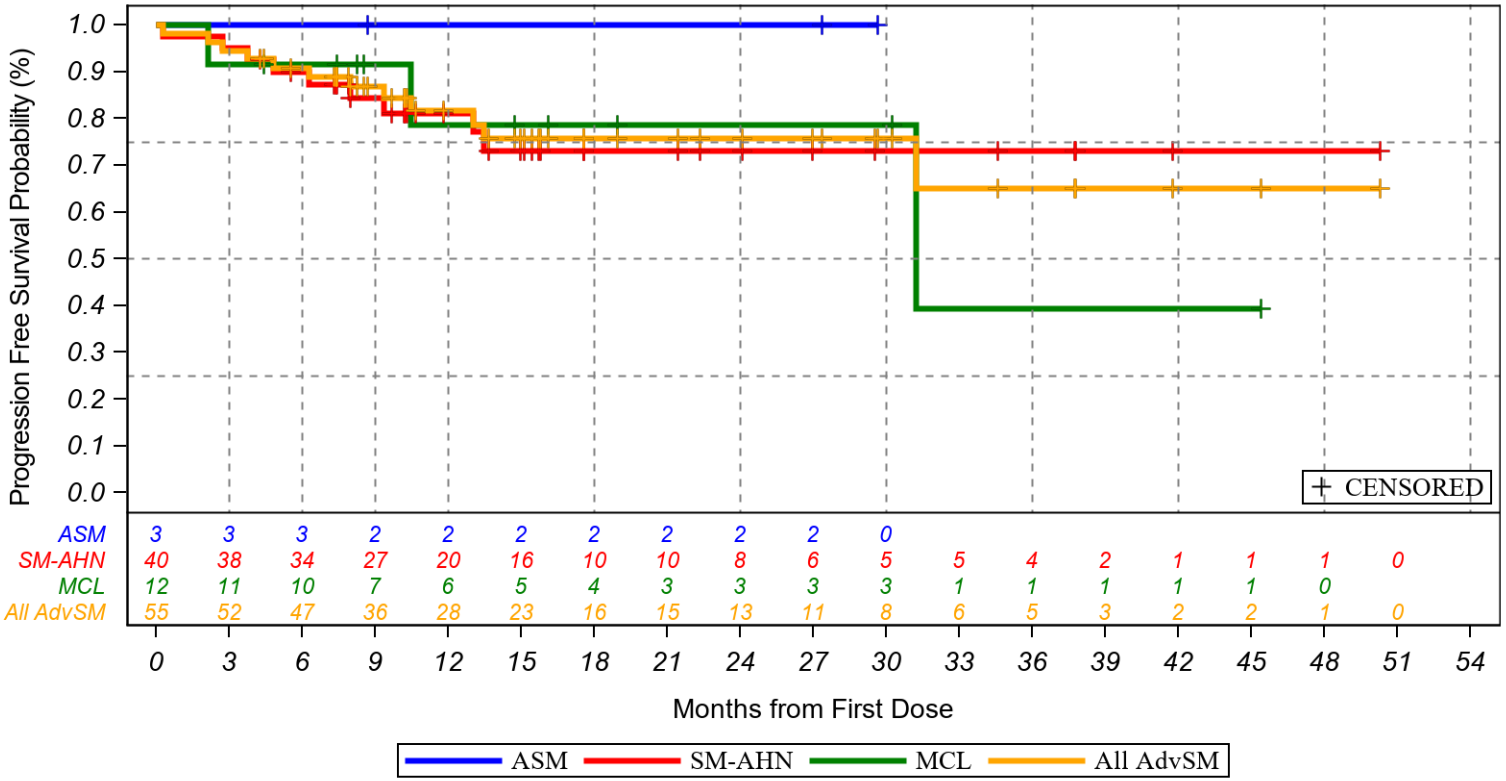


Figure 35.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg

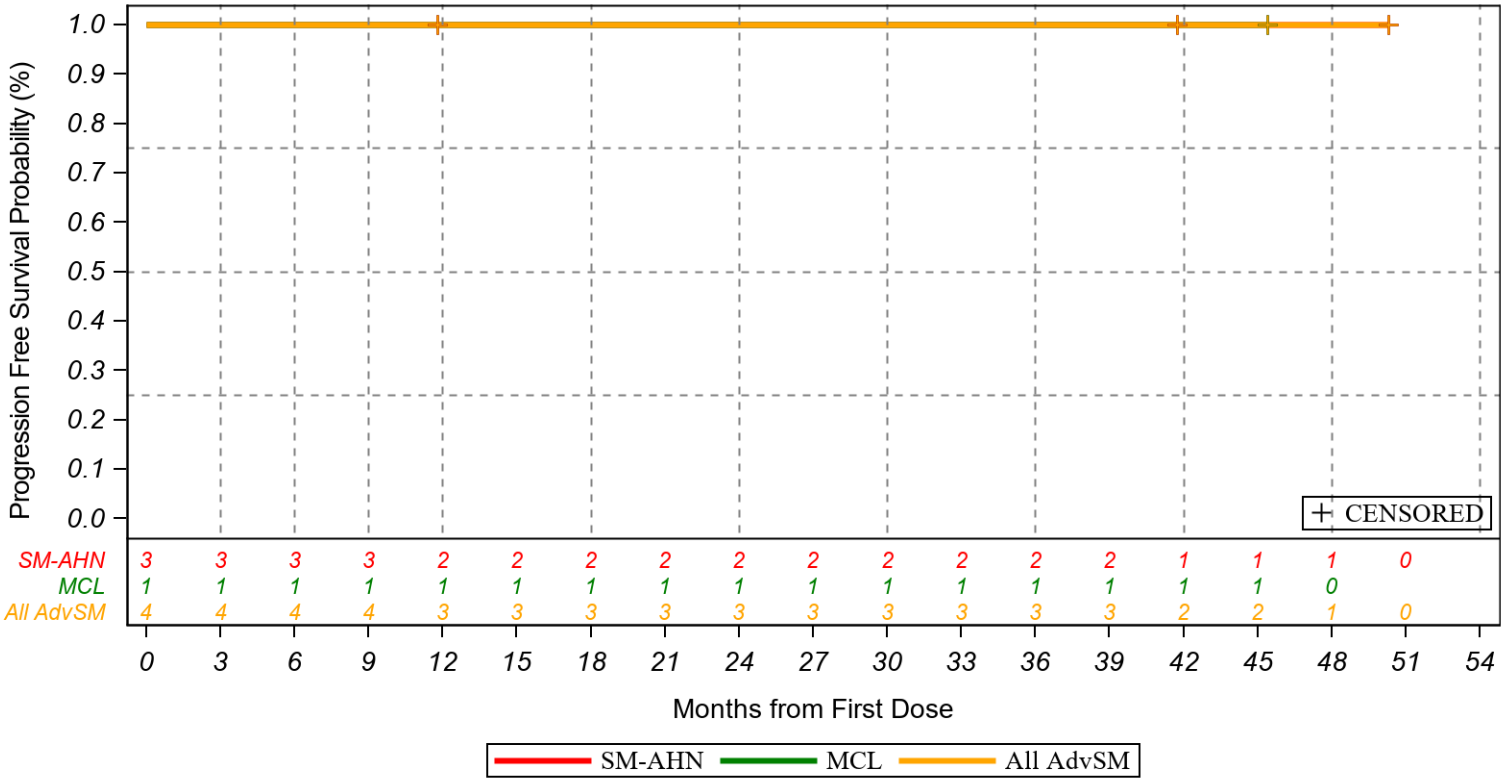


Figure 35.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg

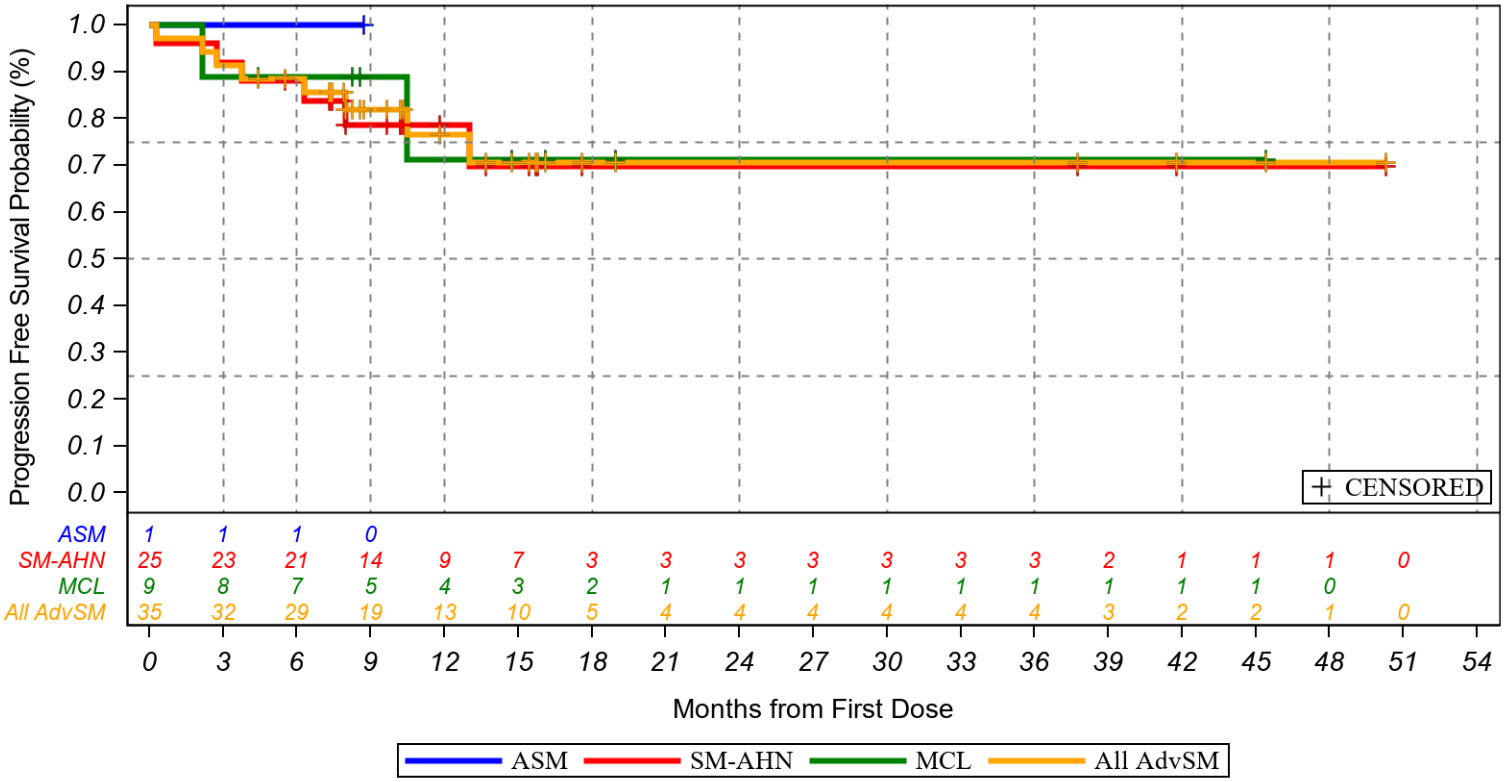


Figure 35.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg

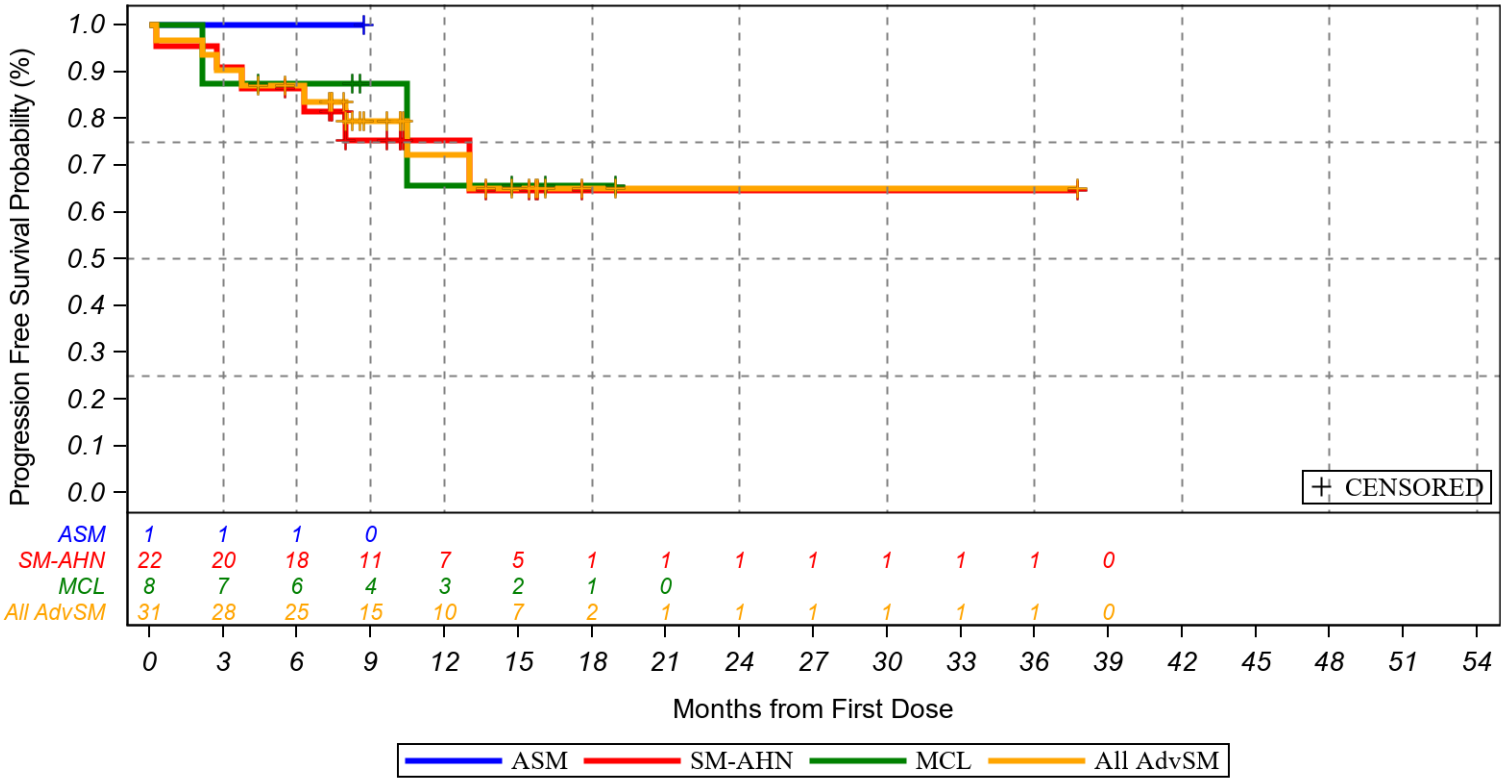


Figure 35.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg

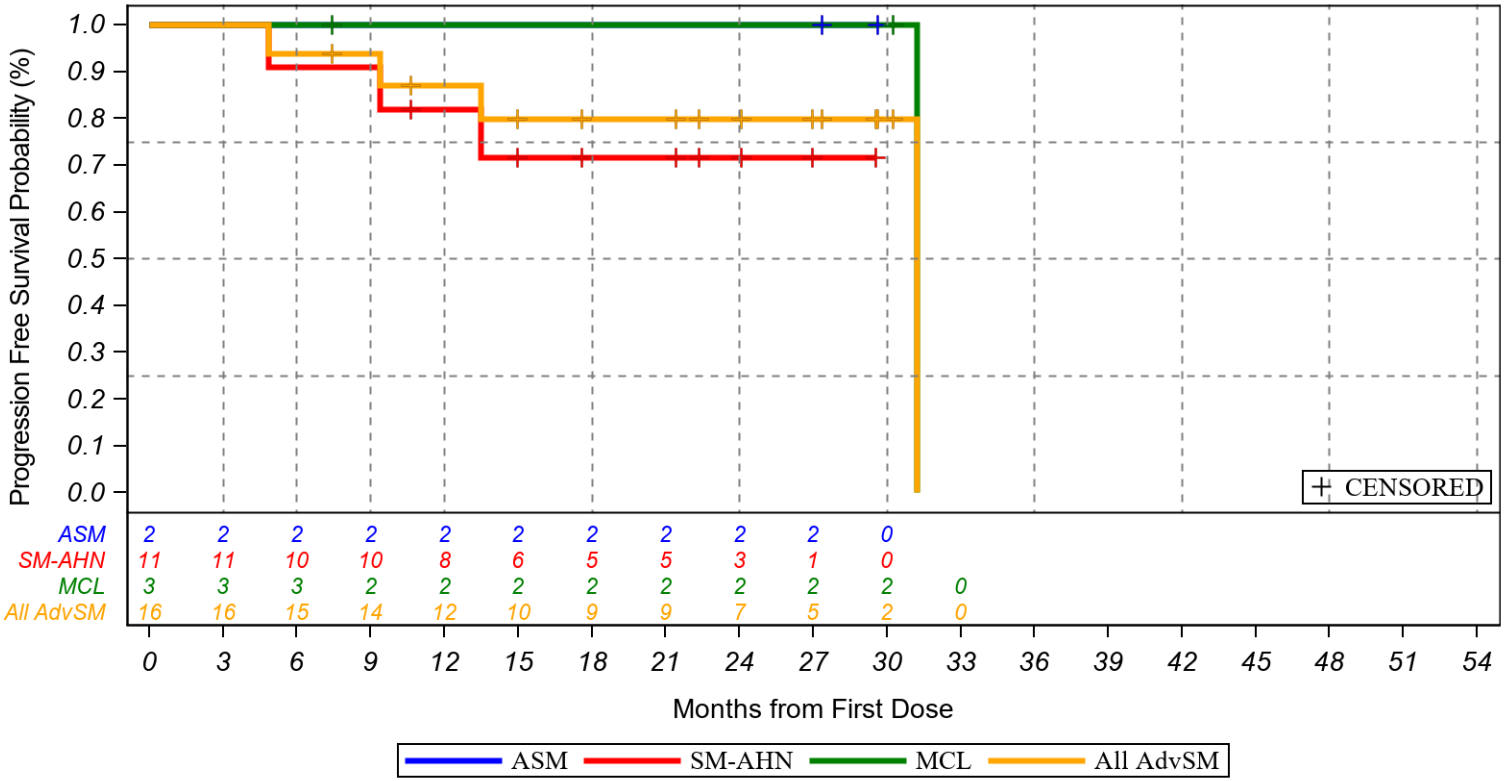


Figure 35.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg

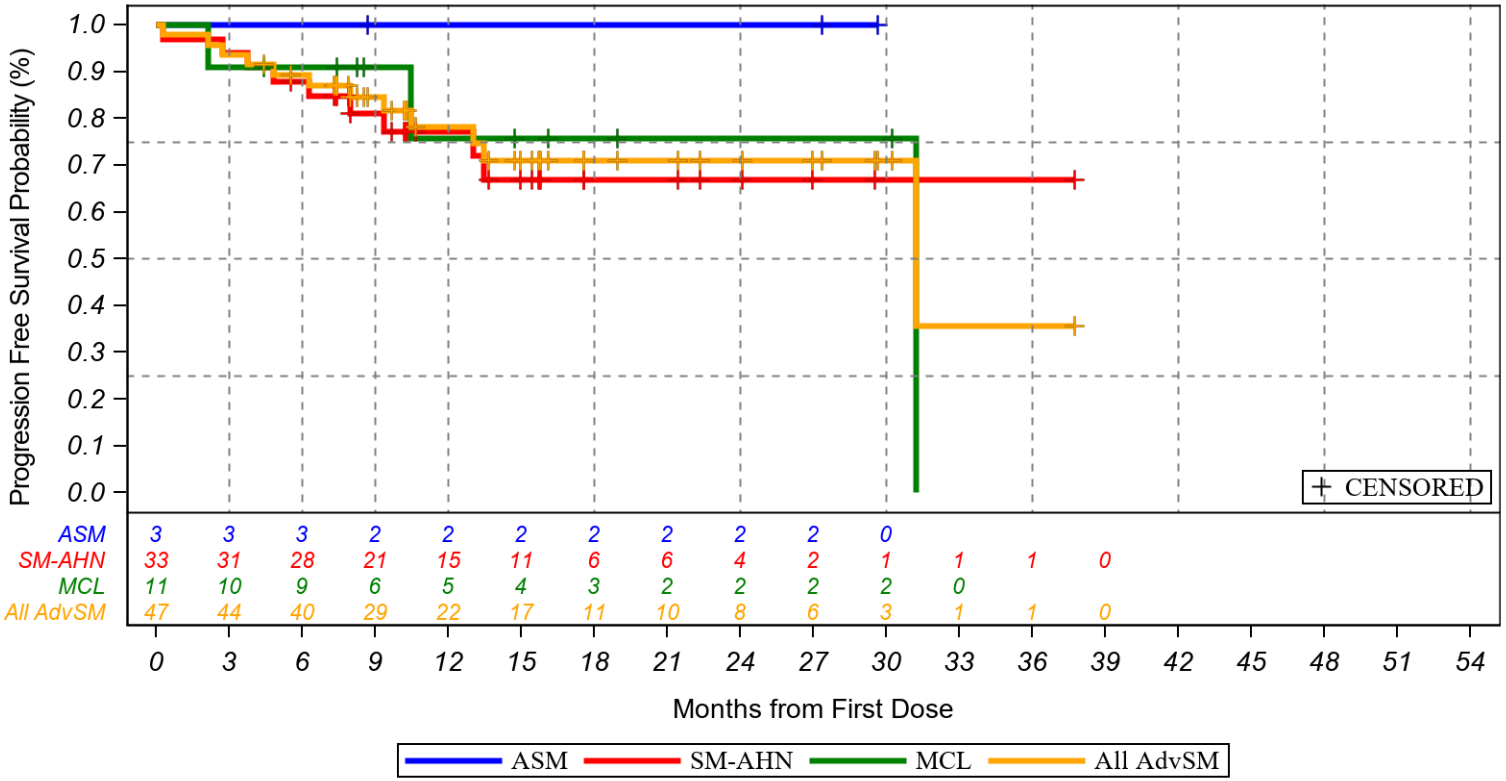
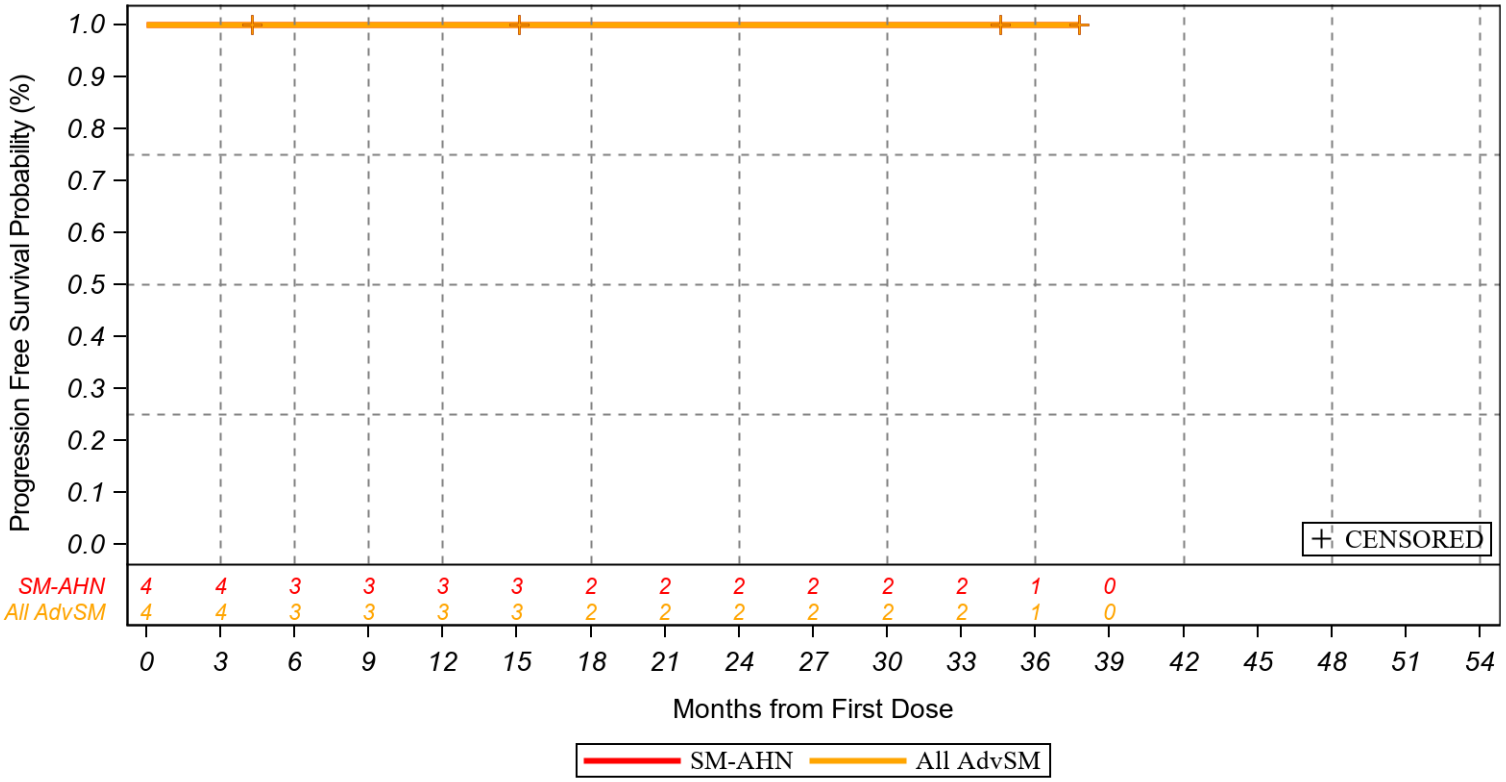


Figure 35.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg



Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/f-adj-m-pfs-rac.sas
Date: 12:50/13OCT2021

Table 35.2.3.2
Summary of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Progression Free Survival	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=22) n (%) (95% CIs)	MCL (N=8) n (%) (95% CIs)	All AdvSM (N=32) n (%) (95% CIs)
Events	0	6 (27.3)	1 (12.5)	7 (21.9)
Censors	2 (100.0)	16 (72.7)	7 (87.5)	25 (78.1)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (13.5 -NE)	NE (31.2 -NE)	NE (31.2 -NE)
25th, 75th percentiles	NE, NE	13.0, NE	31.2, NE	31.2, NE
Min, Max	26.0*, 27.2*	2.4*, 43.9*	5.6*, 43.5*	2.4*, 43.9*
3 Months (95% CIs)	100.0 (100.0 -100.0)	95.2 (86.1 -100.0)	100.0 (100.0 -100.0)	96.8 (90.6 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	90.5 (77.9 -100.0)	100.0 (100.0 -100.0)	93.5 (84.9 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	85.4 (70.2 -100.0)	100.0 (100.0 -100.0)	89.8 (78.8 -100.0)
12 Months (95% CIs)	100.0 (100.0 -100.0)	79.8 (61.9 - 97.6)	100.0 (100.0 -100.0)	85.7 (72.6 - 98.8)
18 Months (95% CIs)	100.0 (100.0 -100.0)	68.4 (47.2 - 89.5)	100.0 (100.0 -100.0)	77.2 (60.9 - 93.4)
24 Months (95% CIs)	100.0 (100.0 -100.0)	68.4 (47.2 - 89.5)	100.0 (100.0 -100.0)	77.2 (60.9 - 93.4)
30 Months (95% CIs)		68.4 (47.2 - 89.5)	100.0 (100.0 -100.0)	77.2 (60.9 - 93.4)
36 Months (95% CIs)		68.4 (47.2 - 89.5)	50.0 (0.0 -100.0)	66.1 (41.7 - 90.5)
42 Months (95% CIs)		68.4 (47.2 - 89.5)	50.0 (0.0 -100.0)	66.1 (41.7 - 90.5)
48 Months (95% CIs)				
Median PFS Follow-up[a] (months) (95% CI)	26.6 (26.0 - 27.2)	21.4 (15.7 - 32.4)	13.4 (5.6 - 43.5)	21.4 (15.4 - 27.6)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-pfs-advsm.sas Date: 15:03/18OCT2021

Table 35.2.3.2
Summary of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: < 200 mg

Progression Free Survival	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=2) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=3) n (%) (95% CIs)
Events		0	0	0
Censors		2 (100.0)	1 (100.0)	3 (100.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE -NE)	NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles		NE, NE	NE, NE	NE, NE
Min, Max		38.1*, 43.9*	43.5*, 43.5*	38.1*, 43.9*
3 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
12 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
18 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
24 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
30 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
36 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
42 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
48 Months (95% CIs)				
Median PFS Follow-up[a] (months) (95% CI)		41.0 (38.1 - 43.9)	43.5 (NE -NE)	43.5 (38.1 - 43.9)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-pfs-advsm.sas Date: 15:03/18OCT2021

Table 35.2.3.2
Summary of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: < 300 mg

Progression Free Survival	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=7) n (%) (95% CIs)	MCL (N=5) n (%) (95% CIs)	All AdvSM (N=12) n (%) (95% CIs)
Events		3 (42.9)	0	3 (25.0)
Censors		4 (57.1)	5 (100.0)	9 (75.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (8.0 -NE)	NE (NE -NE)	NE (13.0 -NE)
25th, 75th percentiles		8.0, NE	NE, NE	13.0, NE
Min, Max		2.7, 43.9*	5.6*, 43.5*	2.7, 43.9*
3 Months (95% CIs)		85.7 (59.8 -100.0)	100.0 (100.0 -100.0)	91.7 (76.0 -100.0)
6 Months (95% CIs)		85.7 (59.8 -100.0)	100.0 (100.0 -100.0)	91.7 (76.0 -100.0)
9 Months (95% CIs)		71.4 (38.0 -100.0)	100.0 (100.0 -100.0)	81.5 (58.1 -100.0)
12 Months (95% CIs)		71.4 (38.0 -100.0)	100.0 (100.0 -100.0)	81.5 (58.1 -100.0)
18 Months (95% CIs)		53.6 (14.2 - 92.9)	100.0 (100.0 -100.0)	67.9 (36.7 - 99.1)
24 Months (95% CIs)		53.6 (14.2 - 92.9)	100.0 (100.0 -100.0)	67.9 (36.7 - 99.1)
30 Months (95% CIs)		53.6 (14.2 - 92.9)	100.0 (100.0 -100.0)	67.9 (36.7 - 99.1)
36 Months (95% CIs)		53.6 (14.2 - 92.9)	100.0 (100.0 -100.0)	67.9 (36.7 - 99.1)
42 Months (95% CIs)		53.6 (14.2 - 92.9)	100.0 (100.0 -100.0)	67.9 (36.7 - 99.1)
48 Months (95% CIs)				
Median PFS Follow-up[a] (months) (95% CI)		38.1 (9.2 - 43.9)	11.3 (5.6 - 43.5)	15.4 (9.2 - 43.5)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-pfs-advsm.sas Date: 15:03/18OCT2021

Table 35.2.3.2
Summary of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Progression Free Survival	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=5) n (%) (95% CIs)	MCL (N=4) n (%) (95% CIs)	All AdvSM (N=9) n (%) (95% CIs)
Events		3 (60.0)	0	3 (33.3)
Censors		2 (40.0)	4 (100.0)	6 (66.7)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		13.0 (2.7 -NE)	NE (NE -NE)	13.0 (8.0 -NE)
25th, 75th percentiles		8.0, NE	NE, NE	8.0, NE
Min, Max		2.7, 37.7*	5.6*, 15.4*	2.7, 37.7*
3 Months (95% CIs)		80.0 (44.9 -100.0)	100.0 (100.0 -100.0)	88.9 (68.4 -100.0)
6 Months (95% CIs)		80.0 (44.9 -100.0)	100.0 (100.0 -100.0)	88.9 (68.4 -100.0)
9 Months (95% CIs)		60.0 (17.1 -100.0)	100.0 (100.0 -100.0)	74.1 (42.5 -100.0)
12 Months (95% CIs)		60.0 (17.1 -100.0)	100.0 (100.0 -100.0)	74.1 (42.5 -100.0)
18 Months (95% CIs)		30.0 (0.0 - 76.8)		49.4 (4.6 - 94.1)
24 Months (95% CIs)		30.0 (0.0 - 76.8)		49.4 (4.6 - 94.1)
30 Months (95% CIs)		30.0 (0.0 - 76.8)		49.4 (4.6 - 94.1)
36 Months (95% CIs)		30.0 (0.0 - 76.8)		49.4 (4.6 - 94.1)
42 Months (95% CIs)				
48 Months (95% CIs)				
Median PFS Follow-up[a] (months) (95% CI)		37.7 (9.2 - 37.7)	8.5 (5.6 - 15.4)	11.3 (5.8 - 37.7)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-pfs-advsm.sas Date: 15:03/18OCT2021

Table 35.2.3.2
Summary of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 300 mg

Progression Free Survival	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=11) n (%) (95% CIs)	MCL (N=3) n (%) (95% CIs)	All AdvSM (N=16) n (%) (95% CIs)
Events	0	3 (27.3)	1 (33.3)	4 (25.0)
Censors	2 (100.0)	8 (72.7)	2 (66.7)	12 (75.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (13.5 -NE)	31.2 (NE -NE)	31.2 (NE -NE)
25th, 75th percentiles	NE, NE	13.5, NE	31.2, 31.2	31.2, 31.2
Min, Max	26.0*, 27.2*	4.8, 27.6*	5.6*, 31.2	4.8, 31.2
3 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	90.9 (73.9 -100.0)	100.0 (100.0 -100.0)	93.8 (81.9 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	90.9 (73.9 -100.0)	100.0 (100.0 -100.0)	93.8 (81.9 -100.0)
12 Months (95% CIs)	100.0 (100.0 -100.0)	79.5 (54.0 -100.0)	100.0 (100.0 -100.0)	85.9 (67.7 -100.0)
18 Months (95% CIs)	100.0 (100.0 -100.0)	68.2 (38.1 - 98.3)	100.0 (100.0 -100.0)	78.1 (56.0 -100.0)
24 Months (95% CIs)	100.0 (100.0 -100.0)	68.2 (38.1 - 98.3)	100.0 (100.0 -100.0)	78.1 (56.0 -100.0)
30 Months (95% CIs)			100.0 (100.0 -100.0)	78.1 (56.0 -100.0)
36 Months (95% CIs)			0.0 (0.0 - 0.0)	0.0 (0.0 - 0.0)
42 Months (95% CIs)			0.0 (0.0 - 0.0)	0.0 (0.0 - 0.0)
48 Months (95% CIs)			0.0 (0.0 - 0.0)	0.0 (0.0 - 0.0)
Median PFS Follow-up[a] (months) (95% CI)	26.6 (26.0 - 27.2)	21.4 (15.7 - 27.0)	26.5 (5.6 -NE)	21.4 (15.7 - 27.0)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-pfs-advsm.sas Date: 15:03/18OCT2021

Table 35.2.3.2
Summary of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg and 300 mg

Progression Free Survival	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=16) n (%) (95% CIs)	MCL (N=7) n (%) (95% CIs)	All AdvSM (N=25) n (%) (95% CIs)
Events	0	6 (37.5)	1 (14.3)	7 (28.0)
Censors	2 (100.0)	10 (62.5)	6 (85.7)	18 (72.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (9.4 -NE)	31.2 (NE -NE)	31.2 (13.5 -NE)
25th, 75th percentiles	NE, NE	9.4, NE	31.2, 31.2	13.5, NE
Min, Max	26.0*, 27.2*	2.7, 37.7*	5.6*, 31.2	2.7, 37.7*
3 Months (95% CIs)	100.0 (100.0 -100.0)	93.8 (81.9 -100.0)	100.0 (100.0 -100.0)	96.0 (88.3 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	87.5 (71.3 -100.0)	100.0 (100.0 -100.0)	92.0 (81.4 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	80.8 (61.2 -100.0)	100.0 (100.0 -100.0)	87.2 (73.5 -100.0)
12 Months (95% CIs)	100.0 (100.0 -100.0)	72.7 (49.5 - 95.9)	100.0 (100.0 -100.0)	81.7 (65.2 - 98.2)
18 Months (95% CIs)	100.0 (100.0 -100.0)	56.5 (29.8 - 83.3)	100.0 (100.0 -100.0)	70.0 (49.5 - 90.6)
24 Months (95% CIs)	100.0 (100.0 -100.0)	56.5 (29.8 - 83.3)	100.0 (100.0 -100.0)	70.0 (49.5 - 90.6)
30 Months (95% CIs)		56.5 (29.8 - 83.3)	100.0 (100.0 -100.0)	70.0 (49.5 - 90.6)
36 Months (95% CIs)		56.5 (29.8 - 83.3)	0.0 (0.0 - 0.0)	35.0 (0.0 - 84.6)
42 Months (95% CIs)			0.0 (0.0 - 0.0)	
48 Months (95% CIs)			0.0 (0.0 - 0.0)	
Median PFS Follow-up[a] (months) (95% CI)	26.6 (26.0 - 27.2)	21.4 (15.7 - 27.0)	11.3 (5.6 - 26.5)	21.4 (11.3 - 26.5)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-pfs-advsm.sas Date: 15:03/18OCT2021

Table 35.2.3.2
Summary of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 400 mg

Progression Free Survival	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=4) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=4) n (%) (95% CIs)
Events		0		0
Censors		4 (100.0)		4 (100.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE -NE)		NE (NE -NE)
25th, 75th percentiles		NE, NE		NE, NE
Min, Max		2.4*, 32.8*		2.4*, 32.8*
3 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
6 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
9 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
12 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
18 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
24 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
30 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				
Median PFS Follow-up[a] (months) (95% CI)		23.8 (2.4 - 32.8)		23.8 (2.4 - 32.8)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-pfs-advsm.sas Date: 15:03/18OCT2021

Table 35.2.3.2
Summary of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Progression Free Survival	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=18) n (%) (95% CIs)	MCL (N=4) n (%) (95% CIs)	All AdvSM (N=23) n (%) (95% CIs)
Events	0	3 (16.7)	2 (50.0)	5 (21.7)
Censors	1 (100.0)	15 (83.3)	2 (50.0)	18 (78.3)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (NE -NE)	10.5 (4.8 -NE)	NE (10.5 -NE)
25th, 75th percentiles	NE, NE	NE, NE	4.8, NE	10.5, NE
Min, Max	0.0*, 0.0*	0.3, 17.6*	4.4*, 14.9*	0.0*, 17.6*
3 Months (95% CIs)		94.4 (83.9 -100.0)	100.0 (100.0 -100.0)	95.5 (86.8 -100.0)
6 Months (95% CIs)		88.9 (74.4 -100.0)	66.7 (13.3 -100.0)	86.1 (71.5 -100.0)
9 Months (95% CIs)		82.1 (63.5 -100.0)	66.7 (13.3 -100.0)	80.4 (63.0 - 97.8)
12 Months (95% CIs)		82.1 (63.5 -100.0)	33.3 (0.0 - 86.7)	53.6 (9.2 - 98.0)
18 Months (95% CIs)				
24 Months (95% CIs)				
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				
Median PFS Follow-up[a] (months) (95% CI)	0.0 (NE -NE)	8.2 (7.4 - 9.3)	14.9 (4.4 - 14.9)	8.2 (7.4 - 9.3)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-pfs-advsm.sas Date: 15:03/18OCT2021

Table 35.2.3.2
Summary of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Progression Free Survival	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=17) n (%) (95% CIs)	MCL (N=4) n (%) (95% CIs)	All AdvSM (N=22) n (%) (95% CIs)
Events	0	3 (17.6)	2 (50.0)	5 (22.7)
Censors	1 (100.0)	14 (82.4)	2 (50.0)	17 (77.3)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (NE -NE)	10.5 (4.8 -NE)	NE (10.5 -NE)
25th, 75th percentiles	NE, NE	NE, NE	4.8, NE	10.5, NE
Min, Max	0.0*, 0.0*	0.3, 17.6*	4.4*, 14.9*	0.0*, 17.6*
3 Months (95% CIs)		94.1 (82.9 -100.0)	100.0 (100.0 -100.0)	95.2 (86.1 -100.0)
6 Months (95% CIs)		88.2 (72.9 -100.0)	66.7 (13.3 -100.0)	85.4 (70.2 -100.0)
9 Months (95% CIs)		80.9 (61.2 -100.0)	66.7 (13.3 -100.0)	79.3 (61.1 - 97.6)
12 Months (95% CIs)		80.9 (61.2 -100.0)	33.3 (0.0 - 86.7)	52.9 (8.9 - 96.9)
18 Months (95% CIs)				
24 Months (95% CIs)				
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				
Median PFS Follow-up[a] (months) (95% CI)	0.0 (NE -NE)	8.2 (7.3 - 9.3)	14.9 (4.4 - 14.9)	8.2 (7.3 - 9.3)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-pfs-advsm.sas Date: 15:03/18OCT2021

Table 35.2.3.2
Summary of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Progression Free Survival	ASM (N=3) n (%) (95% CIs)	SM-AHN (N=40) n (%) (95% CIs)	MCL (N=12) n (%) (95% CIs)	All AdvSM (N=55) n (%) (95% CIs)
Events	0	9 (22.5)	3 (25.0)	12 (21.8)
Censors	3 (100.0)	31 (77.5)	9 (75.0)	43 (78.2)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (13.5 -NE)	31.2 (31.2 -NE)	NE (31.2 -NE)
25th, 75th percentiles	NE, NE	13.0, NE	31.2, NE	13.5, NE
Min, Max	0.0*, 27.2*	0.3, 43.9*	4.4*, 43.5*	0.0*, 43.9*
3 Months (95% CIs)	100.0 (100.0 -100.0)	94.9 (88.1 -100.0)	100.0 (100.0 -100.0)	96.3 (91.2 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	89.8 (80.3 - 99.3)	90.9 (73.9 -100.0)	90.5 (82.6 - 98.4)
9 Months (95% CIs)	100.0 (100.0 -100.0)	83.6 (71.4 - 95.7)	90.9 (73.9 -100.0)	85.7 (75.8 - 95.6)
12 Months (95% CIs)	100.0 (100.0 -100.0)	78.6 (63.9 - 93.4)	77.9 (50.2 -100.0)	79.0 (66.2 - 91.8)
18 Months (95% CIs)	100.0 (100.0 -100.0)	68.2 (49.5 - 86.8)	77.9 (50.2 -100.0)	71.8 (56.8 - 86.8)
24 Months (95% CIs)	100.0 (100.0 -100.0)	68.2 (49.5 - 86.8)	77.9 (50.2 -100.0)	71.8 (56.8 - 86.8)
30 Months (95% CIs)		68.2 (49.5 - 86.8)	77.9 (50.2 -100.0)	71.8 (56.8 - 86.8)
36 Months (95% CIs)		68.2 (49.5 - 86.8)	39.0 (0.0 - 94.7)	61.6 (38.9 - 84.2)
42 Months (95% CIs)		68.2 (49.5 - 86.8)	39.0 (0.0 - 94.7)	61.6 (38.9 - 84.2)
48 Months (95% CIs)				
Median PFS Follow-up[a] (months) (95% CI)	26.0 (0.0 - 27.2)	9.6 (9.2 - 21.2)	14.9 (5.6 - 26.5)	14.9 (9.2 - 21.2)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-pfs-advsm.sas Date: 15:03/18OCT2021

Table 35.2.3.2
Summary of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: < 200 mg

Progression Free Survival	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=3) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=4) n (%) (95% CIs)
Events		0	0	0
Censors		3 (100.0)	1 (100.0)	4 (100.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE -NE)	NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles		NE, NE	NE, NE	NE, NE
Min, Max		9.6*, 43.9*	43.5*, 43.5*	9.6*, 43.9*
3 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
12 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
18 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
24 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
30 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
36 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
42 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
48 Months (95% CIs)				
Median PFS Follow-up[a] (months) (95% CI)		38.1 (9.6 - 43.9)	43.5 (NE -NE)	40.8 (9.6 - 43.9)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-pfs-advsm.sas Date: 15:03/18OCT2021

Table 35.2.3.2
Summary of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: < 300 mg

Progression Free Survival	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=25) n (%) (95% CIs)	MCL (N=9) n (%) (95% CIs)	All AdvSM (N=35) n (%) (95% CIs)
Events	0	6 (24.0)	2 (22.2)	8 (22.9)
Censors	1 (100.0)	19 (76.0)	7 (77.8)	27 (77.1)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (13.0 -NE)	NE (10.5 -NE)	NE (13.0 -NE)
25th, 75th percentiles	NE, NE	13.0, NE	10.5, NE	10.5, NE
Min, Max	0.0*, 0.0*	0.3, 43.9*	4.4*, 43.5*	0.0*, 43.9*
3 Months (95% CIs)		92.0 (81.4 -100.0)	100.0 (100.0 -100.0)	94.1 (86.2 -100.0)
6 Months (95% CIs)		88.0 (75.3 -100.0)	87.5 (64.6 -100.0)	88.1 (77.2 - 99.1)
9 Months (95% CIs)		77.4 (59.5 - 95.3)	87.5 (64.6 -100.0)	80.0 (65.4 - 94.7)
12 Months (95% CIs)		77.4 (59.5 - 95.3)	70.0 (34.3 -100.0)	72.0 (52.1 - 91.9)
18 Months (95% CIs)		61.9 (31.3 - 92.6)	70.0 (34.3 -100.0)	63.0 (39.0 - 87.0)
24 Months (95% CIs)		61.9 (31.3 - 92.6)	70.0 (34.3 -100.0)	63.0 (39.0 - 87.0)
30 Months (95% CIs)		61.9 (31.3 - 92.6)	70.0 (34.3 -100.0)	63.0 (39.0 - 87.0)
36 Months (95% CIs)		61.9 (31.3 - 92.6)	70.0 (34.3 -100.0)	63.0 (39.0 - 87.0)
42 Months (95% CIs)		61.9 (31.3 - 92.6)	70.0 (34.3 -100.0)	63.0 (39.0 - 87.0)
48 Months (95% CIs)				
Median PFS Follow-up[a] (months) (95% CI)	0.0 (NE -NE)	9.2 (7.9 - 9.6)	11.3 (5.6 - 15.4)	9.2 (7.9 - 11.3)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-pfs-advsm.sas Date: 15:03/18OCT2021

Table 35.2.3.2
Summary of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Progression Free Survival	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=22) n (%) (95% CIs)	MCL (N=8) n (%) (95% CIs)	All AdvSM (N=31) n (%) (95% CIs)
Events	0	6 (27.3)	2 (25.0)	8 (25.8)
Censors	1 (100.0)	16 (72.7)	6 (75.0)	23 (74.2)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	13.0 (13.0 -NE)	NE (10.5 -NE)	NE (10.5 -NE)
25th, 75th percentiles	NE, NE	8.0, NE	10.5, NE	10.5, NE
Min, Max	0.0*, 0.0*	0.3, 37.7*	4.4*, 15.4*	0.0*, 37.7*
3 Months (95% CIs)		90.9 (78.9 -100.0)	100.0 (100.0 -100.0)	93.3 (84.4 -100.0)
6 Months (95% CIs)		86.4 (72.0 -100.0)	85.7 (59.8 -100.0)	86.5 (74.3 - 98.8)
9 Months (95% CIs)		73.6 (53.0 - 94.2)	85.7 (59.8 -100.0)	76.7 (59.8 - 93.6)
12 Months (95% CIs)		73.6 (53.0 - 94.2)	64.3 (23.0 -100.0)	65.8 (41.2 - 90.4)
18 Months (95% CIs)		49.1 (7.5 - 90.7)		52.6 (22.3 - 82.9)
24 Months (95% CIs)		49.1 (7.5 - 90.7)		52.6 (22.3 - 82.9)
30 Months (95% CIs)		49.1 (7.5 - 90.7)		52.6 (22.3 - 82.9)
36 Months (95% CIs)		49.1 (7.5 - 90.7)		52.6 (22.3 - 82.9)
42 Months (95% CIs)				
48 Months (95% CIs)				
Median PFS Follow-up[a] (months) (95% CI)	0.0 (NE -NE)	9.2 (7.5 - 9.3)	11.3 (5.6 - 15.4)	9.2 (7.4 - 9.3)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-pfs-advsm.sas Date: 15:03/18OCT2021

Table 35.2.3.2
Summary of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg

Progression Free Survival	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=11) n (%) (95% CIs)	MCL (N=3) n (%) (95% CIs)	All AdvSM (N=16) n (%) (95% CIs)
Events	0	3 (27.3)	1 (33.3)	4 (25.0)
Censors	2 (100.0)	8 (72.7)	2 (66.7)	12 (75.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (13.5 -NE)	31.2 (NE -NE)	31.2 (NE -NE)
25th, 75th percentiles	NE, NE	13.5, NE	31.2, 31.2	31.2, 31.2
Min, Max	26.0*, 27.2*	4.8, 27.6*	5.6*, 31.2	4.8, 31.2
3 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	90.9 (73.9 -100.0)	100.0 (100.0 -100.0)	93.8 (81.9 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	90.9 (73.9 -100.0)	100.0 (100.0 -100.0)	93.8 (81.9 -100.0)
12 Months (95% CIs)	100.0 (100.0 -100.0)	79.5 (54.0 -100.0)	100.0 (100.0 -100.0)	85.9 (67.7 -100.0)
18 Months (95% CIs)	100.0 (100.0 -100.0)	68.2 (38.1 - 98.3)	100.0 (100.0 -100.0)	78.1 (56.0 -100.0)
24 Months (95% CIs)	100.0 (100.0 -100.0)	68.2 (38.1 - 98.3)	100.0 (100.0 -100.0)	78.1 (56.0 -100.0)
30 Months (95% CIs)			100.0 (100.0 -100.0)	78.1 (56.0 -100.0)
36 Months (95% CIs)			0.0 (0.0 - 0.0)	0.0 (0.0 - 0.0)
42 Months (95% CIs)			0.0 (0.0 - 0.0)	0.0 (0.0 - 0.0)
48 Months (95% CIs)			0.0 (0.0 - 0.0)	0.0 (0.0 - 0.0)
Median PFS Follow-up[a] (months) (95% CI)	26.6 (26.0 - 27.2)	21.4 (15.7 - 27.0)	26.5 (5.6 -NE)	21.4 (15.7 - 27.0)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-pfs-advsm.sas Date: 15:03/18OCT2021

Table 35.2.3.2
Summary of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg

Progression Free Survival	ASM (N=3) n (%) (95% CIs)	SM-AHN (N=33) n (%) (95% CIs)	MCL (N=11) n (%) (95% CIs)	All AdvSM (N=47) n (%) (95% CIs)
Events	0	9 (27.3)	3 (27.3)	12 (25.5)
Censors	3 (100.0)	24 (72.7)	8 (72.7)	35 (74.5)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (13.0 -NE)	31.2 (10.5 - 31.2)	31.2 (13.5 -NE)
25th, 75th percentiles	NE, NE	9.4, NE	20.8, 31.2	10.5, NE
Min, Max	0.0*, 27.2*	0.3, 37.7*	4.4*, 31.2	0.0*, 37.7*
3 Months (95% CIs)	100.0 (100.0 -100.0)	93.9 (85.8 -100.0)	100.0 (100.0 -100.0)	95.7 (89.8 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	87.9 (76.7 - 99.0)	90.0 (71.4 -100.0)	89.0 (79.9 - 98.1)
9 Months (95% CIs)	100.0 (100.0 -100.0)	80.1 (65.7 - 94.6)	90.0 (71.4 -100.0)	83.2 (71.7 - 94.8)
12 Months (95% CIs)	100.0 (100.0 -100.0)	72.9 (53.9 - 91.8)	75.0 (44.0 -100.0)	74.5 (59.1 - 89.9)
18 Months (95% CIs)	100.0 (100.0 -100.0)	58.3 (34.7 - 81.9)	75.0 (44.0 -100.0)	65.2 (47.1 - 83.3)
24 Months (95% CIs)	100.0 (100.0 -100.0)	58.3 (34.7 - 81.9)	75.0 (44.0 -100.0)	65.2 (47.1 - 83.3)
30 Months (95% CIs)		58.3 (34.7 - 81.9)	75.0 (44.0 -100.0)	65.2 (47.1 - 83.3)
36 Months (95% CIs)		58.3 (34.7 - 81.9)	0.0 (0.0 - 0.0)	32.6 (0.0 - 78.6)
42 Months (95% CIs)			0.0 (0.0 - 0.0)	
48 Months (95% CIs)			0.0 (0.0 - 0.0)	
Median PFS Follow-up[a] (months) (95% CI)	26.0 (0.0 - 27.2)	9.3 (9.2 - 17.6)	11.3 (5.6 - 26.5)	9.3 (9.2 - 17.6)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-pfs-advsm.sas Date: 15:03/18OCT2021

Table 35.2.3.2
Summary of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg

Progression Free Survival	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=4) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=4) n (%) (95% CIs)
Events		0		0
Censors		4 (100.0)		4 (100.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE -NE)		NE (NE -NE)
25th, 75th percentiles		NE, NE		NE, NE
Min, Max		2.4*, 32.8*		2.4*, 32.8*
3 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
6 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
9 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
12 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
18 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
24 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
30 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				
Median PFS Follow-up[a] (months) (95% CI)		23.8 (2.4 - 32.8)		23.8 (2.4 - 32.8)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-inv-pfs-advsm.sas Date: 15:03/18OCT2021

Blueprint Medicines Corporation
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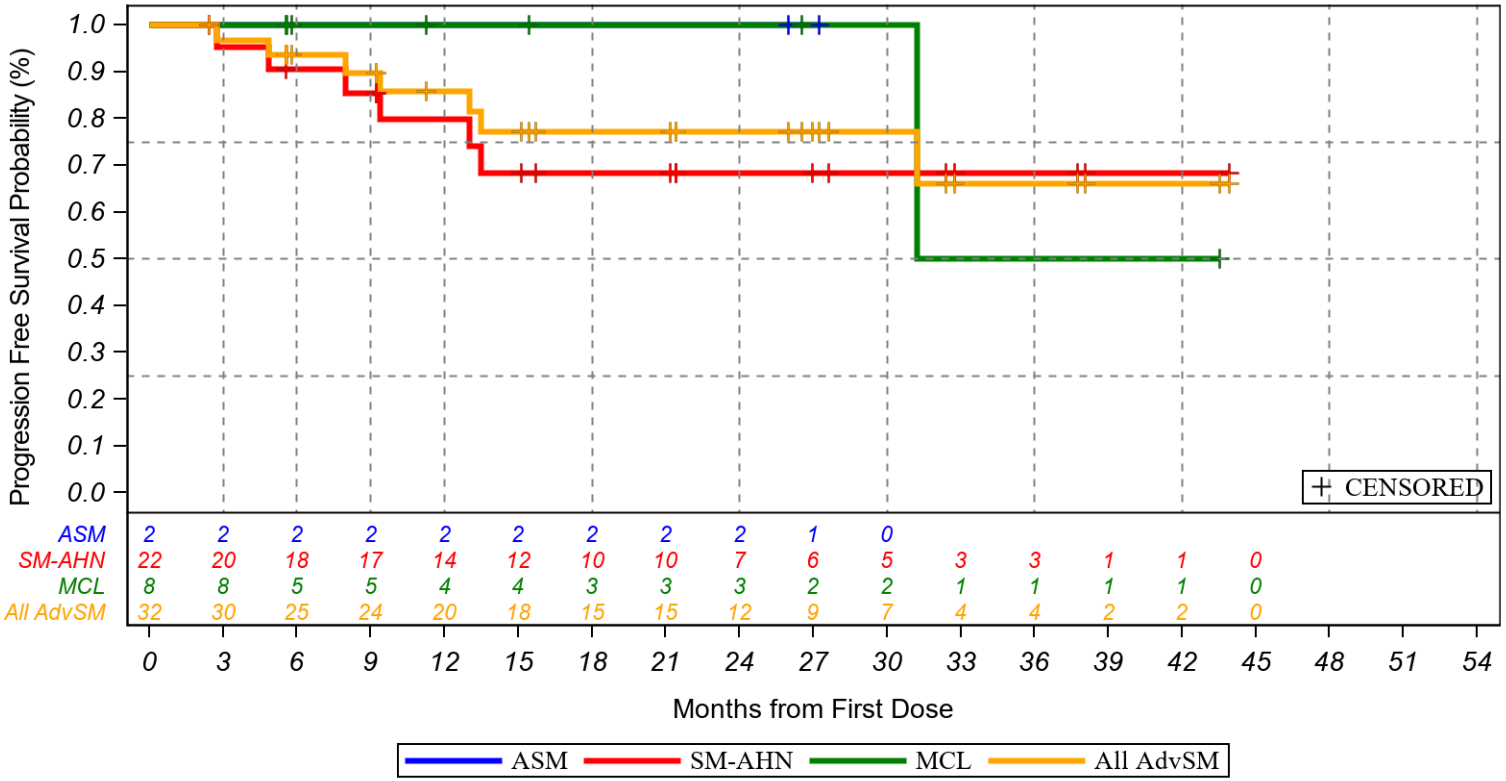
Avapritinib Systemic Mastocytosis Integrated Summary of Efficacy
BLU-285 SM Germany HTA Analysis
Cutoff date: 27may2020 (2101), 23jun2020 (2202)

Figure 35.2.3.2
Kaplan-Meier Curves of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101
Starting Dose: Overall



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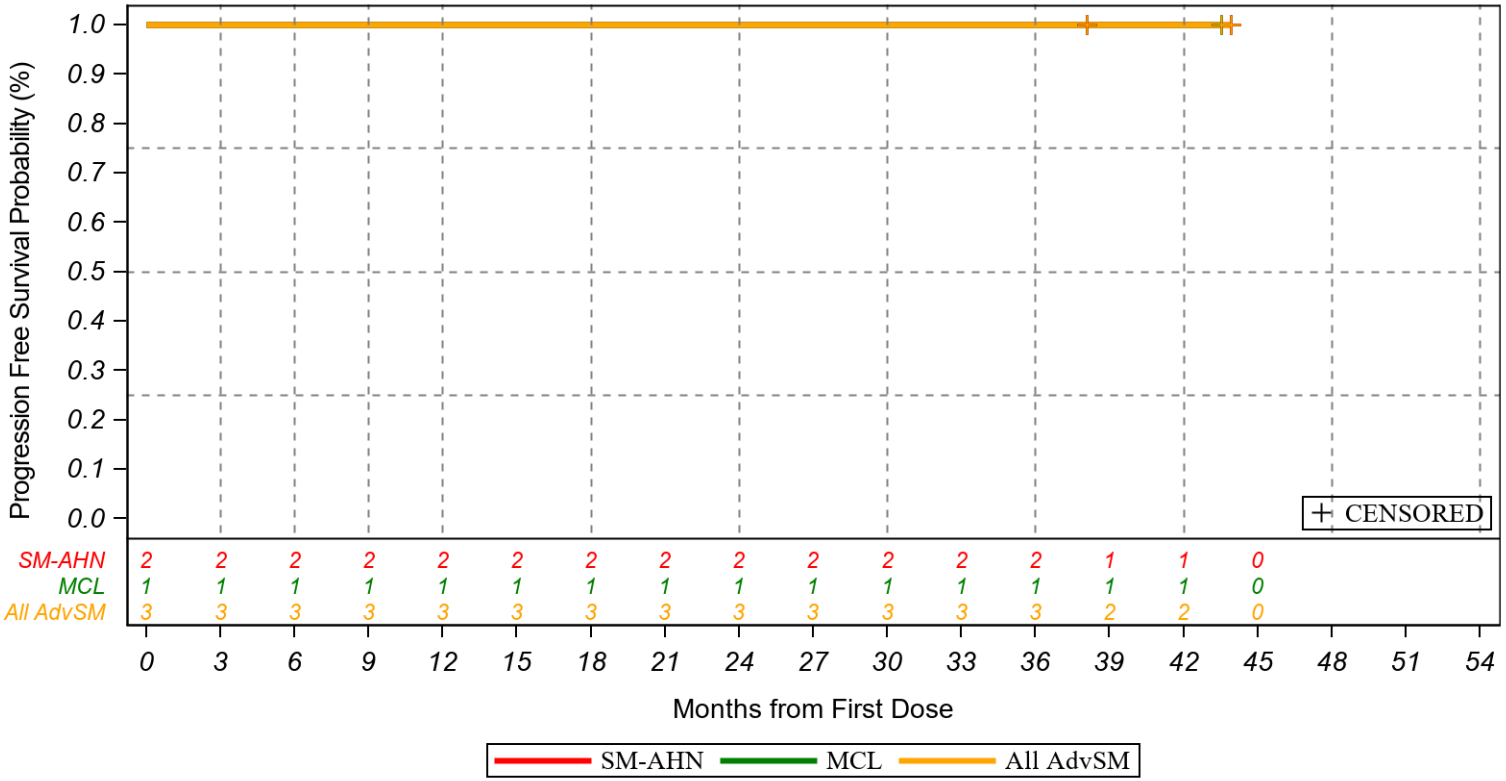
Date: 12:17/19OCT2021

Figure 35.2.3.2
Kaplan-Meier Curves of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101
Starting Dose: < 200 mg



Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/f-inv-pfs.sas
Date: 12:17/19OCT2021

Figure 35.2.3.2
Kaplan-Meier Curves of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101
Starting Dose: < 300 mg

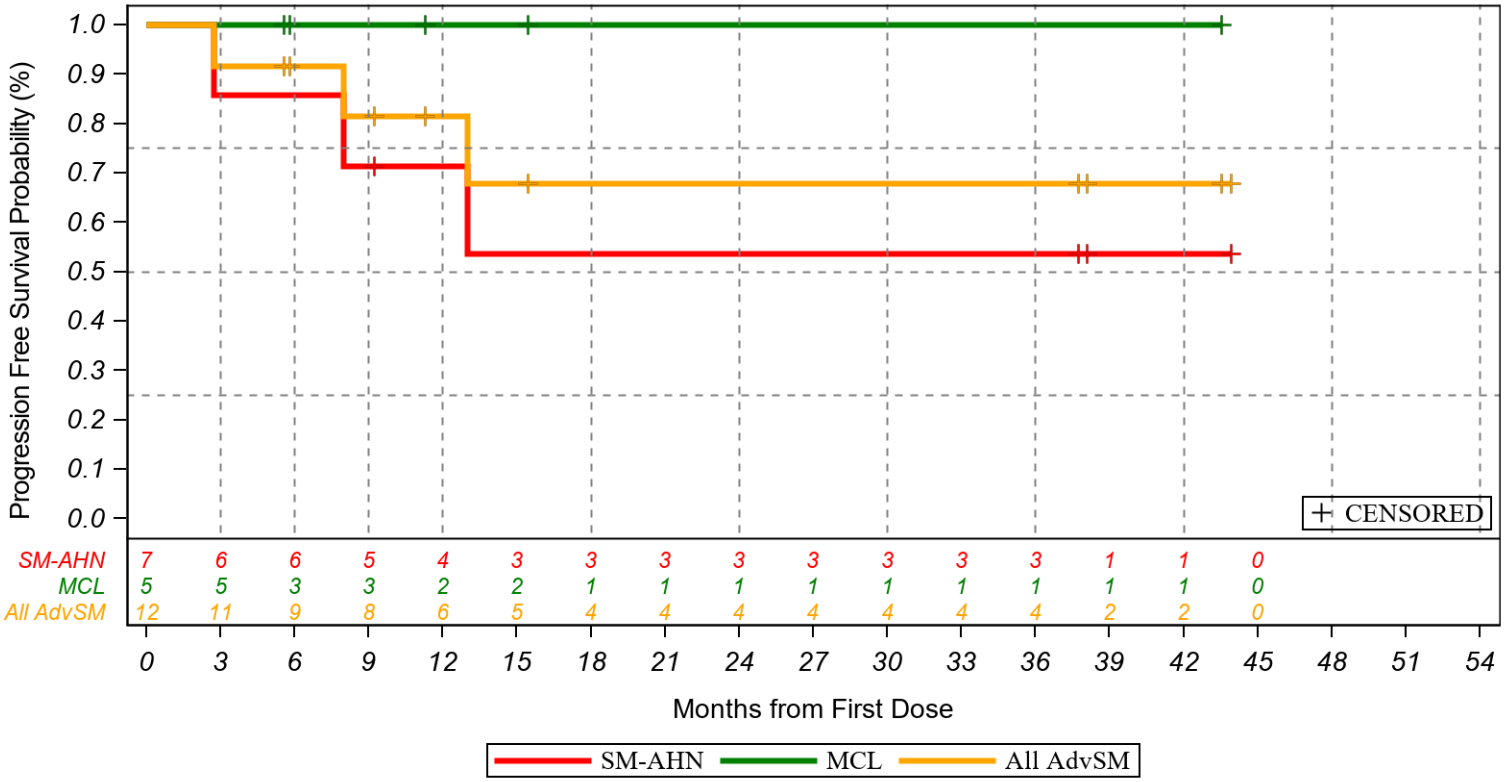


Figure 35.2.3.2
Kaplan-Meier Curves of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101
Starting Dose: 200 mg

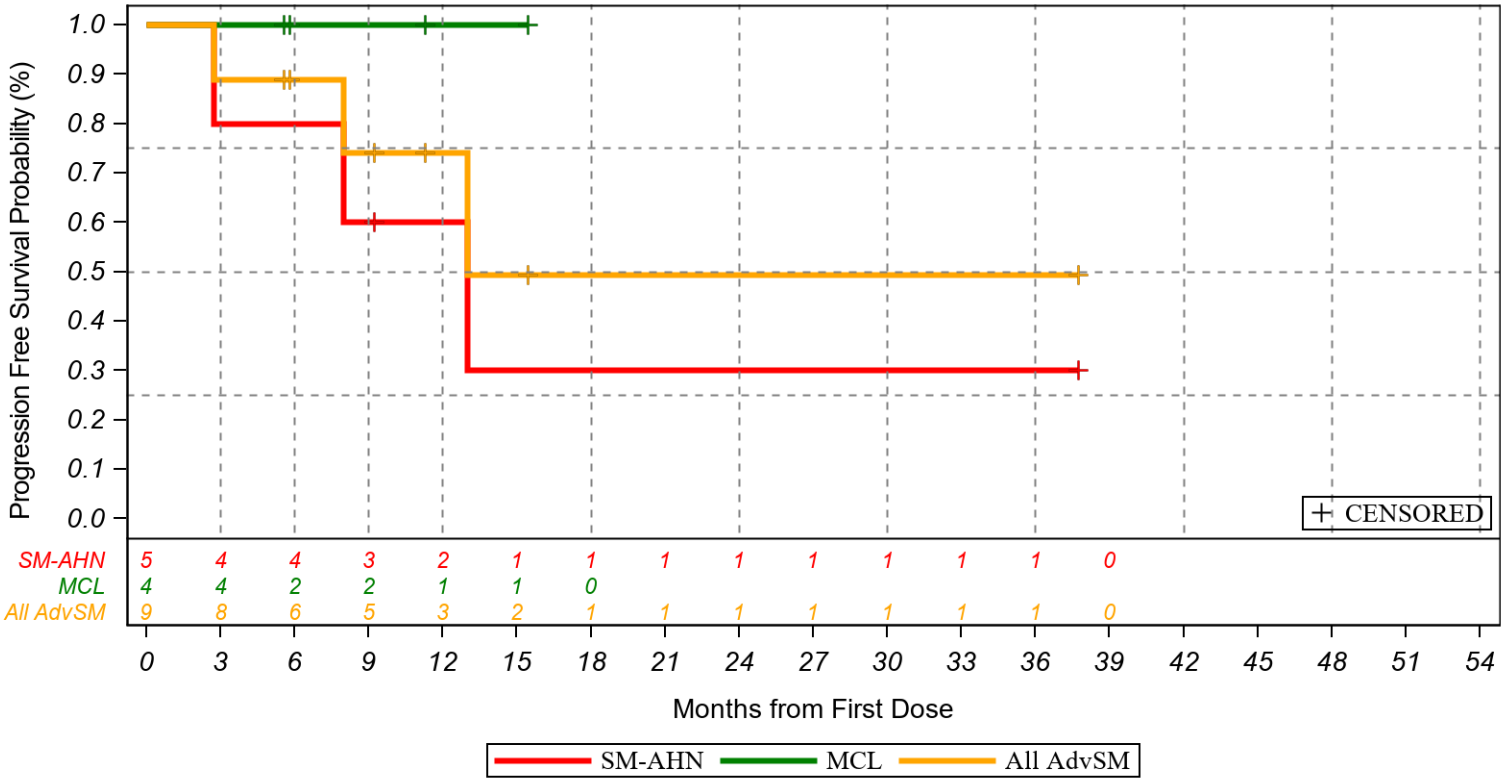


Figure 35.2.3.2
Kaplan-Meier Curves of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101
Starting Dose: 300 mg

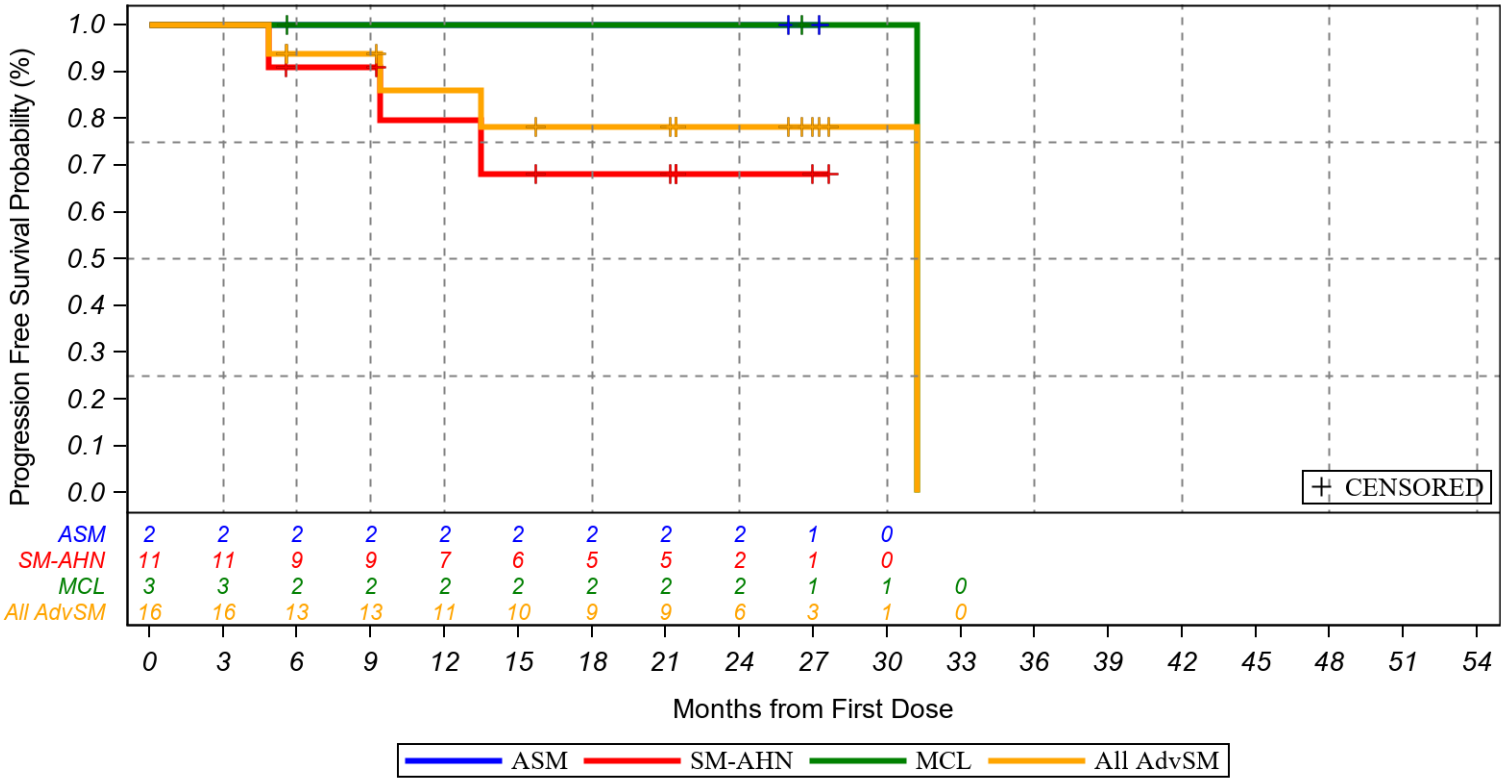


Figure 35.2.3.2
Kaplan-Meier Curves of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101
Starting Dose: 200 mg and 300 mg

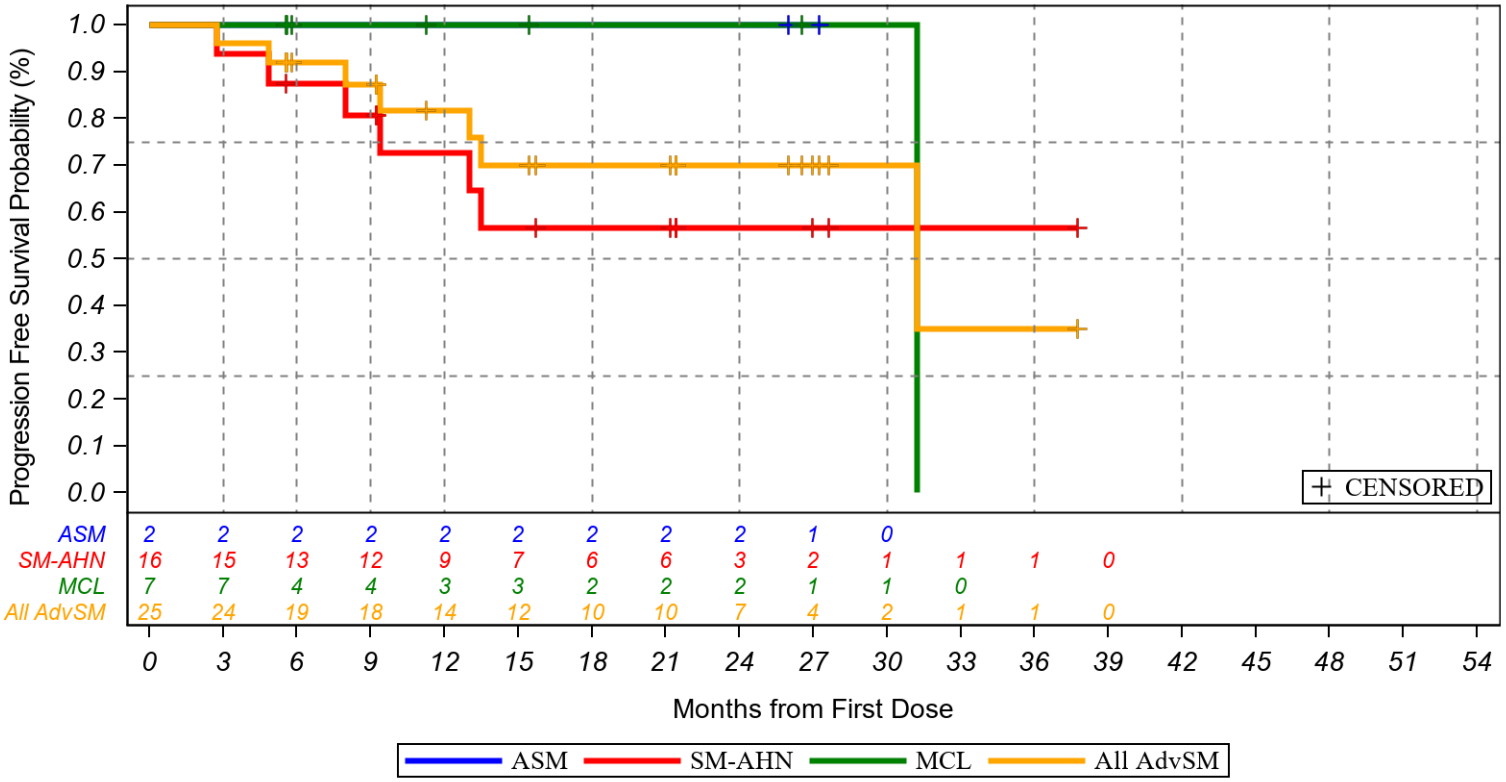


Figure 35.2.3.2
Kaplan-Meier Curves of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101
Starting Dose: 400 mg

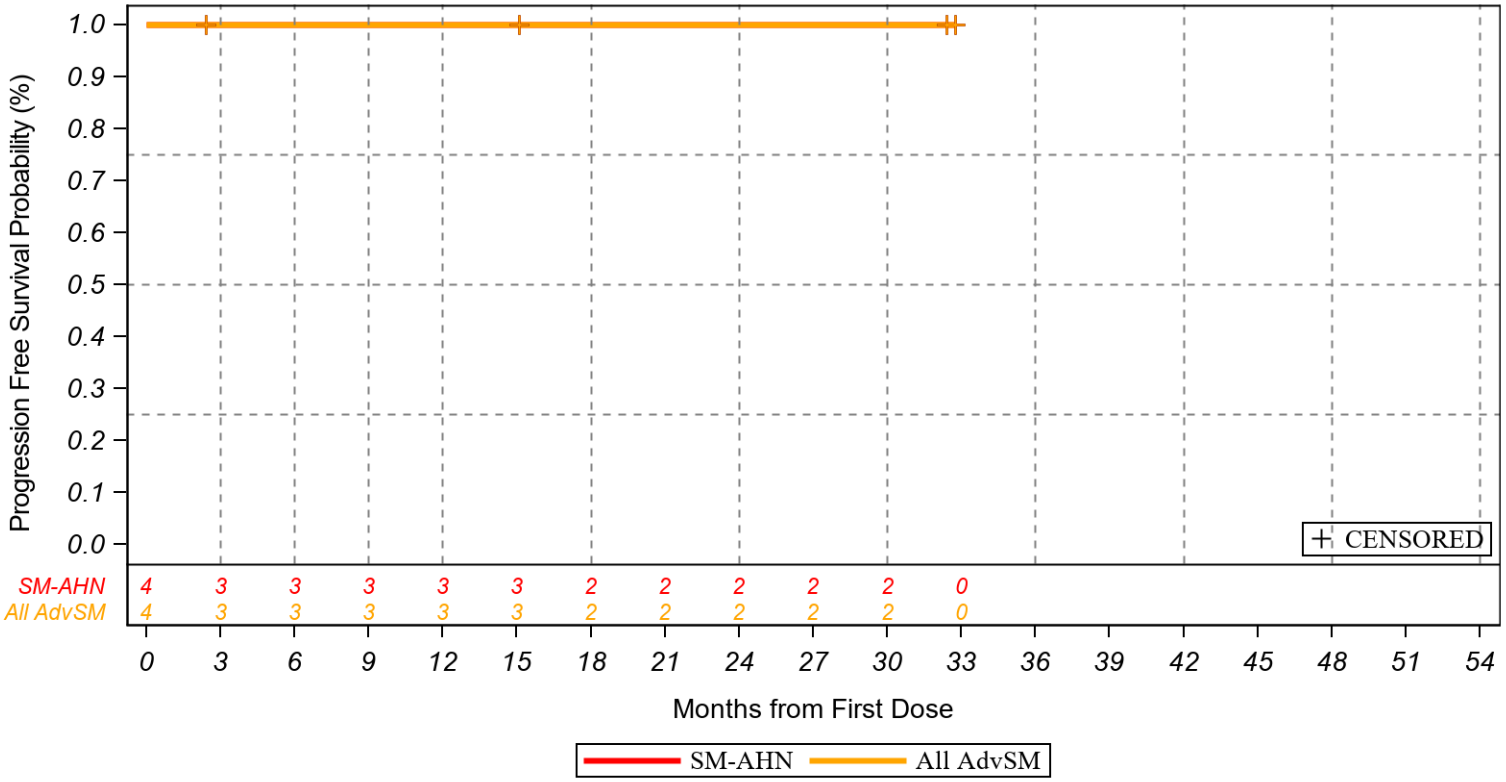


Figure 35.2.3.2
Kaplan-Meier Curves of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2202
Starting Dose: Overall

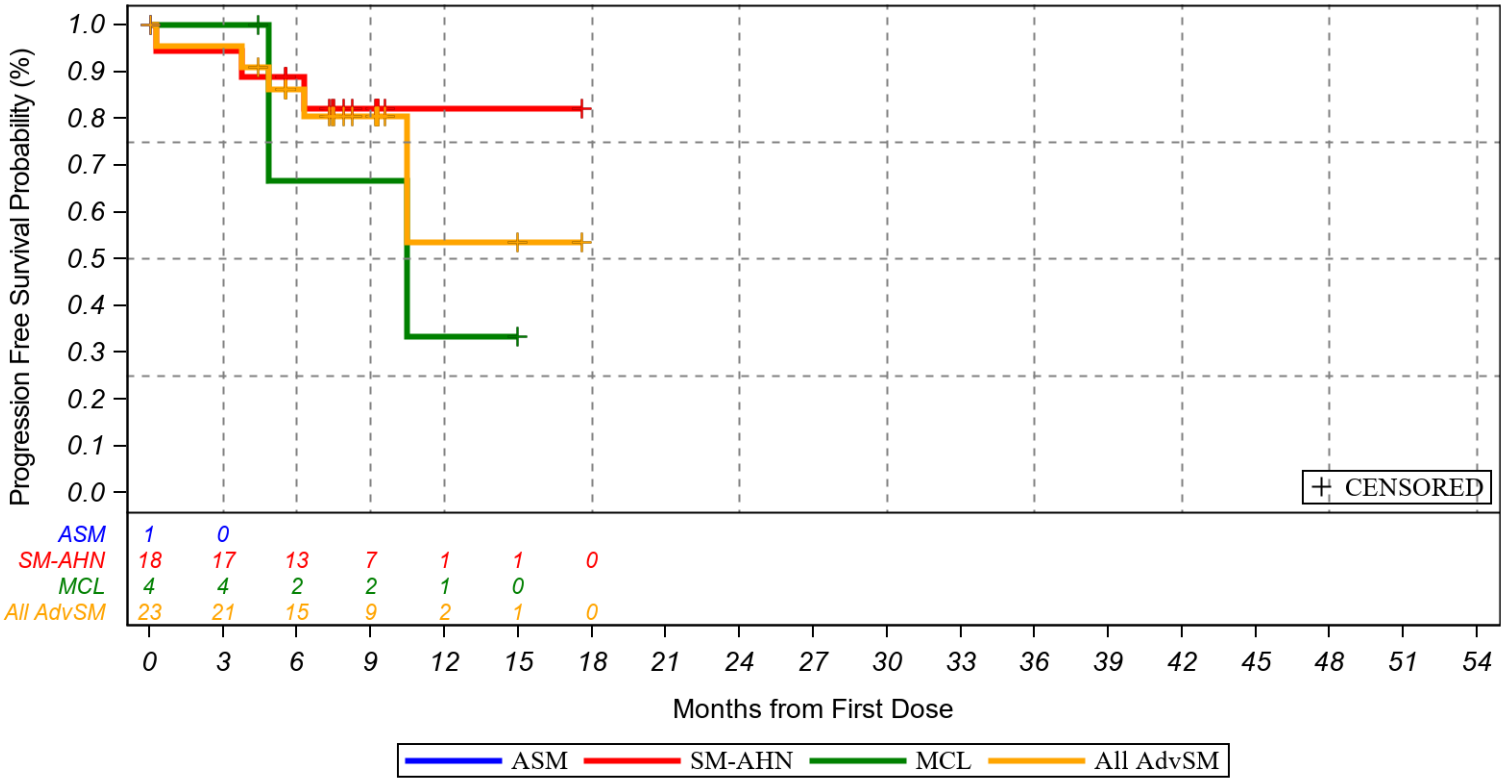


Figure 35.2.3.2
Kaplan-Meier Curves of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2202
Starting Dose: 200 mg

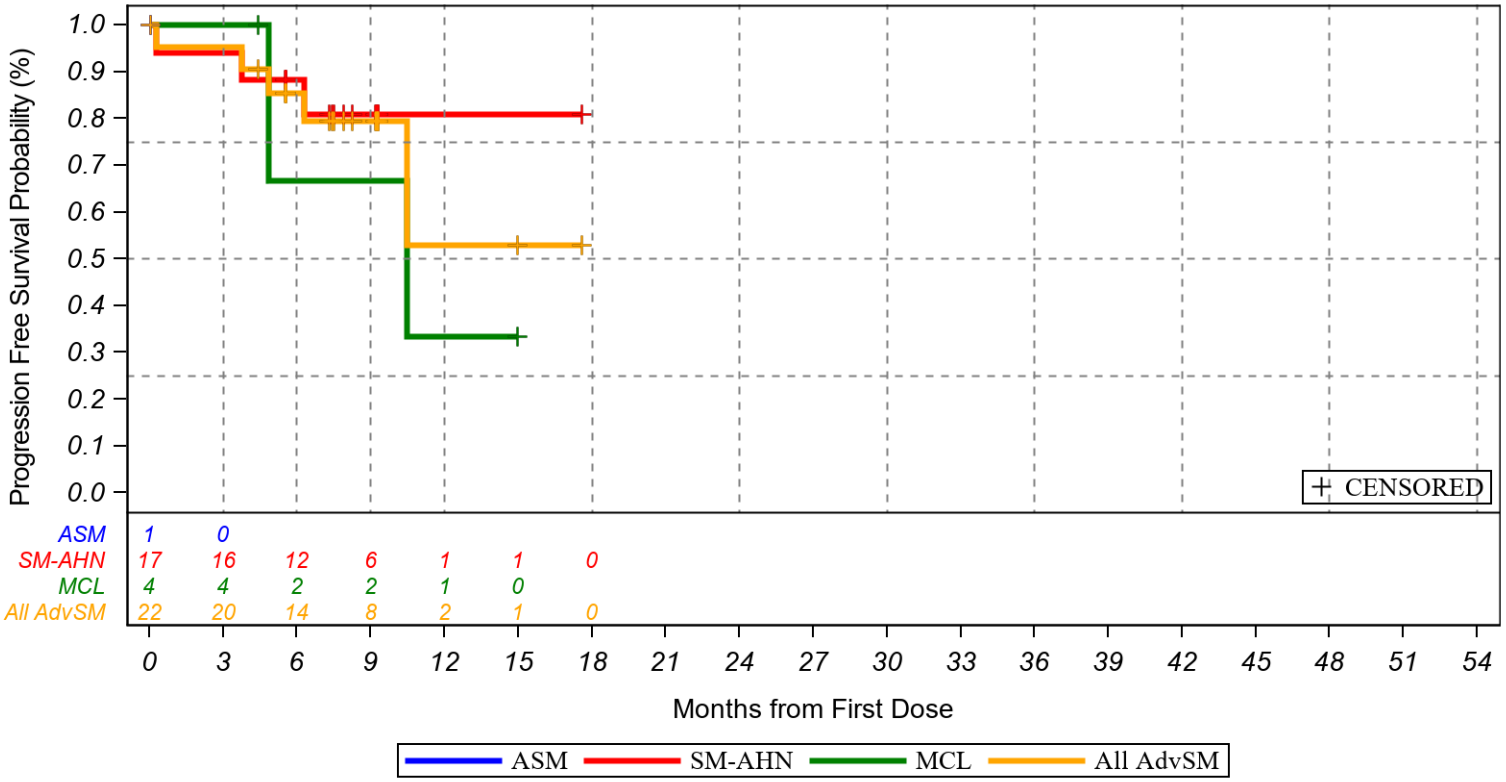


Figure 35.2.3.2
Kaplan-Meier Curves of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall

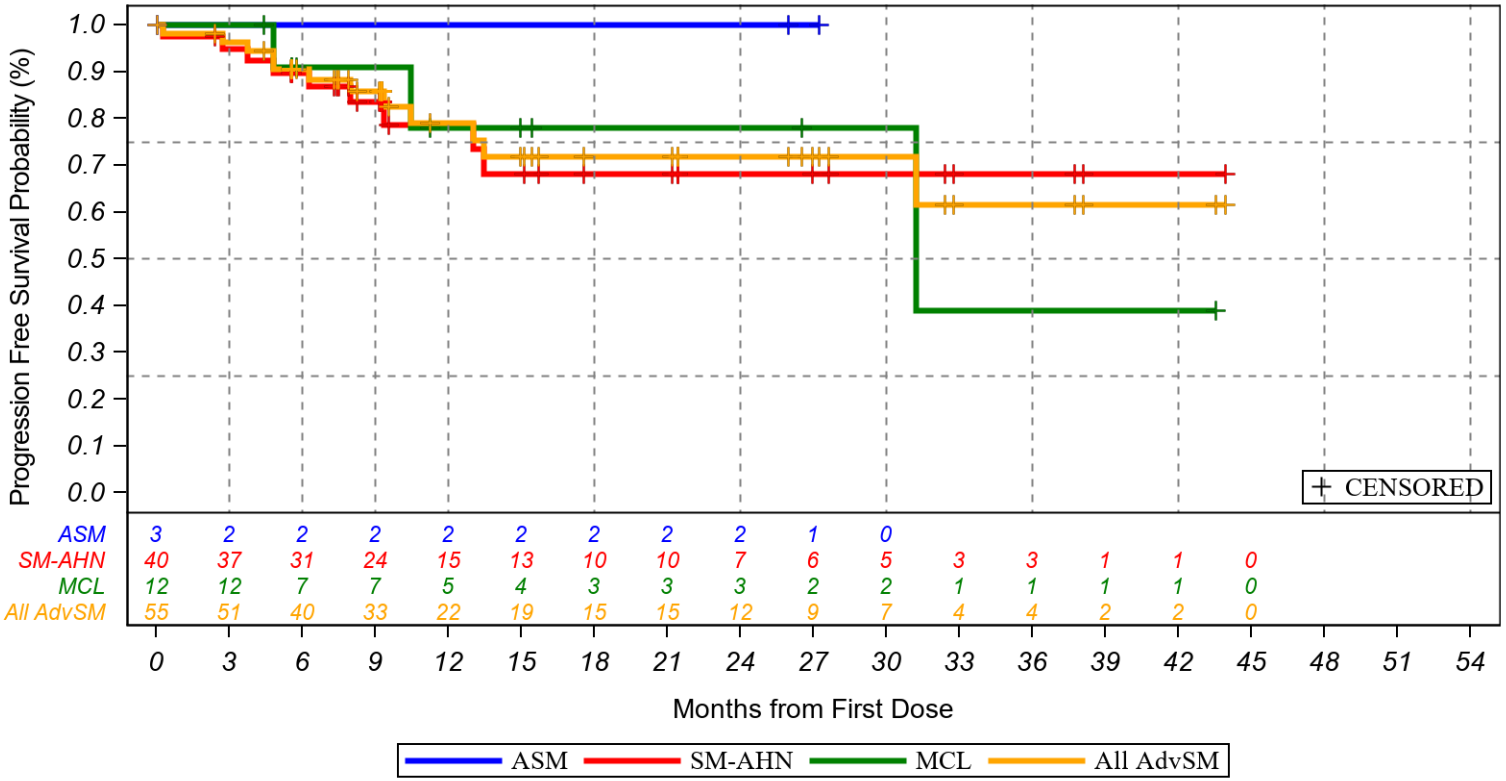
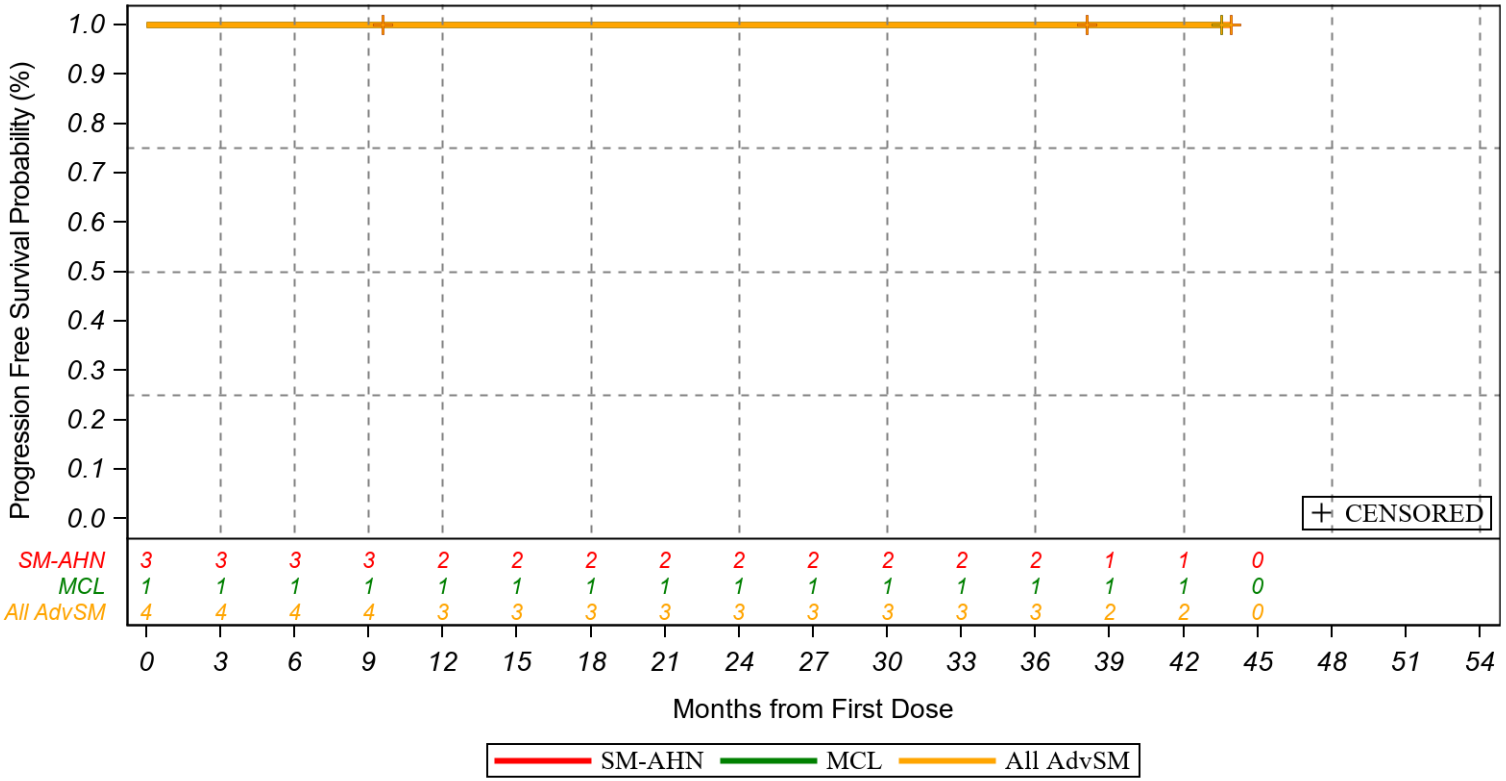


Figure 35.2.3.2
Kaplan-Meier Curves of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg



Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/f-inv-pfs.sas
Date: 12:17/19OCT2021

Figure 35.2.3.2
Kaplan-Meier Curves of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg

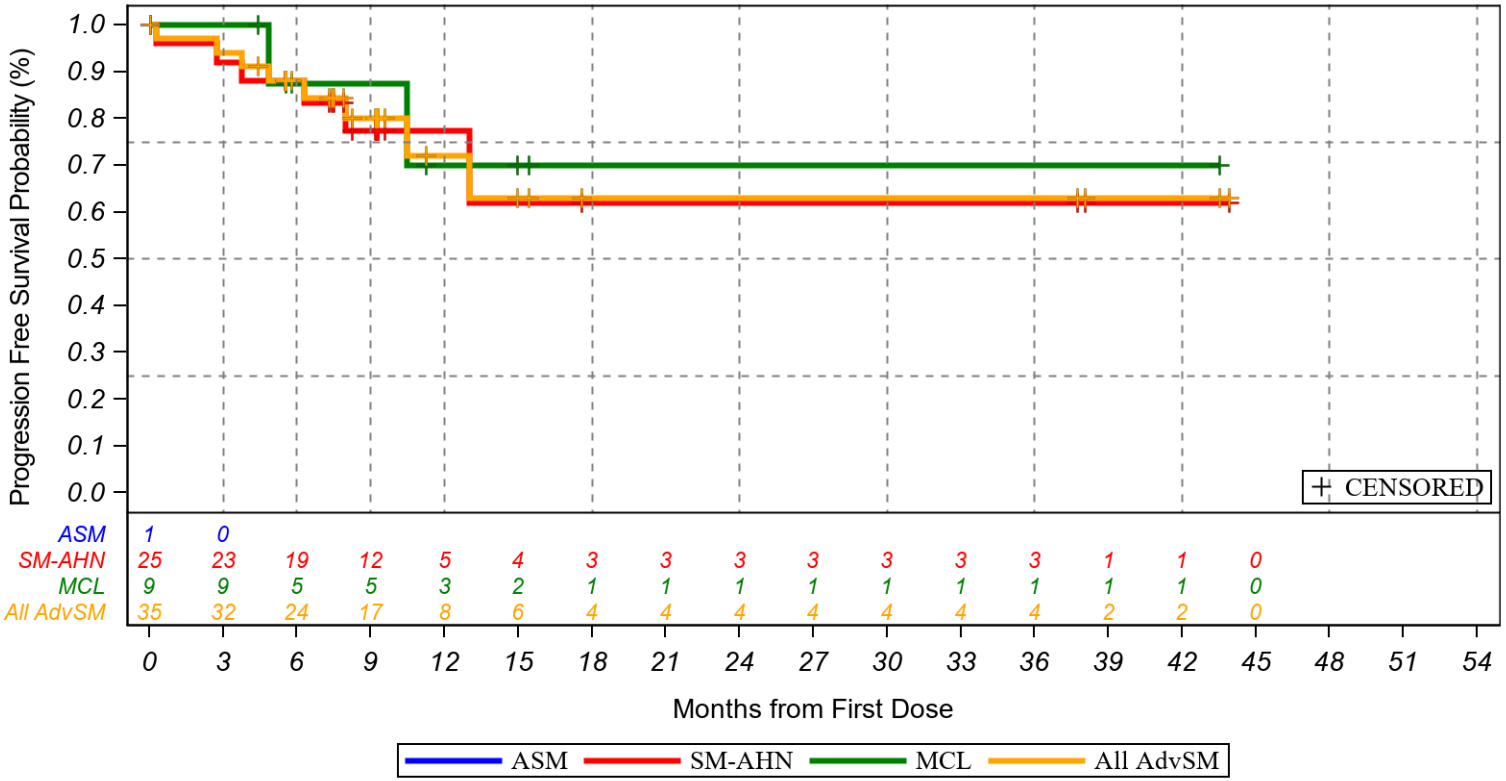


Figure 35.2.3.2
Kaplan-Meier Curves of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg

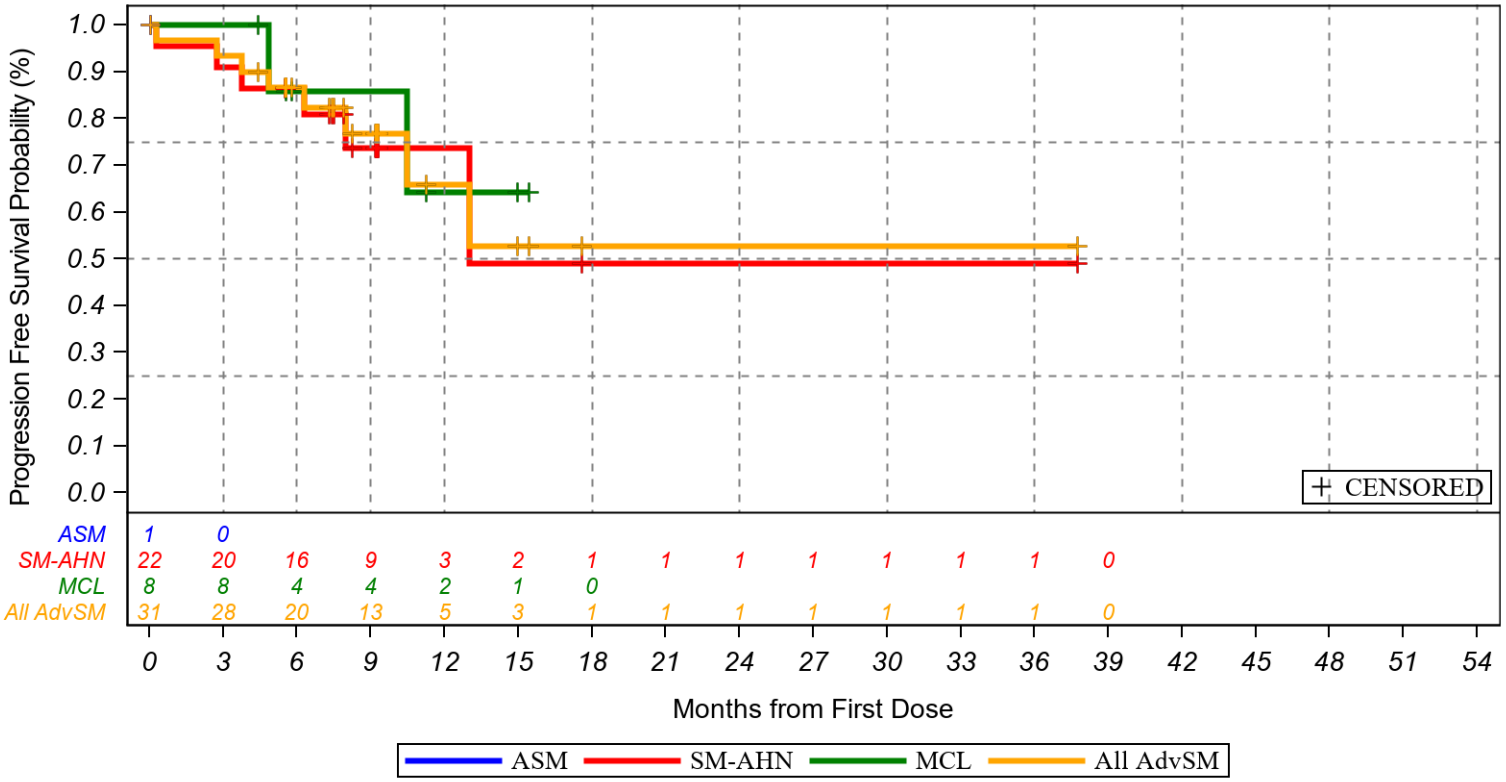


Figure 35.2.3.2
Kaplan-Meier Curves of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg

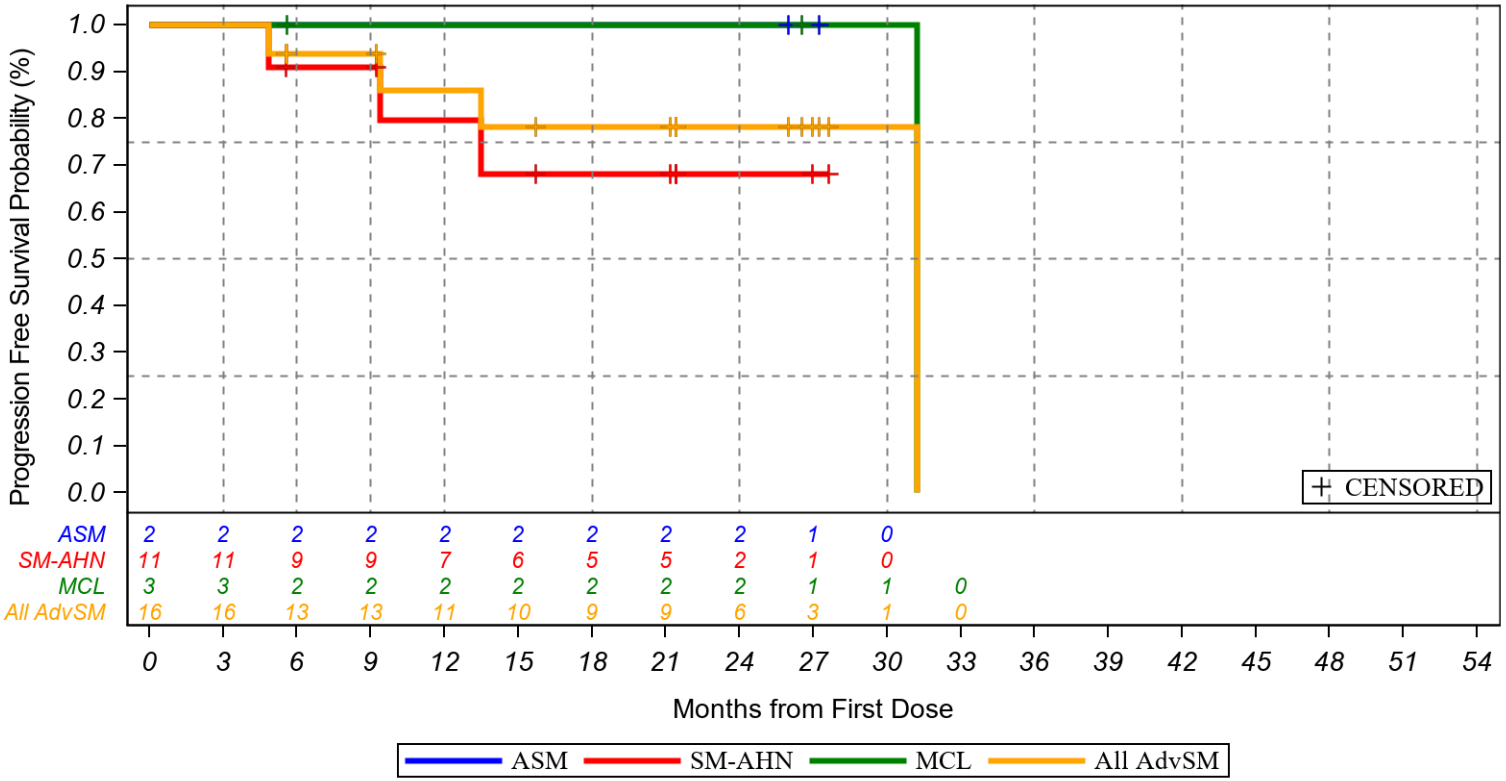


Figure 35.2.3.2
Kaplan-Meier Curves of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg

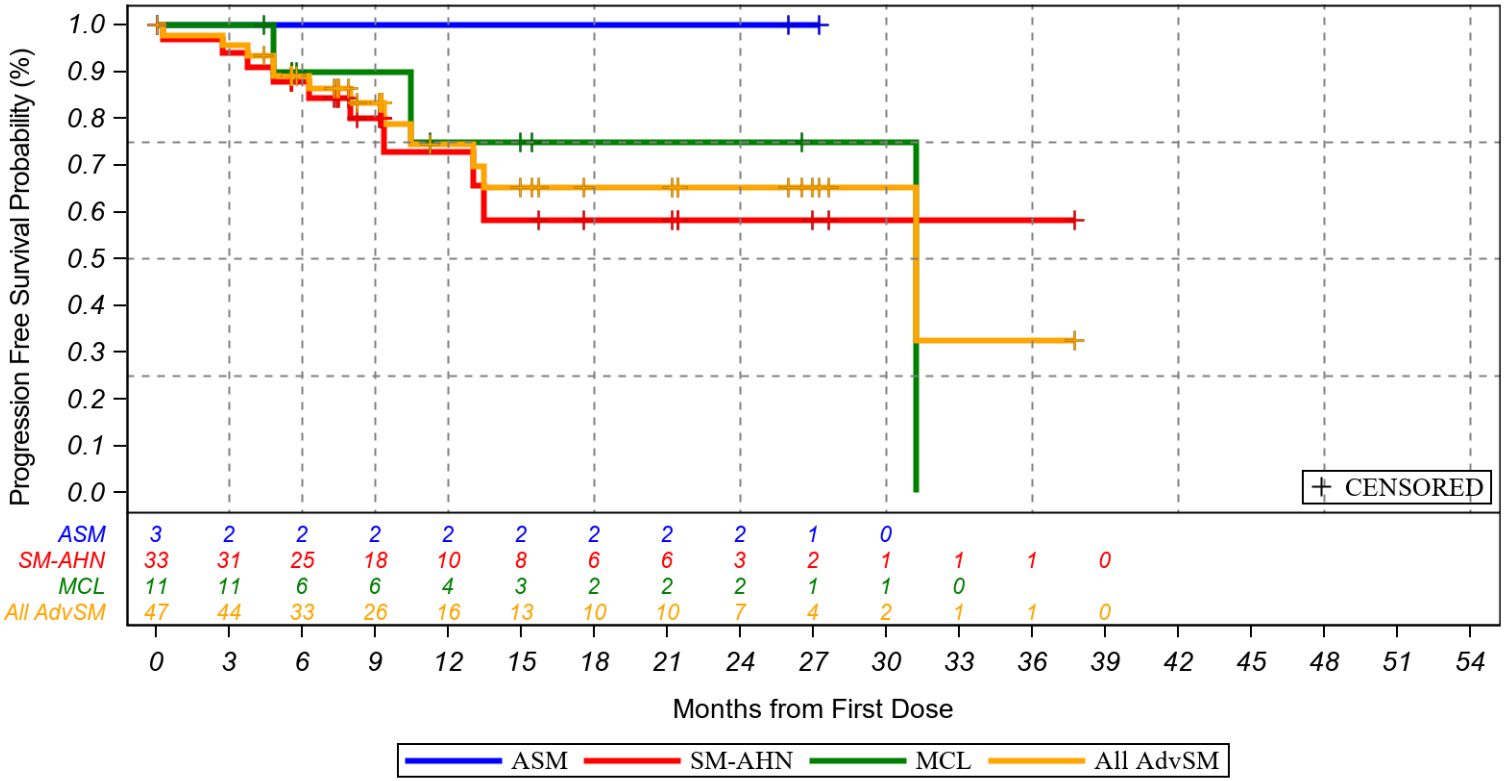


Figure 35.2.3.2
Kaplan-Meier Curves of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg

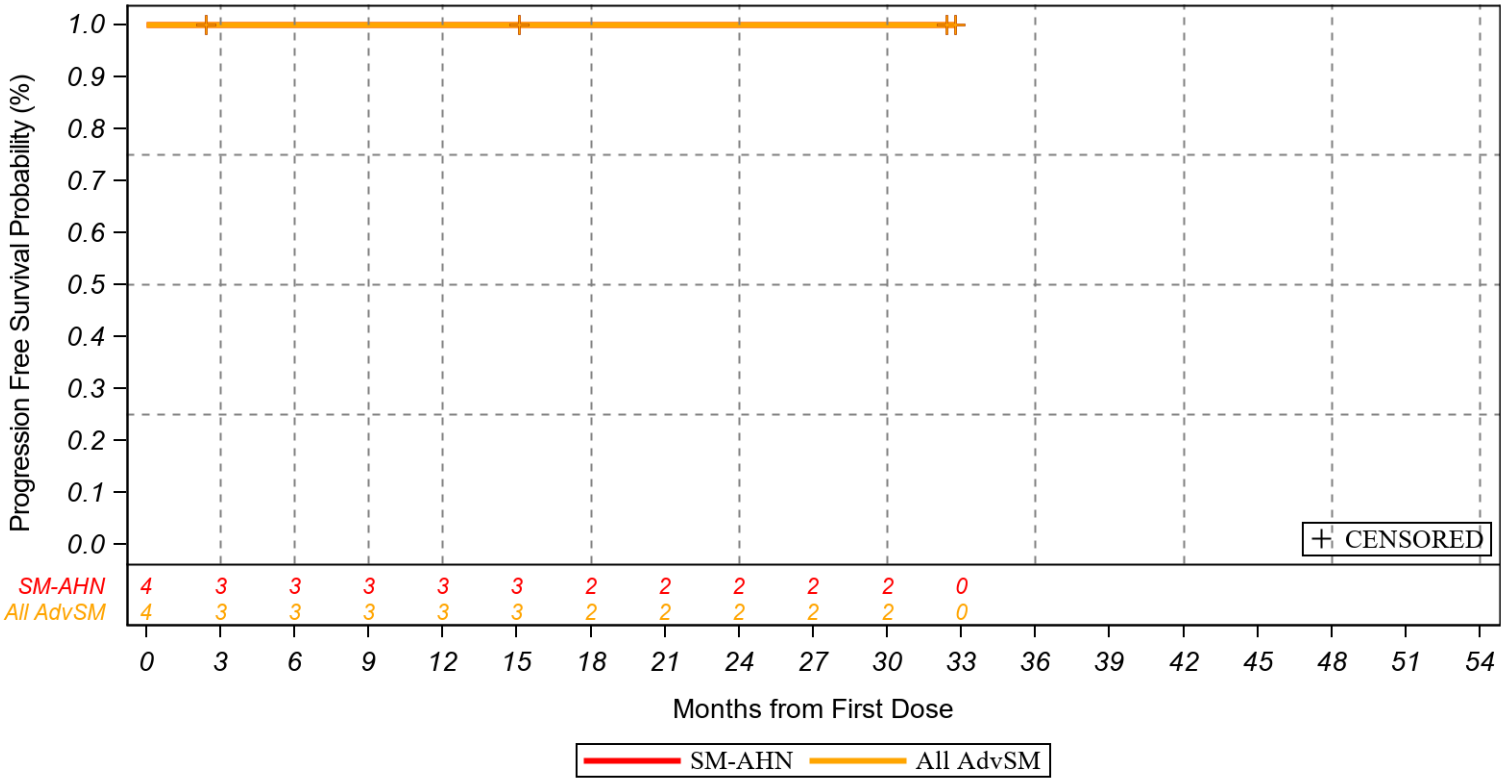


Table 35.2.3.4
Summary of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy - Patients Evaluable per IWG Criteria
Study BLU-285-2101

All Doses

Progression Free Survival	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=20) n (%) (95% CIs)	MCL (N=8) n (%) (95% CIs)	All AdvSM (N=30) n (%) (95% CIs)
Events	0	6 (30.0)	1 (12.5)	7 (23.3)
Censors	2 (100.0)	14 (70.0)	7 (87.5)	23 (76.7)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (13.5 -NE)	NE (31.2 -NE)	NE (31.2 -NE)
25th, 75th percentiles	NE, NE	13.0, NE	31.2, NE	31.2, NE
Min, Max	27.4*, 29.7*	2.7, 41.7*	8.0*, 45.3*	2.7, 45.3*
3 Months (95% CIs)	100.0 (100.0 -100.0)	95.0 (85.4 -100.0)	100.0 (100.0 -100.0)	96.7 (90.2 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	89.7 (76.2 -100.0)	100.0 (100.0 -100.0)	93.2 (84.1 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	84.4 (68.2 -100.0)	100.0 (100.0 -100.0)	89.6 (78.5 -100.0)
12 Months (95% CIs)	100.0 (100.0 -100.0)	79.2 (61.0 - 97.4)	100.0 (100.0 -100.0)	85.7 (72.7 - 98.7)
18 Months (95% CIs)	100.0 (100.0 -100.0)	68.6 (47.8 - 89.4)	100.0 (100.0 -100.0)	77.9 (62.3 - 93.6)
24 Months (95% CIs)	100.0 (100.0 -100.0)	68.6 (47.8 - 89.4)	100.0 (100.0 -100.0)	77.9 (62.3 - 93.6)
30 Months (95% CIs)		68.6 (47.8 - 89.4)	100.0 (100.0 -100.0)	77.9 (62.3 - 93.6)
36 Months (95% CIs)		68.6 (47.8 - 89.4)	50.0 (0.0 -100.0)	64.9 (38.3 - 91.6)
42 Months (95% CIs)			50.0 (0.0 -100.0)	64.9 (38.3 - 91.6)
48 Months (95% CIs)				
Median PFS Follow-up[a] (months) (95% CI)	28.6 (27.4 - 29.7)	22.3 (15.4 - 34.4)	16.8 (8.5 - 45.3)	22.3 (17.5 - 29.7)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-alg-iwg-pfs-rac.sas Date: 14:36/18OCT2021

Table 35.2.3.4
Summary of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy - Patients Evaluable per IWG Criteria
Study BLU-285-2101

Starting Dose: < 200 mg

Progression Free Survival	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=1) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=2) n (%) (95% CIs)
Events		0	0	0
Censors		1 (100.0)	1 (100.0)	2 (100.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE -NE)	NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles		NE, NE	NE, NE	NE, NE
Min, Max		41.7*, 41.7*	45.3*, 45.3*	41.7*, 45.3*
3 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
12 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
18 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
24 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
30 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
36 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
42 Months (95% CIs)			100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
48 Months (95% CIs)				
Median PFS Follow-up[a] (months) (95% CI)		41.7 (NE -NE)	45.3 (NE -NE)	43.5 (41.7 - 45.3)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-alg-iwg-pfs-rac.sas Date: 14:36/18OCT2021

Table 35.2.3.4
Summary of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy - Patients Evaluable per IWG Criteria
Study BLU-285-2101

Starting Dose: < 300 mg

Progression Free Survival	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=6) n (%) (95% CIs)	MCL (N=5) n (%) (95% CIs)	All AdvSM (N=11) n (%) (95% CIs)
Events		3 (50.0)	0	3 (27.3)
Censors		3 (50.0)	5 (100.0)	8 (72.7)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (8.0 -NE)	NE (NE -NE)	NE (13.0 -NE)
25th, 75th percentiles		8.0, NE	NE, NE	13.0, NE
Min, Max		2.7, 41.7*	8.5*, 45.3*	2.7, 45.3*
3 Months (95% CIs)		83.3 (53.5 -100.0)	100.0 (100.0 -100.0)	90.9 (73.9 -100.0)
6 Months (95% CIs)		83.3 (53.5 -100.0)	100.0 (100.0 -100.0)	90.9 (73.9 -100.0)
9 Months (95% CIs)		66.7 (28.9 -100.0)	100.0 (100.0 -100.0)	81.8 (59.0 -100.0)
12 Months (95% CIs)		66.7 (28.9 -100.0)	100.0 (100.0 -100.0)	81.8 (59.0 -100.0)
18 Months (95% CIs)		50.0 (10.0 - 90.0)	100.0 (100.0 -100.0)	70.1 (41.3 - 99.0)
24 Months (95% CIs)		50.0 (10.0 - 90.0)	100.0 (100.0 -100.0)	70.1 (41.3 - 99.0)
30 Months (95% CIs)		50.0 (10.0 - 90.0)	100.0 (100.0 -100.0)	70.1 (41.3 - 99.0)
36 Months (95% CIs)		50.0 (10.0 - 90.0)	100.0 (100.0 -100.0)	70.1 (41.3 - 99.0)
42 Months (95% CIs)			100.0 (100.0 -100.0)	70.1 (41.3 - 99.0)
48 Months (95% CIs)				
Median PFS Follow-up[a] (months) (95% CI)		37.7 (15.4 - 41.7)	14.7 (8.5 - 45.3)	19.0 (14.7 - 41.7)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-alg-iwg-pfs-rac.sas Date: 14:36/18OCT2021

Table 35.2.3.4
Summary of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy - Patients Evaluable per IWG Criteria
Study BLU-285-2101

Starting Dose: 200 mg

Progression Free Survival	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=5) n (%) (95% CIs)	MCL (N=4) n (%) (95% CIs)	All AdvSM (N=9) n (%) (95% CIs)
Events		3 (60.0)	0	3 (33.3)
Censors		2 (40.0)	4 (100.0)	6 (66.7)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		13.0 (2.7 -NE)	NE (NE -NE)	NE (13.0 -NE)
25th, 75th percentiles		8.0, NE	NE, NE	13.0, NE
Min, Max		2.7, 37.7*	8.5*, 19.0*	2.7, 37.7*
3 Months (95% CIs)		80.0 (44.9 -100.0)	100.0 (100.0 -100.0)	88.9 (68.4 -100.0)
6 Months (95% CIs)		80.0 (44.9 -100.0)	100.0 (100.0 -100.0)	88.9 (68.4 -100.0)
9 Months (95% CIs)		60.0 (17.1 -100.0)	100.0 (100.0 -100.0)	77.8 (50.6 -100.0)
12 Months (95% CIs)		60.0 (17.1 -100.0)	100.0 (100.0 -100.0)	77.8 (50.6 -100.0)
18 Months (95% CIs)		40.0 (0.0 - 82.9)	100.0 (100.0 -100.0)	62.2 (27.4 - 97.1)
24 Months (95% CIs)		40.0 (0.0 - 82.9)		62.2 (27.4 - 97.1)
30 Months (95% CIs)		40.0 (0.0 - 82.9)		62.2 (27.4 - 97.1)
36 Months (95% CIs)		40.0 (0.0 - 82.9)		62.2 (27.4 - 97.1)
42 Months (95% CIs)				
48 Months (95% CIs)				
Median PFS Follow-up[a] (months) (95% CI)		26.6 (15.4 - 37.7)	11.6 (8.5 - 19.0)	15.4 (8.5 - 19.0)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-alg-iwg-pfs-rac.sas Date: 14:36/18OCT2021

Table 35.2.3.4
Summary of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy - Patients Evaluable per IWG Criteria
Study BLU-285-2101

Starting Dose: 300 mg

Progression Free Survival	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=10) n (%) (95% CIs)	MCL (N=3) n (%) (95% CIs)	All AdvSM (N=15) n (%) (95% CIs)
Events	0	3 (30.0)	1 (33.3)	4 (26.7)
Censors	2 (100.0)	7 (70.0)	2 (66.7)	11 (73.3)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (13.5 -NE)	31.2 (NE -NE)	31.2 (NE -NE)
25th, 75th percentiles	NE, NE	13.5, NE	31.2, 31.2	31.2, 31.2
Min, Max	27.4*, 29.7*	4.8, 29.3*	8.0*, 31.2	4.8, 31.2
3 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	90.0 (71.4 -100.0)	100.0 (100.0 -100.0)	93.3 (80.7 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	90.0 (71.4 -100.0)	100.0 (100.0 -100.0)	93.3 (80.7 -100.0)
12 Months (95% CIs)	100.0 (100.0 -100.0)	80.0 (55.2 -100.0)	100.0 (100.0 -100.0)	86.2 (68.3 -100.0)
18 Months (95% CIs)	100.0 (100.0 -100.0)	70.0 (41.6 - 98.4)	100.0 (100.0 -100.0)	79.0 (57.8 -100.0)
24 Months (95% CIs)	100.0 (100.0 -100.0)	70.0 (41.6 - 98.4)	100.0 (100.0 -100.0)	79.0 (57.8 -100.0)
30 Months (95% CIs)			100.0 (100.0 -100.0)	79.0 (57.8 -100.0)
36 Months (95% CIs)			0.0 (0.0 - 0.0)	0.0 (0.0 - 0.0)
42 Months (95% CIs)			0.0 (0.0 - 0.0)	0.0 (0.0 - 0.0)
48 Months (95% CIs)			0.0 (0.0 - 0.0)	0.0 (0.0 - 0.0)
Median PFS Follow-up[a] (months) (95% CI)	28.6 (27.4 - 29.7)	22.1 (17.5 - 27.0)	30.2 (8.0 -NE)	27.0 (21.4 - 29.7)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-alg-iwg-pfs-rac.sas Date: 14:36/18OCT2021

Table 35.2.3.4
Summary of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy - Patients Evaluable per IWG Criteria
Study BLU-285-2101

Starting Dose: 200 mg and 300 mg

Progression Free Survival	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=15) n (%) (95% CIs)	MCL (N=7) n (%) (95% CIs)	All AdvSM (N=24) n (%) (95% CIs)
Events	0	6 (40.0)	1 (14.3)	7 (29.2)
Censors	2 (100.0)	9 (60.0)	6 (85.7)	17 (70.8)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (13.0 -NE)	31.2 (NE -NE)	31.2 (31.2 -NE)
25th, 75th percentiles	NE, NE	9.4, NE	31.2, 31.2	13.5, NE
Min, Max	27.4*, 29.7*	2.7, 37.7*	8.0*, 31.2	2.7, 37.7*
3 Months (95% CIs)	100.0 (100.0 -100.0)	93.3 (80.7 -100.0)	100.0 (100.0 -100.0)	95.8 (87.8 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	86.7 (69.5 -100.0)	100.0 (100.0 -100.0)	91.7 (80.6 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	80.0 (59.8 -100.0)	100.0 (100.0 -100.0)	87.3 (73.9 -100.0)
12 Months (95% CIs)	100.0 (100.0 -100.0)	73.3 (51.0 - 95.7)	100.0 (100.0 -100.0)	82.5 (66.8 - 98.2)
18 Months (95% CIs)	100.0 (100.0 -100.0)	60.0 (35.2 - 84.8)	100.0 (100.0 -100.0)	72.8 (54.0 - 91.5)
24 Months (95% CIs)	100.0 (100.0 -100.0)	60.0 (35.2 - 84.8)	100.0 (100.0 -100.0)	72.8 (54.0 - 91.5)
30 Months (95% CIs)		60.0 (35.2 - 84.8)	100.0 (100.0 -100.0)	72.8 (54.0 - 91.5)
36 Months (95% CIs)		60.0 (35.2 - 84.8)	0.0 (0.0 - 0.0)	36.4 (0.0 - 87.7)
42 Months (95% CIs)			0.0 (0.0 - 0.0)	
48 Months (95% CIs)			0.0 (0.0 - 0.0)	
Median PFS Follow-up[a] (months) (95% CI)	28.6 (27.4 - 29.7)	22.1 (17.5 - 27.0)	14.7 (8.5 - 30.2)	22.1 (15.4 - 27.4)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-alg-iwg-pfs-rac.sas Date: 14:36/18OCT2021

Table 35.2.3.4
Summary of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy - Patients Evaluable per IWG Criteria
Study BLU-285-2101

Starting Dose: 400 mg

Progression Free Survival	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=4) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=4) n (%) (95% CIs)
Events		0		0
Censors		4 (100.0)		4 (100.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE -NE)		NE (NE -NE)
25th, 75th percentiles		NE, NE		NE, NE
Min, Max		4.3*, 37.8*		4.3*, 37.8*
3 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
6 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
9 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
12 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
18 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
24 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
30 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
36 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
42 Months (95% CIs)				
48 Months (95% CIs)				
Median PFS Follow-up[a] (months) (95% CI)		24.8 (4.3 - 37.8)		24.8 (4.3 - 37.8)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-alg-iwg-pfs-rac.sas Date: 14:36/18OCT2021

Table 35.2.3.4
Summary of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy - Patients Evaluable per IWG Criteria
Study BLU-285-2202

All Doses

Progression Free Survival	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=18) n (%) (95% CIs)	MCL (N=4) n (%) (95% CIs)	All AdvSM (N=23) n (%) (95% CIs)
Events	0	3 (16.7)	2 (50.0)	5 (21.7)
Censors	1 (100.0)	15 (83.3)	2 (50.0)	18 (78.3)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (NE -NE)	10.5 (4.8 -NE)	NE (10.5 -NE)
25th, 75th percentiles	NE, NE	NE, NE	4.8, NE	10.5, NE
Min, Max	8.7*, 8.7*	0.3, 17.6*	4.4*, 16.1*	0.3, 17.6*
3 Months (95% CIs)	100.0 (100.0 -100.0)	94.4 (83.9 -100.0)	100.0 (100.0 -100.0)	95.7 (87.3 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	88.9 (74.4 -100.0)	66.7 (13.3 -100.0)	86.7 (72.7 -100.0)
9 Months (95% CIs)		83.0 (65.4 -100.0)	66.7 (13.3 -100.0)	81.9 (65.8 - 98.0)
12 Months (95% CIs)		83.0 (65.4 -100.0)	33.3 (0.0 - 86.7)	70.2 (44.9 - 95.5)
18 Months (95% CIs)				
24 Months (95% CIs)				
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				
Median PFS Follow-up[a] (months) (95% CI)	8.7 (NE -NE)	10.2 (7.9 - 11.8)	16.1 (4.4 - 16.1)	10.2 (7.9 - 13.7)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-alg-iwg-pfs-rac.sas Date: 14:36/18OCT2021

Table 35.2.3.4
Summary of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy - Patients Evaluable per IWG Criteria
Study BLU-285-2202

Starting Dose: 200 mg

Progression Free Survival	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=17) n (%) (95% CIs)	MCL (N=4) n (%) (95% CIs)	All AdvSM (N=22) n (%) (95% CIs)
Events	0	3 (17.6)	2 (50.0)	5 (22.7)
Censors	1 (100.0)	14 (82.4)	2 (50.0)	17 (77.3)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (NE -NE)	10.5 (4.8 -NE)	NE (10.5 -NE)
25th, 75th percentiles	NE, NE	NE, NE	4.8, NE	10.5, NE
Min, Max	8.7*, 8.7*	0.3, 17.6*	4.4*, 16.1*	0.3, 17.6*
3 Months (95% CIs)	100.0 (100.0 -100.0)	94.1 (82.9 -100.0)	100.0 (100.0 -100.0)	95.5 (86.8 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	88.2 (72.9 -100.0)	66.7 (13.3 -100.0)	86.1 (71.5 -100.0)
9 Months (95% CIs)		81.9 (63.4 -100.0)	66.7 (13.3 -100.0)	81.1 (64.3 - 97.8)
12 Months (95% CIs)		81.9 (63.4 -100.0)	33.3 (0.0 - 86.7)	67.5 (39.6 - 95.5)
18 Months (95% CIs)				
24 Months (95% CIs)				
30 Months (95% CIs)				
36 Months (95% CIs)				
42 Months (95% CIs)				
48 Months (95% CIs)				
Median PFS Follow-up[a] (months) (95% CI)	8.7 (NE -NE)	10.2 (7.4 - 13.7)	16.1 (4.4 - 16.1)	10.2 (7.9 - 13.7)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-alg-iwg-pfs-rac.sas Date: 14:36/18OCT2021

Table 35.2.3.4
Summary of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy - Patients Evaluable per IWG Criteria
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Progression Free Survival	ASM (N=3) n (%) (95% CIs)	SM-AHN (N=38) n (%) (95% CIs)	MCL (N=12) n (%) (95% CIs)	All AdvSM (N=53) n (%) (95% CIs)
Events	0	9 (23.7)	3 (25.0)	12 (22.6)
Censors	3 (100.0)	29 (76.3)	9 (75.0)	41 (77.4)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (NE -NE)	31.2 (31.2 -NE)	NE (31.2 -NE)
25th, 75th percentiles	NE, NE	13.5, NE	31.2, NE	13.5, NE
Min, Max	8.7*, 29.7*	0.3, 41.7*	4.4*, 45.3*	0.3, 45.3*
3 Months (95% CIs)	100.0 (100.0 -100.0)	94.7 (87.6 -100.0)	100.0 (100.0 -100.0)	96.2 (91.1 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	89.4 (79.6 - 99.2)	90.9 (73.9 -100.0)	90.4 (82.4 - 98.4)
9 Months (95% CIs)	100.0 (100.0 -100.0)	83.4 (71.2 - 95.6)	90.9 (73.9 -100.0)	86.1 (76.6 - 95.7)
12 Months (95% CIs)	100.0 (100.0 -100.0)	80.1 (66.7 - 93.4)	77.9 (50.2 -100.0)	80.7 (69.2 - 92.3)
18 Months (95% CIs)	100.0 (100.0 -100.0)	71.6 (55.4 - 87.9)	77.9 (50.2 -100.0)	74.7 (61.4 - 88.1)
24 Months (95% CIs)	100.0 (100.0 -100.0)	71.6 (55.4 - 87.9)	77.9 (50.2 -100.0)	74.7 (61.4 - 88.1)
30 Months (95% CIs)		71.6 (55.4 - 87.9)	77.9 (50.2 -100.0)	74.7 (61.4 - 88.1)
36 Months (95% CIs)		71.6 (55.4 - 87.9)	39.0 (0.0 - 94.7)	62.3 (37.4 - 87.2)
42 Months (95% CIs)			39.0 (0.0 - 94.7)	62.3 (37.4 - 87.2)
48 Months (95% CIs)				
Median PFS Follow-up[a] (months) (95% CI)	27.4 (8.7 - 29.7)	15.4 (10.3 - 21.4)	16.1 (8.5 - 30.2)	15.7 (11.8 - 19.0)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-alg-iwg-pfs-rac.sas Date: 14:36/18OCT2021

Table 35.2.3.4
Summary of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy - Patients Evaluable per IWG Criteria
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: < 200 mg

Progression Free Survival	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=2) n (%) (95% CIs)	MCL (N=1) n (%) (95% CIs)	All AdvSM (N=3) n (%) (95% CIs)
Events		0	0	0
Censors		2 (100.0)	1 (100.0)	3 (100.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE -NE)	NE (NE -NE)	NE (NE -NE)
25th, 75th percentiles		NE, NE	NE, NE	NE, NE
Min, Max		11.8*, 41.7*	45.3*, 45.3*	11.8*, 45.3*
3 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
9 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
12 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
18 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
24 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
30 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
36 Months (95% CIs)		100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
42 Months (95% CIs)			100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
48 Months (95% CIs)				
Median PFS Follow-up[a] (months) (95% CI)		26.7 (11.8 - 41.7)	45.3 (NE -NE)	41.7 (11.8 - 45.3)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-alg-iwg-pfs-rac.sas Date: 14:36/18OCT2021

Table 35.2.3.4
Summary of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy - Patients Evaluable per IWG Criteria
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: < 300 mg

Progression Free Survival	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=24) n (%) (95% CIs)	MCL (N=9) n (%) (95% CIs)	All AdvSM (N=34) n (%) (95% CIs)
Events	0	6 (25.0)	2 (22.2)	8 (23.5)
Censors	1 (100.0)	18 (75.0)	7 (77.8)	26 (76.5)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (13.0 -NE)	NE (10.5 -NE)	NE (13.0 -NE)
25th, 75th percentiles	NE, NE	13.0, NE	10.5, NE	13.0, NE
Min, Max	8.7*, 8.7*	0.3, 41.7*	4.4*, 45.3*	0.3, 45.3*
3 Months (95% CIs)	100.0 (100.0 -100.0)	91.7 (80.6 -100.0)	100.0 (100.0 -100.0)	94.1 (86.2 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	87.5 (74.3 -100.0)	87.5 (64.6 -100.0)	88.1 (77.2 - 99.1)
9 Months (95% CIs)		77.6 (60.0 - 95.2)	87.5 (64.6 -100.0)	81.3 (67.7 - 94.9)
12 Months (95% CIs)		77.6 (60.0 - 95.2)	70.0 (34.3 -100.0)	75.5 (58.8 - 92.2)
18 Months (95% CIs)		67.9 (44.4 - 91.4)	70.0 (34.3 -100.0)	69.2 (49.8 - 88.6)
24 Months (95% CIs)		67.9 (44.4 - 91.4)	70.0 (34.3 -100.0)	69.2 (49.8 - 88.6)
30 Months (95% CIs)		67.9 (44.4 - 91.4)	70.0 (34.3 -100.0)	69.2 (49.8 - 88.6)
36 Months (95% CIs)		67.9 (44.4 - 91.4)	70.0 (34.3 -100.0)	69.2 (49.8 - 88.6)
42 Months (95% CIs)			70.0 (34.3 -100.0)	69.2 (49.8 - 88.6)
48 Months (95% CIs)				
Median PFS Follow-up[a] (months) (95% CI)	8.7 (NE -NE)	10.3 (9.7 - 15.7)	14.7 (8.5 - 19.0)	11.8 (8.7 - 15.7)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-alg-iwg-pfs-rac.sas Date: 14:36/18OCT2021

Table 35.2.3.4
Summary of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy - Patients Evaluable per IWG Criteria
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Progression Free Survival	ASM (N=1) n (%) (95% CIs)	SM-AHN (N=22) n (%) (95% CIs)	MCL (N=8) n (%) (95% CIs)	All AdvSM (N=31) n (%) (95% CIs)
Events	0	6 (27.3)	2 (25.0)	8 (25.8)
Censors	1 (100.0)	16 (72.7)	6 (75.0)	23 (74.2)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (13.0 -NE)	NE (10.5 -NE)	NE (13.0 -NE)
25th, 75th percentiles	NE, NE	13.0, NE	10.5, NE	10.5, NE
Min, Max	8.7*, 8.7*	0.3, 37.7*	4.4*, 19.0*	0.3, 37.7*
3 Months (95% CIs)	100.0 (100.0 -100.0)	90.9 (78.9 -100.0)	100.0 (100.0 -100.0)	93.5 (84.9 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	86.4 (72.0 -100.0)	85.7 (59.8 -100.0)	87.0 (75.1 - 98.9)
9 Months (95% CIs)		75.3 (56.1 - 94.4)	85.7 (59.8 -100.0)	79.3 (64.4 - 94.2)
12 Months (95% CIs)		75.3 (56.1 - 94.4)	64.3 (23.0 -100.0)	72.1 (53.0 - 91.2)
18 Months (95% CIs)		64.5 (39.0 - 90.0)	64.3 (23.0 -100.0)	64.9 (43.1 - 86.7)
24 Months (95% CIs)		64.5 (39.0 - 90.0)		64.9 (43.1 - 86.7)
30 Months (95% CIs)		64.5 (39.0 - 90.0)		64.9 (43.1 - 86.7)
36 Months (95% CIs)		64.5 (39.0 - 90.0)		64.9 (43.1 - 86.7)
42 Months (95% CIs)				
48 Months (95% CIs)				
Median PFS Follow-up[a] (months) (95% CI)	8.7 (NE -NE)	10.2 (8.0 - 15.7)	14.7 (8.5 - 19.0)	10.2 (8.5 - 15.4)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-alg-iwg-pfs-rac.sas Date: 14:36/18OCT2021

Table 35.2.3.4
Summary of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy - Patients Evaluable per IWG Criteria
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg

Progression Free Survival	ASM (N=2) n (%) (95% CIs)	SM-AHN (N=10) n (%) (95% CIs)	MCL (N=3) n (%) (95% CIs)	All AdvSM (N=15) n (%) (95% CIs)
Events	0	3 (30.0)	1 (33.3)	4 (26.7)
Censors	2 (100.0)	7 (70.0)	2 (66.7)	11 (73.3)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (13.5 -NE)	31.2 (NE -NE)	31.2 (NE -NE)
25th, 75th percentiles	NE, NE	13.5, NE	31.2, 31.2	31.2, 31.2
Min, Max	27.4*, 29.7*	4.8, 29.3*	8.0*, 31.2	4.8, 31.2
3 Months (95% CIs)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)	100.0 (100.0 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	90.0 (71.4 -100.0)	100.0 (100.0 -100.0)	93.3 (80.7 -100.0)
9 Months (95% CIs)	100.0 (100.0 -100.0)	90.0 (71.4 -100.0)	100.0 (100.0 -100.0)	93.3 (80.7 -100.0)
12 Months (95% CIs)	100.0 (100.0 -100.0)	80.0 (55.2 -100.0)	100.0 (100.0 -100.0)	86.2 (68.3 -100.0)
18 Months (95% CIs)	100.0 (100.0 -100.0)	70.0 (41.6 - 98.4)	100.0 (100.0 -100.0)	79.0 (57.8 -100.0)
24 Months (95% CIs)	100.0 (100.0 -100.0)	70.0 (41.6 - 98.4)	100.0 (100.0 -100.0)	79.0 (57.8 -100.0)
30 Months (95% CIs)			100.0 (100.0 -100.0)	79.0 (57.8 -100.0)
36 Months (95% CIs)			0.0 (0.0 - 0.0)	0.0 (0.0 - 0.0)
42 Months (95% CIs)			0.0 (0.0 - 0.0)	0.0 (0.0 - 0.0)
48 Months (95% CIs)			0.0 (0.0 - 0.0)	0.0 (0.0 - 0.0)
Median PFS Follow-up[a] (months) (95% CI)	28.6 (27.4 - 29.7)	22.1 (17.5 - 27.0)	30.2 (8.0 -NE)	27.0 (21.4 - 29.7)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-alg-iwg-pfs-rac.sas Date: 14:36/18OCT2021

Table 35.2.3.4
Summary of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy - Patients Evaluable per IWG Criteria
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg

Progression Free Survival	ASM (N=3) n (%) (95% CIs)	SM-AHN (N=32) n (%) (95% CIs)	MCL (N=11) n (%) (95% CIs)	All AdvSM (N=46) n (%) (95% CIs)
Events	0	9 (28.1)	3 (27.3)	12 (26.1)
Censors	3 (100.0)	23 (71.9)	8 (72.7)	34 (73.9)
Kaplan-Meier Estimates				
Median (months) (95% CIs)	NE (NE -NE)	NE (13.5 -NE)	31.2 (10.5 - 31.2)	31.2 (31.2 -NE)
25th, 75th percentiles	NE, NE	13.0, NE	20.8, 31.2	13.0, NE
Min, Max	8.7*, 29.7*	0.3, 37.7*	4.4*, 31.2	0.3, 37.7*
3 Months (95% CIs)	100.0 (100.0 -100.0)	93.8 (85.4 -100.0)	100.0 (100.0 -100.0)	95.7 (89.8 -100.0)
6 Months (95% CIs)	100.0 (100.0 -100.0)	87.5 (76.0 - 99.0)	90.0 (71.4 -100.0)	89.0 (79.9 - 98.1)
9 Months (95% CIs)	100.0 (100.0 -100.0)	80.4 (66.3 - 94.6)	90.0 (71.4 -100.0)	84.1 (73.3 - 95.0)
12 Months (95% CIs)	100.0 (100.0 -100.0)	76.4 (60.9 - 91.9)	75.0 (44.0 -100.0)	77.6 (64.3 - 90.9)
18 Months (95% CIs)	100.0 (100.0 -100.0)	66.2 (47.4 - 85.0)	75.0 (44.0 -100.0)	70.5 (55.3 - 85.8)
24 Months (95% CIs)	100.0 (100.0 -100.0)	66.2 (47.4 - 85.0)	75.0 (44.0 -100.0)	70.5 (55.3 - 85.8)
30 Months (95% CIs)		66.2 (47.4 - 85.0)	75.0 (44.0 -100.0)	70.5 (55.3 - 85.8)
36 Months (95% CIs)		66.2 (47.4 - 85.0)	0.0 (0.0 - 0.0)	35.3 (0.0 - 84.7)
42 Months (95% CIs)			0.0 (0.0 - 0.0)	
48 Months (95% CIs)			0.0 (0.0 - 0.0)	
Median PFS Follow-up[a] (months) (95% CI)	27.4 (8.7 - 29.7)	15.4 (10.2 - 17.6)	14.7 (8.5 - 30.2)	15.4 (10.2 - 17.6)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-alg-iwg-pfs-rac.sas Date: 14:36/18OCT2021

Table 35.2.3.4
Summary of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy - Patients Evaluable per IWG Criteria
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg

Progression Free Survival	ASM (N=0) n (%) (95% CIs)	SM-AHN (N=4) n (%) (95% CIs)	MCL (N=0) n (%) (95% CIs)	All AdvSM (N=4) n (%) (95% CIs)
Events		0		0
Censors		4 (100.0)		4 (100.0)
Kaplan-Meier Estimates				
Median (months) (95% CIs)		NE (NE -NE)		NE (NE -NE)
25th, 75th percentiles		NE, NE		NE, NE
Min, Max		4.3*, 37.8*		4.3*, 37.8*
3 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
6 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
9 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
12 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
18 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
24 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
30 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
36 Months (95% CIs)		100.0 (100.0 -100.0)		100.0 (100.0 -100.0)
42 Months (95% CIs)				
48 Months (95% CIs)				
Median PFS Follow-up[a] (months) (95% CI)		24.8 (4.3 - 37.8)		24.8 (4.3 - 37.8)

Source: Listing 16.3.9.7.1
Abbreviations: CIs=Confidence intervals, LoR=Loss of response, PD=Progressive disease, SD=Stable disease, NE=Not Evaluable
Notes: Progression free survival is defined as the time in months from the start of treatment to the date of first documented PD or death due to any cause, whichever occurs first. If a patient has not had an event, progression free survival is censored at the date of last valid assessment that is LoR or better.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-alg-iwg-pfs-rac.sas Date: 14:36/18OCT2021

Figure 35.2.3.4
Kaplan-Meier Curves of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101
Starting Dose: Overall

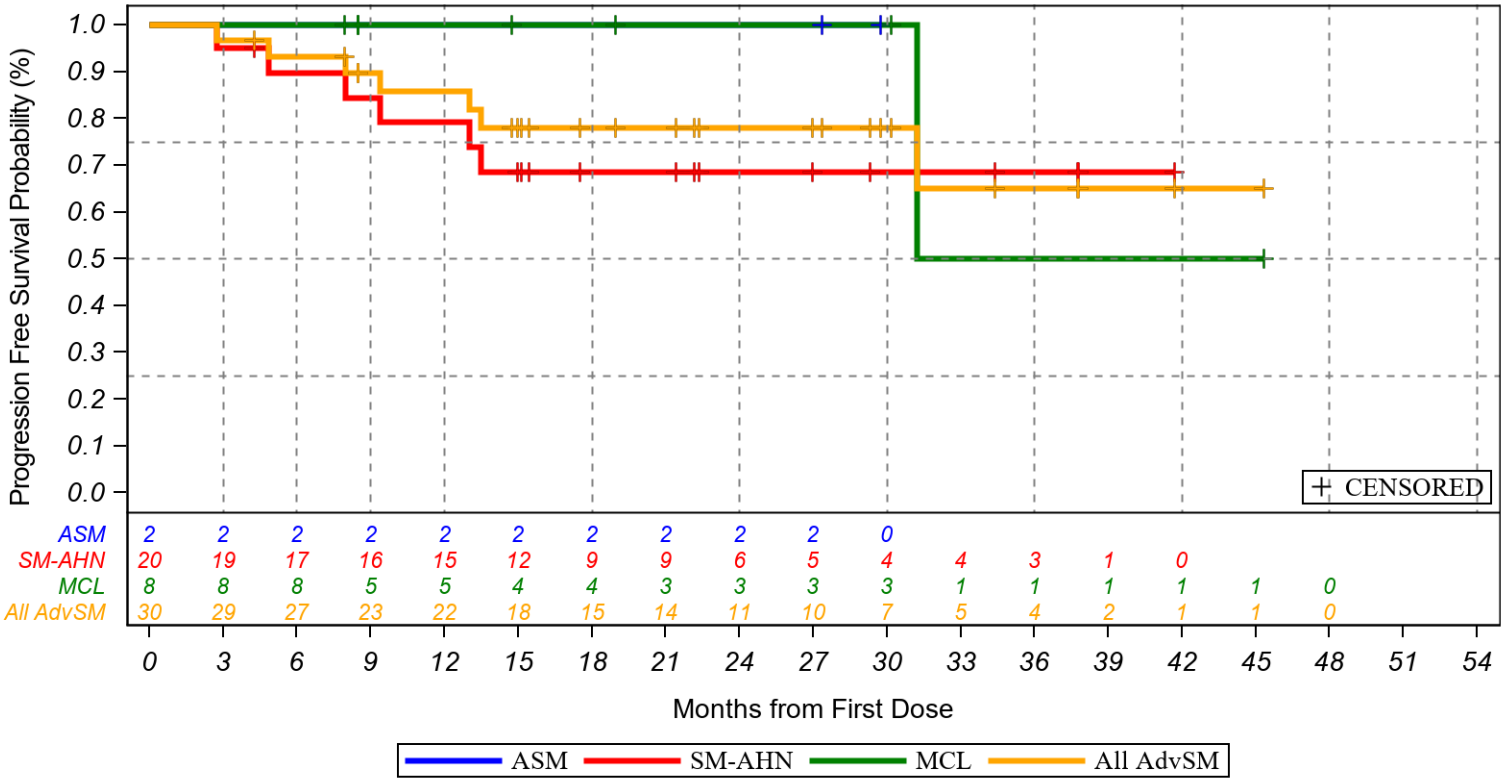


Figure 35.2.3.4
Kaplan-Meier Curves of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101
Starting Dose: < 200 mg

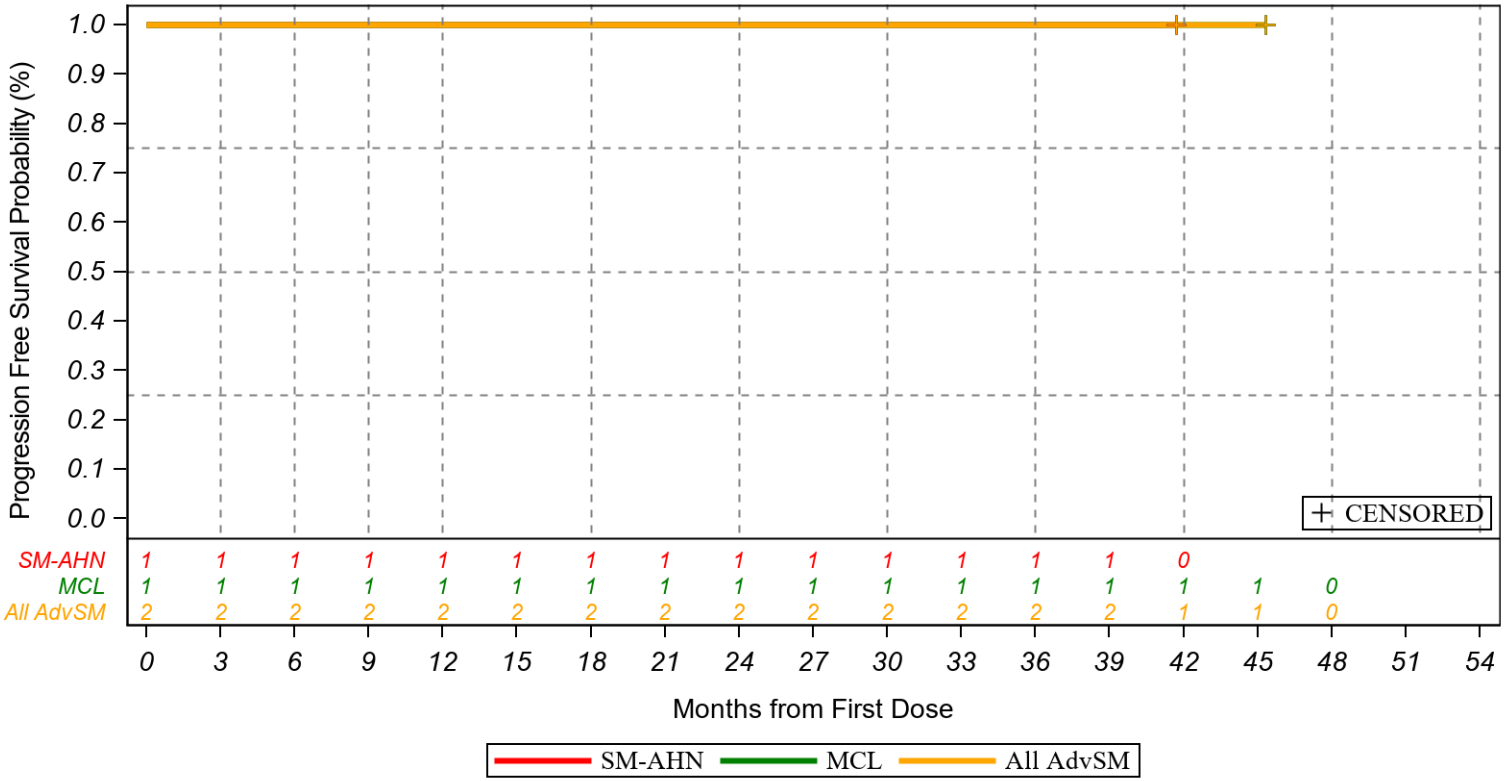


Figure 35.2.3.4
Kaplan-Meier Curves of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101
Starting Dose: < 300 mg

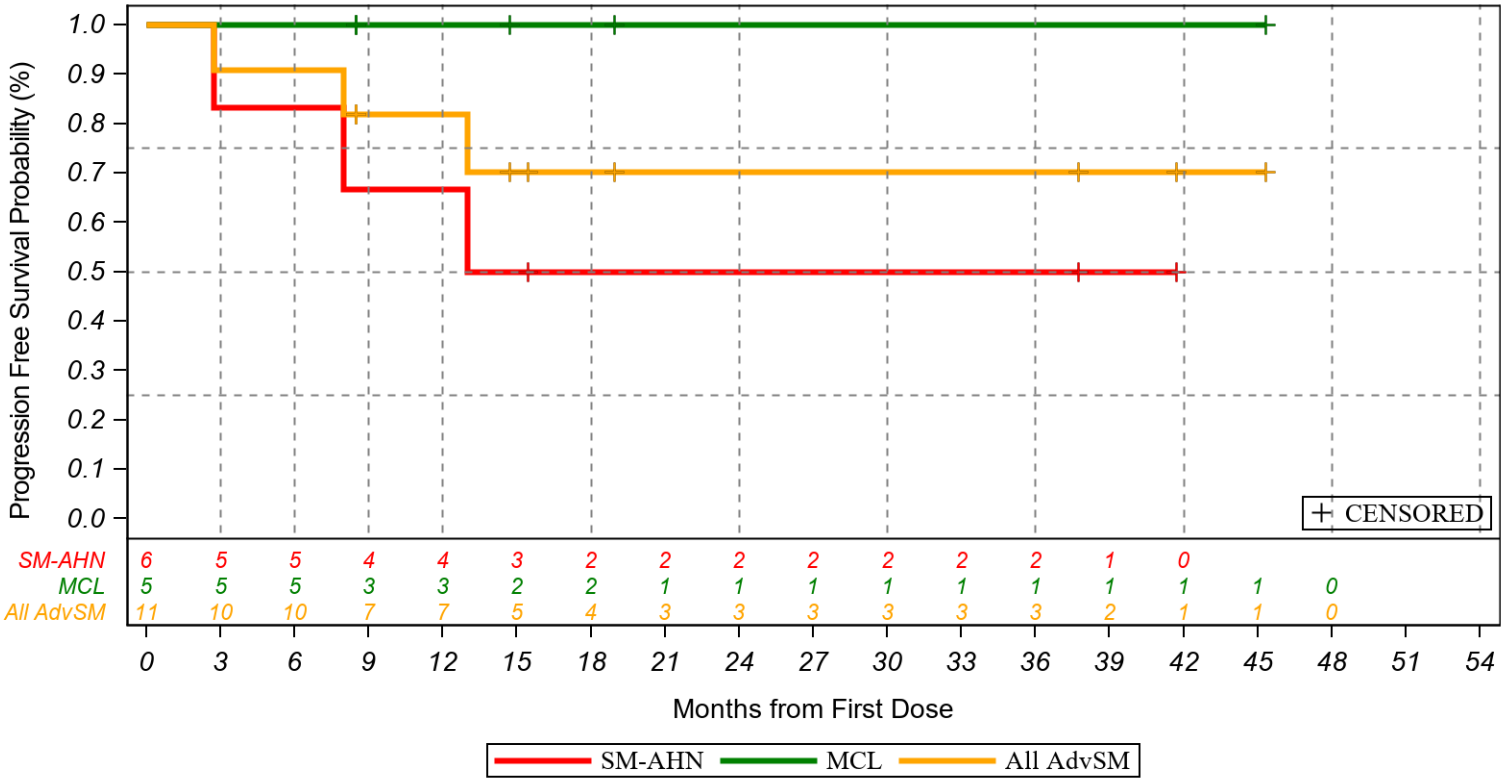


Figure 35.2.3.4
Kaplan-Meier Curves of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101
Starting Dose: 200 mg

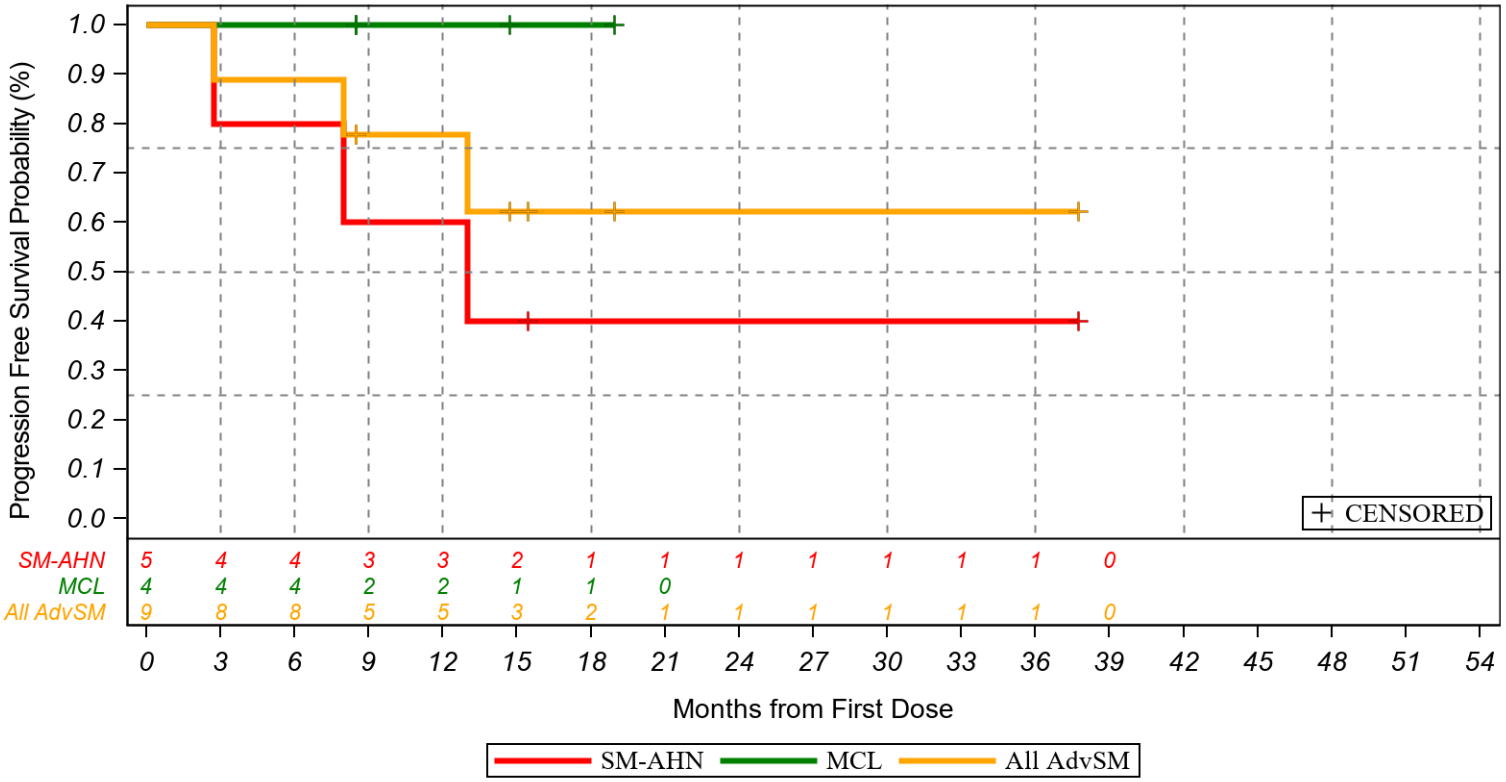
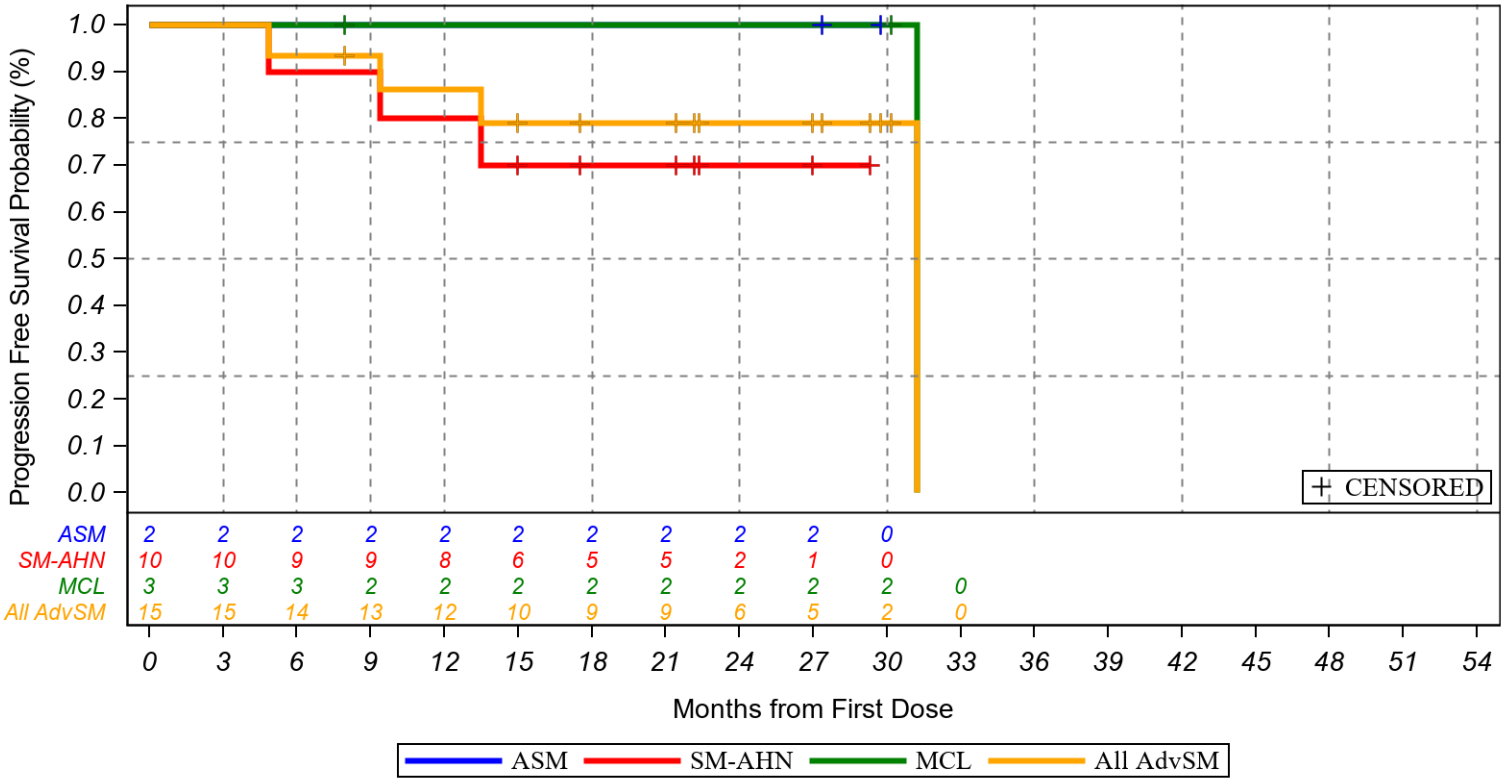


Figure 35.2.3.4
Kaplan-Meier Curves of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101
Starting Dose: 300 mg



Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/f-alg-pfs-rac.sas
Date: 13:34/13OCT2021

Figure 35.2.3.4
Kaplan-Meier Curves of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101
Starting Dose: 200 mg and 300 mg

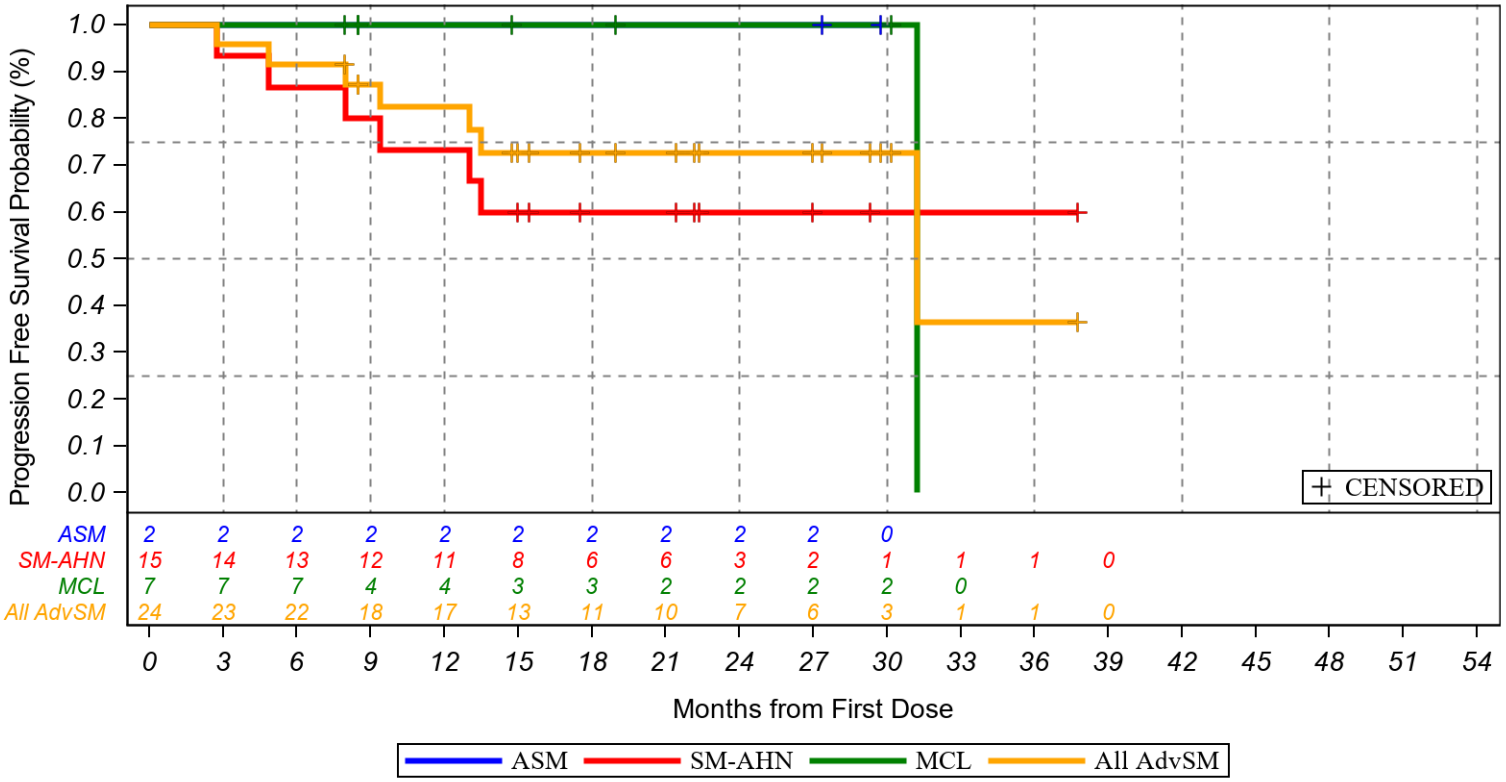
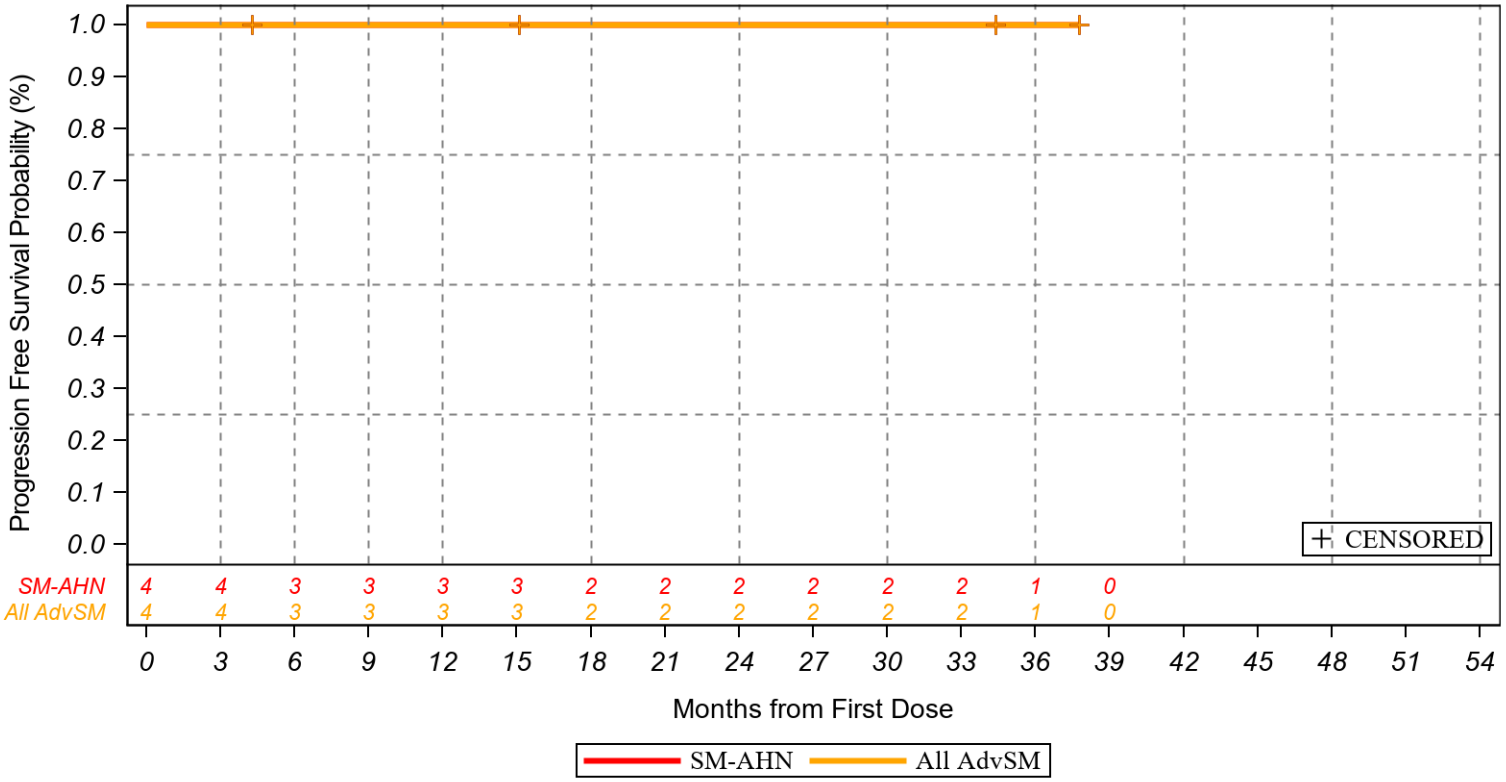


Figure 35.2.3.4
Kaplan-Meier Curves of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101
Starting Dose: 400 mg



Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/f-alg-pfs-rac.sas
Date: 13:34/13OCT2021

Figure 35.2.3.4
Kaplan-Meier Curves of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2202
Starting Dose: Overall

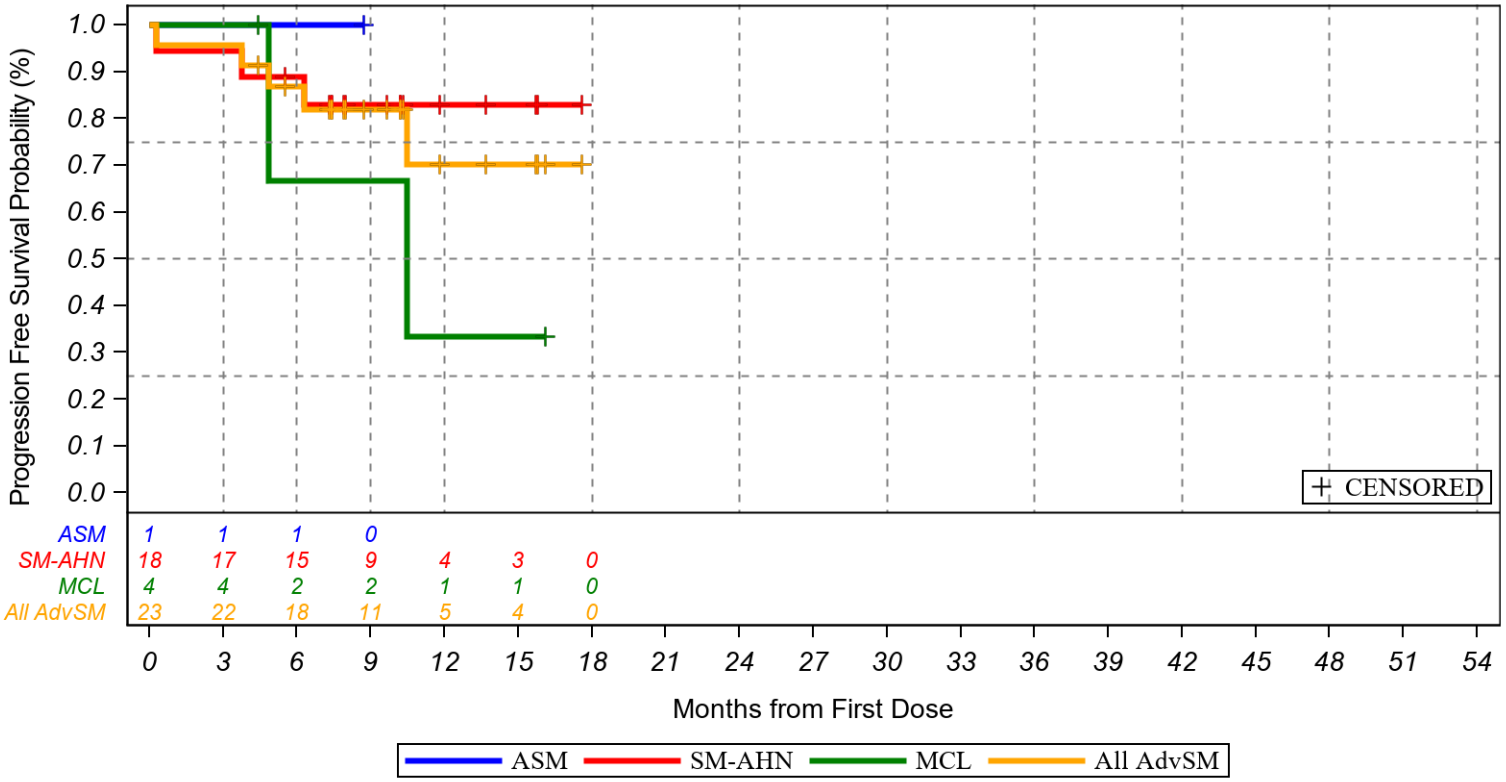


Figure 35.2.3.4
Kaplan-Meier Curves of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2202
Starting Dose: 200 mg

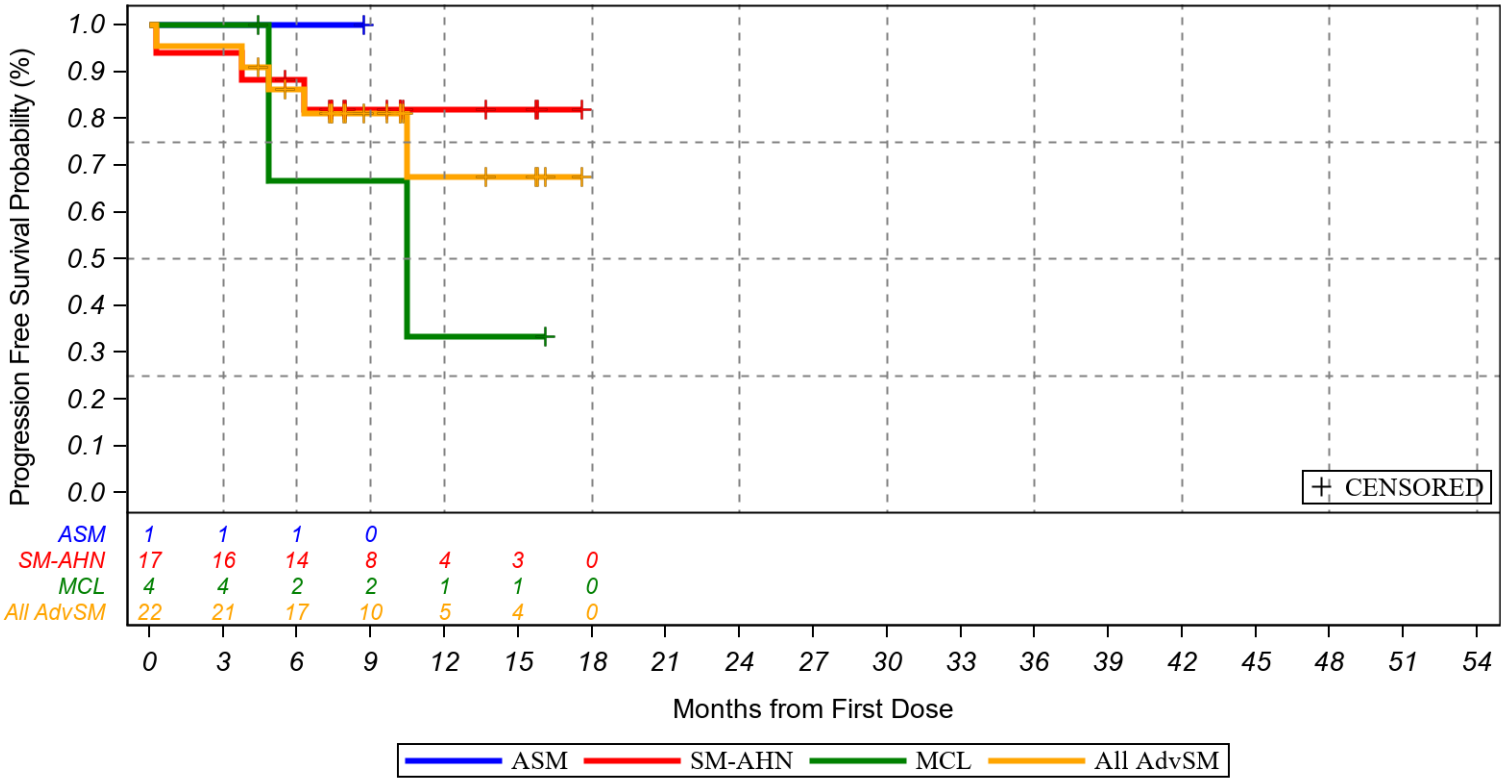


Figure 35.2.3.4
Kaplan-Meier Curves of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall

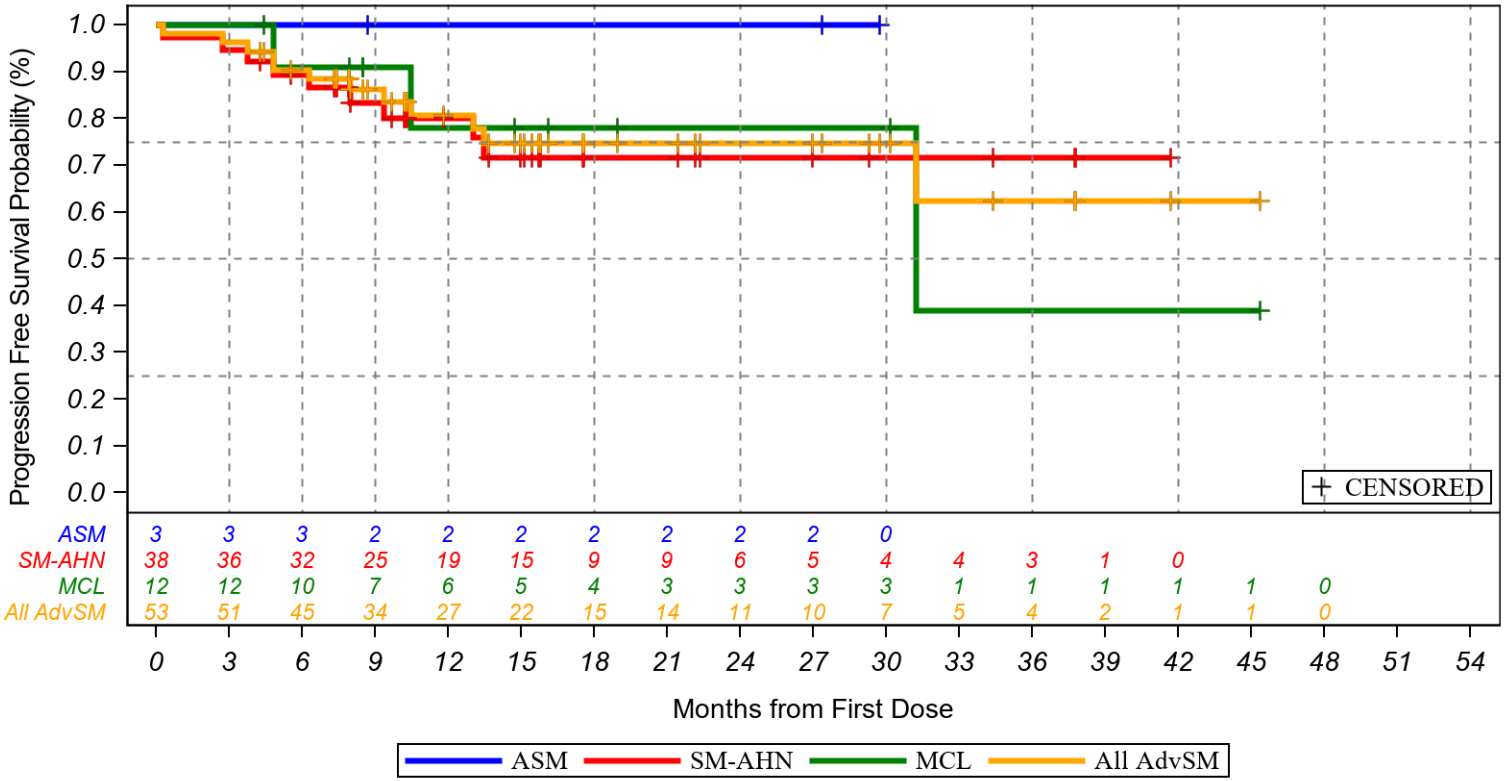


Figure 35.2.3.4
Kaplan-Meier Curves of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg

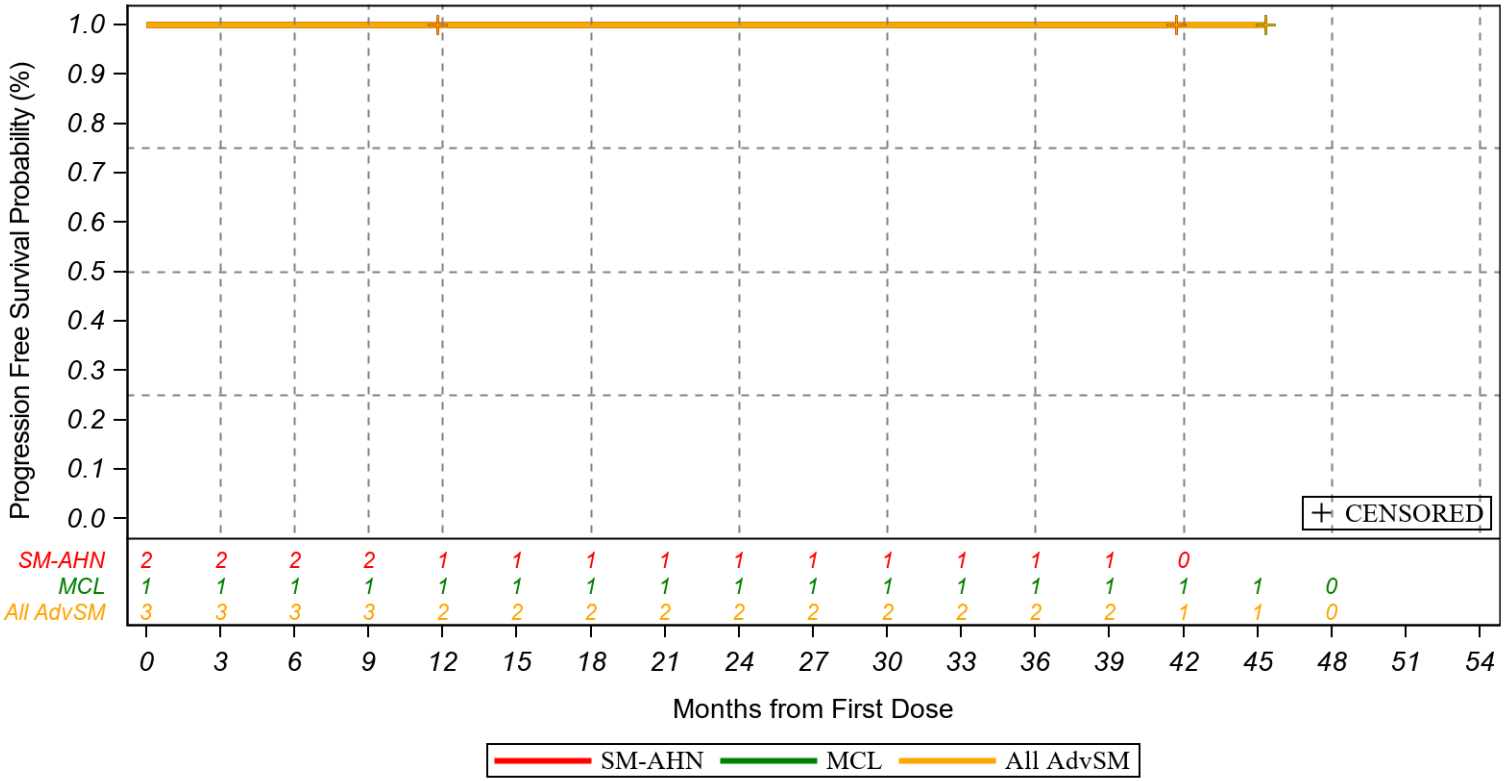


Figure 35.2.3.4
Kaplan-Meier Curves of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg

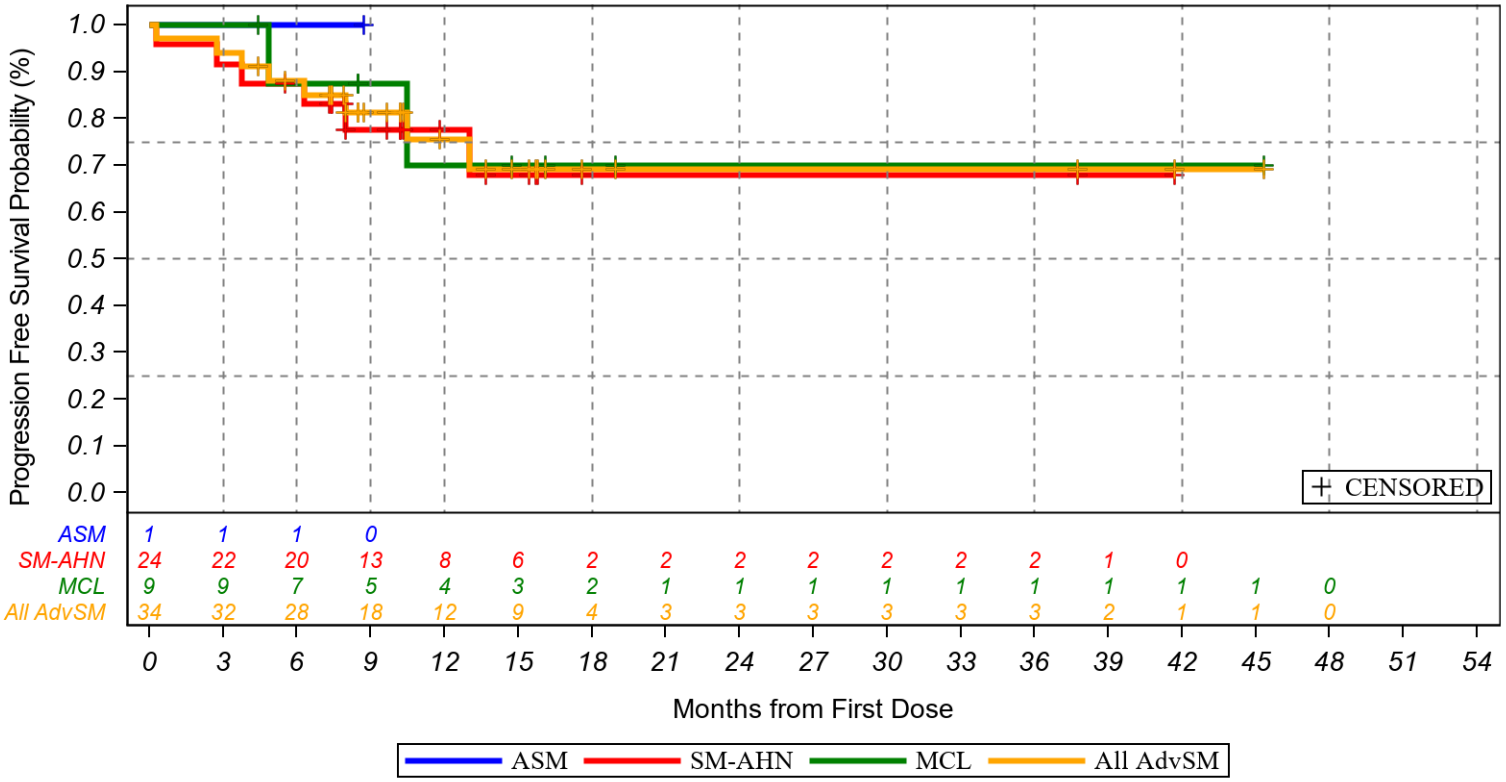


Figure 35.2.3.4
Kaplan-Meier Curves of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg

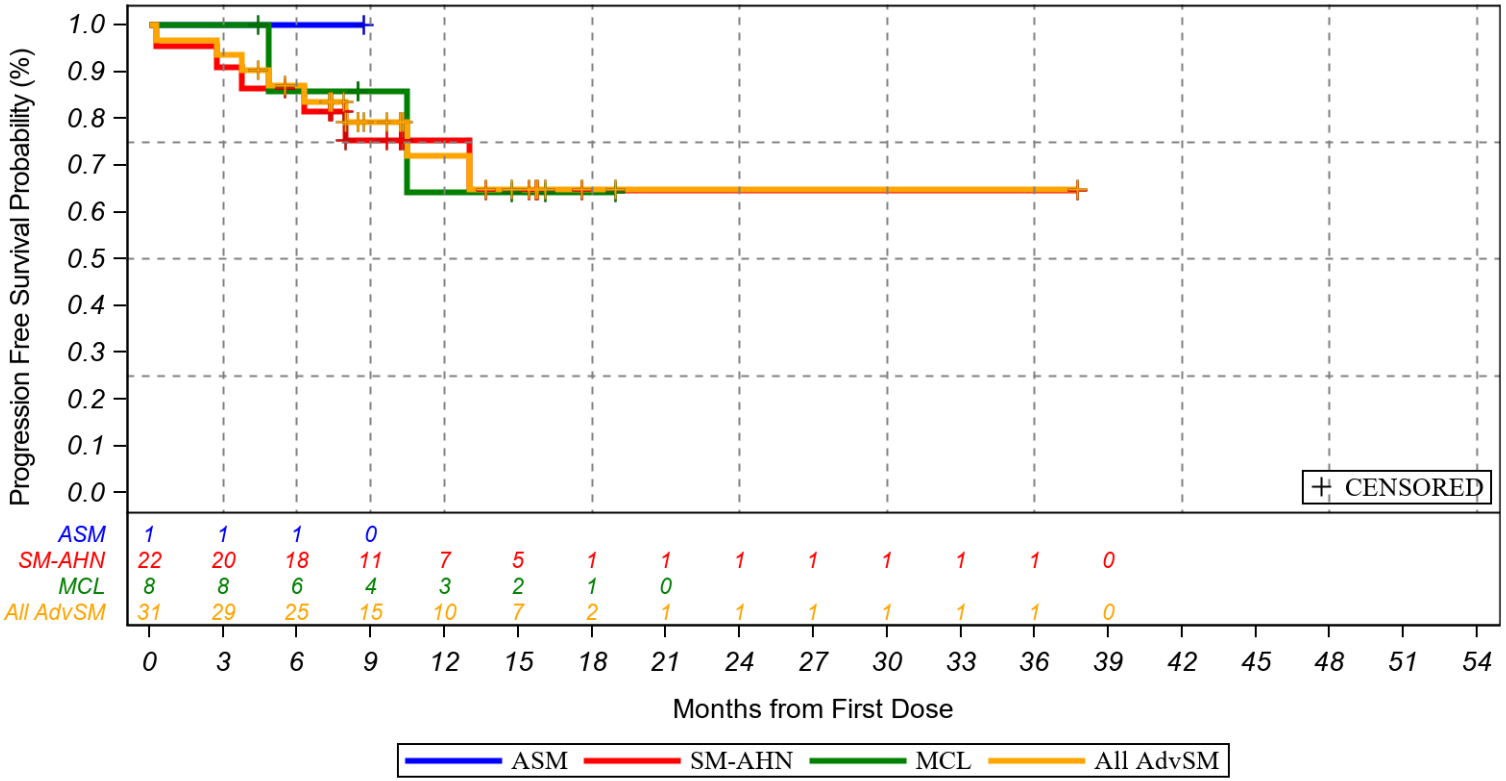


Figure 35.2.3.4
Kaplan-Meier Curves of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg

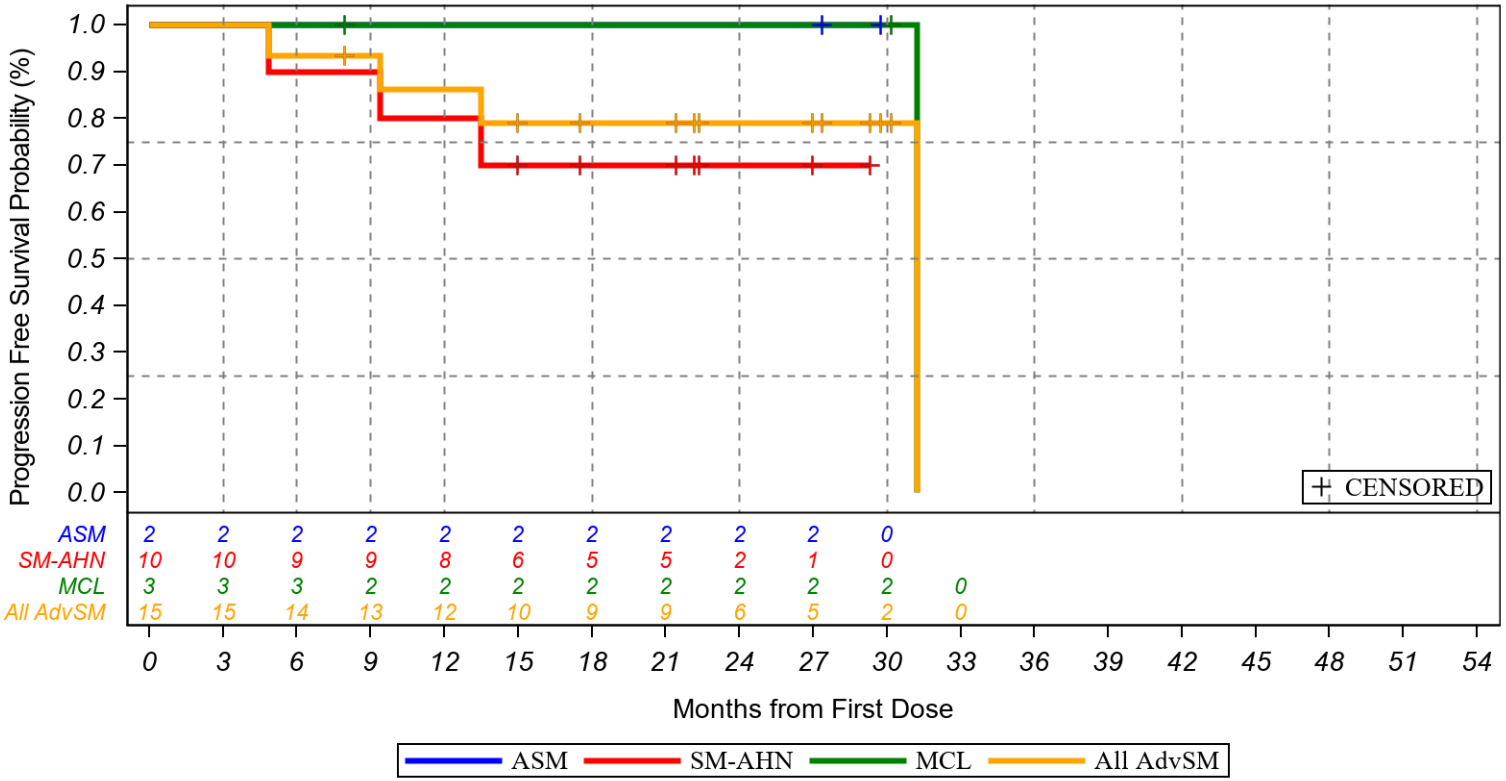


Figure 35.2.3.4
Kaplan-Meier Curves of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg

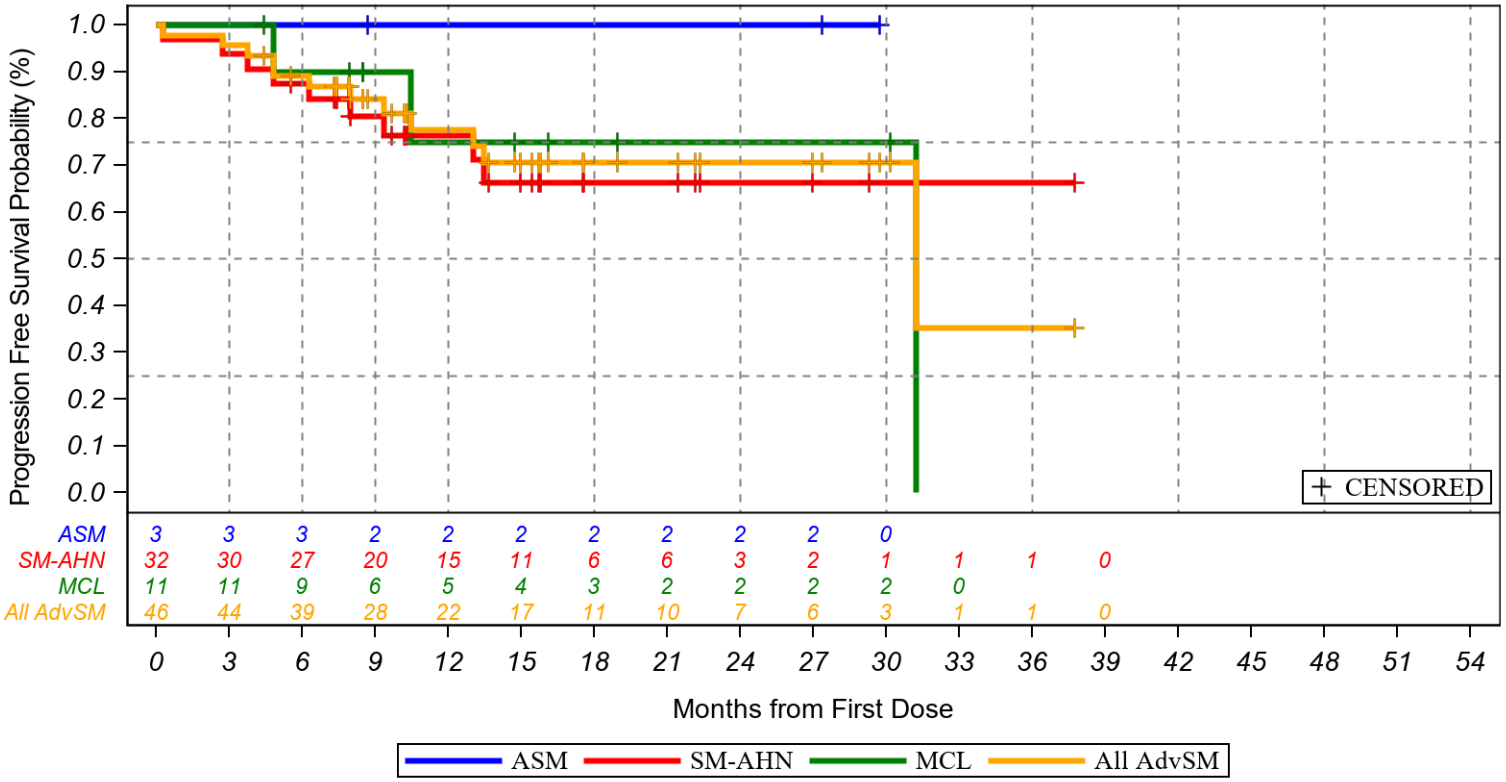


Figure 35.2.3.4
Kaplan-Meier Curves of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg

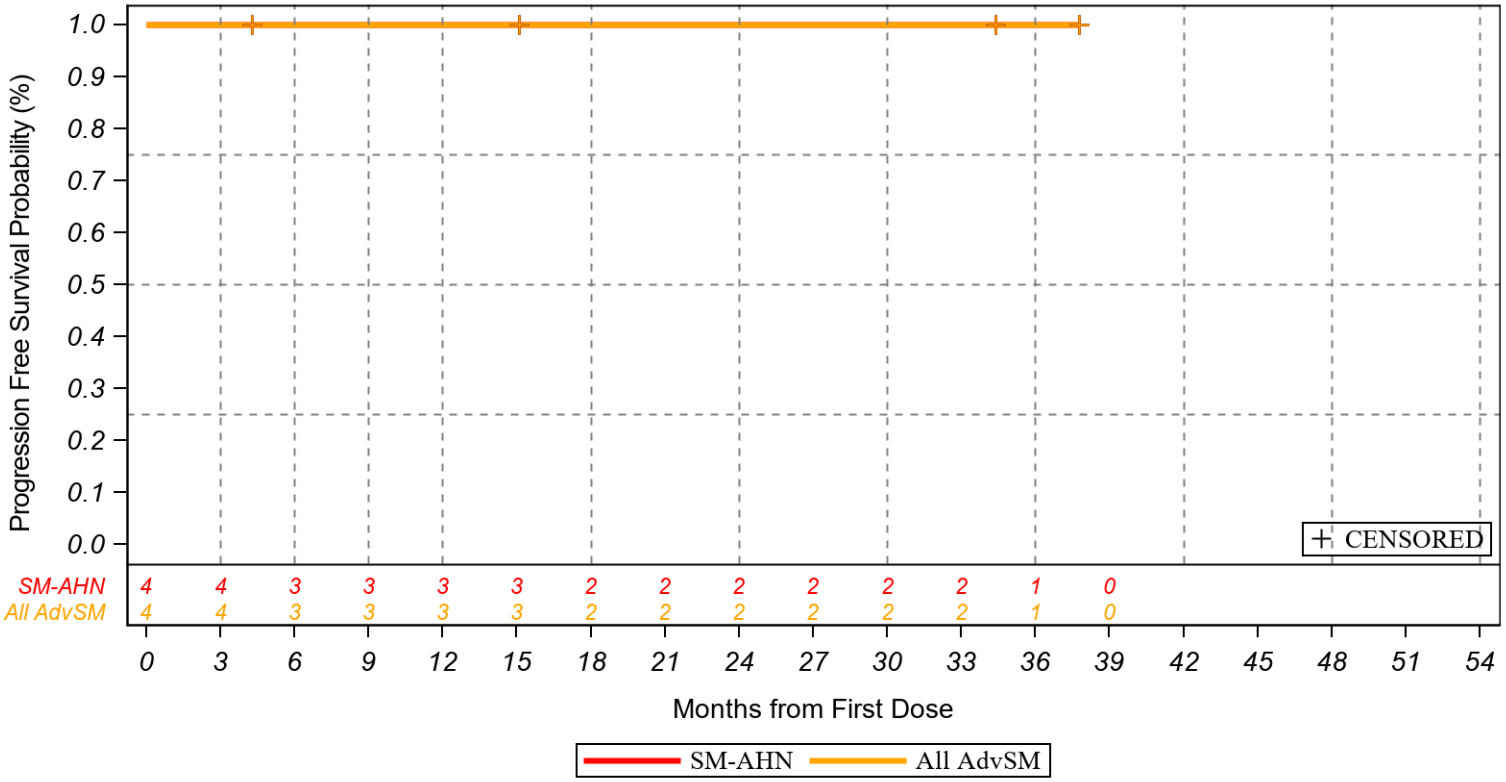


Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Overall

Bone Marrow Mast Cells (%)	ASM (N=7)	SM-AHN (N=26)	MCL (N=8)	All AdvSM (N=41)
Baseline				
n	7	21	8	36
Mean (StdDev)	35.0 (36.86)	39.3 (24.46)	67.5 (25.63)	44.7 (29.35)
Median	10.0	30.0	77.5	40.0
Min, Max	10, 95	5, 80	25, 90	5, 95
Cycle 3 Day 1				
n	5	22	7	34
Mean (StdDev)	23.6 (25.24)	5.0 (3.65)	37.1 (25.80)	14.3 (19.72)
Median	10.0	5.0	50.0	5.0
Min, Max	3, 60	1, 10	5, 75	1, 75
Cycle 7 Day 1				
n	5	17	7	29
Mean (StdDev)	14.6 (17.24)	4.0 (5.76)	36.4 (31.05)	13.7 (21.32)
Median	5.0	2.0	25.0	5.0
Min, Max	1, 40	1, 25	10, 90	1, 90

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Overall

Bone Marrow Mast Cells (%)	ASM (N=7)	SM-AHN (N=26)	MCL (N=8)	All AdvSM (N=41)
Cycle 11 Day 1				
n	3	11	4	18
Mean (StdDev)	29.3 (28.75)	3.1 (2.88)	30.0 (40.62)	13.5 (23.90)
Median	25.0	1.5	12.5	5.0
Min, Max	3, 60	1, 10	5, 90	1, 90
Cycle 18 Day 1				
n	2	8	2	12
Mean (StdDev)	42.5 (38.89)	2.3 (1.75)	3.3 (1.06)	9.1 (19.56)
Median	42.5	1.5	3.3	2.3
Min, Max	15, 70	1, 5	3, 4	1, 70
Cycle 24 Day 1				
n	3	7	2	12
Mean (StdDev)	32.0 (42.15)	1.9 (1.57)	15.0 (7.07)	11.6 (22.47)
Median	15.0	1.0	15.0	2.0
Min, Max	1, 80	1, 5	10, 20	1, 80
Cycle 30 Day 1				
n	2	4	1	7
Mean (StdDev)	36.5 (47.38)	1.0 (0.00)	4.0 (-)	11.6 (25.79)
Median	36.5	1.0	4.0	1.0
Min, Max	3, 70	1, 1	4, 4	1, 70

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas
Date: 19:33/27SEP2021

Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Overall

Bone Marrow Mast Cells (%)	ASM (N=7)	SM-AHN (N=26)	MCL (N=8)	All AdvSM (N=41)
Cycle 36 Day 1				
n	2	4	0	6
Mean (StdDev)	41.0 (55.15)	1.5 (0.58)		14.7 (32.01)
Median	41.0	1.5		2.0
Min, Max	2, 80	1, 2		1, 80
Cycle 42 Day 1				
n	1	3	1	5
Mean (StdDev)	80.0 (-)	1.7 (1.15)	2.0 (-)	17.4 (35.00)
Median	80.0	1.0	2.0	2.0
Min, Max	80, 80	1, 3	2, 2	1, 80
Cycle 48 Day 1				
n	1	0	1	2
Mean (StdDev)	60.0 (-)		2.0 (-)	31.0 (41.01)
Median	60.0		2.0	31.0
Min, Max	60, 60		2, 2	2, 60

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <200 mg

Bone Marrow Mast Cells (%)	ASM (N=1)	SM-AHN (N=2)	MCL (N=1)	All AdvSM (N=4)
Baseline				
n	1	2	1	4
Mean (StdDev)	30.0 (-)	12.5 (10.61)	30.0 (-)	21.3 (11.81)
Median	30.0	12.5	30.0	25.0
Min, Max	30, 30	5, 20	30, 30	5, 30
Cycle 3 Day 1				
n	1	2	0	3
Mean (StdDev)	40.0 (-)	5.5 (6.36)		17.0 (20.42)
Median	40.0	5.5		10.0
Min, Max	40, 40	1, 10		1, 40
Cycle 7 Day 1				
n	1	2	1	4
Mean (StdDev)	40.0 (-)	6.0 (1.41)	30.0 (-)	20.5 (17.25)
Median	40.0	6.0	30.0	18.5
Min, Max	40, 40	5, 7	30, 30	5, 40

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <200 mg

Bone Marrow Mast Cells (%)	ASM (N=1)	SM-AHN (N=2)	MCL (N=1)	All AdvSM (N=4)
Cycle 11 Day 1				
n	1	2	0	3
Mean (StdDev)	60.0 (-)	2.0 (1.41)		21.3 (33.50)
Median	60.0	2.0		3.0
Min, Max	60, 60	1, 3		1, 60
Cycle 18 Day 1				
n	1	2	0	3
Mean (StdDev)	70.0 (-)	1.5 (0.71)		24.3 (39.55)
Median	70.0	1.5		2.0
Min, Max	70, 70	1, 2		1, 70
Cycle 24 Day 1				
n	1	2	1	4
Mean (StdDev)	80.0 (-)	1.0 (0.01)	20.0 (-)	25.5 (37.42)
Median	80.0	1.0	20.0	10.5
Min, Max	80, 80	1, 1	20, 20	1, 80
Cycle 30 Day 1				
n	1	2	0	3
Mean (StdDev)	70.0 (-)	1.0 (0.00)		24.0 (39.84)
Median	70.0	1.0		1.0
Min, Max	70, 70	1, 1		1, 70

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas
Date: 19:33/27SEP2021

Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <200 mg

Bone Marrow Mast Cells (%)	ASM (N=1)	SM-AHN (N=2)	MCL (N=1)	All AdvSM (N=4)
Cycle 36 Day 1				
n	1	2	0	3
Mean (StdDev)	80.0 (-)	1.5 (0.71)		27.7 (45.32)
Median	80.0	1.5		2.0
Min, Max	80, 80	1, 2		1, 80
Cycle 42 Day 1				
n	1	2	1	4
Mean (StdDev)	80.0 (-)	2.0 (1.41)	2.0 (-)	21.5 (39.01)
Median	80.0	2.0	2.0	2.5
Min, Max	80, 80	1, 3	2, 2	1, 80
Cycle 48 Day 1				
n	1	0	1	2
Mean (StdDev)	60.0 (-)		2.0 (-)	31.0 (41.01)
Median	60.0		2.0	31.0
Min, Max	60, 60		2, 2	2, 60

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas
Date: 19:33/27SEP2021

Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <300 mg

Bone Marrow Mast Cells (%)	ASM (N=2)	SM-AHN (N=9)	MCL (N=5)	All AdvSM (N=16)
Baseline				
n	2	7	5	14
Mean (StdDev)	20.0 (14.14)	27.9 (20.38)	58.0 (27.97)	37.5 (26.58)
Median	20.0	20.0	75.0	30.0
Min, Max	10, 30	5, 60	25, 80	5, 80
Cycle 3 Day 1				
n	2	7	4	13
Mean (StdDev)	21.5 (26.16)	6.0 (4.08)	42.5 (15.00)	19.6 (20.12)
Median	21.5	5.0	50.0	10.0
Min, Max	3, 40	1, 10	20, 50	1, 50
Cycle 7 Day 1				
n	1	6	5	12
Mean (StdDev)	40.0 (-)	7.3 (8.98)	35.0 (31.42)	21.6 (24.88)
Median	40.0	5.0	25.0	15.0
Min, Max	40, 40	1, 25	15, 90	1, 90

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas
Date: 19:33/27SEP2021

Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <300 mg

Bone Marrow Mast Cells (%)	ASM (N=2)	SM-AHN (N=9)	MCL (N=5)	All AdvSM (N=16)
Cycle 11 Day 1				
n	1	3	2	6
Mean (StdDev)	60.0 (-)	3.0 (2.00)	12.5 (10.61)	15.7 (22.75)
Median	60.0	3.0	12.5	5.0
Min, Max	60, 60	1, 5	5, 20	1, 60
Cycle 18 Day 1				
n	1	3	1	5
Mean (StdDev)	70.0 (-)	1.3 (0.58)	4.0 (-)	15.6 (30.44)
Median	70.0	1.0	4.0	2.0
Min, Max	70, 70	1, 2	4, 4	1, 70
Cycle 24 Day 1				
n	1	3	1	5
Mean (StdDev)	80.0 (-)	1.7 (1.16)	20.0 (-)	21.0 (33.94)
Median	80.0	1.0	20.0	3.0
Min, Max	80, 80	1, 3	20, 20	1, 80
Cycle 30 Day 1				
n	1	3	0	4
Mean (StdDev)	70.0 (-)	1.0 (0.00)		18.3 (34.50)
Median	70.0	1.0		1.0
Min, Max	70, 70	1, 1		1, 70

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas
Date: 19:33/27SEP2021

Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <300 mg

Bone Marrow Mast Cells (%)	ASM (N=2)	SM-AHN (N=9)	MCL (N=5)	All AdvSM (N=16)
Cycle 36 Day 1				
n	1	3	0	4
Mean (StdDev)	80.0 (-)	1.7 (0.58)		21.3 (39.17)
Median	80.0	2.0		2.0
Min, Max	80, 80	1, 2		1, 80
Cycle 42 Day 1				
n	1	3	1	5
Mean (StdDev)	80.0 (-)	1.7 (1.15)	2.0 (-)	17.4 (35.00)
Median	80.0	1.0	2.0	2.0
Min, Max	80, 80	1, 3	2, 2	1, 80
Cycle 48 Day 1				
n	1	0	1	2
Mean (StdDev)	60.0 (-)		2.0 (-)	31.0 (41.01)
Median	60.0		2.0	31.0
Min, Max	60, 60		2, 2	2, 60

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg				
Bone Marrow Mast Cells (%)	ASM (N=1)	SM-AHN (N=7)	MCL (N=4)	All AdvSM (N=12)
Baseline				
n	1	5	4	10
Mean (StdDev)	10.0 (-)	34.0 (20.74)	65.0 (26.77)	44.0 (28.46)
Median	10.0	30.0	77.5	40.0
Min, Max	10, 10	10, 60	25, 80	10, 80
Cycle 3 Day 1				
n	1	5	4	10
Mean (StdDev)	3.0 (-)	6.2 (3.83)	42.5 (15.00)	20.4 (21.08)
Median	3.0	5.0	50.0	10.0
Min, Max	3, 3	1, 10	20, 50	1, 50
Cycle 7 Day 1				
n	0	4	4	8
Mean (StdDev)		8.0 (11.49)	36.3 (36.14)	22.1 (29.06)
Median		3.0	20.0	15.0
Min, Max		1, 25	15, 90	1, 90

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg

Bone Marrow Mast Cells (%)	ASM (N=1)	SM-AHN (N=7)	MCL (N=4)	All AdvSM (N=12)
Cycle 11 Day 1				
n	0	1	2	3
Mean (StdDev)		5.0 (-)	12.5 (10.61)	10.0 (8.66)
Median		5.0	12.5	5.0
Min, Max		5, 5	5, 20	5, 20
Cycle 18 Day 1				
n	0	1	1	2
Mean (StdDev)		1.0 (-)	4.0 (-)	2.5 (2.12)
Median		1.0	4.0	2.5
Min, Max		1, 1	4, 4	1, 4
Cycle 24 Day 1				
n	0	1	0	1
Mean (StdDev)		3.0 (-)		3.0 (-)
Median		3.0		3.0
Min, Max		3, 3		3, 3
Cycle 30 Day 1				
n	0	1	0	1
Mean (StdDev)		1.0 (-)		1.0 (-)
Median		1.0		1.0
Min, Max		1, 1		1, 1

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg

Bone Marrow Mast Cells (%)	ASM (N=1)	SM-AHN (N=7)	MCL (N=4)	All AdvSM (N=12)
Cycle 36 Day 1				
n	0	1	0	1
Mean (StdDev)		2.0 (-)		2.0 (-)
Median		2.0		2.0
Min, Max		2, 2		2, 2
Cycle 42 Day 1				
n	0	1	0	1
Mean (StdDev)		1.0 (-)		1.0 (-)
Median		1.0		1.0
Min, Max		1, 1		1, 1

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas
Date: 19:33/27SEP2021

Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 300 mg

Bone Marrow Mast Cells (%)	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Baseline				
n	4	10	3	17
Mean (StdDev)	48.8 (45.16)	44.5 (21.40)	83.3 (11.55)	52.4 (29.64)
Median	45.0	50.0	90.0	50.0
Min, Max	10, 95	10, 75	70, 90	10, 95
Cycle 3 Day 1				
n	3	13	3	19
Mean (StdDev)	25.0 (30.41)	4.9 (3.50)	30.0 (39.05)	12.1 (19.97)
Median	10.0	5.0	10.0	5.0
Min, Max	5, 60	1, 10	5, 75	1, 75
Cycle 7 Day 1				
n	3	8	2	13
Mean (StdDev)	10.3 (12.86)	2.0 (1.41)	40.0 (42.43)	9.8 (19.27)
Median	5.0	1.5	40.0	2.0
Min, Max	1, 25	1, 5	10, 70	1, 70

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 300 mg				
Bone Marrow Mast Cells (%)	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Cycle 11 Day 1				
n	2	7	2	11
Mean (StdDev)	14.0 (15.56)	2.2 (1.91)	47.5 (60.10)	12.6 (26.59)
Median	14.0	1.0	47.5	3.0
Min, Max	3, 25	1, 5	5, 90	1, 90
Cycle 18 Day 1				
n	1	5	1	7
Mean (StdDev)	15.0 (-)	2.8 (2.05)	2.5 (-)	4.5 (4.92)
Median	15.0	2.0	2.5	2.5
Min, Max	15, 15	1, 5	3, 3	1, 15
Cycle 24 Day 1				
n	2	2	1	5
Mean (StdDev)	8.0 (9.90)	3.0 (2.83)	10.0 (-)	6.4 (6.07)
Median	8.0	3.0	10.0	5.0
Min, Max	1, 15	1, 5	10, 10	1, 15
Cycle 30 Day 1				
n	1	0	1	2
Mean (StdDev)	3.0 (-)		4.0 (-)	3.5 (0.71)
Median	3.0		4.0	3.5
Min, Max	3, 3		4, 4	3, 4

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 300 mg				
Bone Marrow Mast Cells (%)	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Cycle 36 Day 1				
n	1	0	0	1
Mean (StdDev)	2.0 (-)			2.0 (-)
Median	2.0			2.0
Min, Max	2, 2			2, 2

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg

Bone Marrow Mast Cells (%)	ASM (N=5)	SM-AHN (N=20)	MCL (N=7)	All AdvSM (N=32)
Baseline				
n	5	15	7	27
Mean (StdDev)	41.0 (42.78)	41.0 (21.06)	72.9 (22.33)	49.3 (28.95)
Median	10.0	50.0	80.0	50.0
Min, Max	10, 95	10, 75	25, 90	10, 95
Cycle 3 Day 1				
n	4	18	7	29
Mean (StdDev)	19.5 (27.16)	5.3 (3.53)	37.1 (25.80)	14.9 (20.38)
Median	7.5	5.0	50.0	5.0
Min, Max	3, 60	1, 10	5, 75	1, 75
Cycle 7 Day 1				
n	3	12	6	21
Mean (StdDev)	10.3 (12.86)	4.0 (6.78)	37.5 (33.87)	14.5 (23.58)
Median	5.0	1.5	20.0	5.0
Min, Max	1, 25	1, 25	10, 90	1, 90

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg

Bone Marrow Mast Cells (%)	ASM (N=5)	SM-AHN (N=20)	MCL (N=7)	All AdvSM (N=32)
Cycle 11 Day 1				
n	2	8	4	14
Mean (StdDev)	14.0 (15.56)	2.6 (2.03)	30.0 (40.62)	12.0 (23.60)
Median	14.0	1.3	12.5	5.0
Min, Max	3, 25	1, 5	5, 90	1, 90
Cycle 18 Day 1				
n	1	6	2	9
Mean (StdDev)	15.0 (-)	2.5 (1.97)	3.3 (1.06)	4.1 (4.42)
Median	15.0	1.5	3.3	2.5
Min, Max	15, 15	1, 5	3, 4	1, 15
Cycle 24 Day 1				
n	2	3	1	6
Mean (StdDev)	8.0 (9.90)	3.0 (2.00)	10.0 (-)	5.8 (5.60)
Median	8.0	3.0	10.0	4.0
Min, Max	1, 15	1, 5	10, 10	1, 15
Cycle 30 Day 1				
n	1	1	1	3
Mean (StdDev)	3.0 (-)	1.0 (-)	4.0 (-)	2.7 (1.53)
Median	3.0	1.0	4.0	3.0
Min, Max	3, 3	1, 1	4, 4	1, 4

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg				
Bone Marrow Mast Cells (%)	ASM (N=5)	SM-AHN (N=20)	MCL (N=7)	All AdvSM (N=32)
Cycle 36 Day 1				
n	1	1	0	2
Mean (StdDev)	2.0 (-)	2.0 (-)		2.0 (0.00)
Median	2.0	2.0		2.0
Min, Max	2, 2	2, 2		2, 2
Cycle 42 Day 1				
n	0	1	0	1
Mean (StdDev)		1.0 (-)		1.0 (-)
Median		1.0		1.0
Min, Max		1, 1		1, 1

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 400 mg

Bone Marrow Mast Cells (%)	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Baseline				
n	1	4	0	5
Mean (StdDev)	10.0 (-)	46.3 (36.37)		39.0 (35.43)
Median	10.0	47.5		20.0
Min, Max	10, 10	10, 80		10, 80
Cycle 3 Day 1				
n	0	2	0	2
Mean (StdDev)		1.5 (0.71)		1.5 (0.71)
Median		1.5		1.5
Min, Max		1, 2		1, 2
Cycle 7 Day 1				
n	1	3	0	4
Mean (StdDev)	2.0 (-)	2.7 (2.09)		2.5 (1.73)
Median	2.0	2.0		2.0
Min, Max	2, 2	1, 5		1, 5

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 400 mg

Bone Marrow Mast Cells (%)	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Cycle 11 Day 1				
n	0	1	0	1
Mean (StdDev)		10.0 (-)		10.0 (-)
Median		10.0		10.0
Min, Max		10, 10		10, 10
Cycle 24 Day 1				
n	0	2	0	2
Mean (StdDev)		1.0 (0.00)		1.0 (0.00)
Median		1.0		1.0
Min, Max		1, 1		1, 1
Cycle 30 Day 1				
n	0	1	0	1
Mean (StdDev)		1.0 (-)		1.0 (-)
Median		1.0		1.0
Min, Max		1, 1		1, 1
Cycle 36 Day 1				
n	0	1	0	1
Mean (StdDev)		1.0 (-)		1.0 (-)
Median		1.0		1.0
Min, Max		1, 1		1, 1

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2202

Overall

Bone Marrow Mast Cells (%)	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Baseline				
n	5	28	9	42
Mean (StdDev)	39.0 (30.08)	47.4 (26.23)	73.3 (21.65)	51.9 (27.72)
Median	30.0	45.0	80.0	55.0
Min, Max	10, 80	1, 90	20, 95	1, 95
Cycle 3 Day 1				
n	4	20	8	32
Mean (StdDev)	11.8 (12.61)	16.4 (24.92)	43.4 (23.29)	22.5 (25.89)
Median	7.5	5.0	40.0	10.0
Min, Max	2, 30	1, 90	7, 80	1, 90
Cycle 7 Day 1				
n	1	14	2	17
Mean (StdDev)	5.0 (-)	13.2 (22.93)	45.0 (49.50)	16.5 (26.45)
Median	5.0	5.0	45.0	5.0
Min, Max	5, 5	2, 90	10, 80	2, 90

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2202

Overall

Bone Marrow Mast Cells (%)	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Cycle 11 Day 1				
n	0	7	1	8
Mean (StdDev)		15.4 (26.63)	10.0 (-)	14.8 (24.73)
Median		5.0	10.0	5.0
Min, Max		2, 75	10, 10	2, 75
Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		30.0 (-)	10.0 (-)	20.0 (14.14)
Median		30.0	10.0	20.0
Min, Max		30, 30	10, 10	10, 30

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2202

Starting Dose: 200 mg				
Bone Marrow Mast Cells (%)	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Baseline				
n	4	27	9	40
Mean (StdDev)	41.3 (34.25)	47.6 (26.69)	73.3 (21.65)	52.8 (28.12)
Median	37.5	50.0	80.0	60.0
Min, Max	10, 80	1, 90	20, 95	1, 95
Cycle 3 Day 1				
n	4	19	8	31
Mean (StdDev)	11.8 (12.61)	16.7 (25.56)	43.4 (23.29)	22.9 (26.22)
Median	7.5	5.0	40.0	10.0
Min, Max	2, 30	1, 90	7, 80	1, 90
Cycle 7 Day 1				
n	1	13	2	16
Mean (StdDev)	5.0 (-)	12.7 (23.78)	45.0 (49.50)	16.3 (27.30)
Median	5.0	5.0	45.0	5.0
Min, Max	5, 5	2, 90	10, 80	2, 90

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2202

Starting Dose: 200 mg

Bone Marrow Mast Cells (%)	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Cycle 11 Day 1				
n	0	6	1	7
Mean (StdDev)		5.5 (4.81)	10.0 (-)	6.1 (4.71)
Median		4.0	10.0	5.0
Min, Max		2, 15	10, 10	2, 15
Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		30.0 (-)	10.0 (-)	20.0 (14.14)
Median		30.0	10.0	20.0
Min, Max		30, 30	10, 10	10, 30

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Overall

Bone Marrow Mast Cells (%)	ASM (N=12)	SM-AHN (N=54)	MCL (N=17)	All AdvSM (N=83)
Baseline				
n	12	49	17	78
Mean (StdDev)	36.7 (32.78)	43.9 (25.55)	70.6 (23.04)	48.6 (28.52)
Median	22.5	40.0	80.0	50.0
Min, Max	10, 95	1, 90	20, 95	1, 95
Cycle 3 Day 1				
n	9	42	15	66
Mean (StdDev)	18.3 (20.43)	10.4 (18.11)	40.5 (23.81)	18.3 (23.11)
Median	10.0	5.0	40.0	8.5
Min, Max	2, 60	1, 90	5, 80	1, 90
Cycle 7 Day 1				
n	6	31	9	46
Mean (StdDev)	13.0 (15.91)	8.2 (16.35)	38.3 (32.31)	14.7 (23.10)
Median	5.0	3.0	25.0	5.0
Min, Max	1, 40	1, 90	10, 90	1, 90

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas
Date: 19:33/27SEP2021

Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Overall

Bone Marrow Mast Cells (%)	ASM (N=12)	SM-AHN (N=54)	MCL (N=17)	All AdvSM (N=83)
Cycle 11 Day 1				
n	3	18	5	26
Mean (StdDev)	29.3 (28.75)	7.9 (17.12)	26.0 (36.30)	13.9 (23.66)
Median	25.0	3.0	10.0	5.0
Min, Max	3, 60	1, 75	5, 90	1, 90
Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		30.0 (-)	10.0 (-)	20.0 (14.14)
Median		30.0	10.0	20.0
Min, Max		30, 30	10, 10	10, 30
Cycle 18 Day 1				
n	2	8	2	12
Mean (StdDev)	42.5 (38.89)	2.3 (1.75)	3.3 (1.06)	9.1 (19.56)
Median	42.5	1.5	3.3	2.3
Min, Max	15, 70	1, 5	3, 4	1, 70
Cycle 24 Day 1				
n	3	7	2	12
Mean (StdDev)	32.0 (42.15)	1.9 (1.57)	15.0 (7.07)	11.6 (22.47)
Median	15.0	1.0	15.0	2.0
Min, Max	1, 80	1, 5	10, 20	1, 80

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Overall

Bone Marrow Mast Cells (%)	ASM (N=12)	SM-AHN (N=54)	MCL (N=17)	All AdvSM (N=83)
Cycle 30 Day 1				
n	2	4	1	7
Mean (StdDev)	36.5 (47.38)	1.0 (0.00)	4.0 (-)	11.6 (25.79)
Median	36.5	1.0	4.0	1.0
Min, Max	3, 70	1, 1	4, 4	1, 70
Cycle 36 Day 1				
n	2	4	0	6
Mean (StdDev)	41.0 (55.15)	1.5 (0.58)		14.7 (32.01)
Median	41.0	1.5		2.0
Min, Max	2, 80	1, 2		1, 80
Cycle 42 Day 1				
n	1	3	1	5
Mean (StdDev)	80.0 (-)	1.7 (1.15)	2.0 (-)	17.4 (35.00)
Median	80.0	1.0	2.0	2.0
Min, Max	80, 80	1, 3	2, 2	1, 80
Cycle 48 Day 1				
n	1	0	1	2
Mean (StdDev)	60.0 (-)		2.0 (-)	31.0 (41.01)
Median	60.0		2.0	31.0
Min, Max	60, 60		2, 2	2, 60

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg

Bone Marrow Mast Cells (%)	ASM (N=2)	SM-AHN (N=3)	MCL (N=1)	All AdvSM (N=6)
Baseline				
n	2	3	1	6
Mean (StdDev)	30.0 (0.00)	21.7 (17.56)	30.0 (-)	25.8 (12.01)
Median	30.0	20.0	30.0	30.0
Min, Max	30, 30	5, 40	30, 30	5, 40
Cycle 3 Day 1				
n	1	3	0	4
Mean (StdDev)	40.0 (-)	7.0 (5.20)		15.3 (17.04)
Median	40.0	10.0		10.0
Min, Max	40, 40	1, 10		1, 40
Cycle 7 Day 1				
n	1	3	1	5
Mean (StdDev)	40.0 (-)	10.7 (8.14)	30.0 (-)	20.4 (14.94)
Median	40.0	7.0	30.0	20.0
Min, Max	40, 40	5, 20	30, 30	5, 40

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg

Bone Marrow Mast Cells (%)	ASM (N=2)	SM-AHN (N=3)	MCL (N=1)	All AdvSM (N=6)
Cycle 11 Day 1				
n	1	3	0	4
Mean (StdDev)	60.0 (-)	26.3 (42.16)		34.8 (38.32)
Median	60.0	3.0		31.5
Min, Max	60, 60	1, 75		1, 75
Cycle 18 Day 1				
n	1	2	0	3
Mean (StdDev)	70.0 (-)	1.5 (0.71)		24.3 (39.55)
Median	70.0	1.5		2.0
Min, Max	70, 70	1, 2		1, 70
Cycle 24 Day 1				
n	1	2	1	4
Mean (StdDev)	80.0 (-)	1.0 (0.01)	20.0 (-)	25.5 (37.42)
Median	80.0	1.0	20.0	10.5
Min, Max	80, 80	1, 1	20, 20	1, 80
Cycle 30 Day 1				
n	1	2	0	3
Mean (StdDev)	70.0 (-)	1.0 (0.00)		24.0 (39.84)
Median	70.0	1.0		1.0
Min, Max	70, 70	1, 1		1, 70

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas
Date: 19:33/27SEP2021

Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg

Bone Marrow Mast Cells (%)	ASM (N=2)	SM-AHN (N=3)	MCL (N=1)	All AdvSM (N=6)
Cycle 36 Day 1				
n	1	2	0	3
Mean (StdDev)	80.0 (-)	1.5 (0.71)		27.7 (45.32)
Median	80.0	1.5		2.0
Min, Max	80, 80	1, 2		1, 80
Cycle 42 Day 1				
n	1	2	1	4
Mean (StdDev)	80.0 (-)	2.0 (1.41)	2.0 (-)	21.5 (39.01)
Median	80.0	2.0	2.0	2.5
Min, Max	80, 80	1, 3	2, 2	1, 80
Cycle 48 Day 1				
n	1	0	1	2
Mean (StdDev)	60.0 (-)		2.0 (-)	31.0 (41.01)
Median	60.0		2.0	31.0
Min, Max	60, 60		2, 2	2, 60

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg

Bone Marrow Mast Cells (%)	ASM (N=7)	SM-AHN (N=37)	MCL (N=14)	All AdvSM (N=58)
Baseline				
n	7	35	14	56
Mean (StdDev)	33.6 (26.88)	43.5 (26.12)	67.9 (24.24)	48.3 (27.92)
Median	30.0	40.0	77.5	50.0
Min, Max	10, 80	1, 90	20, 95	1, 95
Cycle 3 Day 1				
n	6	27	12	45
Mean (StdDev)	15.0 (16.05)	13.7 (21.89)	43.1 (20.17)	21.7 (24.18)
Median	7.5	5.0	45.0	10.0
Min, Max	2, 40	1, 90	7, 80	1, 90
Cycle 7 Day 1				
n	2	20	7	29
Mean (StdDev)	22.5 (24.75)	11.5 (19.72)	37.9 (33.02)	18.6 (25.49)
Median	22.5	5.0	25.0	9.0
Min, Max	5, 40	1, 90	10, 90	1, 90

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg

Bone Marrow Mast Cells (%)	ASM (N=7)	SM-AHN (N=37)	MCL (N=14)	All AdvSM (N=58)
Cycle 11 Day 1				
n	1	10	3	14
Mean (StdDev)	60.0 (-)	11.7 (22.58)	11.7 (7.64)	15.1 (22.99)
Median	60.0	4.0	10.0	5.0
Min, Max	60, 60	1, 75	5, 20	1, 75
Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		30.0 (-)	10.0 (-)	20.0 (14.14)
Median		30.0	10.0	20.0
Min, Max		30, 30	10, 10	10, 30
Cycle 18 Day 1				
n	1	3	1	5
Mean (StdDev)	70.0 (-)	1.3 (0.58)	4.0 (-)	15.6 (30.44)
Median	70.0	1.0	4.0	2.0
Min, Max	70, 70	1, 2	4, 4	1, 70
Cycle 24 Day 1				
n	1	3	1	5
Mean (StdDev)	80.0 (-)	1.7 (1.16)	20.0 (-)	21.0 (33.94)
Median	80.0	1.0	20.0	3.0
Min, Max	80, 80	1, 3	20, 20	1, 80

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas
Date: 19:33/27SEP2021

Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg

Bone Marrow Mast Cells (%)	ASM (N=7)	SM-AHN (N=37)	MCL (N=14)	All AdvSM (N=58)
Cycle 30 Day 1				
n	1	3	0	4
Mean (StdDev)	70.0 (-)	1.0 (0.00)		18.3 (34.50)
Median	70.0	1.0		1.0
Min, Max	70, 70	1, 1		1, 70
Cycle 36 Day 1				
n	1	3	0	4
Mean (StdDev)	80.0 (-)	1.7 (0.58)		21.3 (39.17)
Median	80.0	2.0		2.0
Min, Max	80, 80	1, 2		1, 80
Cycle 42 Day 1				
n	1	3	1	5
Mean (StdDev)	80.0 (-)	1.7 (1.15)	2.0 (-)	17.4 (35.00)
Median	80.0	1.0	2.0	2.0
Min, Max	80, 80	1, 3	2, 2	1, 80
Cycle 48 Day 1				
n	1	0	1	2
Mean (StdDev)	60.0 (-)		2.0 (-)	31.0 (41.01)
Median	60.0		2.0	31.0
Min, Max	60, 60		2, 2	2, 60

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas
Date: 19:33/27SEP2021

Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg				
Bone Marrow Mast Cells (%)	ASM (N=5)	SM-AHN (N=34)	MCL (N=13)	All AdvSM (N=52)
Baseline				
n	5	32	13	50
Mean (StdDev)	35.0 (32.79)	45.5 (26.04)	70.8 (22.53)	51.0 (28.12)
Median	15.0	45.0	80.0	55.0
Min, Max	10, 80	1, 90	20, 95	1, 95
Cycle 3 Day 1				
n	5	24	12	41
Mean (StdDev)	10.0 (11.60)	14.5 (23.08)	43.1 (20.17)	22.3 (24.83)
Median	5.0	5.0	45.0	10.0
Min, Max	2, 30	1, 90	7, 80	1, 90
Cycle 7 Day 1				
n	1	17	6	24
Mean (StdDev)	5.0 (-)	11.6 (21.29)	39.2 (35.97)	18.2 (27.41)
Median	5.0	5.0	20.0	7.0
Min, Max	5, 5	1, 90	10, 90	1, 90

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg				
Bone Marrow Mast Cells (%)	ASM (N=5)	SM-AHN (N=34)	MCL (N=13)	All AdvSM (N=52)
Cycle 11 Day 1				
n	0	7	3	10
Mean (StdDev)		5.4 (4.39)	11.7 (7.64)	7.3 (5.91)
Median		5.0	10.0	5.0
Min, Max		2, 15	5, 20	2, 20
Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		30.0 (-)	10.0 (-)	20.0 (14.14)
Median		30.0	10.0	20.0
Min, Max		30, 30	10, 10	10, 30
Cycle 18 Day 1				
n	0	1	1	2
Mean (StdDev)		1.0 (-)	4.0 (-)	2.5 (2.12)
Median		1.0	4.0	2.5
Min, Max		1, 1	4, 4	1, 4
Cycle 24 Day 1				
n	0	1	0	1
Mean (StdDev)		3.0 (-)		3.0 (-)
Median		3.0		3.0
Min, Max		3, 3		3, 3

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas
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Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg				
Bone Marrow Mast Cells (%)	ASM (N=5)	SM-AHN (N=34)	MCL (N=13)	All AdvSM (N=52)
Cycle 30 Day 1				
n	0	1	0	1
Mean (StdDev)		1.0 (-)		1.0 (-)
Median		1.0		1.0
Min, Max		1, 1		1, 1
Cycle 36 Day 1				
n	0	1	0	1
Mean (StdDev)		2.0 (-)		2.0 (-)
Median		2.0		2.0
Min, Max		2, 2		2, 2
Cycle 42 Day 1				
n	0	1	0	1
Mean (StdDev)		1.0 (-)		1.0 (-)
Median		1.0		1.0
Min, Max		1, 1		1, 1

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas
Date: 19:33/27SEP2021

Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg				
Bone Marrow Mast Cells (%)	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Baseline				
n	4	10	3	17
Mean (StdDev)	48.8 (45.16)	44.5 (21.40)	83.3 (11.55)	52.4 (29.64)
Median	45.0	50.0	90.0	50.0
Min, Max	10, 95	10, 75	70, 90	10, 95
Cycle 3 Day 1				
n	3	13	3	19
Mean (StdDev)	25.0 (30.41)	4.9 (3.50)	30.0 (39.05)	12.1 (19.97)
Median	10.0	5.0	10.0	5.0
Min, Max	5, 60	1, 10	5, 75	1, 75
Cycle 7 Day 1				
n	3	8	2	13
Mean (StdDev)	10.3 (12.86)	2.0 (1.41)	40.0 (42.43)	9.8 (19.27)
Median	5.0	1.5	40.0	2.0
Min, Max	1, 25	1, 5	10, 70	1, 70

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas
Date: 19:33/27SEP2021

Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg

Bone Marrow Mast Cells (%)	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Cycle 11 Day 1				
n	2	7	2	11
Mean (StdDev)	14.0 (15.56)	2.2 (1.91)	47.5 (60.10)	12.6 (26.59)
Median	14.0	1.0	47.5	3.0
Min, Max	3, 25	1, 5	5, 90	1, 90
Cycle 18 Day 1				
n	1	5	1	7
Mean (StdDev)	15.0 (-)	2.8 (2.05)	2.5 (-)	4.5 (4.92)
Median	15.0	2.0	2.5	2.5
Min, Max	15, 15	1, 5	3, 3	1, 15
Cycle 24 Day 1				
n	2	2	1	5
Mean (StdDev)	8.0 (9.90)	3.0 (2.83)	10.0 (-)	6.4 (6.07)
Median	8.0	3.0	10.0	5.0
Min, Max	1, 15	1, 5	10, 10	1, 15
Cycle 30 Day 1				
n	1	0	1	2
Mean (StdDev)	3.0 (-)		4.0 (-)	3.5 (0.71)
Median	3.0		4.0	3.5
Min, Max	3, 3		4, 4	3, 4

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas
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Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg				
Bone Marrow Mast Cells (%)	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Cycle 36 Day 1				
n	1	0	0	1
Mean (StdDev)	2.0 (-)			2.0 (-)
Median	2.0			2.0
Min, Max	2, 2			2, 2

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg				
Bone Marrow Mast Cells (%)	ASM (N=9)	SM-AHN (N=47)	MCL (N=16)	All AdvSM (N=72)
Baseline				
n	9	42	16	67
Mean (StdDev)	41.1 (36.81)	45.3 (24.77)	73.1 (21.20)	51.4 (28.29)
Median	15.0	50.0	80.0	50.0
Min, Max	10, 95	1, 90	20, 95	1, 95
Cycle 3 Day 1				
n	8	37	15	60
Mean (StdDev)	15.6 (20.04)	11.1 (19.13)	40.5 (23.81)	19.1 (23.73)
Median	7.5	5.0	40.0	8.5
Min, Max	2, 60	1, 90	5, 80	1, 90
Cycle 7 Day 1				
n	4	25	8	37
Mean (StdDev)	9.0 (10.83)	8.5 (17.99)	39.4 (34.38)	15.2 (24.91)
Median	5.0	3.0	20.0	5.0
Min, Max	1, 25	1, 90	10, 90	1, 90

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg

Bone Marrow Mast Cells (%)	ASM (N=9)	SM-AHN (N=47)	MCL (N=16)	All AdvSM (N=72)
Cycle 11 Day 1				
n	2	14	5	21
Mean (StdDev)	14.0 (15.56)	3.8 (3.66)	26.0 (36.30)	10.1 (19.41)
Median	14.0	3.0	10.0	5.0
Min, Max	3, 25	1, 15	5, 90	1, 90
Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		30.0 (-)	10.0 (-)	20.0 (14.14)
Median		30.0	10.0	20.0
Min, Max		30, 30	10, 10	10, 30
Cycle 18 Day 1				
n	1	6	2	9
Mean (StdDev)	15.0 (-)	2.5 (1.97)	3.3 (1.06)	4.1 (4.42)
Median	15.0	1.5	3.3	2.5
Min, Max	15, 15	1, 5	3, 4	1, 15
Cycle 24 Day 1				
n	2	3	1	6
Mean (StdDev)	8.0 (9.90)	3.0 (2.00)	10.0 (-)	5.8 (5.60)
Median	8.0	3.0	10.0	4.0
Min, Max	1, 15	1, 5	10, 10	1, 15

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas
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Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg

Bone Marrow Mast Cells (%)	ASM (N=9)	SM-AHN (N=47)	MCL (N=16)	All AdvSM (N=72)
Cycle 30 Day 1				
n	1	1	1	3
Mean (StdDev)	3.0 (-)	1.0 (-)	4.0 (-)	2.7 (1.53)
Median	3.0	1.0	4.0	3.0
Min, Max	3, 3	1, 1	4, 4	1, 4
Cycle 36 Day 1				
n	1	1	0	2
Mean (StdDev)	2.0 (-)	2.0 (-)		2.0 (0.00)
Median	2.0	2.0		2.0
Min, Max	2, 2	2, 2		2, 2
Cycle 42 Day 1				
n	0	1	0	1
Mean (StdDev)		1.0 (-)		1.0 (-)
Median		1.0		1.0
Min, Max		1, 1		1, 1

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg

Bone Marrow Mast Cells (%)	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Baseline				
n	1	4	0	5
Mean (StdDev)	10.0 (-)	46.3 (36.37)		39.0 (35.43)
Median	10.0	47.5		20.0
Min, Max	10, 10	10, 80		10, 80
Cycle 3 Day 1				
n	0	2	0	2
Mean (StdDev)		1.5 (0.71)		1.5 (0.71)
Median		1.5		1.5
Min, Max		1, 2		1, 2
Cycle 7 Day 1				
n	1	3	0	4
Mean (StdDev)	2.0 (-)	2.7 (2.09)		2.5 (1.73)
Median	2.0	2.0		2.0
Min, Max	2, 2	1, 5		1, 5

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.1
Summary of Bone Marrow Mast Cells
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg

Bone Marrow Mast Cells (%)	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Cycle 11 Day 1				
n	0	1	0	1
Mean (StdDev)		10.0 (-)		10.0 (-)
Median		10.0		10.0
Min, Max		10, 10		10, 10
Cycle 24 Day 1				
n	0	2	0	2
Mean (StdDev)		1.0 (0.00)		1.0 (0.00)
Median		1.0		1.0
Min, Max		1, 1		1, 1
Cycle 30 Day 1				
n	0	1	0	1
Mean (StdDev)		1.0 (-)		1.0 (-)
Median		1.0		1.0
Min, Max		1, 1		1, 1
Cycle 36 Day 1				
n	0	1	0	1
Mean (StdDev)		1.0 (-)		1.0 (-)
Median		1.0		1.0
Min, Max		1, 1		1, 1

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.2
Summary of Bone Marrow Mast Cells Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Overall

Bone Marrow Mast Cells (%) Percent Change from Baseline	ASM (N=7)	SM-AHN (N=26)	MCL (N=8)	All AdvSM (N=41)
Baseline				
n	7	21	8	36
Mean (StdDev)	35.0 (36.86)	39.3 (24.46)	67.5 (25.63)	44.7 (29.35)
Median	10.0	30.0	77.5	40.0
Min, Max	10, 95	5, 80	25, 90	5, 95
Percent Change from Baseline to Cycle 3 Day 1				
n	5	18	7	30
Mean (StdDev)	-42.2 (46.42)	-76.7 (44.87)	-35.0 (66.02)	-61.2 (52.49)
Median	-50.0	-88.0	-37.5	-83.3
Min, Max	-88, 33	-99, 100	-94, 100	-99, 100
Percent Change from Baseline to Cycle 7 Day 1				
n	5	14	7	26
Mean (StdDev)	-60.8 (53.23)	-75.8 (40.88)	-40.6 (39.13)	-63.4 (43.85)
Median	-80.0	-95.9	-40.0	-82.9
Min, Max	-94, 33	-99, 40	-86, 13	-99, 40

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-pchg-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.2
Summary of Bone Marrow Mast Cells Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Overall

Bone Marrow Mast Cells (%) Percent Change from Baseline	ASM (N=7)	SM-AHN (N=26)	MCL (N=8)	All AdvSM (N=41)
Percent Change from Baseline to Cycle 11 Day 1				
n	3	9	4	16
Mean (StdDev)	-23.3 (107.39)	-77.8 (34.63)	-65.3 (44.36)	-64.5 (54.92)
Median	-73.7	-95.0	-83.9	-91.4
Min, Max	-96, 100	-99, 0	-93, 0	-99, 100
Percent Change from Baseline to Cycle 18 Day 1				
n	2	6	2	10
Mean (StdDev)	24.6 (153.83)	-85.7 (14.75)	-95.5 (1.25)	-65.6 (70.89)
Median	24.6	-89.2	-95.5	-89.4
Min, Max	-84, 133	-98, -60	-96, -95	-98, 133
Percent Change from Baseline to Cycle 24 Day 1				
n	3	6	2	11
Mean (StdDev)	-2.5 (146.54)	-92.3 (8.41)	-59.5 (37.04)	-61.9 (77.98)
Median	-84.2	-96.5	-59.5	-85.7
Min, Max	-90, 167	-99, -80	-86, -33	-99, 167
Percent Change from Baseline to Cycle 30 Day 1				
n	2	3	1	6
Mean (StdDev)	31.7 (143.78)	-91.3 (9.92)	-94.3 (-)	-50.8 (90.85)
Median	31.7	-95.0	-94.3	-87.1
Min, Max	-70, 133	-99, -80	-94, -94	-99, 133

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-pchg-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.2
Summary of Bone Marrow Mast Cells Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Overall

Bone Marrow Mast Cells (%) Percent Change from Baseline	ASM (N=7)	SM-AHN (N=26)	MCL (N=8)	All AdvSM (N=41)
Percent Change from Baseline to Cycle 36 Day 1				
n	2	3	0	5
Mean (StdDev)	43.3 (174.42)	-89.6 (9.38)		-36.4 (113.80)
Median	43.3	-90.0		-80.0
Min, Max	-80, 167	-99, -80		-99, 167
Percent Change from Baseline to Cycle 42 Day 1				
n	1	2	1	4
Mean (StdDev)	166.7 (-)	-82.5 (3.54)	-93.3 (-)	-22.9 (126.51)
Median	166.7	-82.5	-93.3	-82.5
Min, Max	167, 167	-85, -80	-93, -93	-93, 167
Percent Change from Baseline to Cycle 48 Day 1				
n	1	0	1	2
Mean (StdDev)	100.0 (-)		-93.3 (-)	3.3 (136.71)
Median	100.0		-93.3	3.3
Min, Max	100, 100		-93, -93	-93, 100

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-pchg-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.2
Summary of Bone Marrow Mast Cells Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <200 mg				
Bone Marrow Mast Cells (%) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=2)	MCL (N=1)	All AdvSM (N=4)
Baseline				
n	1	2	1	4
Mean (StdDev)	30.0 (-)	12.5 (10.61)	30.0 (-)	21.3 (11.81)
Median	30.0	12.5	30.0	25.0
Min, Max	30, 30	5, 20	30, 30	5, 30
Percent Change from Baseline to Cycle 3 Day 1				
n	1	2	0	3
Mean (StdDev)	33.3 (-)	2.5 (137.89)		12.8 (99.11)
Median	33.3	2.5		33.3
Min, Max	33, 33	-95, 100		-95, 100
Percent Change from Baseline to Cycle 7 Day 1				
n	1	2	1	4
Mean (StdDev)	33.3 (-)	-17.5 (81.32)	0.0 (-)	-0.4 (52.71)
Median	33.3	-17.5	0.0	16.7
Min, Max	33, 33	-75, 40	0, 0	-75, 40

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-pchg-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.2
Summary of Bone Marrow Mast Cells Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <200 mg				
Bone Marrow Mast Cells (%) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=2)	MCL (N=1)	All AdvSM (N=4)
Percent Change from Baseline to Cycle 11 Day 1				
n	1	2	0	3
Mean (StdDev)	100.0 (-)	-67.5 (38.89)		-11.7 (100.54)
Median	100.0	-67.5		-40.0
Min, Max	100, 100	-95, -40		-95, 100
Percent Change from Baseline to Cycle 18 Day 1				
n	1	2	0	3
Mean (StdDev)	133.3 (-)	-77.5 (24.75)		-7.2 (122.98)
Median	133.3	-77.5		-60.0
Min, Max	133, 133	-95, -60		-95, 133
Percent Change from Baseline to Cycle 24 Day 1				
n	1	2	1	4
Mean (StdDev)	166.7 (-)	-87.5 (10.64)	-33.3 (-)	-10.4 (120.95)
Median	166.7	-87.5	-33.3	-56.7
Min, Max	167, 167	-95, -80	-33, -33	-95, 167
Percent Change from Baseline to Cycle 30 Day 1				
n	1	2	0	3
Mean (StdDev)	133.3 (-)	-87.5 (10.61)		-13.9 (127.72)
Median	133.3	-87.5		-80.0
Min, Max	133, 133	-95, -80		-95, 133

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-pchg-advsm.sas
Date: 19:33/27SEP2021

Table 35.2.5.2
Summary of Bone Marrow Mast Cells Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <200 mg				
Bone Marrow Mast Cells (%) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=2)	MCL (N=1)	All AdvSM (N=4)
Percent Change from Baseline to Cycle 36 Day 1				
n	1	2	0	3
Mean (StdDev)	166.7 (-)	-85.0 (7.07)		-1.1 (145.39)
Median	166.7	-85.0		-80.0
Min, Max	167, 167	-90, -80		-90, 167
Percent Change from Baseline to Cycle 42 Day 1				
n	1	2	1	4
Mean (StdDev)	166.7 (-)	-82.5 (3.54)	-93.3 (-)	-22.9 (126.51)
Median	166.7	-82.5	-93.3	-82.5
Min, Max	167, 167	-85, -80	-93, -93	-93, 167
Percent Change from Baseline to Cycle 48 Day 1				
n	1	0	1	2
Mean (StdDev)	100.0 (-)		-93.3 (-)	3.3 (136.71)
Median	100.0		-93.3	3.3
Min, Max	100, 100		-93, -93	-93, 100

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-pchg-advsm.sas
Date: 19:33/27SEP2021

Table 35.2.5.2
Summary of Bone Marrow Mast Cells Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <300 mg				
Bone Marrow Mast Cells (%) Percent Change from Baseline	ASM (N=2)	SM-AHN (N=9)	MCL (N=5)	All AdvSM (N=16)
Baseline				
n	2	7	5	14
Mean (StdDev)	20.0 (14.14)	27.9 (20.38)	58.0 (27.97)	37.5 (26.58)
Median	20.0	20.0	75.0	30.0
Min, Max	10, 30	5, 60	25, 80	5, 80
Percent Change from Baseline to Cycle 3 Day 1				
n	2	6	4	12
Mean (StdDev)	-18.3 (73.07)	-56.9 (77.02)	-12.1 (76.61)	-35.6 (72.70)
Median	-18.3	-86.7	-37.5	-71.7
Min, Max	-70, 33	-95, 100	-73, 100	-95, 100
Percent Change from Baseline to Cycle 7 Day 1				
n	1	5	5	11
Mean (StdDev)	33.3 (-)	-48.0 (58.63)	-35.3 (40.84)	-34.8 (50.93)
Median	33.3	-75.0	-40.0	-40.0
Min, Max	33, 33	-98, 40	-80, 13	-98, 40

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-pchg-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.2
Summary of Bone Marrow Mast Cells Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <300 mg				
Bone Marrow Mast Cells (%) Percent Change from Baseline	ASM (N=2)	SM-AHN (N=9)	MCL (N=5)	All AdvSM (N=16)
Percent Change from Baseline to Cycle 11 Day 1				
n	1	2	2	5
Mean (StdDev)	100.0 (-)	-67.5 (38.89)	-84.2 (12.96)	-40.7 (81.69)
Median	100.0	-67.5	-84.2	-75.0
Min, Max	100, 100	-95, -40	-93, -75	-95, 100
Percent Change from Baseline to Cycle 18 Day 1				
n	1	2	1	4
Mean (StdDev)	133.3 (-)	-77.5 (24.75)	-94.7 (-)	-29.1 (109.52)
Median	133.3	-77.5	-94.7	-77.3
Min, Max	133, 133	-95, -60	-95, -95	-95, 133
Percent Change from Baseline to Cycle 24 Day 1				
n	1	2	1	4
Mean (StdDev)	166.7 (-)	-87.5 (10.64)	-33.3 (-)	-10.4 (120.95)
Median	166.7	-87.5	-33.3	-56.7
Min, Max	167, 167	-95, -80	-33, -33	-95, 167
Percent Change from Baseline to Cycle 30 Day 1				
n	1	2	0	3
Mean (StdDev)	133.3 (-)	-87.5 (10.61)		-13.9 (127.72)
Median	133.3	-87.5		-80.0
Min, Max	133, 133	-95, -80		-95, 133

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-pchg-advsm.sas
Date: 19:33/27SEP2021

Table 35.2.5.2
Summary of Bone Marrow Mast Cells Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <300 mg				
Bone Marrow Mast Cells (%) Percent Change from Baseline	ASM (N=2)	SM-AHN (N=9)	MCL (N=5)	All AdvSM (N=16)
Percent Change from Baseline to Cycle 36 Day 1				
n	1	2	0	3
Mean (StdDev)	166.7 (-)	-85.0 (7.07)		-1.1 (145.39)
Median	166.7	-85.0		-80.0
Min, Max	167, 167	-90, -80		-90, 167
Percent Change from Baseline to Cycle 42 Day 1				
n	1	2	1	4
Mean (StdDev)	166.7 (-)	-82.5 (3.54)	-93.3 (-)	-22.9 (126.51)
Median	166.7	-82.5	-93.3	-82.5
Min, Max	167, 167	-85, -80	-93, -93	-93, 167
Percent Change from Baseline to Cycle 48 Day 1				
n	1	0	1	2
Mean (StdDev)	100.0 (-)		-93.3 (-)	3.3 (136.71)
Median	100.0		-93.3	3.3
Min, Max	100, 100		-93, -93	-93, 100

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-pchg-advsm.sas
Date: 19:33/27SEP2021

Table 35.2.5.2
Summary of Bone Marrow Mast Cells Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg				
Bone Marrow Mast Cells (%) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=7)	MCL (N=4)	All AdvSM (N=12)
Baseline				
n	1	5	4	10
Mean (StdDev)	10.0 (-)	34.0 (20.74)	65.0 (26.77)	44.0 (28.46)
Median	10.0	30.0	77.5	40.0
Min, Max	10, 10	10, 60	25, 80	10, 80
Percent Change from Baseline to Cycle 3 Day 1				
n	1	4	4	9
Mean (StdDev)	-70.0 (-)	-86.7 (3.85)	-12.1 (76.61)	-51.7 (60.37)
Median	-70.0	-86.7	-37.5	-73.3
Min, Max	-70, -70	-90, -83	-73, 100	-90, 100
Percent Change from Baseline to Cycle 7 Day 1				
n	0	3	4	7
Mean (StdDev)		-68.3 (44.94)	-44.1 (41.30)	-54.5 (41.16)
Median		-90.0	-54.4	-68.8
Min, Max		-98, -17	-80, 13	-98, 13

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-pchg-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.2
Summary of Bone Marrow Mast Cells Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg				
Bone Marrow Mast Cells (%) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=7)	MCL (N=4)	All AdvSM (N=12)
Percent Change from Baseline to Cycle 11 Day 1				
n	0	0	2	2
Mean (StdDev)			-84.2 (12.96)	-84.2 (12.96)
Median			-84.2	-84.2
Min, Max			-93, -75	-93, -75
Percent Change from Baseline to Cycle 18 Day 1				
n	0	0	1	1
Mean (StdDev)			-94.7 (-)	-94.7 (-)
Median			-94.7	-94.7
Min, Max			-95, -95	-95, -95

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-pchg-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.2
Summary of Bone Marrow Mast Cells Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 300 mg				
Bone Marrow Mast Cells (%) Percent Change from Baseline	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Baseline				
n	4	10	3	17
Mean (StdDev)	48.8 (45.16)	44.5 (21.40)	83.3 (11.55)	52.4 (29.64)
Median	45.0	50.0	90.0	50.0
Min, Max	10, 95	10, 75	70, 90	10, 95
Percent Change from Baseline to Cycle 3 Day 1				
n	3	10	3	16
Mean (StdDev)	-58.1 (26.29)	-86.0 (9.84)	-65.6 (42.61)	-76.9 (23.30)
Median	-50.0	-88.0	-85.7	-85.9
Min, Max	-88, -37	-98, -67	-94, -17	-98, -17
Percent Change from Baseline to Cycle 7 Day 1				
n	3	6	2	11
Mean (StdDev)	-85.8 (10.67)	-95.8 (3.08)	-54.0 (44.90)	-85.5 (22.18)
Median	-90.0	-96.3	-54.0	-93.8
Min, Max	-94, -74	-99, -90	-86, -22	-99, -22

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-pchg-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.2
Summary of Bone Marrow Mast Cells Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 300 mg				
Bone Marrow Mast Cells (%) Percent Change from Baseline	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Percent Change from Baseline to Cycle 11 Day 1				
n	2	6	2	10
Mean (StdDev)	-85.0 (15.96)	-94.2 (6.25)	-46.4 (65.66)	-82.8 (30.18)
Median	-85.0	-97.5	-46.4	-94.6
Min, Max	-96, -74	-99, -83	-93, 0	-99, 0
Percent Change from Baseline to Cycle 18 Day 1				
n	1	4	1	6
Mean (StdDev)	-84.2 (-)	-89.8 (9.53)	-96.4 (-)	-90.0 (8.33)
Median	-84.2	-90.7	-96.4	-90.3
Min, Max	-84, -84	-98, -80	-96, -96	-98, -80
Percent Change from Baseline to Cycle 24 Day 1				
n	2	2	1	5
Mean (StdDev)	-87.1 (4.09)	-90.7 (10.37)	-85.7 (-)	-88.3 (6.02)
Median	-87.1	-90.7	-85.7	-85.7
Min, Max	-90, -84	-98, -83	-86, -86	-98, -83
Percent Change from Baseline to Cycle 30 Day 1				
n	1	0	1	2
Mean (StdDev)	-70.0 (-)		-94.3 (-)	-82.1 (17.17)
Median	-70.0		-94.3	-82.1
Min, Max	-70, -70		-94, -94	-94, -70

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-pchg-advsm.sas
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Table 35.2.5.2
Summary of Bone Marrow Mast Cells Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 300 mg				
Bone Marrow Mast Cells (%) Percent Change from Baseline	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Percent Change from Baseline to Cycle 36 Day 1				
n	1	0	0	1
Mean (StdDev)	-80.0 (-)			-80.0 (-)
Median	-80.0			-80.0
Min, Max	-80, -80			-80, -80

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-pchg-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.2
Summary of Bone Marrow Mast Cells Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg				
Bone Marrow Mast Cells (%) Percent Change from Baseline	ASM (N=5)	SM-AHN (N=20)	MCL (N=7)	All AdvSM (N=32)
Baseline				
n	5	15	7	27
Mean (StdDev)	41.0 (42.78)	41.0 (21.06)	72.9 (22.33)	49.3 (28.95)
Median	10.0	50.0	80.0	50.0
Min, Max	10, 95	10, 75	25, 90	10, 95
Percent Change from Baseline to Cycle 3 Day 1				
n	4	14	7	25
Mean (StdDev)	-61.1 (22.27)	-86.2 (8.40)	-35.0 (66.02)	-67.8 (41.32)
Median	-60.0	-88.0	-37.5	-83.3
Min, Max	-88, -37	-98, -67	-94, 100	-98, 100
Percent Change from Baseline to Cycle 7 Day 1				
n	3	9	6	18
Mean (StdDev)	-85.8 (10.67)	-86.7 (26.46)	-47.4 (38.11)	-73.4 (33.61)
Median	-90.0	-96.0	-54.4	-90.0
Min, Max	-94, -74	-99, -17	-86, 13	-99, 13

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-pchg-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.2
Summary of Bone Marrow Mast Cells Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg				
Bone Marrow Mast Cells (%) Percent Change from Baseline	ASM (N=5)	SM-AHN (N=20)	MCL (N=7)	All AdvSM (N=32)
Percent Change from Baseline to Cycle 11 Day 1				
n	2	6	4	12
Mean (StdDev)	-85.0 (15.96)	-94.2 (6.25)	-65.3 (44.36)	-83.0 (27.59)
Median	-85.0	-97.5	-83.9	-93.1
Min, Max	-96, -74	-99, -83	-93, 0	-99, 0
Percent Change from Baseline to Cycle 18 Day 1				
n	1	4	2	7
Mean (StdDev)	-84.2 (-)	-89.8 (9.53)	-95.5 (1.25)	-90.7 (7.81)
Median	-84.2	-90.7	-95.5	-94.7
Min, Max	-84, -84	-98, -80	-96, -95	-98, -80
Percent Change from Baseline to Cycle 24 Day 1				
n	2	2	1	5
Mean (StdDev)	-87.1 (4.09)	-90.7 (10.37)	-85.7 (-)	-88.3 (6.02)
Median	-87.1	-90.7	-85.7	-85.7
Min, Max	-90, -84	-98, -83	-86, -86	-98, -83
Percent Change from Baseline to Cycle 30 Day 1				
n	1	0	1	2
Mean (StdDev)	-70.0 (-)		-94.3 (-)	-82.1 (17.17)
Median	-70.0		-94.3	-82.1
Min, Max	-70, -70		-94, -94	-94, -70

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-pchg-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.2
Summary of Bone Marrow Mast Cells Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg				
Bone Marrow Mast Cells (%) Percent Change from Baseline	ASM (N=5)	SM-AHN (N=20)	MCL (N=7)	All AdvSM (N=32)
Percent Change from Baseline to Cycle 36 Day 1				
n	1	0	0	1
Mean (StdDev)	-80.0 (-)			-80.0 (-)
Median	-80.0			-80.0
Min, Max	-80, -80			-80, -80

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-pchg-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.2
Summary of Bone Marrow Mast Cells Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 400 mg				
Bone Marrow Mast Cells (%) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Baseline				
n	1	4	0	5
Mean (StdDev)	10.0 (-)	46.3 (36.37)		39.0 (35.43)
Median	10.0	47.5		20.0
Min, Max	10, 10	10, 80		10, 80
Percent Change from Baseline to Cycle 3 Day 1				
n	0	2	0	2
Mean (StdDev)		-89.3 (13.20)		-89.3 (13.20)
Median		-89.3		-89.3
Min, Max		-99, -80		-99, -80
Percent Change from Baseline to Cycle 7 Day 1				
n	1	3	0	4
Mean (StdDev)	-80.0 (-)	-82.0 (27.75)		-81.5 (22.68)
Median	-80.0	-97.3		-88.7
Min, Max	-80, -80	-99, -50		-99, -50

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-pchg-advsm.sas
Date: 19:33/27SEP2021

Table 35.2.5.2
Summary of Bone Marrow Mast Cells Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 400 mg				
Bone Marrow Mast Cells (%) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Percent Change from Baseline to Cycle 11 Day 1				
n	0	1	0	1
Mean (StdDev)		0.0 (-)		0.0 (-)
Median		0.0		0.0
Min, Max		0, 0		0, 0
Percent Change from Baseline to Cycle 24 Day 1				
n	0	2	0	2
Mean (StdDev)		-98.7 (0.06)		-98.7 (0.06)
Median		-98.7		-98.7
Min, Max		-99, -99		-99, -99
Percent Change from Baseline to Cycle 30 Day 1				
n	0	1	0	1
Mean (StdDev)		-98.8 (-)		-98.8 (-)
Median		-98.8		-98.8
Min, Max		-99, -99		-99, -99
Percent Change from Baseline to Cycle 36 Day 1				
n	0	1	0	1
Mean (StdDev)		-98.8 (-)		-98.8 (-)
Median		-98.8		-98.8
Min, Max		-99, -99		-99, -99

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-pchg-advsm.sas
Date: 19:33/27SEP2021

Table 35.2.5.2
Summary of Bone Marrow Mast Cells Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2202

Overall

Bone Marrow Mast Cells (%) Percent Change from Baseline	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Baseline				
n	5	28	9	42
Mean (StdDev)	39.0 (30.08)	47.4 (26.23)	73.3 (21.65)	51.9 (27.72)
Median	30.0	45.0	80.0	55.0
Min, Max	10, 80	1, 90	20, 95	1, 95
Percent Change from Baseline to Cycle 3 Day 1				
n	4	20	8	32
Mean (StdDev)	-73.1 (10.10)	-62.3 (47.85)	-44.6 (29.41)	-59.2 (41.17)
Median	-73.3	-77.5	-49.2	-70.8
Min, Max	-83, -63	-99, 100	-93, 0	-99, 100
Percent Change from Baseline to Cycle 7 Day 1				
n	1	14	2	17
Mean (StdDev)	-66.7 (-)	-71.2 (34.01)	-44.7 (63.27)	-67.8 (35.59)
Median	-66.7	-88.8	-44.7	-87.5
Min, Max	-67, -67	-98, 0	-89, 0	-98, 0

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-pchg-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.2
Summary of Bone Marrow Mast Cells Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2202

Overall

Bone Marrow Mast Cells (%) Percent Change from Baseline	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Percent Change from Baseline to Cycle 11 Day 1				
n	0	7	1	8
Mean (StdDev)		-61.4 (66.94)	-87.5 (-)	-64.7 (62.66)
Median		-93.8	-87.5	-90.6
Min, Max		-97, 88	-88, -88	-97, 88
Percent Change from Baseline to Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		-25.0 (-)	-89.5 (-)	-57.2 (45.59)
Median		-25.0	-89.5	-57.2
Min, Max		-25, -25	-89, -89	-89, -25

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-pchg-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.2
Summary of Bone Marrow Mast Cells Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2202

Starting Dose: 200 mg				
Bone Marrow Mast Cells (%) Percent Change from Baseline	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Baseline				
n	4	27	9	40
Mean (StdDev)	41.3 (34.25)	47.6 (26.69)	73.3 (21.65)	52.8 (28.12)
Median	37.5	50.0	80.0	60.0
Min, Max	10, 80	1, 90	20, 95	1, 95
Percent Change from Baseline to Cycle 3 Day 1				
n	4	19	8	31
Mean (StdDev)	-73.1 (10.10)	-61.7 (49.06)	-44.6 (29.41)	-58.7 (41.75)
Median	-73.3	-80.0	-49.2	-66.7
Min, Max	-83, -63	-99, 100	-93, 0	-99, 100
Percent Change from Baseline to Cycle 7 Day 1				
n	1	13	2	16
Mean (StdDev)	-66.7 (-)	-72.8 (34.83)	-44.7 (63.27)	-68.9 (36.45)
Median	-66.7	-90.0	-44.7	-88.5
Min, Max	-67, -67	-98, 0	-89, 0	-98, 0

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-pchg-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.2
Summary of Bone Marrow Mast Cells Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2202

Starting Dose: 200 mg				
Bone Marrow Mast Cells (%) Percent Change from Baseline	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Percent Change from Baseline to Cycle 11 Day 1				
n	0	6	1	7
Mean (StdDev)		-86.3 (14.18)	-87.5 (-)	-86.4 (12.95)
Median		-93.9	-87.5	-93.8
Min, Max		-97, -63	-88, -88	-97, -63
Percent Change from Baseline to Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		-25.0 (-)	-89.5 (-)	-57.2 (45.59)
Median		-25.0	-89.5	-57.2
Min, Max		-25, -25	-89, -89	-89, -25

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-pchg-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.2
Summary of Bone Marrow Mast Cells Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Overall

Bone Marrow Mast Cells (%) Percent Change from Baseline	ASM (N=12)	SM-AHN (N=54)	MCL (N=17)	All AdvSM (N=83)
Baseline				
n	12	49	17	78
Mean (StdDev)	36.7 (32.78)	43.9 (25.55)	70.6 (23.04)	48.6 (28.52)
Median	22.5	40.0	80.0	50.0
Min, Max	10, 95	1, 90	20, 95	1, 95
Percent Change from Baseline to Cycle 3 Day 1				
n	9	38	15	62
Mean (StdDev)	-55.9 (37.17)	-69.1 (46.40)	-40.1 (48.21)	-60.2 (46.60)
Median	-66.7	-84.5	-42.9	-77.5
Min, Max	-88, 33	-99, 100	-94, 100	-99, 100
Percent Change from Baseline to Cycle 7 Day 1				
n	6	28	9	43
Mean (StdDev)	-61.8 (47.67)	-73.5 (36.98)	-41.5 (40.64)	-65.2 (40.40)
Median	-76.8	-90.8	-40.0	-85.7
Min, Max	-94, 33	-99, 40	-89, 13	-99, 40

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-pchg-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.2
Summary of Bone Marrow Mast Cells Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Overall

Bone Marrow Mast Cells (%) Percent Change from Baseline	ASM (N=12)	SM-AHN (N=54)	MCL (N=17)	All AdvSM (N=83)
Percent Change from Baseline to Cycle 11 Day 1				
n	3	16	5	24
Mean (StdDev)	-23.3 (107.39)	-70.7 (50.02)	-69.7 (39.68)	-64.5 (56.23)
Median	-73.7	-93.9	-87.5	-91.4
Min, Max	-96, 100	-99, 88	-93, 0	-99, 100
Percent Change from Baseline to Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		-25.0 (-)	-89.5 (-)	-57.2 (45.59)
Median		-25.0	-89.5	-57.2
Min, Max		-25, -25	-89, -89	-89, -25
Percent Change from Baseline to Cycle 18 Day 1				
n	2	6	2	10
Mean (StdDev)	24.6 (153.83)	-85.7 (14.75)	-95.5 (1.25)	-65.6 (70.89)
Median	24.6	-89.2	-95.5	-89.4
Min, Max	-84, 133	-98, -60	-96, -95	-98, 133
Percent Change from Baseline to Cycle 24 Day 1				
n	3	6	2	11
Mean (StdDev)	-2.5 (146.54)	-92.3 (8.41)	-59.5 (37.04)	-61.9 (77.98)
Median	-84.2	-96.5	-59.5	-85.7
Min, Max	-90, 167	-99, -80	-86, -33	-99, 167

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-pchg-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.2
Summary of Bone Marrow Mast Cells Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Overall

Bone Marrow Mast Cells (%) Percent Change from Baseline	ASM (N=12)	SM-AHN (N=54)	MCL (N=17)	All AdvSM (N=83)
Percent Change from Baseline to Cycle 30 Day 1				
n	2	3	1	6
Mean (StdDev)	31.7 (143.78)	-91.3 (9.92)	-94.3 (-)	-50.8 (90.85)
Median	31.7	-95.0	-94.3	-87.1
Min, Max	-70, 133	-99, -80	-94, -94	-99, 133
Percent Change from Baseline to Cycle 36 Day 1				
n	2	3	0	5
Mean (StdDev)	43.3 (174.42)	-89.6 (9.38)		-36.4 (113.80)
Median	43.3	-90.0		-80.0
Min, Max	-80, 167	-99, -80		-99, 167
Percent Change from Baseline to Cycle 42 Day 1				
n	1	2	1	4
Mean (StdDev)	166.7 (-)	-82.5 (3.54)	-93.3 (-)	-22.9 (126.51)
Median	166.7	-82.5	-93.3	-82.5
Min, Max	167, 167	-85, -80	-93, -93	-93, 167
Percent Change from Baseline to Cycle 48 Day 1				
n	1	0	1	2
Mean (StdDev)	100.0 (-)		-93.3 (-)	3.3 (136.71)
Median	100.0		-93.3	3.3
Min, Max	100, 100		-93, -93	-93, 100

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-pchg-advsm.sas
Date: 19:33/27SEP2021

Table 35.2.5.2
Summary of Bone Marrow Mast Cells Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg

Bone Marrow Mast Cells (%) Percent Change from Baseline	ASM (N=2)	SM-AHN (N=3)	MCL (N=1)	All AdvSM (N=6)
Baseline				
n	2	3	1	6
Mean (StdDev)	30.0 (0.00)	21.7 (17.56)	30.0 (-)	25.8 (12.01)
Median	30.0	20.0	30.0	30.0
Min, Max	30, 30	5, 40	30, 30	5, 40
Percent Change from Baseline to Cycle 3 Day 1				
n	1	3	0	4
Mean (StdDev)	33.3 (-)	-23.3 (107.28)		-9.2 (92.06)
Median	33.3	-75.0		-20.8
Min, Max	33, 33	-95, 100		-95, 100
Percent Change from Baseline to Cycle 7 Day 1				
n	1	3	1	5
Mean (StdDev)	33.3 (-)	-28.3 (60.48)	0.0 (-)	-10.3 (50.75)
Median	33.3	-50.0	0.0	0.0
Min, Max	33, 33	-75, 40	0, 0	-75, 40

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-pchg-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.2
Summary of Bone Marrow Mast Cells Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg				
Bone Marrow Mast Cells (%) Percent Change from Baseline	ASM (N=2)	SM-AHN (N=3)	MCL (N=1)	All AdvSM (N=6)
Percent Change from Baseline to Cycle 11 Day 1				
n	1	3	0	4
Mean (StdDev)	100.0 (-)	-15.8 (93.62)		13.1 (95.90)
Median	100.0	-40.0		23.8
Min, Max	100, 100	-95, 88		-95, 100
Percent Change from Baseline to Cycle 18 Day 1				
n	1	2	0	3
Mean (StdDev)	133.3 (-)	-77.5 (24.75)		-7.2 (122.98)
Median	133.3	-77.5		-60.0
Min, Max	133, 133	-95, -60		-95, 133
Percent Change from Baseline to Cycle 24 Day 1				
n	1	2	1	4
Mean (StdDev)	166.7 (-)	-87.5 (10.64)	-33.3 (-)	-10.4 (120.95)
Median	166.7	-87.5	-33.3	-56.7
Min, Max	167, 167	-95, -80	-33, -33	-95, 167
Percent Change from Baseline to Cycle 30 Day 1				
n	1	2	0	3
Mean (StdDev)	133.3 (-)	-87.5 (10.61)		-13.9 (127.72)
Median	133.3	-87.5		-80.0
Min, Max	133, 133	-95, -80		-95, 133

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-pchg-advsm.sas
Date: 19:33/27SEP2021

Table 35.2.5.2
Summary of Bone Marrow Mast Cells Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg				
Bone Marrow Mast Cells (%) Percent Change from Baseline	ASM (N=2)	SM-AHN (N=3)	MCL (N=1)	All AdvSM (N=6)
Percent Change from Baseline to Cycle 36 Day 1				
n	1	2	0	3
Mean (StdDev)	166.7 (-)	-85.0 (7.07)		-1.1 (145.39)
Median	166.7	-85.0		-80.0
Min, Max	167, 167	-90, -80		-90, 167
Percent Change from Baseline to Cycle 42 Day 1				
n	1	2	1	4
Mean (StdDev)	166.7 (-)	-82.5 (3.54)	-93.3 (-)	-22.9 (126.51)
Median	166.7	-82.5	-93.3	-82.5
Min, Max	167, 167	-85, -80	-93, -93	-93, 167
Percent Change from Baseline to Cycle 48 Day 1				
n	1	0	1	2
Mean (StdDev)	100.0 (-)		-93.3 (-)	3.3 (136.71)
Median	100.0		-93.3	3.3
Min, Max	100, 100		-93, -93	-93, 100

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-pchg-advsm.sas
Date: 19:33/27SEP2021

Table 35.2.5.2
Summary of Bone Marrow Mast Cells Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg				
Bone Marrow Mast Cells (%) Percent Change from Baseline	ASM (N=7)	SM-AHN (N=37)	MCL (N=14)	All AdvSM (N=58)
Baseline				
n	7	35	14	56
Mean (StdDev)	33.6 (26.88)	43.5 (26.12)	67.9 (24.24)	48.3 (27.92)
Median	30.0	40.0	77.5	50.0
Min, Max	10, 80	1, 90	20, 95	1, 95
Percent Change from Baseline to Cycle 3 Day 1				
n	6	26	12	44
Mean (StdDev)	-54.9 (43.93)	-61.1 (54.14)	-33.7 (49.06)	-52.8 (51.84)
Median	-68.3	-83.3	-40.2	-71.7
Min, Max	-83, 33	-99, 100	-93, 100	-99, 100
Percent Change from Baseline to Cycle 7 Day 1				
n	2	19	7	28
Mean (StdDev)	-16.7 (70.71)	-65.1 (41.34)	-38.0 (42.43)	-54.8 (44.50)
Median	-16.7	-87.5	-40.0	-71.9
Min, Max	-67, 33	-98, 40	-89, 13	-98, 40

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-pchg-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.2
Summary of Bone Marrow Mast Cells Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg

Bone Marrow Mast Cells (%) Percent Change from Baseline	ASM (N=7)	SM-AHN (N=37)	MCL (N=14)	All AdvSM (N=58)
Percent Change from Baseline to Cycle 11 Day 1				
n	1	9	3	13
Mean (StdDev)	100.0 (-)	-62.8 (59.64)	-85.3 (9.37)	-55.5 (68.28)
Median	100.0	-93.8	-87.5	-87.5
Min, Max	100, 100	-97, 88	-93, -75	-97, 100
Percent Change from Baseline to Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		-25.0 (-)	-89.5 (-)	-57.2 (45.59)
Median		-25.0	-89.5	-57.2
Min, Max		-25, -25	-89, -89	-89, -25
Percent Change from Baseline to Cycle 18 Day 1				
n	1	2	1	4
Mean (StdDev)	133.3 (-)	-77.5 (24.75)	-94.7 (-)	-29.1 (109.52)
Median	133.3	-77.5	-94.7	-77.3
Min, Max	133, 133	-95, -60	-95, -95	-95, 133
Percent Change from Baseline to Cycle 24 Day 1				
n	1	2	1	4
Mean (StdDev)	166.7 (-)	-87.5 (10.64)	-33.3 (-)	-10.4 (120.95)
Median	166.7	-87.5	-33.3	-56.7
Min, Max	167, 167	-95, -80	-33, -33	-95, 167

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-pchg-advsm.sas
Date: 19:33/27SEP2021

Table 35.2.5.2
Summary of Bone Marrow Mast Cells Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg

Bone Marrow Mast Cells (%) Percent Change from Baseline	ASM (N=7)	SM-AHN (N=37)	MCL (N=14)	All AdvSM (N=58)
Percent Change from Baseline to Cycle 30 Day 1				
n	1	2	0	3
Mean (StdDev)	133.3 (-)	-87.5 (10.61)		-13.9 (127.72)
Median	133.3	-87.5		-80.0
Min, Max	133, 133	-95, -80		-95, 133
Percent Change from Baseline to Cycle 36 Day 1				
n	1	2	0	3
Mean (StdDev)	166.7 (-)	-85.0 (7.07)		-1.1 (145.39)
Median	166.7	-85.0		-80.0
Min, Max	167, 167	-90, -80		-90, 167
Percent Change from Baseline to Cycle 42 Day 1				
n	1	2	1	4
Mean (StdDev)	166.7 (-)	-82.5 (3.54)	-93.3 (-)	-22.9 (126.51)
Median	166.7	-82.5	-93.3	-82.5
Min, Max	167, 167	-85, -80	-93, -93	-93, 167
Percent Change from Baseline to Cycle 48 Day 1				
n	1	0	1	2
Mean (StdDev)	100.0 (-)		-93.3 (-)	3.3 (136.71)
Median	100.0		-93.3	3.3
Min, Max	100, 100		-93, -93	-93, 100

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-pchg-advsm.sas
Date: 19:33/27SEP2021

Table 35.2.5.2
Summary of Bone Marrow Mast Cells Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg				
Bone Marrow Mast Cells (%) Percent Change from Baseline	ASM (N=5)	SM-AHN (N=34)	MCL (N=13)	All AdvSM (N=52)
Baseline				
n	5	32	13	50
Mean (StdDev)	35.0 (32.79)	45.5 (26.04)	70.8 (22.53)	51.0 (28.12)
Median	15.0	45.0	80.0	55.0
Min, Max	10, 80	1, 90	20, 95	1, 95
Percent Change from Baseline to Cycle 3 Day 1				
n	5	23	12	40
Mean (StdDev)	-72.5 (8.86)	-66.0 (45.45)	-33.7 (49.06)	-57.1 (45.79)
Median	-70.0	-83.3	-40.2	-71.7
Min, Max	-83, -63	-99, 100	-93, 100	-99, 100
Percent Change from Baseline to Cycle 7 Day 1				
n	1	16	6	23
Mean (StdDev)	-66.7 (-)	-72.0 (35.25)	-44.3 (42.71)	-64.5 (37.60)
Median	-66.7	-90.0	-54.4	-80.0
Min, Max	-67, -67	-98, 0	-89, 13	-98, 13

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-pchg-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.2
Summary of Bone Marrow Mast Cells Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Bone Marrow Mast Cells (%) Percent Change from Baseline	ASM (N=5)	SM-AHN (N=34)	MCL (N=13)	All AdvSM (N=52)
Percent Change from Baseline to Cycle 11 Day 1				
n	0	6	3	9
Mean (StdDev)		-86.3 (14.18)	-85.3 (9.37)	-85.9 (12.16)
Median		-93.9	-87.5	-93.3
Min, Max		-97, -63	-93, -75	-97, -63
Percent Change from Baseline to Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		-25.0 (-)	-89.5 (-)	-57.2 (45.59)
Median		-25.0	-89.5	-57.2
Min, Max		-25, -25	-89, -89	-89, -25
Percent Change from Baseline to Cycle 18 Day 1				
n	0	0	1	1
Mean (StdDev)			-94.7 (-)	-94.7 (-)
Median			-94.7	-94.7
Min, Max			-95, -95	-95, -95

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-pchg-advsm.sas
Date: 19:33/27SEP2021

Table 35.2.5.2
Summary of Bone Marrow Mast Cells Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg				
Bone Marrow Mast Cells (%) Percent Change from Baseline	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Baseline				
n	4	10	3	17
Mean (StdDev)	48.8 (45.16)	44.5 (21.40)	83.3 (11.55)	52.4 (29.64)
Median	45.0	50.0	90.0	50.0
Min, Max	10, 95	10, 75	70, 90	10, 95
Percent Change from Baseline to Cycle 3 Day 1				
n	3	10	3	16
Mean (StdDev)	-58.1 (26.29)	-86.0 (9.84)	-65.6 (42.61)	-76.9 (23.30)
Median	-50.0	-88.0	-85.7	-85.9
Min, Max	-88, -37	-98, -67	-94, -17	-98, -17
Percent Change from Baseline to Cycle 7 Day 1				
n	3	6	2	11
Mean (StdDev)	-85.8 (10.67)	-95.8 (3.08)	-54.0 (44.90)	-85.5 (22.18)
Median	-90.0	-96.3	-54.0	-93.8
Min, Max	-94, -74	-99, -90	-86, -22	-99, -22

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-pchg-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.2
Summary of Bone Marrow Mast Cells Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg				
Bone Marrow Mast Cells (%) Percent Change from Baseline	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Percent Change from Baseline to Cycle 11 Day 1				
n	2	6	2	10
Mean (StdDev)	-85.0 (15.96)	-94.2 (6.25)	-46.4 (65.66)	-82.8 (30.18)
Median	-85.0	-97.5	-46.4	-94.6
Min, Max	-96, -74	-99, -83	-93, 0	-99, 0
Percent Change from Baseline to Cycle 18 Day 1				
n	1	4	1	6
Mean (StdDev)	-84.2 (-)	-89.8 (9.53)	-96.4 (-)	-90.0 (8.33)
Median	-84.2	-90.7	-96.4	-90.3
Min, Max	-84, -84	-98, -80	-96, -96	-98, -80
Percent Change from Baseline to Cycle 24 Day 1				
n	2	2	1	5
Mean (StdDev)	-87.1 (4.09)	-90.7 (10.37)	-85.7 (-)	-88.3 (6.02)
Median	-87.1	-90.7	-85.7	-85.7
Min, Max	-90, -84	-98, -83	-86, -86	-98, -83
Percent Change from Baseline to Cycle 30 Day 1				
n	1	0	1	2
Mean (StdDev)	-70.0 (-)		-94.3 (-)	-82.1 (17.17)
Median	-70.0		-94.3	-82.1
Min, Max	-70, -70		-94, -94	-94, -70

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-pchg-advsm.sas
Date: 19:33/27SEP2021

Table 35.2.5.2
Summary of Bone Marrow Mast Cells Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg				
Bone Marrow Mast Cells (%) Percent Change from Baseline	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Percent Change from Baseline to Cycle 36 Day 1				
n	1	0	0	1
Mean (StdDev)	-80.0 (-)			-80.0 (-)
Median	-80.0			-80.0
Min, Max	-80, -80			-80, -80

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-pchg-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.2
Summary of Bone Marrow Mast Cells Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg				
Bone Marrow Mast Cells (%) Percent Change from Baseline	ASM (N=9)	SM-AHN (N=47)	MCL (N=16)	All AdvSM (N=72)
Baseline				
n	9	42	16	67
Mean (StdDev)	41.1 (36.81)	45.3 (24.77)	73.1 (21.20)	51.4 (28.29)
Median	15.0	50.0	80.0	50.0
Min, Max	10, 95	1, 90	20, 95	1, 95
Percent Change from Baseline to Cycle 3 Day 1				
n	8	33	15	56
Mean (StdDev)	-67.1 (17.25)	-72.1 (39.16)	-40.1 (48.21)	-62.8 (41.43)
Median	-68.3	-85.7	-42.9	-77.5
Min, Max	-88, -37	-99, 100	-94, 100	-99, 100
Percent Change from Baseline to Cycle 7 Day 1				
n	4	22	8	34
Mean (StdDev)	-81.0 (12.94)	-78.5 (31.76)	-46.7 (40.14)	-71.3 (34.51)
Median	-81.8	-92.7	-54.4	-89.7
Min, Max	-94, -67	-99, 0	-89, 13	-99, 13

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-pchg-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.2
Summary of Bone Marrow Mast Cells Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg

Bone Marrow Mast Cells (%) Percent Change from Baseline	ASM (N=9)	SM-AHN (N=47)	MCL (N=16)	All AdvSM (N=72)
Percent Change from Baseline to Cycle 11 Day 1				
n	2	12	5	19
Mean (StdDev)	-85.0 (15.96)	-90.2 (11.24)	-69.7 (39.68)	-84.3 (22.89)
Median	-85.0	-94.9	-87.5	-93.3
Min, Max	-96, -74	-99, -63	-93, 0	-99, 0
Percent Change from Baseline to Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		-25.0 (-)	-89.5 (-)	-57.2 (45.59)
Median		-25.0	-89.5	-57.2
Min, Max		-25, -25	-89, -89	-89, -25
Percent Change from Baseline to Cycle 18 Day 1				
n	1	4	2	7
Mean (StdDev)	-84.2 (-)	-89.8 (9.53)	-95.5 (1.25)	-90.7 (7.81)
Median	-84.2	-90.7	-95.5	-94.7
Min, Max	-84, -84	-98, -80	-96, -95	-98, -80
Percent Change from Baseline to Cycle 24 Day 1				
n	2	2	1	5
Mean (StdDev)	-87.1 (4.09)	-90.7 (10.37)	-85.7 (-)	-88.3 (6.02)
Median	-87.1	-90.7	-85.7	-85.7
Min, Max	-90, -84	-98, -83	-86, -86	-98, -83

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-pchg-advsm.sas
Date: 19:33/27SEP2021

Table 35.2.5.2
Summary of Bone Marrow Mast Cells Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg

Bone Marrow Mast Cells (%) Percent Change from Baseline	ASM (N=9)	SM-AHN (N=47)	MCL (N=16)	All AdvSM (N=72)
Percent Change from Baseline to Cycle 30 Day 1				
n	1	0	1	2
Mean (StdDev)	-70.0 (-)		-94.3 (-)	-82.1 (17.17)
Median	-70.0		-94.3	-82.1
Min, Max	-70, -70		-94, -94	-94, -70
Percent Change from Baseline to Cycle 36 Day 1				
n	1	0	0	1
Mean (StdDev)	-80.0 (-)			-80.0 (-)
Median	-80.0			-80.0
Min, Max	-80, -80			-80, -80

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-pchg-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.2
Summary of Bone Marrow Mast Cells Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg				
Bone Marrow Mast Cells (%) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Baseline				
n	1	4	0	5
Mean (StdDev)	10.0 (-)	46.3 (36.37)		39.0 (35.43)
Median	10.0	47.5		20.0
Min, Max	10, 10	10, 80		10, 80
Percent Change from Baseline to Cycle 3 Day 1				
n	0	2	0	2
Mean (StdDev)		-89.3 (13.20)		-89.3 (13.20)
Median		-89.3		-89.3
Min, Max		-99, -80		-99, -80
Percent Change from Baseline to Cycle 7 Day 1				
n	1	3	0	4
Mean (StdDev)	-80.0 (-)	-82.0 (27.75)		-81.5 (22.68)
Median	-80.0	-97.3		-88.7
Min, Max	-80, -80	-99, -50		-99, -50

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-pchg-advsm.sas Date: 19:33/27SEP2021

Table 35.2.5.2
Summary of Bone Marrow Mast Cells Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg

Bone Marrow Mast Cells (%) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Percent Change from Baseline to Cycle 11 Day 1				
n	0	1	0	1
Mean (StdDev)		0.0 (-)		0.0 (-)
Median		0.0		0.0
Min, Max		0, 0		0, 0
Percent Change from Baseline to Cycle 24 Day 1				
n	0	2	0	2
Mean (StdDev)		-98.7 (0.06)		-98.7 (0.06)
Median		-98.7		-98.7
Min, Max		-99, -99		-99, -99
Percent Change from Baseline to Cycle 30 Day 1				
n	0	1	0	1
Mean (StdDev)		-98.8 (-)		-98.8 (-)
Median		-98.8		-98.8
Min, Max		-99, -99		-99, -99
Percent Change from Baseline to Cycle 36 Day 1				
n	0	1	0	1
Mean (StdDev)		-98.8 (-)		-98.8 (-)
Median		-98.8		-98.8
Min, Max		-99, -99		-99, -99

Notes: Bone marrow mast cells (%) by central pathology review are summarized.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-bmmc-pchg-advsm.sas
Date: 19:33/27SEP2021

Table 99.2.5.3.1b
Summary of Bone Marrow Mast Cells Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101 & 200 mg Dose Group

Prior antineoplastic therapy = Yes

Bone Marrow Mast Cells Best Response	ASM (N=1) n (%)	SM-AHN (N=7) n (%)	MCL (N=4) n (%)	All AdvSM (N=12) n (%)	ISM/SSM (N=1) n (%)	All Patients (N=13) n (%)
Patients with Neoplastic MC at Baseline	1	5	4	10	0	10
Patients achieved total clearance of neoplastic MC aggregates (CR)	1 (100.0)	4 (80.0)	1 (25.0)	6 (60.0)	0	6 (60.0)
Patients achieved >=50% reduction from baseline	1 (100.0)	4 (80.0)	3 (75.0)	8 (80.0)	0	8 (80.0)
Patients achieved >=50% reduction from baseline for at least two consecutive biopsies (PR)	0	2 (40.0)	1 (25.0)	3 (30.0)	0	3 (30.0)

Notes: Bone marrow mast cells (%) by central pathlogy review are summarized. Mast cells that are either interstitial or with multifocal dense infiltrates are added together to represent the quantity of neoplastic mast cells.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/EMA_D120/t99.2.5.3.1b-bmmc-resp-nat.sas Date: 10:41/04AUG2021

Table 99.2.5.3.1b
Summary of Bone Marrow Mast Cells Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101 & <=200 mg Dose Group

Prior antineoplastic therapy = Yes

Bone Marrow Mast Cells Best Response	ASM (N=2) n (%)	SM-AHN (N=9) n (%)	MCL (N=5) n (%)	All AdvSM (N=16) n (%)	ISM/SSM (N=4) n (%)	All Patients (N=20) n (%)
Patients with Neoplastic MC at Baseline	2	7	5	14	3	17
Patients achieved total clearance of neoplastic MC aggregates (CR)	1 (50.0)	6 (85.7)	2 (40.0)	9 (64.3)	3 (100.0)	12 (70.6)
Patients achieved >=50% reduction from baseline	1 (50.0)	6 (85.7)	4 (80.0)	11 (78.6)	3 (100.0)	14 (82.4)
Patients achieved >=50% reduction from baseline for at least two consecutive biopsies (PR)	0	4 (57.1)	2 (40.0)	6 (42.9)	3 (100.0)	9 (52.9)

Notes: Bone marrow mast cells (%) by central pathlogy review are summarized. Mast cells that are either interstitial or with multifocal dense infiltrates are added together to represent the quantity of neoplastic mast cells.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/EMA_D120/t99.2.5.3.1b-bmmc-resp-nat.sas Date: 10:41/04AUG2021

Table 99.2.5.3.1b
Summary of Bone Marrow Mast Cells Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101 & All Dose Groups

Prior antineoplastic therapy = Yes

Bone Marrow Mast Cells Best Response	ASM (N=7) n (%)	SM-AHN (N=26) n (%)	MCL (N=8) n (%)	All AdvSM (N=41) n (%)	ISM/SSM (N=9) n (%)	All Patients (N=50) n (%)
Patients with Neoplastic MC at Baseline	7	21	8	36	7	43
Patients achieved total clearance of neoplastic MC aggregates (CR)	5 (71.4)	19 (90.5)	4 (50.0)	28 (77.8)	6 (85.7)	34 (79.1)
Patients achieved >=50% reduction from baseline	6 (85.7)	20 (95.2)	6 (75.0)	32 (88.9)	7 (100.0)	39 (90.7)
Patients achieved >=50% reduction from baseline for at least two consecutive biopsies (PR)	5 (71.4)	17 (81.0)	3 (37.5)	25 (69.4)	6 (85.7)	31 (72.1)

Notes: Bone marrow mast cells (%) by central pathlogy review are summarized. Mast cells that are either interstitial or with multifocal dense infiltrates are added together to represent the quantity of neoplastic mast cells.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/EMA_D120/t99.2.5.3.1b-bmmc-resp-nat.sas Date: 10:41/04AUG2021

Table 99.2.5.3.1b
Summary of Bone Marrow Mast Cells Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101 & 200 mg Dose Group

Prior antineoplastic therapy = No

Bone Marrow Mast Cells Best Response	ASM (N=0) n (%)	SM-AHN (N=6) n (%)	MCL (N=2) n (%)	All AdvSM (N=8) n (%)	ISM/SSM (N=0) n (%)	All Patients (N=8) n (%)
Patients with Neoplastic MC at Baseline	0	6	2	8	0	8
Patients achieved total clearance of neoplastic MC aggregates (CR)	0	3 (50.0)	1 (50.0)	4 (50.0)	0	4 (50.0)
Patients achieved >=50% reduction from baseline	0	6 (100.0)	2 (100.0)	8 (100.0)	0	8 (100.0)
Patients achieved >=50% reduction from baseline for at least two consecutive biopsies (PR)	0	4 (66.7)	2 (100.0)	6 (75.0)	0	6 (75.0)

Notes: Bone marrow mast cells (%) by central pathlogy review are summarized. Mast cells that are either interstitial or with multifocal dense infiltrates are added together to represent the quantity of neoplastic mast cells.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/EMA_D120/t99.2.5.3.1b-bmmc-resp-nat.sas Date: 10:41/04AUG2021

Table 99.2.5.3.1b
Summary of Bone Marrow Mast Cells Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101 & <=200 mg Dose Group

Prior antineoplastic therapy = No

Bone Marrow Mast Cells Best Response	ASM (N=0) n (%)	SM-AHN (N=11) n (%)	MCL (N=2) n (%)	All AdvSM (N=13) n (%)	ISM/SSM (N=2) n (%)	All Patients (N=15) n (%)
Patients with Neoplastic MC at Baseline	0	11	2	13	2	15
Patients achieved total clearance of neoplastic MC aggregates (CR)	0	7 (63.6)	1 (50.0)	8 (61.5)	2 (100.0)	10 (66.7)
Patients achieved >=50% reduction from baseline	0	11 (100.0)	2 (100.0)	13 (100.0)	2 (100.0)	15 (100.0)
Patients achieved >=50% reduction from baseline for at least two consecutive biopsies (PR)	0	8 (72.7)	2 (100.0)	10 (76.9)	2 (100.0)	12 (80.0)

Notes: Bone marrow mast cells (%) by central pathlogy review are summarized. Mast cells that are either interstitial or with multifocal dense infiltrates are added together to represent the quantity of neoplastic mast cells.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/EMA_D120/t99.2.5.3.1b-bmmc-resp-nat.sas Date: 10:41/04AUG2021

Table 99.2.5.3.1b
Summary of Bone Marrow Mast Cells Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101 & All Dose Groups

Prior antineoplastic therapy = No

Bone Marrow Mast Cells Best Response	ASM (N=1) n (%)	SM-AHN (N=22) n (%)	MCL (N=5) n (%)	All AdvSM (N=28) n (%)	ISM/SSM (N=7) n (%)	All Patients (N=35) n (%)
Patients with Neoplastic MC at Baseline	1	22	5	28	7	35
Patients achieved total clearance of neoplastic MC aggregates (CR)	1 (100.0)	17 (77.3)	3 (60.0)	21 (75.0)	7 (100.0)	28 (80.0)
Patients achieved >=50% reduction from baseline	1 (100.0)	21 (95.5)	5 (100.0)	27 (96.4)	7 (100.0)	34 (97.1)
Patients achieved >=50% reduction from baseline for at least two consecutive biopsies (PR)	1 (100.0)	17 (77.3)	4 (80.0)	22 (78.6)	7 (100.0)	29 (82.9)

Notes: Bone marrow mast cells (%) by central pathlogy review are summarized. Mast cells that are either interstitial or with multifocal dense infiltrates are added together to represent the quantity of neoplastic mast cells.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/EMA_D120/t99.2.5.3.1b-bmmc-resp-nat.sas Date: 10:41/04AUG2021

Table 99.2.5.3.1b
Summary of Bone Marrow Mast Cells Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2202 & 200 mg Dose Group

Prior antineoplastic therapy = Yes				
Bone Marrow Mast Cells Best Response	ASM (N=4) n (%)	SM-AHN (N=27) n (%)	MCL (N=9) n (%)	All AdvSM (N=40) n (%)
Patients with Neoplastic MC at Baseline	4	27	9	40
Patients achieved total clearance of neoplastic MC aggregates (CR)	2 (50.0)	14 (51.9)	0	16 (40.0)
Patients achieved >=50% reduction from baseline	4 (100.0)	18 (66.7)	5 (55.6)	27 (67.5)
Patients achieved >=50% reduction from baseline for at least two consecutive biopsies (PR)	2 (50.0)	10 (37.0)	1 (11.1)	13 (32.5)

Notes: Bone marrow mast cells (%) by central pathlogy review are summarized. Mast cells that are either interstitial or with multifocal dense infiltrates are added together to represent the quantity of neoplastic mast cells.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/EMA_D120/t99.2.5.3.1b-bmmc-resp-nat.sas Date: 10:41/04AUG2021

Table 99.2.5.3.1b
Summary of Bone Marrow Mast Cells Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2202 & <=200 mg Dose Group

Prior antineoplastic therapy = Yes

Bone Marrow Mast Cells Best Response	ASM (N=5) n (%)	SM-AHN (N=28) n (%)	MCL (N=9) n (%)	All AdvSM (N=42) n (%)
Patients with Neoplastic MC at Baseline	5	28	9	42
Patients achieved total clearance of neoplastic MC aggregates (CR)	2 (40.0)	15 (53.6)	0	17 (40.5)
Patients achieved >=50% reduction from baseline	4 (80.0)	19 (67.9)	5 (55.6)	28 (66.7)
Patients achieved >=50% reduction from baseline for at least two consecutive biopsies (PR)	2 (40.0)	11 (39.3)	1 (11.1)	14 (33.3)

Notes: Bone marrow mast cells (%) by central pathlogy review are summarized. Mast cells that are either interstitial or with multifocal dense infiltrates are added together to represent the quantity of neoplastic mast cells.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/EMA_D120/t99.2.5.3.1b-bmmc-resp-nat.sas Date: 10:41/04AUG2021

Table 99.2.5.3.1b
Summary of Bone Marrow Mast Cells Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2202 & All Dose Groups

Prior antineoplastic therapy = Yes

Bone Marrow Mast Cells Best Response	ASM (N=5) n (%)	SM-AHN (N=28) n (%)	MCL (N=9) n (%)	All AdvSM (N=42) n (%)
Patients with Neoplastic MC at Baseline	5	28	9	42
Patients achieved total clearance of neoplastic MC aggregates (CR)	2 (40.0)	15 (53.6)	0	17 (40.5)
Patients achieved >=50% reduction from baseline	4 (80.0)	19 (67.9)	5 (55.6)	28 (66.7)
Patients achieved >=50% reduction from baseline for at least two consecutive biopsies (PR)	2 (40.0)	11 (39.3)	1 (11.1)	14 (33.3)

Notes: Bone marrow mast cells (%) by central pathlogy review are summarized. Mast cells that are either interstitial or with multifocal dense infiltrates are added together to represent the quantity of neoplastic mast cells.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/EMA_D120/t99.2.5.3.1b-bmmc-resp-nat.sas Date: 10:41/04AUG2021

Table 99.2.5.3.1b
Summary of Bone Marrow Mast Cells Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2202 & 200 mg Dose Group

Prior antineoplastic therapy = No				
Bone Marrow Mast Cells Best Response	ASM (N=4) n (%)	SM-AHN (N=15) n (%)	MCL (N=1) n (%)	All AdvSM (N=20) n (%)
Patients with Neoplastic MC at Baseline	4	15	1	20
Patients achieved total clearance of neoplastic MC aggregates (CR)	3 (75.0)	10 (66.7)	0	13 (65.0)
Patients achieved >=50% reduction from baseline	3 (75.0)	13 (86.7)	0	16 (80.0)
Patients achieved >=50% reduction from baseline for at least two consecutive biopsies (PR)	1 (25.0)	7 (46.7)	0	8 (40.0)

Notes: Bone marrow mast cells (%) by central pathlogy review are summarized. Mast cells that are either interstitial or with multifocal dense infiltrates are added together to represent the quantity of neoplastic mast cells.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/EMA_D120/t99.2.5.3.1b-bmmc-resp-nat.sas Date: 10:41/04AUG2021

Table 99.2.5.3.1b
Summary of Bone Marrow Mast Cells Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2202 & <=200 mg Dose Group

Prior antineoplastic therapy = No				
Bone Marrow Mast Cells Best Response	ASM (N=4) n (%)	SM-AHN (N=15) n (%)	MCL (N=1) n (%)	All AdvSM (N=20) n (%)
Patients with Neoplastic MC at Baseline	4	15	1	20
Patients achieved total clearance of neoplastic MC aggregates (CR)	3 (75.0)	10 (66.7)	0	13 (65.0)
Patients achieved >=50% reduction from baseline	3 (75.0)	13 (86.7)	0	16 (80.0)
Patients achieved >=50% reduction from baseline for at least two consecutive biopsies (PR)	1 (25.0)	7 (46.7)	0	8 (40.0)

Notes: Bone marrow mast cells (%) by central pathlogy review are summarized. Mast cells that are either interstitial or with multifocal dense infiltrates are added together to represent the quantity of neoplastic mast cells.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/EMA_D120/t99.2.5.3.1b-bmmc-resp-nat.sas Date: 10:41/04AUG2021

Table 99.2.5.3.1b
Summary of Bone Marrow Mast Cells Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2202 & All Dose Groups

Prior antineoplastic therapy = No

Bone Marrow Mast Cells Best Response	ASM (N=4) n (%)	SM-AHN (N=15) n (%)	MCL (N=1) n (%)	All AdvSM (N=20) n (%)
Patients with Neoplastic MC at Baseline	4	15	1	20
Patients achieved total clearance of neoplastic MC aggregates (CR)	3 (75.0)	10 (66.7)	0	13 (65.0)
Patients achieved >=50% reduction from baseline	3 (75.0)	13 (86.7)	0	16 (80.0)
Patients achieved >=50% reduction from baseline for at least two consecutive biopsies (PR)	1 (25.0)	7 (46.7)	0	8 (40.0)

Notes: Bone marrow mast cells (%) by central pathlogy review are summarized. Mast cells that are either interstitial or with multifocal dense infiltrates are added together to represent the quantity of neoplastic mast cells.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/EMA_D120/t99.2.5.3.1b-bmmc-resp-nat.sas Date: 10:41/04AUG2021

Table 99.2.5.3.1b
Summary of Bone Marrow Mast Cells Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101/2202 & 200 mg Dose Group

Prior antineoplastic therapy = Yes

Bone Marrow Mast Cells Best Response	ASM (N=5) n (%)	SM-AHN (N=34) n (%)	MCL (N=13) n (%)	All AdvSM (N=52) n (%)	ISM/SSM (N=1) n (%)	All Patients (N=53) n (%)
Patients with Neoplastic MC at Baseline	5	32	13	50	0	50
Patients achieved total clearance of neoplastic MC aggregates (CR)	3 (60.0)	18 (56.3)	1 (7.7)	22 (44.0)	0	22 (44.0)
Patients achieved >=50% reduction from baseline	5 (100.0)	22 (68.8)	8 (61.5)	35 (70.0)	0	35 (70.0)
Patients achieved >=50% reduction from baseline for at least two consecutive biopsies (PR)	2 (40.0)	12 (37.5)	2 (15.4)	16 (32.0)	0	16 (32.0)

Notes: Bone marrow mast cells (%) by central pathlogy review are summarized. Mast cells that are either interstitial or with multifocal dense infiltrates are added together to represent the quantity of neoplastic mast cells.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/EMA_D120/t99.2.5.3.1b-bmmc-resp-nat.sas Date: 10:41/04AUG2021

Table 99.2.5.3.1b
Summary of Bone Marrow Mast Cells Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101/2202 & <=200 mg Dose Group

Prior antineoplastic therapy = Yes

Bone Marrow Mast Cells Best Response	ASM (N=7) n (%)	SM-AHN (N=37) n (%)	MCL (N=14) n (%)	All AdvSM (N=58) n (%)	ISM/SSM (N=4) n (%)	All Patients (N=62) n (%)
Patients with Neoplastic MC at Baseline	7	35	14	56	3	59
Patients achieved total clearance of neoplastic MC aggregates (CR)	3 (42.9)	21 (60.0)	2 (14.3)	26 (46.4)	3 (100.0)	29 (49.2)
Patients achieved >=50% reduction from baseline	5 (71.4)	25 (71.4)	9 (64.3)	39 (69.6)	3 (100.0)	42 (71.2)
Patients achieved >=50% reduction from baseline for at least two consecutive biopsies (PR)	2 (28.6)	15 (42.9)	3 (21.4)	20 (35.7)	3 (100.0)	23 (39.0)

Notes: Bone marrow mast cells (%) by central pathlogy review are summarized. Mast cells that are either interstitial or with multifocal dense infiltrates are added together to represent the quantity of neoplastic mast cells.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/EMA_D120/t99.2.5.3.1b-bmmc-resp-nat.sas Date: 10:41/04AUG2021

Table 99.2.5.3.1b
Summary of Bone Marrow Mast Cells Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101/2202 & All Dose Groups

Prior antineoplastic therapy = Yes

Bone Marrow Mast Cells Best Response	ASM (N=12) n (%)	SM-AHN (N=54) n (%)	MCL (N=17) n (%)	All AdvSM (N=83) n (%)	ISM/SSM (N=9) n (%)	All Patients (N=92) n (%)
Patients with Neoplastic MC at Baseline	12	49	17	78	7	85
Patients achieved total clearance of neoplastic MC aggregates (CR)	7 (58.3)	34 (69.4)	4 (23.5)	45 (57.7)	6 (85.7)	51 (60.0)
Patients achieved >=50% reduction from baseline	10 (83.3)	39 (79.6)	11 (64.7)	60 (76.9)	7 (100.0)	67 (78.8)
Patients achieved >=50% reduction from baseline for at least two consecutive biopsies (PR)	7 (58.3)	28 (57.1)	4 (23.5)	39 (50.0)	6 (85.7)	45 (52.9)

Notes: Bone marrow mast cells (%) by central pathlogy review are summarized. Mast cells that are either interstitial or with multifocal dense infiltrates are added together to represent the quantity of neoplastic mast cells.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/EMA_D120/t99.2.5.3.1b-bmmc-resp-nat.sas Date: 10:41/04AUG2021

Table 99.2.5.3.1b
Summary of Bone Marrow Mast Cells Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101/2202 & 200 mg Dose Group

Prior antineoplastic therapy = No

Bone Marrow Mast Cells Best Response	ASM (N=4) n (%)	SM-AHN (N=21) n (%)	MCL (N=3) n (%)	All AdvSM (N=28) n (%)	ISM/SSM (N=0) n (%)	All Patients (N=28) n (%)
Patients with Neoplastic MC at Baseline	4	21	3	28	0	28
Patients achieved total clearance of neoplastic MC aggregates (CR)	3 (75.0)	13 (61.9)	1 (33.3)	17 (60.7)	0	17 (60.7)
Patients achieved >=50% reduction from baseline	3 (75.0)	19 (90.5)	2 (66.7)	24 (85.7)	0	24 (85.7)
Patients achieved >=50% reduction from baseline for at least two consecutive biopsies (PR)	1 (25.0)	11 (52.4)	2 (66.7)	14 (50.0)	0	14 (50.0)

Notes: Bone marrow mast cells (%) by central pathlogy review are summarized. Mast cells that are either interstitial or with multifocal dense infiltrates are added together to represent the quantity of neoplastic mast cells.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/EMA_D120/t99.2.5.3.1b-bmmc-resp-nat.sas Date: 10:41/04AUG2021

Table 99.2.5.3.1b
Summary of Bone Marrow Mast Cells Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101/2202 & <=200 mg Dose Group

Prior antineoplastic therapy = No						
Bone Marrow Mast Cells Best Response	ASM (N=4) n (%)	SM-AHN (N=26) n (%)	MCL (N=3) n (%)	All AdvSM (N=33) n (%)	ISM/SSM (N=2) n (%)	All Patients (N=35) n (%)
Patients with Neoplastic MC at Baseline	4	26	3	33	2	35
Patients achieved total clearance of neoplastic MC aggregates (CR)	3 (75.0)	17 (65.4)	1 (33.3)	21 (63.6)	2 (100.0)	23 (65.7)
Patients achieved >=50% reduction from baseline	3 (75.0)	24 (92.3)	2 (66.7)	29 (87.9)	2 (100.0)	31 (88.6)
Patients achieved >=50% reduction from baseline for at least two consecutive biopsies (PR)	1 (25.0)	15 (57.7)	2 (66.7)	18 (54.5)	2 (100.0)	20 (57.1)

Notes: Bone marrow mast cells (%) by central pathlogy review are summarized. Mast cells that are either interstitial or with multifocal dense infiltrates are added together to represent the quantity of neoplastic mast cells.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/EMA_D120/t99.2.5.3.1b-bmmc-resp-nat.sas Date: 10:41/04AUG2021

Table 99.2.5.3.1b
Summary of Bone Marrow Mast Cells Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101/2202 & All Dose Groups

Prior antineoplastic therapy = No						
Bone Marrow Mast Cells Best Response	ASM (N=5) n (%)	SM-AHN (N=37) n (%)	MCL (N=6) n (%)	All AdvSM (N=48) n (%)	ISM/SSM (N=7) n (%)	All Patients (N=55) n (%)
Patients with Neoplastic MC at Baseline	5	37	6	48	7	55
Patients achieved total clearance of neoplastic MC aggregates (CR)	4 (80.0)	27 (73.0)	3 (50.0)	34 (70.8)	7 (100.0)	41 (74.5)
Patients achieved >=50% reduction from baseline	4 (80.0)	34 (91.9)	5 (83.3)	43 (89.6)	7 (100.0)	50 (90.9)
Patients achieved >=50% reduction from baseline for at least two consecutive biopsies (PR)	2 (40.0)	24 (64.9)	4 (66.7)	30 (62.5)	7 (100.0)	37 (67.3)

Notes: Bone marrow mast cells (%) by central pathlogy review are summarized. Mast cells that are either interstitial or with multifocal dense infiltrates are added together to represent the quantity of neoplastic mast cells.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/EMA_D120/t99.2.5.3.1b-bmmc-resp-nat.sas Date: 10:41/04AUG2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Overall

Serum Tryptase (ug/L)	ASM (N=7)	SM-AHN (N=26)	MCL (N=8)	All AdvSM (N=41)
Baseline				
n	7	26	8	41
Mean (StdDev)	398.34 (478.584)	228.82 (186.751)	451.69 (242.478)	301.25 (275.734)
Median	270.50	149.95	415.85	214.90
Min, Max	19.9, 1414.3	21.2, 631.3	214.9, 760.1	19.9, 1414.3
Cycle 1 Day 15				
n	6	26	8	40
Mean (StdDev)	153.50 (229.620)	72.10 (79.959)	128.23 (49.746)	95.53 (111.376)
Median	62.10	46.85	129.25	71.65
Min, Max	6.3, 603.7	5.0, 392.5	60.9, 196.5	5.0, 603.7
Cycle 2 Day 1				
n	7	25	8	40
Mean (StdDev)	101.57 (151.462)	53.04 (64.580)	112.34 (50.873)	73.40 (85.319)
Median	42.60	37.10	114.10	51.15
Min, Max	5.2, 423.0	2.7, 261.3	44.5, 171.4	2.7, 423.0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Overall

Serum Tryptase (ug/L)	ASM (N=7)	SM-AHN (N=26)	MCL (N=8)	All AdvSM (N=41)
Cycle 3 Day 1				
n	6	23	8	37
Mean (StdDev)	88.57 (144.906)	50.87 (55.258)	91.99 (51.754)	65.87 (75.395)
Median	24.00	27.90	85.90	36.70
Min, Max	4.7, 375.3	2.8, 198.2	24.5, 150.8	2.8, 375.3
Cycle 5 Day 1				
n	6	22	8	36
Mean (StdDev)	56.80 (84.464)	69.43 (158.009)	71.50 (38.055)	67.79 (127.728)
Median	22.45	19.95	82.10	25.20
Min, Max	3.7, 223.7	1.5, 744.3	17.0, 124.3	1.5, 744.3
Cycle 7 Day 1				
n	5	17	7	29
Mean (StdDev)	64.32 (103.761)	87.48 (188.696)	160.77 (240.343)	101.18 (188.433)
Median	20.40	21.50	89.40	42.70
Min, Max	4.6, 247.9	7.1, 789.3	12.7, 698.3	4.6, 789.3
Cycle 11 Day 1				
n	4	13	5	22
Mean (StdDev)	85.05 (122.333)	42.02 (50.413)	81.94 (109.424)	58.92 (79.397)
Median	34.40	25.60	33.80	27.75
Min, Max	4.7, 266.7	3.0, 163.1	6.8, 272.4	3.0, 272.4

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Overall

Serum Tryptase (ug/L)	ASM (N=7)	SM-AHN (N=26)	MCL (N=8)	All AdvSM (N=41)
Cycle 18 Day 1				
n	3	8	3	14
Mean (StdDev)	57.90 (62.658)	18.23 (15.426)	20.70 (15.570)	27.26 (32.346)
Median	24.10	12.20	19.80	19.60
Min, Max	19.4, 130.2	3.4, 46.4	5.6, 36.7	3.4, 130.2
Cycle 24 Day 1				
n	3	8	2	13
Mean (StdDev)	106.93 (148.748)	20.53 (20.715)	22.45 (23.688)	40.76 (73.541)
Median	26.00	15.50	22.45	24.00
Min, Max	16.2, 278.6	2.5, 61.4	5.7, 39.2	2.5, 278.6
Cycle 30 Day 1				
n	2	4	2	8
Mean (StdDev)	141.95 (162.422)	6.53 (7.389)	15.05 (15.344)	42.51 (87.215)
Median	141.95	3.35	15.05	10.90
Min, Max	27.1, 256.8	1.9, 17.5	4.2, 25.9	1.9, 256.8
Cycle 36 Day 1				
n	2	4	0	6
Mean (StdDev)	95.55 (107.975)	4.40 (3.349)		34.78 (67.483)
Median	95.55	3.20		6.50
Min, Max	19.2, 171.9	1.9, 9.3		1.9, 171.9

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas
Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Overall

Serum Tryptase (ug/L)	ASM (N=7)	SM-AHN (N=26)	MCL (N=8)	All AdvSM (N=41)
Cycle 42 Day 1				
n	1	3	1	5
Mean (StdDev)	173.00 (-)	7.13 (4.743)	6.70 (-)	40.22 (74.302)
Median	173.00	6.40	6.70	6.70
Min, Max	173.0, 173.0	2.8, 12.2	6.7, 6.7	2.8, 173.0
Cycle 48 Day 1				
n	1	0	1	2
Mean (StdDev)	141.70 (-)		6.80 (-)	74.25 (95.389)
Median	141.70		6.80	74.25
Min, Max	141.7, 141.7		6.8, 6.8	6.8, 141.7

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <200 mg

Serum Tryptase (ug/L)	ASM (N=1)	SM-AHN (N=2)	MCL (N=1)	All AdvSM (N=4)
Baseline				
n	1	2	1	4
Mean (StdDev)	1414.30 (-)	54.25 (2.333)	226.60 (-)	437.35 (656.349)
Median	1414.30	54.25	226.60	141.25
Min, Max	1414.3, 1414.3	52.6, 55.9	226.6, 226.6	52.6, 1414.3
Cycle 1 Day 15				
n	1	2	1	4
Mean (StdDev)	603.70 (-)	40.40 (25.173)	133.40 (-)	204.48 (270.128)
Median	603.70	40.40	133.40	95.80
Min, Max	603.7, 603.7	22.6, 58.2	133.4, 133.4	22.6, 603.7
Cycle 2 Day 1				
n	1	2	1	4
Mean (StdDev)	423.00 (-)	31.50 (34.790)	85.80 (-)	142.95 (189.514)
Median	423.00	31.50	85.80	70.95
Min, Max	423.0, 423.0	6.9, 56.1	85.8, 85.8	6.9, 423.0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <200 mg

Serum Tryptase (ug/L)	ASM (N=1)	SM-AHN (N=2)	MCL (N=1)	All AdvSM (N=4)
Cycle 3 Day 1				
n	1	2	1	4
Mean (StdDev)	375.30 (-)	36.75 (44.477)	62.70 (-)	127.88 (167.384)
Median	375.30	36.75	62.70	65.45
Min, Max	375.3, 375.3	5.3, 68.2	62.7, 62.7	5.3, 375.3
Cycle 5 Day 1				
n	1	2	1	4
Mean (StdDev)	223.70 (-)	38.65 (45.326)	88.70 (-)	97.43 (91.260)
Median	223.70	38.65	88.70	79.70
Min, Max	223.7, 223.7	6.6, 70.7	88.7, 88.7	6.6, 223.7
Cycle 7 Day 1				
n	1	2	1	4
Mean (StdDev)	247.90 (-)	34.40 (31.396)	99.70 (-)	104.10 (102.306)
Median	247.90	34.40	99.70	78.15
Min, Max	247.9, 247.9	12.2, 56.6	99.7, 99.7	12.2, 247.9
Cycle 11 Day 1				
n	1	2	1	4
Mean (StdDev)	266.70 (-)	19.15 (9.122)	74.80 (-)	94.95 (117.585)
Median	266.70	19.15	74.80	50.20
Min, Max	266.7, 266.7	12.7, 25.6	74.8, 74.8	12.7, 266.7

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <200 mg

Serum Tryptase (ug/L)	ASM (N=1)	SM-AHN (N=2)	MCL (N=1)	All AdvSM (N=4)
Cycle 18 Day 1				
n	1	2	1	4
Mean (StdDev)	130.20 (-)	5.85 (3.465)	36.70 (-)	44.65 (58.892)
Median	130.20	5.85	36.70	22.50
Min, Max	130.2, 130.2	3.4, 8.3	36.7, 36.7	3.4, 130.2
Cycle 24 Day 1				
n	1	2	1	4
Mean (StdDev)	278.60 (-)	4.75 (3.182)	39.20 (-)	81.83 (132.197)
Median	278.60	4.75	39.20	23.10
Min, Max	278.6, 278.6	2.5, 7.0	39.2, 39.2	2.5, 278.6
Cycle 30 Day 1				
n	1	2	1	4
Mean (StdDev)	256.80 (-)	3.10 (1.697)	25.90 (-)	72.23 (123.522)
Median	256.80	3.10	25.90	15.10
Min, Max	256.8, 256.8	1.9, 4.3	25.9, 25.9	1.9, 256.8
Cycle 36 Day 1				
n	1	2	0	3
Mean (StdDev)	171.90 (-)	3.20 (0.707)		59.43 (97.400)
Median	171.90	3.20		3.70
Min, Max	171.9, 171.9	2.7, 3.7		2.7, 171.9

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <200 mg				
Serum Tryptase (ug/L)	ASM (N=1)	SM-AHN (N=2)	MCL (N=1)	All AdvSM (N=4)
Cycle 42 Day 1				
n	1	2	1	4
Mean (StdDev)	173.00 (-)	4.60 (2.546)	6.70 (-)	47.23 (83.869)
Median	173.00	4.60	6.70	6.55
Min, Max	173.0, 173.0	2.8, 6.4	6.7, 6.7	2.8, 173.0
Cycle 48 Day 1				
n	1	0	1	2
Mean (StdDev)	141.70 (-)		6.80 (-)	74.25 (95.389)
Median	141.70		6.80	74.25
Min, Max	141.7, 141.7		6.8, 6.8	6.8, 141.7

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <300 mg

Serum Tryptase (ug/L)	ASM (N=2)	SM-AHN (N=9)	MCL (N=5)	All AdvSM (N=16)
Baseline				
n	2	9	5	16
Mean (StdDev)	717.10 (985.990)	190.03 (209.418)	482.28 (226.530)	347.24 (375.543)
Median	717.10	100.90	575.90	182.00
Min, Max	19.9, 1414.3	40.7, 583.0	226.6, 723.2	19.9, 1414.3
Cycle 1 Day 15				
n	2	9	5	16
Mean (StdDev)	305.00 (422.426)	79.21 (120.762)	157.94 (35.388)	132.04 (160.919)
Median	305.00	30.80	138.50	80.35
Min, Max	6.3, 603.7	8.9, 392.5	125.1, 196.5	6.3, 603.7
Cycle 2 Day 1				
n	2	9	5	16
Mean (StdDev)	214.10 (295.429)	57.34 (81.159)	136.42 (39.216)	101.65 (114.054)
Median	214.10	39.20	156.90	67.45
Min, Max	5.2, 423.0	5.0, 261.3	85.8, 171.4	5.0, 423.0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <300 mg

Serum Tryptase (ug/L)	ASM (N=2)	SM-AHN (N=9)	MCL (N=5)	All AdvSM (N=16)
Cycle 3 Day 1				
n	2	8	5	15
Mean (StdDev)	190.40 (261.488)	75.86 (70.448)	118.10 (42.191)	105.21 (97.275)
Median	190.40	52.45	146.30	82.40
Min, Max	5.5, 375.3	4.1, 198.2	62.7, 150.8	4.1, 375.3
Cycle 5 Day 1				
n	2	6	5	13
Mean (StdDev)	114.80 (154.008)	175.92 (290.219)	81.72 (36.101)	130.28 (198.920)
Median	114.80	41.90	88.70	75.50
Min, Max	5.9, 223.7	2.6, 744.3	25.6, 124.3	2.6, 744.3
Cycle 7 Day 1				
n	1	7	5	13
Mean (StdDev)	247.90 (-)	176.03 (280.999)	82.88 (36.714)	145.73 (207.318)
Median	247.90	56.60	89.40	89.40
Min, Max	247.9, 247.9	7.5, 789.3	42.9, 132.0	7.5, 789.3
Cycle 11 Day 1				
n	1	5	3	9
Mean (StdDev)	266.70 (-)	68.56 (75.472)	43.50 (27.752)	82.22 (89.294)
Median	266.70	25.60	33.80	33.80
Min, Max	266.7, 266.7	4.1, 163.1	21.9, 74.8	4.1, 266.7

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <300 mg

Serum Tryptase (ug/L)	ASM (N=2)	SM-AHN (N=9)	MCL (N=5)	All AdvSM (N=16)
Cycle 18 Day 1				
n	1	2	2	5
Mean (StdDev)	130.20 (-)	5.85 (3.465)	28.25 (11.950)	39.68 (52.199)
Median	130.20	5.85	28.25	19.80
Min, Max	130.2, 130.2	3.4, 8.3	19.8, 36.7	3.4, 130.2
Cycle 24 Day 1				
n	1	3	1	5
Mean (StdDev)	278.60 (-)	14.37 (16.808)	39.20 (-)	72.18 (116.500)
Median	278.60	7.00	39.20	33.60
Min, Max	278.6, 278.6	2.5, 33.6	39.2, 39.2	2.5, 278.6
Cycle 30 Day 1				
n	1	3	1	5
Mean (StdDev)	256.80 (-)	7.90 (8.400)	25.90 (-)	61.28 (109.737)
Median	256.80	4.30	25.90	17.50
Min, Max	256.8, 256.8	1.9, 17.5	25.9, 25.9	1.9, 256.8
Cycle 36 Day 1				
n	1	3	0	4
Mean (StdDev)	171.90 (-)	5.23 (3.557)		46.90 (83.384)
Median	171.90	3.70		6.50
Min, Max	171.9, 171.9	2.7, 9.3		2.7, 171.9

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <300 mg				
Serum Tryptase (ug/L)	ASM (N=2)	SM-AHN (N=9)	MCL (N=5)	All AdvSM (N=16)
Cycle 42 Day 1				
n	1	3	1	5
Mean (StdDev)	173.00 (-)	7.13 (4.743)	6.70 (-)	40.22 (74.302)
Median	173.00	6.40	6.70	6.70
Min, Max	173.0, 173.0	2.8, 12.2	6.7, 6.7	2.8, 173.0
Cycle 48 Day 1				
n	1	0	1	2
Mean (StdDev)	141.70 (-)		6.80 (-)	74.25 (95.389)
Median	141.70		6.80	74.25
Min, Max	141.7, 141.7		6.8, 6.8	6.8, 141.7

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg				
Serum Tryptase (ug/L)	ASM (N=1)	SM-AHN (N=7)	MCL (N=4)	All AdvSM (N=12)
Baseline				
n	1	7	4	12
Mean (StdDev)	19.90 (-)	228.83 (224.882)	546.20 (202.936)	317.21 (266.253)
Median	19.90	134.50	602.90	196.60
Min, Max	19.9, 19.9	40.7, 583.0	255.8, 723.2	19.9, 723.2
Cycle 1 Day 15				
n	1	7	4	12
Mean (StdDev)	6.30 (-)	90.30 (136.723)	164.08 (37.668)	107.89 (113.430)
Median	6.30	30.80	167.35	80.35
Min, Max	6.3, 6.3	8.9, 392.5	125.1, 196.5	6.3, 392.5
Cycle 2 Day 1				
n	1	7	4	12
Mean (StdDev)	5.20 (-)	64.73 (91.074)	149.08 (31.351)	87.88 (84.360)
Median	5.20	39.20	161.00	67.45
Min, Max	5.2, 5.2	5.0, 261.3	102.9, 171.4	5.0, 261.3

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg				
Serum Tryptase (ug/L)	ASM (N=1)	SM-AHN (N=7)	MCL (N=4)	All AdvSM (N=12)
Cycle 3 Day 1				
n	1	6	4	11
Mean (StdDev)	5.50 (-)	88.90 (75.741)	131.95 (33.085)	96.97 (67.542)
Median	5.50	81.55	147.30	126.40
Min, Max	5.5, 5.5	4.1, 198.2	82.4, 150.8	4.1, 198.2
Cycle 5 Day 1				
n	1	4	4	9
Mean (StdDev)	5.90 (-)	244.55 (347.636)	79.98 (41.442)	144.89 (235.480)
Median	5.90	115.65	85.00	75.50
Min, Max	5.9, 5.9	2.6, 744.3	25.6, 124.3	2.6, 744.3
Cycle 7 Day 1				
n	0	5	4	9
Mean (StdDev)		232.68 (322.728)	78.68 (40.979)	164.23 (243.505)
Median		177.70	69.90	89.40
Min, Max		7.5, 789.3	42.9, 132.0	7.5, 789.3
Cycle 11 Day 1				
n	0	3	2	5
Mean (StdDev)		101.50 (85.332)	27.85 (8.415)	72.04 (72.703)
Median		137.30	27.85	33.80
Min, Max		4.1, 163.1	21.9, 33.8	4.1, 163.1

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg				
Serum Tryptase (ug/L)	ASM (N=1)	SM-AHN (N=7)	MCL (N=4)	All AdvSM (N=12)
Cycle 18 Day 1				
n	0	0	1	1
Mean (StdDev)			19.80 (-)	19.80 (-)
Median			19.80	19.80
Min, Max			19.8, 19.8	19.8, 19.8
Cycle 24 Day 1				
n	0	1	0	1
Mean (StdDev)		33.60 (-)		33.60 (-)
Median		33.60		33.60
Min, Max		33.6, 33.6		33.6, 33.6
Cycle 30 Day 1				
n	0	1	0	1
Mean (StdDev)		17.50 (-)		17.50 (-)
Median		17.50		17.50
Min, Max		17.5, 17.5		17.5, 17.5
Cycle 36 Day 1				
n	0	1	0	1
Mean (StdDev)		9.30 (-)		9.30 (-)
Median		9.30		9.30
Min, Max		9.3, 9.3		9.3, 9.3

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg				
Serum Tryptase (ug/L)	ASM (N=1)	SM-AHN (N=7)	MCL (N=4)	All AdvSM (N=12)
Cycle 42 Day 1				
n	0	1	0	1
Mean (StdDev)		12.20 (-)		12.20 (-)
Median		12.20		12.20
Min, Max		12.2, 12.2		12.2, 12.2

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 300 mg				
Serum Tryptase (ug/L)	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Baseline				
n	4	13	3	20
Mean (StdDev)	330.75 (123.554)	286.91 (184.332)	400.70 (311.309)	312.75 (189.257)
Median	313.80	367.40	227.10	313.80
Min, Max	204.7, 490.7	21.2, 631.3	214.9, 760.1	21.2, 760.1
Cycle 1 Day 15				
n	3	13	3	19
Mean (StdDev)	100.20 (71.686)	83.07 (49.982)	78.70 (16.435)	85.08 (48.107)
Median	90.10	94.60	81.90	90.10
Min, Max	34.1, 176.4	12.1, 149.6	60.9, 93.3	12.1, 176.4
Cycle 2 Day 1				
n	4	13	3	20
Mean (StdDev)	69.23 (62.457)	59.70 (58.661)	72.20 (46.000)	63.48 (55.143)
Median	50.80	55.50	46.80	51.15
Min, Max	16.2, 159.1	4.6, 223.9	44.5, 125.3	4.6, 223.9

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 300 mg				
Serum Tryptase (ug/L)	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Cycle 3 Day 1				
n	3	13	3	19
Mean (StdDev)	48.63 (45.031)	41.93 (43.660)	48.47 (35.622)	44.02 (40.584)
Median	38.40	26.60	31.50	27.90
Min, Max	9.6, 97.9	2.8, 156.6	24.5, 89.4	2.8, 156.6
Cycle 5 Day 1				
n	3	13	3	19
Mean (StdDev)	35.83 (23.299)	30.98 (25.929)	54.47 (42.020)	35.45 (27.919)
Median	24.80	20.80	46.50	21.50
Min, Max	20.1, 62.6	6.4, 71.0	17.0, 99.9	6.4, 99.9
Cycle 7 Day 1				
n	3	8	2	13
Mean (StdDev)	23.03 (18.491)	27.05 (18.915)	355.50 (484.792)	76.65 (187.535)
Median	20.40	19.20	355.50	20.40
Min, Max	6.0, 42.7	7.1, 53.7	12.7, 698.3	6.0, 698.3
Cycle 11 Day 1				
n	3	7	2	12
Mean (StdDev)	24.50 (21.220)	22.33 (15.550)	139.60 (187.808)	42.42 (74.039)
Median	21.90	20.50	139.60	21.20
Min, Max	4.7, 46.9	3.0, 44.2	6.8, 272.4	3.0, 272.4

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 300 mg

Serum Tryptase (ug/L)	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Cycle 18 Day 1				
n	2	6	1	9
Mean (StdDev)	21.75 (3.323)	22.35 (15.783)	5.60 (-)	20.36 (13.702)
Median	21.75	21.65	5.60	19.40
Min, Max	19.4, 24.1	4.0, 46.4	5.6, 5.6	4.0, 46.4
Cycle 24 Day 1				
n	2	4	1	7
Mean (StdDev)	21.10 (6.930)	29.25 (24.157)	5.70 (-)	23.56 (19.405)
Median	21.10	26.30	5.70	24.00
Min, Max	16.2, 26.0	3.0, 61.4	5.7, 5.7	3.0, 61.4
Cycle 30 Day 1				
n	1	0	1	2
Mean (StdDev)	27.10 (-)		4.20 (-)	15.65 (16.193)
Median	27.10		4.20	15.65
Min, Max	27.1, 27.1		4.2, 4.2	4.2, 27.1
Cycle 36 Day 1				
n	1	0	0	1
Mean (StdDev)	19.20 (-)			19.20 (-)
Median	19.20			19.20
Min, Max	19.2, 19.2			19.2, 19.2

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg				
Serum Tryptase (ug/L)	ASM (N=5)	SM-AHN (N=20)	MCL (N=7)	All AdvSM (N=32)
Baseline				
n	5	20	7	32
Mean (StdDev)	268.58 (175.427)	266.58 (195.545)	483.84 (242.785)	314.42 (217.055)
Median	270.50	158.00	575.90	263.15
Min, Max	19.9, 490.7	21.2, 631.3	214.9, 760.1	19.9, 760.1
Cycle 1 Day 15				
n	4	20	7	31
Mean (StdDev)	76.73 (75.035)	85.60 (86.565)	127.49 (53.684)	93.91 (78.954)
Median	62.10	71.65	125.10	90.10
Min, Max	6.3, 176.4	8.9, 392.5	60.9, 196.5	6.3, 392.5
Cycle 2 Day 1				
n	5	20	7	32
Mean (StdDev)	56.42 (61.200)	61.46 (69.272)	116.13 (53.715)	72.63 (67.327)
Median	42.60	47.35	125.30	57.25
Min, Max	5.2, 159.1	4.6, 261.3	44.5, 171.4	4.6, 261.3

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg

Serum Tryptase (ug/L)	ASM (N=5)	SM-AHN (N=20)	MCL (N=7)	All AdvSM (N=32)
Cycle 3 Day 1				
n	4	19	7	30
Mean (StdDev)	37.85 (42.626)	56.76 (58.030)	96.17 (54.420)	63.44 (57.175)
Median	24.00	32.20	89.40	37.55
Min, Max	5.5, 97.9	2.8, 198.2	24.5, 150.8	2.8, 198.2
Cycle 5 Day 1				
n	4	17	7	28
Mean (StdDev)	28.35 (24.206)	81.23 (178.561)	69.04 (40.413)	70.63 (140.209)
Median	22.45	20.80	75.50	25.20
Min, Max	5.9, 62.6	2.6, 744.3	17.0, 124.3	2.6, 744.3
Cycle 7 Day 1				
n	3	13	6	22
Mean (StdDev)	23.03 (18.491)	106.14 (213.936)	170.95 (261.625)	112.48 (211.253)
Median	20.40	21.50	69.90	42.80
Min, Max	6.0, 42.7	7.1, 789.3	12.7, 698.3	6.0, 789.3
Cycle 11 Day 1				
n	3	10	4	17
Mean (StdDev)	24.50 (21.220)	46.08 (56.937)	83.73 (126.268)	51.13 (72.689)
Median	21.90	25.20	27.85	21.90
Min, Max	4.7, 46.9	3.0, 163.1	6.8, 272.4	3.0, 272.4

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg				
Serum Tryptase (ug/L)	ASM (N=5)	SM-AHN (N=20)	MCL (N=7)	All AdvSM (N=32)
Cycle 18 Day 1				
n	2	6	2	10
Mean (StdDev)	21.75 (3.323)	22.35 (15.783)	12.70 (10.041)	20.30 (12.920)
Median	21.75	21.65	12.70	19.60
Min, Max	19.4, 24.1	4.0, 46.4	5.6, 19.8	4.0, 46.4
Cycle 24 Day 1				
n	2	5	1	8
Mean (StdDev)	21.10 (6.930)	30.12 (21.011)	5.70 (-)	24.81 (18.313)
Median	21.10	28.60	5.70	25.00
Min, Max	16.2, 26.0	3.0, 61.4	5.7, 5.7	3.0, 61.4
Cycle 30 Day 1				
n	1	1	1	3
Mean (StdDev)	27.10 (-)	17.50 (-)	4.20 (-)	16.27 (11.500)
Median	27.10	17.50	4.20	17.50
Min, Max	27.1, 27.1	17.5, 17.5	4.2, 4.2	4.2, 27.1
Cycle 36 Day 1				
n	1	1	0	2
Mean (StdDev)	19.20 (-)	9.30 (-)		14.25 (7.000)
Median	19.20	9.30		14.25
Min, Max	19.2, 19.2	9.3, 9.3		9.3, 19.2

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg

Serum Tryptase (ug/L)	ASM (N=5)	SM-AHN (N=20)	MCL (N=7)	All AdvSM (N=32)
Cycle 42 Day 1				
n	0	1	0	1
Mean (StdDev)		12.20 (-)		12.20 (-)
Median		12.20		12.20
Min, Max		12.2, 12.2		12.2, 12.2

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 400 mg				
Serum Tryptase (ug/L)	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Baseline				
n	1	4	0	5
Mean (StdDev)	31.20 (-)	127.30 (69.954)		108.08 (74.278)
Median	31.20	151.00		130.00
Min, Max	31.2, 31.2	27.6, 179.6		27.6, 179.6
Cycle 1 Day 15				
n	1	4	0	5
Mean (StdDev)	10.40 (-)	20.43 (12.777)		18.42 (11.939)
Median	10.40	20.60		17.10
Min, Max	10.4, 10.4	5.0, 35.5		5.0, 35.5
Cycle 2 Day 1				
n	1	3	0	4
Mean (StdDev)	5.90 (-)	11.30 (8.229)		9.95 (7.241)
Median	5.90	12.10		9.00
Min, Max	5.9, 5.9	2.7, 19.1		2.7, 19.1

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 400 mg				
Serum Tryptase (ug/L)	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Cycle 3 Day 1				
n	1	2	0	3
Mean (StdDev)	4.70 (-)	8.95 (3.323)		7.53 (3.398)
Median	4.70	8.95		6.60
Min, Max	4.7, 4.7	6.6, 11.3		4.7, 11.3
Cycle 5 Day 1				
n	1	3	0	4
Mean (StdDev)	3.70 (-)	23.10 (26.521)		18.25 (23.728)
Median	3.70	15.10		9.40
Min, Max	3.7, 3.7	1.5, 52.7		1.5, 52.7
Cycle 7 Day 1				
n	1	2	0	3
Mean (StdDev)	4.60 (-)	19.25 (4.172)		14.37 (8.958)
Median	4.60	19.25		16.30
Min, Max	4.6, 4.6	16.3, 22.2		4.6, 22.2
Cycle 11 Day 1				
n	0	1	0	1
Mean (StdDev)		47.20 (-)		47.20 (-)
Median		47.20		47.20
Min, Max		47.2, 47.2		47.2, 47.2

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 400 mg

Serum Tryptase (ug/L)	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Cycle 24 Day 1				
n	0	1	0	1
Mean (StdDev)		4.10 (-)		4.10 (-)
Median		4.10		4.10
Min, Max		4.1, 4.1		4.1, 4.1
Cycle 30 Day 1				
n	0	1	0	1
Mean (StdDev)		2.40 (-)		2.40 (-)
Median		2.40		2.40
Min, Max		2.4, 2.4		2.4, 2.4
Cycle 36 Day 1				
n	0	1	0	1
Mean (StdDev)		1.90 (-)		1.90 (-)
Median		1.90		1.90
Min, Max		1.9, 1.9		1.9, 1.9

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2202

Overall

Serum Tryptase (ug/L)	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Baseline				
n	5	28	9	42
Mean (StdDev)	217.40 (192.597)	402.51 (333.010)	468.38 (460.358)	394.59 (350.808)
Median	145.00	314.00	325.20	314.00
Min, Max	23.8, 492.0	47.7, 1600.0	31.0, 1600.0	23.8, 1600.0
Cycle 1 Day 15				
n	5	24	8	37
Mean (StdDev)	58.54 (78.740)	166.45 (175.001)	292.23 (500.076)	179.06 (271.754)
Median	31.50	95.10	99.00	87.20
Min, Max	5.4, 197.0	9.2, 608.0	10.0, 1496.0	5.4, 1496.0
Cycle 2 Day 1				
n	3	23	9	35
Mean (StdDev)	29.73 (30.433)	132.13 (162.545)	251.22 (463.984)	153.98 (268.315)
Median	23.50	43.30	75.50	62.80
Min, Max	2.9, 62.8	2.8, 572.0	8.8, 1464.0	2.8, 1464.0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2202

Overall

Serum Tryptase (ug/L)	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Cycle 3 Day 1				
n	4	20	7	31
Mean (StdDev)	34.00 (34.095)	147.19 (196.626)	321.84 (534.121)	172.02 (299.746)
Median	29.05	64.10	78.10	63.50
Min, Max	2.0, 75.9	4.1, 660.0	28.7, 1504.0	2.0, 1504.0
Cycle 7 Day 1				
n	1	15	2	18
Mean (StdDev)	64.10 (-)	112.83 (208.768)	111.50 (122.329)	109.98 (192.105)
Median	64.10	31.90	111.50	34.30
Min, Max	64.1, 64.1	3.8, 760.0	25.0, 198.0	3.8, 760.0
Cycle 11 Day 1				
n	0	8	2	10
Mean (StdDev)		151.30 (359.184)	89.30 (85.843)	138.90 (319.133)
Median		27.65	89.30	27.90
Min, Max		10.7, 1040.0	28.6, 150.0	10.7, 1040.0
Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		45.60 (-)	32.20 (-)	38.90 (9.475)
Median		45.60	32.20	38.90
Min, Max		45.6, 45.6	32.2, 32.2	32.2, 45.6

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2202

Starting Dose: 200 mg				
Serum Tryptase (ug/L)	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Baseline				
n	4	27	9	40
Mean (StdDev)	235.50 (217.425)	358.16 (240.759)	468.38 (460.358)	370.69 (299.896)
Median	213.10	312.00	325.20	314.00
Min, Max	23.8, 492.0	47.7, 856.0	31.0, 1600.0	23.8, 1600.0
Cycle 1 Day 15				
n	4	23	8	35
Mean (StdDev)	69.25 (86.614)	147.26 (150.898)	292.23 (500.076)	171.48 (268.214)
Median	37.30	87.20	99.00	87.20
Min, Max	5.4, 197.0	9.2, 532.0	10.0, 1496.0	5.4, 1496.0
Cycle 2 Day 1				
n	3	22	9	34
Mean (StdDev)	29.73 (30.433)	120.78 (156.751)	251.22 (463.984)	147.27 (269.356)
Median	23.50	43.05	75.50	54.75
Min, Max	2.9, 62.8	2.8, 572.0	8.8, 1464.0	2.8, 1464.0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2202

Starting Dose: 200 mg				
Serum Tryptase (ug/L)	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Cycle 3 Day 1				
n	4	19	7	30
Mean (StdDev)	34.00 (34.095)	126.31 (177.768)	321.84 (534.121)	159.62 (296.674)
Median	29.05	63.50	78.10	58.60
Min, Max	2.0, 75.9	4.1, 660.0	28.7, 1504.0	2.0, 1504.0
Cycle 7 Day 1				
n	1	14	2	17
Mean (StdDev)	64.10 (-)	66.61 (111.438)	111.50 (122.329)	71.74 (106.064)
Median	64.10	29.85	111.50	31.90
Min, Max	64.1, 64.1	3.8, 430.4	25.0, 198.0	3.8, 430.4
Cycle 11 Day 1				
n	0	7	2	9
Mean (StdDev)		24.34 (8.916)	89.30 (85.843)	38.78 (42.440)
Median		27.60	89.30	27.70
Min, Max		10.7, 38.1	28.6, 150.0	10.7, 150.0
Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		45.60 (-)	32.20 (-)	38.90 (9.475)
Median		45.60	32.20	38.90
Min, Max		45.6, 45.6	32.2, 32.2	32.2, 45.6

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Overall

Serum Tryptase (ug/L)	ASM (N=12)	SM-AHN (N=54)	MCL (N=17)	All AdvSM (N=83)
Baseline				
n	12	54	17	83
Mean (StdDev)	322.95 (383.539)	318.88 (283.934)	460.52 (362.990)	348.48 (317.529)
Median	237.60	218.50	325.20	270.00
Min, Max	19.9, 1414.3	21.2, 1600.0	31.0, 1600.0	19.9, 1600.0
Cycle 1 Day 15				
n	11	50	16	77
Mean (StdDev)	110.34 (176.923)	117.39 (141.084)	210.23 (353.595)	135.67 (207.634)
Median	34.10	65.85	109.50	78.30
Min, Max	5.4, 603.7	5.0, 608.0	10.0, 1496.0	5.0, 1496.0
Cycle 2 Day 1				
n	10	48	17	75
Mean (StdDev)	80.02 (129.243)	90.94 (126.851)	185.86 (337.459)	111.00 (196.347)
Median	33.05	42.10	87.50	55.50
Min, Max	2.9, 423.0	2.7, 572.0	8.8, 1464.0	2.7, 1464.0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.

Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas
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Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Overall

Serum Tryptase (ug/L)	ASM (N=12)	SM-AHN (N=54)	MCL (N=17)	All AdvSM (N=83)
Cycle 3 Day 1				
n	10	43	15	68
Mean (StdDev)	66.74 (113.344)	95.67 (146.467)	199.25 (371.070)	114.26 (214.759)
Median	24.65	32.20	82.40	45.80
Min, Max	2.0, 375.3	2.8, 660.0	24.5, 1504.0	2.0, 1504.0
Cycle 5 Day 1				
n	6	22	8	36
Mean (StdDev)	56.80 (84.464)	69.43 (158.009)	71.50 (38.055)	67.79 (127.728)
Median	22.45	19.95	82.10	25.20
Min, Max	3.7, 223.7	1.5, 744.3	17.0, 124.3	1.5, 744.3
Cycle 7 Day 1				
n	6	32	9	47
Mean (StdDev)	64.28 (92.807)	99.36 (195.514)	149.82 (213.697)	104.55 (187.804)
Median	31.55	26.55	89.40	36.70
Min, Max	4.6, 247.9	3.8, 789.3	12.7, 698.3	3.8, 789.3
Cycle 11 Day 1				
n	4	21	7	32
Mean (StdDev)	85.05 (122.333)	83.65 (222.792)	84.04 (96.039)	83.91 (187.769)
Median	34.40	27.60	33.80	27.90
Min, Max	4.7, 266.7	3.0, 1040.0	6.8, 272.4	3.0, 1040.0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Overall

Serum Tryptase (ug/L)	ASM (N=12)	SM-AHN (N=54)	MCL (N=17)	All AdvSM (N=83)
Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		45.60 (-)	32.20 (-)	38.90 (9.475)
Median		45.60	32.20	38.90
Min, Max		45.6, 45.6	32.2, 32.2	32.2, 45.6
Cycle 18 Day 1				
n	3	8	3	14
Mean (StdDev)	57.90 (62.658)	18.23 (15.426)	20.70 (15.570)	27.26 (32.346)
Median	24.10	12.20	19.80	19.60
Min, Max	19.4, 130.2	3.4, 46.4	5.6, 36.7	3.4, 130.2
Cycle 24 Day 1				
n	3	8	2	13
Mean (StdDev)	106.93 (148.748)	20.53 (20.715)	22.45 (23.688)	40.76 (73.541)
Median	26.00	15.50	22.45	24.00
Min, Max	16.2, 278.6	2.5, 61.4	5.7, 39.2	2.5, 278.6
Cycle 30 Day 1				
n	2	4	2	8
Mean (StdDev)	141.95 (162.422)	6.53 (7.389)	15.05 (15.344)	42.51 (87.215)
Median	141.95	3.35	15.05	10.90
Min, Max	27.1, 256.8	1.9, 17.5	4.2, 25.9	1.9, 256.8

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Overall

Serum Tryptase (ug/L)	ASM (N=12)	SM-AHN (N=54)	MCL (N=17)	All AdvSM (N=83)
Cycle 36 Day 1				
n	2	4	0	6
Mean (StdDev)	95.55 (107.975)	4.40 (3.349)		34.78 (67.483)
Median	95.55	3.20		6.50
Min, Max	19.2, 171.9	1.9, 9.3		1.9, 171.9
Cycle 42 Day 1				
n	1	3	1	5
Mean (StdDev)	173.00 (-)	7.13 (4.743)	6.70 (-)	40.22 (74.302)
Median	173.00	6.40	6.70	6.70
Min, Max	173.0, 173.0	2.8, 12.2	6.7, 6.7	2.8, 173.0
Cycle 48 Day 1				
n	1	0	1	2
Mean (StdDev)	141.70 (-)		6.80 (-)	74.25 (95.389)
Median	141.70		6.80	74.25
Min, Max	141.7, 141.7		6.8, 6.8	6.8, 141.7

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg

Serum Tryptase (ug/L)	ASM (N=2)	SM-AHN (N=3)	MCL (N=1)	All AdvSM (N=6)
Baseline				
n	2	3	1	6
Mean (StdDev)	779.65 (897.531)	569.50 (892.441)	226.60 (-)	582.40 (721.577)
Median	779.65	55.90	226.60	185.80
Min, Max	145.0, 1414.3	52.6, 1600.0	226.6, 226.6	52.6, 1600.0
Cycle 1 Day 15				
n	2	3	1	6
Mean (StdDev)	309.70 (415.779)	229.60 (328.187)	133.40 (-)	240.27 (286.248)
Median	309.70	58.20	133.40	95.80
Min, Max	15.7, 603.7	22.6, 608.0	133.4, 133.4	15.7, 608.0
Cycle 2 Day 1				
n	1	3	1	5
Mean (StdDev)	423.00 (-)	148.33 (203.851)	85.80 (-)	190.76 (195.871)
Median	423.00	56.10	85.80	85.80
Min, Max	423.0, 423.0	6.9, 382.0	85.8, 85.8	6.9, 423.0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg

Serum Tryptase (ug/L)	ASM (N=2)	SM-AHN (N=3)	MCL (N=1)	All AdvSM (N=6)
Cycle 3 Day 1				
n	1	3	1	5
Mean (StdDev)	375.30 (-)	205.83 (294.545)	62.70 (-)	211.10 (235.892)
Median	375.30	68.20	62.70	68.20
Min, Max	375.3, 375.3	5.3, 544.0	62.7, 62.7	5.3, 544.0
Cycle 5 Day 1				
n	1	2	1	4
Mean (StdDev)	223.70 (-)	38.65 (45.326)	88.70 (-)	97.43 (91.260)
Median	223.70	38.65	88.70	79.70
Min, Max	223.7, 223.7	6.6, 70.7	88.7, 88.7	6.6, 223.7
Cycle 7 Day 1				
n	1	3	1	5
Mean (StdDev)	247.90 (-)	276.27 (419.513)	99.70 (-)	235.28 (306.416)
Median	247.90	56.60	99.70	99.70
Min, Max	247.9, 247.9	12.2, 760.0	99.7, 99.7	12.2, 760.0
Cycle 11 Day 1				
n	1	3	1	5
Mean (StdDev)	266.70 (-)	359.43 (589.423)	74.80 (-)	283.96 (434.734)
Median	266.70	25.60	74.80	74.80
Min, Max	266.7, 266.7	12.7, 1040.0	74.8, 74.8	12.7, 1040.0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg

Serum Tryptase (ug/L)	ASM (N=2)	SM-AHN (N=3)	MCL (N=1)	All AdvSM (N=6)
Cycle 18 Day 1				
n	1	2	1	4
Mean (StdDev)	130.20 (-)	5.85 (3.465)	36.70 (-)	44.65 (58.892)
Median	130.20	5.85	36.70	22.50
Min, Max	130.2, 130.2	3.4, 8.3	36.7, 36.7	3.4, 130.2
Cycle 24 Day 1				
n	1	2	1	4
Mean (StdDev)	278.60 (-)	4.75 (3.182)	39.20 (-)	81.83 (132.197)
Median	278.60	4.75	39.20	23.10
Min, Max	278.6, 278.6	2.5, 7.0	39.2, 39.2	2.5, 278.6
Cycle 30 Day 1				
n	1	2	1	4
Mean (StdDev)	256.80 (-)	3.10 (1.697)	25.90 (-)	72.23 (123.522)
Median	256.80	3.10	25.90	15.10
Min, Max	256.8, 256.8	1.9, 4.3	25.9, 25.9	1.9, 256.8
Cycle 36 Day 1				
n	1	2	0	3
Mean (StdDev)	171.90 (-)	3.20 (0.707)		59.43 (97.400)
Median	171.90	3.20		3.70
Min, Max	171.9, 171.9	2.7, 3.7		2.7, 171.9

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg

Serum Tryptase (ug/L)	ASM (N=2)	SM-AHN (N=3)	MCL (N=1)	All AdvSM (N=6)
Cycle 42 Day 1				
n	1	2	1	4
Mean (StdDev)	173.00 (-)	4.60 (2.546)	6.70 (-)	47.23 (83.869)
Median	173.00	4.60	6.70	6.55
Min, Max	173.0, 173.0	2.8, 6.4	6.7, 6.7	2.8, 173.0
Cycle 48 Day 1				
n	1	0	1	2
Mean (StdDev)	141.70 (-)		6.80 (-)	74.25 (95.389)
Median	141.70		6.80	74.25
Min, Max	141.7, 141.7		6.8, 6.8	6.8, 141.7

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg

Serum Tryptase (ug/L)	ASM (N=7)	SM-AHN (N=37)	MCL (N=14)	All AdvSM (N=58)
Baseline				
n	7	37	14	58
Mean (StdDev)	360.17 (496.196)	350.83 (318.526)	473.34 (382.434)	381.53 (355.093)
Median	145.00	262.00	329.60	303.60
Min, Max	19.9, 1414.3	40.7, 1600.0	31.0, 1600.0	19.9, 1600.0
Cycle 1 Day 15				
n	7	33	13	53
Mean (StdDev)	128.96 (219.855)	142.66 (164.969)	240.58 (388.483)	164.87 (243.047)
Median	31.50	66.80	125.10	87.20
Min, Max	5.4, 603.7	8.9, 608.0	10.0, 1496.0	5.4, 1496.0
Cycle 2 Day 1				
n	5	32	14	51
Mean (StdDev)	103.48 (180.222)	111.10 (147.028)	210.22 (369.070)	137.56 (231.212)
Median	23.50	43.05	95.20	62.80
Min, Max	2.9, 423.0	2.8, 572.0	8.8, 1464.0	2.8, 1464.0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg

Serum Tryptase (ug/L)	ASM (N=7)	SM-AHN (N=37)	MCL (N=14)	All AdvSM (N=58)
Cycle 3 Day 1				
n	6	28	12	46
Mean (StdDev)	86.13 (144.553)	126.81 (171.959)	236.95 (408.979)	150.24 (252.675)
Median	29.05	64.10	114.35	66.15
Min, Max	2.0, 375.3	4.1, 660.0	28.7, 1504.0	2.0, 1504.0
Cycle 5 Day 1				
n	2	6	5	13
Mean (StdDev)	114.80 (154.008)	175.92 (290.219)	81.72 (36.101)	130.28 (198.920)
Median	114.80	41.90	88.70	75.50
Min, Max	5.9, 223.7	2.6, 744.3	25.6, 124.3	2.6, 744.3
Cycle 7 Day 1				
n	2	22	7	31
Mean (StdDev)	156.00 (129.966)	132.94 (229.181)	91.06 (59.897)	124.97 (196.027)
Median	156.00	34.30	89.40	50.40
Min, Max	64.1, 247.9	3.8, 789.3	25.0, 198.0	3.8, 789.3
Cycle 11 Day 1				
n	1	13	5	19
Mean (StdDev)	266.70 (-)	119.48 (280.912)	61.82 (53.447)	112.05 (235.185)
Median	266.70	27.60	33.80	28.10
Min, Max	266.7, 266.7	4.1, 1040.0	21.9, 150.0	4.1, 1040.0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg

Serum Tryptase (ug/L)	ASM (N=7)	SM-AHN (N=37)	MCL (N=14)	All AdvSM (N=58)
Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		45.60 (-)	32.20 (-)	38.90 (9.475)
Median		45.60	32.20	38.90
Min, Max		45.6, 45.6	32.2, 32.2	32.2, 45.6
Cycle 18 Day 1				
n	1	2	2	5
Mean (StdDev)	130.20 (-)	5.85 (3.465)	28.25 (11.950)	39.68 (52.199)
Median	130.20	5.85	28.25	19.80
Min, Max	130.2, 130.2	3.4, 8.3	19.8, 36.7	3.4, 130.2
Cycle 24 Day 1				
n	1	3	1	5
Mean (StdDev)	278.60 (-)	14.37 (16.808)	39.20 (-)	72.18 (116.500)
Median	278.60	7.00	39.20	33.60
Min, Max	278.6, 278.6	2.5, 33.6	39.2, 39.2	2.5, 278.6
Cycle 30 Day 1				
n	1	3	1	5
Mean (StdDev)	256.80 (-)	7.90 (8.400)	25.90 (-)	61.28 (109.737)
Median	256.80	4.30	25.90	17.50
Min, Max	256.8, 256.8	1.9, 17.5	25.9, 25.9	1.9, 256.8

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg

Serum Tryptase (ug/L)	ASM (N=7)	SM-AHN (N=37)	MCL (N=14)	All AdvSM (N=58)
Cycle 36 Day 1				
n	1	3	0	4
Mean (StdDev)	171.90 (-)	5.23 (3.557)		46.90 (83.384)
Median	171.90	3.70		6.50
Min, Max	171.9, 171.9	2.7, 9.3		2.7, 171.9
Cycle 42 Day 1				
n	1	3	1	5
Mean (StdDev)	173.00 (-)	7.13 (4.743)	6.70 (-)	40.22 (74.302)
Median	173.00	6.40	6.70	6.70
Min, Max	173.0, 173.0	2.8, 12.2	6.7, 6.7	2.8, 173.0
Cycle 48 Day 1				
n	1	0	1	2
Mean (StdDev)	141.70 (-)		6.80 (-)	74.25 (95.389)
Median	141.70		6.80	74.25
Min, Max	141.7, 141.7		6.8, 6.8	6.8, 141.7

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas
Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Serum Tryptase (ug/L)	ASM (N=5)	SM-AHN (N=34)	MCL (N=13)	All AdvSM (N=52)
Baseline				
n	5	34	13	52
Mean (StdDev)	192.38 (211.547)	331.53 (240.170)	492.32 (391.126)	358.35 (290.833)
Median	90.20	266.00	334.00	312.00
Min, Max	19.9, 492.0	40.7, 856.0	31.0, 1600.0	19.9, 1600.0
Cycle 1 Day 15				
n	5	30	12	47
Mean (StdDev)	56.66 (80.119)	133.97 (147.451)	249.51 (404.361)	155.24 (238.818)
Median	31.50	72.55	119.55	87.20
Min, Max	5.4, 197.0	8.9, 532.0	10.0, 1496.0	5.4, 1496.0
Cycle 2 Day 1				
n	4	29	13	46
Mean (StdDev)	23.60 (27.711)	107.25 (144.227)	219.79 (382.327)	131.78 (235.881)
Median	14.35	42.80	102.90	62.05
Min, Max	2.9, 62.8	2.8, 572.0	8.8, 1464.0	2.8, 1464.0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg				
Serum Tryptase (ug/L)	ASM (N=5)	SM-AHN (N=34)	MCL (N=13)	All AdvSM (N=52)
Cycle 3 Day 1				
n	5	25	11	41
Mean (StdDev)	28.30 (32.161)	117.33 (158.625)	252.79 (425.063)	142.81 (256.401)
Median	10.90	63.50	146.30	64.70
Min, Max	2.0, 75.9	4.1, 660.0	28.7, 1504.0	2.0, 1504.0
Cycle 5 Day 1				
n	1	4	4	9
Mean (StdDev)	5.90 (-)	244.55 (347.636)	79.98 (41.442)	144.89 (235.480)
Median	5.90	115.65	85.00	75.50
Min, Max	5.9, 5.9	2.6, 744.3	25.6, 124.3	2.6, 744.3
Cycle 7 Day 1				
n	1	19	6	26
Mean (StdDev)	64.10 (-)	110.31 (194.317)	89.62 (65.481)	103.76 (167.892)
Median	64.10	31.90	69.90	40.10
Min, Max	64.1, 64.1	3.8, 789.3	25.0, 198.0	3.8, 789.3
Cycle 11 Day 1				
n	0	10	4	14
Mean (StdDev)		47.49 (55.319)	58.58 (61.144)	50.66 (54.848)
Median		27.65	31.20	27.90
Min, Max		4.1, 163.1	21.9, 150.0	4.1, 163.1

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg				
Serum Tryptase (ug/L)	ASM (N=5)	SM-AHN (N=34)	MCL (N=13)	All AdvSM (N=52)
Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		45.60 (-)	32.20 (-)	38.90 (9.475)
Median		45.60	32.20	38.90
Min, Max		45.6, 45.6	32.2, 32.2	32.2, 45.6
Cycle 18 Day 1				
n	0	0	1	1
Mean (StdDev)			19.80 (-)	19.80 (-)
Median			19.80	19.80
Min, Max			19.8, 19.8	19.8, 19.8
Cycle 24 Day 1				
n	0	1	0	1
Mean (StdDev)		33.60 (-)		33.60 (-)
Median		33.60		33.60
Min, Max		33.6, 33.6		33.6, 33.6
Cycle 30 Day 1				
n	0	1	0	1
Mean (StdDev)		17.50 (-)		17.50 (-)
Median		17.50		17.50
Min, Max		17.5, 17.5		17.5, 17.5

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg				
Serum Tryptase (ug/L)	ASM (N=5)	SM-AHN (N=34)	MCL (N=13)	All AdvSM (N=52)
Cycle 36 Day 1				
n	0	1	0	1
Mean (StdDev)		9.30 (-)		9.30 (-)
Median		9.30		9.30
Min, Max		9.3, 9.3		9.3, 9.3
Cycle 42 Day 1				
n	0	1	0	1
Mean (StdDev)		12.20 (-)		12.20 (-)
Median		12.20		12.20
Min, Max		12.2, 12.2		12.2, 12.2

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg				
Serum Tryptase (ug/L)	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Baseline				
n	4	13	3	20
Mean (StdDev)	330.75 (123.554)	286.91 (184.332)	400.70 (311.309)	312.75 (189.257)
Median	313.80	367.40	227.10	313.80
Min, Max	204.7, 490.7	21.2, 631.3	214.9, 760.1	21.2, 760.1
Cycle 1 Day 15				
n	3	13	3	19
Mean (StdDev)	100.20 (71.686)	83.07 (49.982)	78.70 (16.435)	85.08 (48.107)
Median	90.10	94.60	81.90	90.10
Min, Max	34.1, 176.4	12.1, 149.6	60.9, 93.3	12.1, 176.4
Cycle 2 Day 1				
n	4	13	3	20
Mean (StdDev)	69.23 (62.457)	59.70 (58.661)	72.20 (46.000)	63.48 (55.143)
Median	50.80	55.50	46.80	51.15
Min, Max	16.2, 159.1	4.6, 223.9	44.5, 125.3	4.6, 223.9

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas
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Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg				
Serum Tryptase (ug/L)	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Cycle 3 Day 1				
n	3	13	3	19
Mean (StdDev)	48.63 (45.031)	41.93 (43.660)	48.47 (35.622)	44.02 (40.584)
Median	38.40	26.60	31.50	27.90
Min, Max	9.6, 97.9	2.8, 156.6	24.5, 89.4	2.8, 156.6
Cycle 5 Day 1				
n	3	13	3	19
Mean (StdDev)	35.83 (23.299)	30.98 (25.929)	54.47 (42.020)	35.45 (27.919)
Median	24.80	20.80	46.50	21.50
Min, Max	20.1, 62.6	6.4, 71.0	17.0, 99.9	6.4, 99.9
Cycle 7 Day 1				
n	3	8	2	13
Mean (StdDev)	23.03 (18.491)	27.05 (18.915)	355.50 (484.792)	76.65 (187.535)
Median	20.40	19.20	355.50	20.40
Min, Max	6.0, 42.7	7.1, 53.7	12.7, 698.3	6.0, 698.3
Cycle 11 Day 1				
n	3	7	2	12
Mean (StdDev)	24.50 (21.220)	22.33 (15.550)	139.60 (187.808)	42.42 (74.039)
Median	21.90	20.50	139.60	21.20
Min, Max	4.7, 46.9	3.0, 44.2	6.8, 272.4	3.0, 272.4

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg				
Serum Tryptase (ug/L)	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Cycle 18 Day 1				
n	2	6	1	9
Mean (StdDev)	21.75 (3.323)	22.35 (15.783)	5.60 (-)	20.36 (13.702)
Median	21.75	21.65	5.60	19.40
Min, Max	19.4, 24.1	4.0, 46.4	5.6, 5.6	4.0, 46.4
Cycle 24 Day 1				
n	2	4	1	7
Mean (StdDev)	21.10 (6.930)	29.25 (24.157)	5.70 (-)	23.56 (19.405)
Median	21.10	26.30	5.70	24.00
Min, Max	16.2, 26.0	3.0, 61.4	5.7, 5.7	3.0, 61.4
Cycle 30 Day 1				
n	1	0	1	2
Mean (StdDev)	27.10 (-)		4.20 (-)	15.65 (16.193)
Median	27.10		4.20	15.65
Min, Max	27.1, 27.1		4.2, 4.2	4.2, 27.1
Cycle 36 Day 1				
n	1	0	0	1
Mean (StdDev)	19.20 (-)			19.20 (-)
Median	19.20			19.20
Min, Max	19.2, 19.2			19.2, 19.2

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg

Serum Tryptase (ug/L)	ASM (N=9)	SM-AHN (N=47)	MCL (N=16)	All AdvSM (N=72)
Baseline				
n	9	47	16	72
Mean (StdDev)	253.88 (182.809)	319.19 (225.059)	475.14 (369.689)	345.68 (266.018)
Median	270.50	270.00	329.60	312.00
Min, Max	19.9, 492.0	21.2, 856.0	31.0, 1600.0	19.9, 1600.0
Cycle 1 Day 15				
n	8	43	15	66
Mean (StdDev)	72.99 (75.127)	118.58 (127.614)	215.35 (365.391)	135.05 (205.008)
Median	38.60	78.30	105.00	88.65
Min, Max	5.4, 197.0	8.9, 532.0	10.0, 1496.0	5.4, 1496.0
Cycle 2 Day 1				
n	8	42	16	66
Mean (StdDev)	46.41 (50.948)	92.53 (125.331)	192.12 (347.507)	111.08 (201.020)
Median	33.05	43.05	95.20	57.25
Min, Max	2.9, 159.1	2.8, 572.0	8.8, 1464.0	2.8, 1464.0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg

Serum Tryptase (ug/L)	ASM (N=9)	SM-AHN (N=47)	MCL (N=16)	All AdvSM (N=72)
Cycle 3 Day 1				
n	8	38	14	60
Mean (StdDev)	35.92 (35.793)	91.53 (135.106)	209.01 (383.077)	111.53 (217.303)
Median	24.65	34.45	85.90	45.80
Min, Max	2.0, 97.9	2.8, 660.0	24.5, 1504.0	2.0, 1504.0
Cycle 5 Day 1				
n	4	17	7	28
Mean (StdDev)	28.35 (24.206)	81.23 (178.561)	69.04 (40.413)	70.63 (140.209)
Median	22.45	20.80	75.50	25.20
Min, Max	5.9, 62.6	2.6, 744.3	17.0, 124.3	2.6, 744.3
Cycle 7 Day 1				
n	4	27	8	39
Mean (StdDev)	33.30 (25.487)	85.64 (166.548)	156.09 (227.566)	94.72 (172.679)
Median	31.55	27.80	69.90	36.70
Min, Max	6.0, 64.1	3.8, 789.3	12.7, 698.3	3.8, 789.3
Cycle 11 Day 1				
n	3	17	6	26
Mean (StdDev)	24.50 (21.220)	37.13 (44.441)	85.58 (105.110)	46.85 (63.197)
Median	21.90	27.60	31.20	27.65
Min, Max	4.7, 46.9	3.0, 163.1	6.8, 272.4	3.0, 272.4

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg				
Serum Tryptase (ug/L)	ASM (N=9)	SM-AHN (N=47)	MCL (N=16)	All AdvSM (N=72)
Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		45.60 (-)	32.20 (-)	38.90 (9.475)
Median		45.60	32.20	38.90
Min, Max		45.6, 45.6	32.2, 32.2	32.2, 45.6
Cycle 18 Day 1				
n	2	6	2	10
Mean (StdDev)	21.75 (3.323)	22.35 (15.783)	12.70 (10.041)	20.30 (12.920)
Median	21.75	21.65	12.70	19.60
Min, Max	19.4, 24.1	4.0, 46.4	5.6, 19.8	4.0, 46.4
Cycle 24 Day 1				
n	2	5	1	8
Mean (StdDev)	21.10 (6.930)	30.12 (21.011)	5.70 (-)	24.81 (18.313)
Median	21.10	28.60	5.70	25.00
Min, Max	16.2, 26.0	3.0, 61.4	5.7, 5.7	3.0, 61.4
Cycle 30 Day 1				
n	1	1	1	3
Mean (StdDev)	27.10 (-)	17.50 (-)	4.20 (-)	16.27 (11.500)
Median	27.10	17.50	4.20	17.50
Min, Max	27.1, 27.1	17.5, 17.5	4.2, 4.2	4.2, 27.1

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg

Serum Tryptase (ug/L)	ASM (N=9)	SM-AHN (N=47)	MCL (N=16)	All AdvSM (N=72)
Cycle 36 Day 1				
n	1	1	0	2
Mean (StdDev)	19.20 (-)	9.30 (-)		14.25 (7.000)
Median	19.20	9.30		14.25
Min, Max	19.2, 19.2	9.3, 9.3		9.3, 19.2
Cycle 42 Day 1				
n	0	1	0	1
Mean (StdDev)		12.20 (-)		12.20 (-)
Median		12.20		12.20
Min, Max		12.2, 12.2		12.2, 12.2

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg				
Serum Tryptase (ug/L)	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Baseline				
n	1	4	0	5
Mean (StdDev)	31.20 (-)	127.30 (69.954)		108.08 (74.278)
Median	31.20	151.00		130.00
Min, Max	31.2, 31.2	27.6, 179.6		27.6, 179.6
Cycle 1 Day 15				
n	1	4	0	5
Mean (StdDev)	10.40 (-)	20.43 (12.777)		18.42 (11.939)
Median	10.40	20.60		17.10
Min, Max	10.4, 10.4	5.0, 35.5		5.0, 35.5
Cycle 2 Day 1				
n	1	3	0	4
Mean (StdDev)	5.90 (-)	11.30 (8.229)		9.95 (7.241)
Median	5.90	12.10		9.00
Min, Max	5.9, 5.9	2.7, 19.1		2.7, 19.1

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas
Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg				
Serum Tryptase (ug/L)	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Cycle 3 Day 1				
n	1	2	0	3
Mean (StdDev)	4.70 (-)	8.95 (3.323)		7.53 (3.398)
Median	4.70	8.95		6.60
Min, Max	4.7, 4.7	6.6, 11.3		4.7, 11.3
Cycle 5 Day 1				
n	1	3	0	4
Mean (StdDev)	3.70 (-)	23.10 (26.521)		18.25 (23.728)
Median	3.70	15.10		9.40
Min, Max	3.7, 3.7	1.5, 52.7		1.5, 52.7
Cycle 7 Day 1				
n	1	2	0	3
Mean (StdDev)	4.60 (-)	19.25 (4.172)		14.37 (8.958)
Median	4.60	19.25		16.30
Min, Max	4.6, 4.6	16.3, 22.2		4.6, 22.2
Cycle 11 Day 1				
n	0	1	0	1
Mean (StdDev)		47.20 (-)		47.20 (-)
Median		47.20		47.20
Min, Max		47.2, 47.2		47.2, 47.2

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.1
Summary of Serum Tryptase
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg				
Serum Tryptase (ug/L)	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Cycle 24 Day 1				
n	0	1	0	1
Mean (StdDev)		4.10 (-)		4.10 (-)
Median		4.10		4.10
Min, Max		4.1, 4.1		4.1, 4.1
Cycle 30 Day 1				
n	0	1	0	1
Mean (StdDev)		2.40 (-)		2.40 (-)
Median		2.40		2.40
Min, Max		2.4, 2.4		2.4, 2.4
Cycle 36 Day 1				
n	0	1	0	1
Mean (StdDev)		1.90 (-)		1.90 (-)
Median		1.90		1.90
Min, Max		1.9, 1.9		1.9, 1.9

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Overall

Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=7)	SM-AHN (N=26)	MCL (N=8)	All AdvSM (N=41)
Baseline				
n	7	26	8	41
Mean (StdDev)	398.3 (478.58)	228.8 (186.75)	451.7 (242.48)	301.2 (275.73)
Median	270.5	150.0	415.9	214.9
Min, Max	20, 1414	21, 631	215, 760	20, 1414
Percent Change from Baseline to Cycle 1 Day 15				
n	6	26	8	40
Mean (StdDev)	-69.8 (10.35)	-65.0 (23.88)	-66.2 (15.19)	-66.0 (20.58)
Median	-67.5	-71.9	-70.3	-68.8
Min, Max	-87, -57	-94, 4	-89, -41	-94, 4
Percent Change from Baseline to Cycle 2 Day 1				
n	7	25	8	40
Mean (StdDev)	-78.5 (8.98)	-72.2 (25.67)	-68.8 (19.08)	-72.6 (22.19)
Median	-79.2	-84.6	-73.8	-79.2
Min, Max	-94, -68	-99, 0	-94, -39	-99, 0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Overall

Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=7)	SM-AHN (N=26)	MCL (N=8)	All AdvSM (N=41)
Percent Change from Baseline to Cycle 3 Day 1				
n	6	23	8	37
Mean (StdDev)	-81.4 (8.78)	-70.7 (34.19)	-74.7 (17.07)	-73.3 (28.24)
Median	-80.6	-83.0	-76.9	-80.0
Min, Max	-96, -72	-99, 25	-97, -42	-99, 25
Percent Change from Baseline to Cycle 5 Day 1				
n	6	22	8	36
Mean (StdDev)	-85.2 (7.63)	-63.4 (55.25)	-80.1 (15.71)	-70.7 (44.49)
Median	-87.7	-88.9	-86.9	-87.2
Min, Max	-91, -70	-98, 116	-96, -51	-98, 116
Percent Change from Baseline to Cycle 7 Day 1				
n	5	17	7	29
Mean (StdDev)	-89.4 (5.90)	-31.8 (185.58)	-68.4 (32.54)	-50.6 (143.08)
Median	-90.0	-79.6	-87.6	-85.3
Min, Max	-98, -82	-98, 682	-94, -8	-98, 682
Percent Change from Baseline to Cycle 11 Day 1				
n	4	13	5	22
Mean (StdDev)	-89.8 (7.01)	-79.3 (16.48)	-66.9 (50.16)	-78.4 (26.42)
Median	-89.9	-76.4	-94.6	-85.2
Min, Max	-98, -81	-99, -54	-97, 20	-99, 20

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Overall

Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=7)	SM-AHN (N=26)	MCL (N=8)	All AdvSM (N=41)
Percent Change from Baseline to Cycle 18 Day 1				
n	3	8	3	14
Mean (StdDev)	-92.1 (2.56)	-88.2 (9.83)	-92.7 (7.70)	-90.0 (8.18)
Median	-90.8	-90.0	-96.9	-92.2
Min, Max	-95, -91	-99, -71	-97, -84	-99, -71
Percent Change from Baseline to Cycle 24 Day 1				
n	3	8	2	13
Mean (StdDev)	-88.1 (8.23)	-89.3 (12.43)	-90.0 (10.36)	-89.1 (10.52)
Median	-87.3	-94.7	-90.0	-94.2
Min, Max	-97, -80	-99, -61	-97, -83	-99, -61
Percent Change from Baseline to Cycle 30 Day 1				
n	2	4	2	8
Mean (StdDev)	-84.3 (3.48)	-94.2 (2.86)	-93.3 (6.70)	-91.5 (5.63)
Median	-84.3	-94.3	-93.3	-91.8
Min, Max	-87, -82	-97, -91	-98, -89	-98, -82
Percent Change from Baseline to Cycle 36 Day 1				
n	2	4	0	6
Mean (StdDev)	-89.2 (1.96)	-94.9 (2.43)		-93.0 (3.61)
Median	-89.2	-94.1		-93.2
Min, Max	-91, -88	-98, -93		-98, -88

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Overall

Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=7)	SM-AHN (N=26)	MCL (N=8)	All AdvSM (N=41)
Percent Change from Baseline to Cycle 42 Day 1				
n	1	3	1	5
Mean (StdDev)	-87.8 (-)	-93.7 (4.75)	-97.0 (-)	-93.2 (4.75)
Median	-87.8	-94.7	-97.0	-94.7
Min, Max	-88, -88	-98, -89	-97, -97	-98, -88
Percent Change from Baseline to Cycle 48 Day 1				
n	1	0	1	2
Mean (StdDev)	-90.0 (-)		-97.0 (-)	-93.5 (4.96)
Median	-90.0		-97.0	-93.5
Min, Max	-90, -90		-97, -97	-97, -90

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <200 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=2)	MCL (N=1)	All AdvSM (N=4)
Baseline				
n	1	2	1	4
Mean (StdDev)	1414.3 (-)	54.3 (2.33)	226.6 (-)	437.4 (656.35)
Median	1414.3	54.3	226.6	141.3
Min, Max	1414, 1414	53, 56	227, 227	53, 1414
Percent Change from Baseline to Cycle 1 Day 15				
n	1	2	1	4
Mean (StdDev)	-57.3 (-)	-26.5 (43.24)	-41.1 (-)	-37.8 (28.98)
Median	-57.3	-26.5	-41.1	-49.1
Min, Max	-57, -57	-57, 4	-41, -41	-57, 4
Percent Change from Baseline to Cycle 2 Day 1				
n	1	2	1	4
Mean (StdDev)	-70.1 (-)	-43.3 (61.69)	-62.1 (-)	-54.7 (38.12)
Median	-70.1	-43.3	-62.1	-66.1
Min, Max	-70, -70	-87, 0	-62, -62	-87, 0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <200 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=2)	MCL (N=1)	All AdvSM (N=4)
Percent Change from Baseline to Cycle 3 Day 1				
n	1	2	1	4
Mean (StdDev)	-73.5 (-)	-34.0 (79.14)	-72.3 (-)	-53.4 (50.93)
Median	-73.5	-34.0	-72.3	-72.9
Min, Max	-73, -73	-90, 22	-72, -72	-90, 22
Percent Change from Baseline to Cycle 5 Day 1				
n	1	2	1	4
Mean (StdDev)	-84.2 (-)	-30.5 (80.56)	-60.9 (-)	-51.5 (53.32)
Median	-84.2	-30.5	-60.9	-72.5
Min, Max	-84, -84	-87, 26	-61, -61	-87, 26
Percent Change from Baseline to Cycle 7 Day 1				
n	1	2	1	4
Mean (StdDev)	-82.5 (-)	-37.8 (55.20)	-56.0 (-)	-53.5 (38.24)
Median	-82.5	-37.8	-56.0	-66.4
Min, Max	-82, -82	-77, 1	-56, -56	-82, 1
Percent Change from Baseline to Cycle 11 Day 1				
n	1	2	1	4
Mean (StdDev)	-81.1 (-)	-65.0 (15.31)	-67.0 (-)	-69.5 (11.78)
Median	-81.1	-65.0	-67.0	-71.4
Min, Max	-81, -81	-76, -54	-67, -67	-81, -54

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <200 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=2)	MCL (N=1)	All AdvSM (N=4)
Percent Change from Baseline to Cycle 18 Day 1				
n	1	2	1	4
Mean (StdDev)	-90.8 (-)	-89.3 (5.93)	-83.8 (-)	-88.3 (4.61)
Median	-90.8	-89.3	-83.8	-88.0
Min, Max	-91, -91	-94, -85	-84, -84	-94, -84
Percent Change from Baseline to Cycle 24 Day 1				
n	1	2	1	4
Mean (StdDev)	-80.3 (-)	-91.4 (5.49)	-82.7 (-)	-86.4 (6.59)
Median	-80.3	-91.4	-82.7	-85.1
Min, Max	-80, -80	-95, -87	-83, -83	-95, -80
Percent Change from Baseline to Cycle 30 Day 1				
n	1	2	1	4
Mean (StdDev)	-81.8 (-)	-94.3 (2.89)	-88.6 (-)	-89.8 (6.18)
Median	-81.8	-94.3	-88.6	-90.4
Min, Max	-82, -82	-96, -92	-89, -89	-96, -82
Percent Change from Baseline to Cycle 36 Day 1				
n	1	2	0	3
Mean (StdDev)	-87.8 (-)	-94.1 (1.05)		-92.0 (3.70)
Median	-87.8	-94.1		-93.4
Min, Max	-88, -88	-95, -93		-95, -88

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.

Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas
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Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <200 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=2)	MCL (N=1)	All AdvSM (N=4)
Percent Change from Baseline to Cycle 42 Day 1				
n	1	2	1	4
Mean (StdDev)	-87.8 (-)	-91.6 (4.33)	-97.0 (-)	-92.0 (4.56)
Median	-87.8	-91.6	-97.0	-91.6
Min, Max	-88, -88	-95, -89	-97, -97	-97, -88
Percent Change from Baseline to Cycle 48 Day 1				
n	1	0	1	2
Mean (StdDev)	-90.0 (-)		-97.0 (-)	-93.5 (4.96)
Median	-90.0		-97.0	-93.5
Min, Max	-90, -90		-97, -97	-97, -90

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <300 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=2)	SM-AHN (N=9)	MCL (N=5)	All AdvSM (N=16)
Baseline				
n	2	9	5	16
Mean (StdDev)	717.1 (985.99)	190.0 (209.42)	482.3 (226.53)	347.2 (375.54)
Median	717.1	100.9	575.9	182.0
Min, Max	20, 1414	41, 583	227, 723	20, 1414
Percent Change from Baseline to Cycle 1 Day 15				
n	2	9	5	16
Mean (StdDev)	-62.8 (7.80)	-54.1 (32.90)	-62.0 (15.11)	-57.7 (25.68)
Median	-62.8	-57.0	-68.9	-62.8
Min, Max	-68, -57	-94, 4	-76, -41	-94, 4
Percent Change from Baseline to Cycle 2 Day 1				
n	2	9	5	16
Mean (StdDev)	-72.0 (2.67)	-63.7 (33.24)	-66.4 (17.38)	-65.6 (26.04)
Median	-72.0	-71.5	-71.3	-71.4
Min, Max	-74, -70	-99, 0	-84, -39	-99, 0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <300 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=2)	SM-AHN (N=9)	MCL (N=5)	All AdvSM (N=16)
Percent Change from Baseline to Cycle 3 Day 1				
n	2	8	5	15
Mean (StdDev)	-72.9 (0.78)	-52.8 (47.86)	-71.0 (17.13)	-61.5 (36.39)
Median	-72.9	-73.7	-74.6	-73.5
Min, Max	-73, -72	-90, 25	-87, -42	-90, 25
Percent Change from Baseline to Cycle 5 Day 1				
n	2	6	5	13
Mean (StdDev)	-77.3 (9.78)	-14.4 (88.65)	-76.4 (19.16)	-47.9 (66.69)
Median	-77.3	-30.5	-86.9	-84.2
Min, Max	-84, -70	-94, 116	-96, -51	-96, 116
Percent Change from Baseline to Cycle 7 Day 1				
n	1	7	5	13
Mean (StdDev)	-82.5 (-)	42.5 (283.76)	-75.3 (21.35)	-12.4 (210.30)
Median	-82.5	-69.5	-87.6	-76.8
Min, Max	-82, -82	-94, 682	-93, -48	-94, 682
Percent Change from Baseline to Cycle 11 Day 1				
n	1	5	3	9
Mean (StdDev)	-81.1 (-)	-74.5 (15.44)	-85.9 (16.43)	-79.0 (14.77)
Median	-81.1	-75.9	-94.6	-76.4
Min, Max	-81, -81	-97, -54	-96, -67	-97, -54

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas
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Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <300 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=2)	SM-AHN (N=9)	MCL (N=5)	All AdvSM (N=16)
Percent Change from Baseline to Cycle 18 Day 1				
n	1	2	2	5
Mean (StdDev)	-90.8 (-)	-89.3 (5.93)	-90.3 (9.23)	-90.0 (5.52)
Median	-90.8	-89.3	-90.3	-90.8
Min, Max	-91, -91	-94, -85	-97, -84	-97, -84
Percent Change from Baseline to Cycle 24 Day 1				
n	1	3	1	5
Mean (StdDev)	-80.3 (-)	-92.3 (4.22)	-82.7 (-)	-88.0 (6.69)
Median	-80.3	-94.2	-82.7	-87.5
Min, Max	-80, -80	-95, -87	-83, -83	-95, -80
Percent Change from Baseline to Cycle 30 Day 1				
n	1	3	1	5
Mean (StdDev)	-81.8 (-)	-95.2 (2.55)	-88.6 (-)	-91.2 (6.25)
Median	-81.8	-96.4	-88.6	-92.3
Min, Max	-82, -82	-97, -92	-89, -89	-97, -82
Percent Change from Baseline to Cycle 36 Day 1				
n	1	3	0	4
Mean (StdDev)	-87.8 (-)	-95.6 (2.58)		-93.6 (4.39)
Median	-87.8	-94.9		-94.1
Min, Max	-88, -88	-98, -93		-98, -88

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <300 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=2)	SM-AHN (N=9)	MCL (N=5)	All AdvSM (N=16)
Percent Change from Baseline to Cycle 42 Day 1				
n	1	3	1	5
Mean (StdDev)	-87.8 (-)	-93.7 (4.75)	-97.0 (-)	-93.2 (4.75)
Median	-87.8	-94.7	-97.0	-94.7
Min, Max	-88, -88	-98, -89	-97, -97	-98, -88
Percent Change from Baseline to Cycle 48 Day 1				
n	1	0	1	2
Mean (StdDev)	-90.0 (-)		-97.0 (-)	-93.5 (4.96)
Median	-90.0		-97.0	-93.5
Min, Max	-90, -90		-97, -97	-97, -90

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=7)	MCL (N=4)	All AdvSM (N=12)
Baseline				
n	1	7	4	12
Mean (StdDev)	19.9 (-)	228.8 (224.88)	546.2 (202.94)	317.2 (266.25)
Median	19.9	134.5	602.9	196.6
Min, Max	20, 20	41, 583	256, 723	20, 723
Percent Change from Baseline to Cycle 1 Day 15				
n	1	7	4	12
Mean (StdDev)	-68.3 (-)	-62.0 (28.35)	-67.2 (11.11)	-64.3 (21.90)
Median	-68.3	-78.1	-70.8	-70.8
Min, Max	-68, -68	-94, -30	-76, -51	-94, -30
Percent Change from Baseline to Cycle 2 Day 1				
n	1	7	4	12
Mean (StdDev)	-73.9 (-)	-69.6 (25.68)	-67.5 (19.87)	-69.3 (21.69)
Median	-73.9	-71.5	-73.8	-72.7
Min, Max	-74, -74	-99, -27	-84, -39	-99, -27

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=7)	MCL (N=4)	All AdvSM (N=12)
Percent Change from Baseline to Cycle 3 Day 1				
n	1	6	4	11
Mean (StdDev)	-72.4 (-)	-59.0 (42.02)	-70.7 (19.76)	-64.5 (32.24)
Median	-72.4	-73.7	-76.9	-74.1
Min, Max	-72, -72	-90, 25	-87, -42	-90, 25
Percent Change from Baseline to Cycle 5 Day 1				
n	1	4	4	9
Mean (StdDev)	-70.4 (-)	-6.4 (103.32)	-80.3 (19.72)	-46.3 (74.80)
Median	-70.4	-24.1	-86.9	-86.9
Min, Max	-70, -70	-94, 116	-96, -51	-96, 116
Percent Change from Baseline to Cycle 7 Day 1				
n	0	5	4	9
Mean (StdDev)		74.6 (339.86)	-80.1 (21.27)	5.9 (254.11)
Median		-69.5	-89.4	-79.6
Min, Max		-94, 682	-93, -48	-94, 682
Percent Change from Baseline to Cycle 11 Day 1				
n	0	3	2	5
Mean (StdDev)		-80.8 (14.52)	-95.4 (1.11)	-86.6 (13.05)
Median		-76.4	-95.4	-94.6
Min, Max		-97, -69	-96, -95	-97, -69

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=7)	MCL (N=4)	All AdvSM (N=12)
Percent Change from Baseline to Cycle 18 Day 1				
n	0	0	1	1
Mean (StdDev)			-96.9 (-)	-96.9 (-)
Median			-96.9	-96.9
Min, Max			-97, -97	-97, -97
Percent Change from Baseline to Cycle 24 Day 1				
n	0	1	0	1
Mean (StdDev)		-94.2 (-)		-94.2 (-)
Median		-94.2		-94.2
Min, Max		-94, -94		-94, -94
Percent Change from Baseline to Cycle 30 Day 1				
n	0	1	0	1
Mean (StdDev)		-97.0 (-)		-97.0 (-)
Median		-97.0		-97.0
Min, Max		-97, -97		-97, -97
Percent Change from Baseline to Cycle 36 Day 1				
n	0	1	0	1
Mean (StdDev)		-98.4 (-)		-98.4 (-)
Median		-98.4		-98.4
Min, Max		-98, -98		-98, -98

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=7)	MCL (N=4)	All AdvSM (N=12)
Percent Change from Baseline to Cycle 42 Day 1				
n	0	1	0	1
Mean (StdDev)		-97.9 (-)		-97.9 (-)
Median		-97.9		-97.9
Min, Max		-98, -98		-98, -98

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 300 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Baseline				
n	4	13	3	20
Mean (StdDev)	330.8 (123.55)	286.9 (184.33)	400.7 (311.31)	312.7 (189.26)
Median	313.8	367.4	227.1	313.8
Min, Max	205, 491	21, 631	215, 760	21, 760
Percent Change from Baseline to Cycle 1 Day 15				
n	3	13	3	19
Mean (StdDev)	-75.4 (11.68)	-66.8 (15.95)	-73.3 (15.22)	-69.2 (14.96)
Median	-74.8	-66.2	-71.7	-68.8
Min, Max	-87, -64	-90, -41	-89, -59	-90, -41
Percent Change from Baseline to Cycle 2 Day 1				
n	4	13	3	20
Mean (StdDev)	-81.1 (10.94)	-73.8 (21.08)	-72.7 (25.17)	-75.1 (19.38)
Median	-81.3	-80.9	-79.3	-80.1
Min, Max	-94, -68	-97, -40	-94, -45	-97, -40

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 300 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Percent Change from Baseline to Cycle 3 Day 1				
n	3	13	3	19
Mean (StdDev)	-85.9 (9.15)	-78.3 (20.99)	-80.9 (18.47)	-79.9 (18.68)
Median	-81.2	-87.9	-85.3	-85.3
Min, Max	-96, -80	-99, -40	-97, -61	-99, -40
Percent Change from Baseline to Cycle 5 Day 1				
n	3	13	3	19
Mean (StdDev)	-89.4 (1.91)	-81.7 (18.91)	-86.2 (6.31)	-83.6 (15.89)
Median	-90.2	-94.1	-86.9	-90.2
Min, Max	-91, -87	-98, -52	-92, -80	-98, -52
Percent Change from Baseline to Cycle 7 Day 1				
n	3	8	2	13
Mean (StdDev)	-93.0 (4.16)	-83.1 (17.32)	-51.1 (60.78)	-80.5 (25.95)
Median	-91.3	-93.0	-51.1	-91.3
Min, Max	-98, -90	-98, -56	-94, -8	-98, -8
Percent Change from Baseline to Cycle 11 Day 1				
n	3	7	2	12
Mean (StdDev)	-92.7 (4.88)	-84.9 (16.95)	-38.4 (82.58)	-79.1 (33.96)
Median	-90.4	-96.4	-38.4	-93.4
Min, Max	-98, -89	-99, -58	-97, 20	-99, 20

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 300 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Percent Change from Baseline to Cycle 18 Day 1				
n	2	6	1	9
Mean (StdDev)	-92.8 (3.23)	-87.8 (11.30)	-97.4 (-)	-90.0 (9.67)
Median	-92.8	-91.0	-97.4	-95.1
Min, Max	-95, -91	-99, -71	-97, -97	-99, -71
Percent Change from Baseline to Cycle 24 Day 1				
n	2	4	1	7
Mean (StdDev)	-92.0 (6.65)	-84.8 (17.01)	-97.3 (-)	-88.7 (13.34)
Median	-92.0	-89.4	-97.3	-95.5
Min, Max	-97, -87	-99, -61	-97, -97	-99, -61
Percent Change from Baseline to Cycle 30 Day 1				
n	1	0	1	2
Mean (StdDev)	-86.8 (-)		-98.0 (-)	-92.4 (7.98)
Median	-86.8		-98.0	-92.4
Min, Max	-87, -87		-98, -98	-98, -87
Percent Change from Baseline to Cycle 36 Day 1				
n	1	0	0	1
Mean (StdDev)	-90.6 (-)			-90.6 (-)
Median	-90.6			-90.6
Min, Max	-91, -91			-91, -91

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=5)	SM-AHN (N=20)	MCL (N=7)	All AdvSM (N=32)
Baseline				
n	5	20	7	32
Mean (StdDev)	268.6 (175.43)	266.6 (195.54)	483.8 (242.79)	314.4 (217.05)
Median	270.5	158.0	575.9	263.2
Min, Max	20, 491	21, 631	215, 760	20, 760
Percent Change from Baseline to Cycle 1 Day 15				
n	4	20	7	31
Mean (StdDev)	-73.6 (10.17)	-65.1 (20.49)	-69.8 (12.23)	-67.3 (17.78)
Median	-71.6	-67.5	-71.7	-68.9
Min, Max	-87, -64	-94, -30	-89, -51	-94, -30
Percent Change from Baseline to Cycle 2 Day 1				
n	5	20	7	32
Mean (StdDev)	-79.6 (10.00)	-72.4 (22.21)	-69.7 (20.40)	-72.9 (20.14)
Median	-79.2	-80.0	-76.3	-79.1
Min, Max	-94, -68	-99, -27	-94, -39	-99, -27

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=5)	SM-AHN (N=20)	MCL (N=7)	All AdvSM (N=32)
Percent Change from Baseline to Cycle 3 Day 1				
n	4	19	7	30
Mean (StdDev)	-82.5 (10.08)	-72.2 (29.47)	-75.1 (18.41)	-74.2 (25.15)
Median	-80.6	-76.1	-79.1	-79.6
Min, Max	-96, -72	-99, 25	-97, -42	-99, 25
Percent Change from Baseline to Cycle 5 Day 1				
n	4	17	7	28
Mean (StdDev)	-84.7 (9.66)	-64.0 (57.92)	-82.8 (14.75)	-71.7 (46.27)
Median	-88.7	-90.3	-86.9	-87.2
Min, Max	-91, -70	-98, 116	-96, -51	-98, 116
Percent Change from Baseline to Cycle 7 Day 1				
n	3	13	6	22
Mean (StdDev)	-93.0 (4.16)	-22.4 (212.26)	-70.4 (35.14)	-45.2 (163.93)
Median	-91.3	-79.6	-89.4	-90.1
Min, Max	-98, -90	-98, 682	-94, -8	-98, 682
Percent Change from Baseline to Cycle 11 Day 1				
n	3	10	4	17
Mean (StdDev)	-92.7 (4.88)	-83.7 (15.57)	-66.9 (57.93)	-81.3 (29.12)
Median	-90.4	-86.6	-95.4	-94.6
Min, Max	-98, -89	-99, -58	-97, 20	-99, 20

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=5)	SM-AHN (N=20)	MCL (N=7)	All AdvSM (N=32)
Percent Change from Baseline to Cycle 18 Day 1				
n	2	6	2	10
Mean (StdDev)	-92.8 (3.23)	-87.8 (11.30)	-97.1 (0.38)	-90.7 (9.37)
Median	-92.8	-91.0	-97.1	-95.3
Min, Max	-95, -91	-99, -71	-97, -97	-99, -71
Percent Change from Baseline to Cycle 24 Day 1				
n	2	5	1	8
Mean (StdDev)	-92.0 (6.65)	-86.7 (15.32)	-97.3 (-)	-89.4 (12.51)
Median	-92.0	-94.2	-97.3	-94.9
Min, Max	-97, -87	-99, -61	-97, -97	-99, -61
Percent Change from Baseline to Cycle 30 Day 1				
n	1	1	1	3
Mean (StdDev)	-86.8 (-)	-97.0 (-)	-98.0 (-)	-93.9 (6.23)
Median	-86.8	-97.0	-98.0	-97.0
Min, Max	-87, -87	-97, -97	-98, -98	-98, -87
Percent Change from Baseline to Cycle 36 Day 1				
n	1	1	0	2
Mean (StdDev)	-90.6 (-)	-98.4 (-)		-94.5 (5.50)
Median	-90.6	-98.4		-94.5
Min, Max	-91, -91	-98, -98		-98, -91

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=5)	SM-AHN (N=20)	MCL (N=7)	All AdvSM (N=32)
Percent Change from Baseline to Cycle 42 Day 1				
n	0	1	0	1
Mean (StdDev)		-97.9 (-)		-97.9 (-)
Median		-97.9		-97.9
Min, Max		-98, -98		-98, -98

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 400 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Baseline				
n	1	4	0	5
Mean (StdDev)	31.2 (-)	127.3 (69.95)		108.1 (74.28)
Median	31.2	151.0		130.0
Min, Max	31, 31	28, 180		28, 180
Percent Change from Baseline to Cycle 1 Day 15				
n	1	4	0	5
Mean (StdDev)	-66.7 (-)	-83.7 (3.67)		-80.3 (8.24)
Median	-66.7	-84.2		-81.9
Min, Max	-67, -67	-87, -79		-87, -67
Percent Change from Baseline to Cycle 2 Day 1				
n	1	3	0	4
Mean (StdDev)	-81.1 (-)	-90.1 (0.67)		-87.8 (4.53)
Median	-81.1	-90.2		-89.8
Min, Max	-81, -81	-91, -89		-91, -81

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 400 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Percent Change from Baseline to Cycle 3 Day 1				
n	1	2	0	3
Mean (StdDev)	-84.9 (-)	-93.8 (3.55)		-90.9 (5.71)
Median	-84.9	-93.8		-91.3
Min, Max	-85, -85	-96, -91		-96, -85
Percent Change from Baseline to Cycle 5 Day 1				
n	1	3	0	4
Mean (StdDev)	-88.1 (-)	-81.9 (19.47)		-83.4 (16.20)
Median	-88.1	-91.6		-89.9
Min, Max	-88, -88	-95, -59		-95, -59
Percent Change from Baseline to Cycle 7 Day 1				
n	1	2	0	3
Mean (StdDev)	-85.3 (-)	-86.9 (5.66)		-86.4 (4.11)
Median	-85.3	-86.9		-85.3
Min, Max	-85, -85	-91, -83		-91, -83
Percent Change from Baseline to Cycle 11 Day 1				
n	0	1	0	1
Mean (StdDev)		-63.7 (-)		-63.7 (-)
Median		-63.7		-63.7
Min, Max		-64, -64		-64, -64

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 400 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Percent Change from Baseline to Cycle 24 Day 1				
n	0	1	0	1
Mean (StdDev)		-97.7 (-)		-97.7 (-)
Median		-97.7		-97.7
Min, Max		-98, -98		-98, -98
Percent Change from Baseline to Cycle 30 Day 1				
n	0	1	0	1
Mean (StdDev)		-91.3 (-)		-91.3 (-)
Median		-91.3		-91.3
Min, Max		-91, -91		-91, -91
Percent Change from Baseline to Cycle 36 Day 1				
n	0	1	0	1
Mean (StdDev)		-93.1 (-)		-93.1 (-)
Median		-93.1		-93.1
Min, Max		-93, -93		-93, -93

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2202

Overall

Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Baseline				
n	5	28	9	42
Mean (StdDev)	217.4 (192.60)	402.5 (333.01)	468.4 (460.36)	394.6 (350.81)
Median	145.0	314.0	325.2	314.0
Min, Max	24, 492	48, 1600	31, 1600	24, 1600
Percent Change from Baseline to Cycle 1 Day 15				
n	5	24	8	37
Mean (StdDev)	-75.7 (13.00)	-62.7 (24.21)	-59.6 (23.79)	-63.8 (22.97)
Median	-77.3	-69.6	-68.1	-68.6
Min, Max	-89, -60	-94, -9	-82, -7	-94, -7
Percent Change from Baseline to Cycle 2 Day 1				
n	3	23	9	35
Mean (StdDev)	-70.4 (34.76)	-71.2 (27.18)	-65.0 (23.39)	-69.5 (26.18)
Median	-87.8	-81.2	-71.6	-75.7
Min, Max	-93, -30	-98, -9	-90, -9	-98, -9

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2202

Overall

Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Percent Change from Baseline to Cycle 3 Day 1				
n	4	20	7	31
Mean (StdDev)	-80.1 (22.22)	-70.7 (34.51)	-61.8 (31.25)	-69.9 (32.07)
Median	-88.1	-86.8	-76.0	-84.6
Min, Max	-97, -48	-99, 28	-91, -6	-99, 28
Percent Change from Baseline to Cycle 7 Day 1				
n	1	15	2	18
Mean (StdDev)	-28.9 (-)	-79.2 (24.14)	-82.7 (13.94)	-76.8 (25.20)
Median	-28.9	-90.6	-82.7	-89.3
Min, Max	-29, -29	-99, -26	-93, -73	-99, -26
Percent Change from Baseline to Cycle 11 Day 1				
n	0	8	2	10
Mean (StdDev)		-79.3 (25.34)	-85.4 (8.51)	-80.5 (22.68)
Median		-93.1	-85.4	-92.2
Min, Max		-98, -35	-91, -79	-98, -35
Percent Change from Baseline to Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		-77.1 (-)	-90.4 (-)	-83.7 (9.39)
Median		-77.1	-90.4	-83.7
Min, Max		-77, -77	-90, -90	-90, -77

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2202

Starting Dose: 200 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Baseline				
n	4	27	9	40
Mean (StdDev)	235.5 (217.43)	358.2 (240.76)	468.4 (460.36)	370.7 (299.90)
Median	213.1	312.0	325.2	314.0
Min, Max	24, 492	48, 856	31, 1600	24, 1600
Percent Change from Baseline to Cycle 1 Day 15				
n	4	23	8	35
Mean (StdDev)	-72.4 (12.26)	-62.8 (24.75)	-59.6 (23.79)	-63.1 (23.22)
Median	-71.2	-69.7	-68.1	-68.6
Min, Max	-87, -60	-94, -9	-82, -7	-94, -7
Percent Change from Baseline to Cycle 2 Day 1				
n	3	22	9	34
Mean (StdDev)	-70.4 (34.76)	-71.0 (27.80)	-65.0 (23.39)	-69.4 (26.55)
Median	-87.8	-84.1	-71.6	-75.6
Min, Max	-93, -30	-98, -9	-90, -9	-98, -9

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2202

Starting Dose: 200 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Percent Change from Baseline to Cycle 3 Day 1				
n	4	19	7	30
Mean (StdDev)	-80.1 (22.22)	-70.9 (35.44)	-61.8 (31.25)	-70.0 (32.61)
Median	-88.1	-86.9	-76.0	-85.6
Min, Max	-97, -48	-99, 28	-91, -6	-99, 28
Percent Change from Baseline to Cycle 7 Day 1				
n	1	14	2	17
Mean (StdDev)	-28.9 (-)	-81.1 (23.85)	-82.7 (13.94)	-78.2 (25.21)
Median	-28.9	-90.7	-82.7	-90.6
Min, Max	-29, -29	-99, -26	-93, -73	-99, -26
Percent Change from Baseline to Cycle 11 Day 1				
n	0	7	2	9
Mean (StdDev)		-85.6 (19.37)	-85.4 (8.51)	-85.6 (17.05)
Median		-93.2	-85.4	-92.9
Min, Max		-98, -44	-91, -79	-98, -44
Percent Change from Baseline to Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		-77.1 (-)	-90.4 (-)	-83.7 (9.39)
Median		-77.1	-90.4	-83.7
Min, Max		-77, -77	-90, -90	-90, -77

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Overall				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=12)	SM-AHN (N=54)	MCL (N=17)	All AdvSM (N=83)
Baseline				
n	12	54	17	83
Mean (StdDev)	323.0 (383.54)	318.9 (283.93)	460.5 (362.99)	348.5 (317.53)
Median	237.6	218.5	325.2	270.0
Min, Max	20, 1414	21, 1600	31, 1600	20, 1600
Percent Change from Baseline to Cycle 1 Day 15				
n	11	50	16	77
Mean (StdDev)	-72.5 (11.44)	-63.9 (23.82)	-62.9 (19.58)	-64.9 (21.64)
Median	-68.3	-69.6	-68.5	-68.8
Min, Max	-89, -57	-94, 4	-89, -7	-94, 4
Percent Change from Baseline to Cycle 2 Day 1				
n	10	48	17	75
Mean (StdDev)	-76.1 (18.37)	-71.7 (26.12)	-66.7 (20.90)	-71.2 (24.02)
Median	-80.1	-82.9	-71.6	-79.0
Min, Max	-94, -30	-99, 0	-94, -9	-99, 0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Overall

Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=12)	SM-AHN (N=54)	MCL (N=17)	All AdvSM (N=83)
Percent Change from Baseline to Cycle 3 Day 1				
n	10	43	15	68
Mean (StdDev)	-80.9 (14.42)	-70.7 (33.93)	-68.7 (24.67)	-71.8 (29.87)
Median	-82.9	-86.6	-76.0	-82.4
Min, Max	-97, -48	-99, 28	-97, -6	-99, 28
Percent Change from Baseline to Cycle 5 Day 1				
n	6	22	8	36
Mean (StdDev)	-85.2 (7.63)	-63.4 (55.25)	-80.1 (15.71)	-70.7 (44.49)
Median	-87.7	-88.9	-86.9	-87.2
Min, Max	-91, -70	-98, 116	-96, -51	-98, 116
Percent Change from Baseline to Cycle 7 Day 1				
n	6	32	9	47
Mean (StdDev)	-79.3 (25.23)	-54.0 (136.44)	-71.6 (29.29)	-60.6 (113.41)
Median	-87.6	-87.0	-87.6	-87.6
Min, Max	-98, -29	-99, 682	-94, -8	-99, 682
Percent Change from Baseline to Cycle 11 Day 1				
n	4	21	7	32
Mean (StdDev)	-89.8 (7.01)	-79.3 (19.69)	-72.2 (42.08)	-79.0 (24.96)
Median	-89.9	-80.9	-91.4	-89.9
Min, Max	-98, -81	-99, -35	-97, 20	-99, 20

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Overall

Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=12)	SM-AHN (N=54)	MCL (N=17)	All AdvSM (N=83)
Percent Change from Baseline to Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		-77.1 (-)	-90.4 (-)	-83.7 (9.39)
Median		-77.1	-90.4	-83.7
Min, Max		-77, -77	-90, -90	-90, -77
Percent Change from Baseline to Cycle 18 Day 1				
n	3	8	3	14
Mean (StdDev)	-92.1 (2.56)	-88.2 (9.83)	-92.7 (7.70)	-90.0 (8.18)
Median	-90.8	-90.0	-96.9	-92.2
Min, Max	-95, -91	-99, -71	-97, -84	-99, -71
Percent Change from Baseline to Cycle 24 Day 1				
n	3	8	2	13
Mean (StdDev)	-88.1 (8.23)	-89.3 (12.43)	-90.0 (10.36)	-89.1 (10.52)
Median	-87.3	-94.7	-90.0	-94.2
Min, Max	-97, -80	-99, -61	-97, -83	-99, -61
Percent Change from Baseline to Cycle 30 Day 1				
n	2	4	2	8
Mean (StdDev)	-84.3 (3.48)	-94.2 (2.86)	-93.3 (6.70)	-91.5 (5.63)
Median	-84.3	-94.3	-93.3	-91.8
Min, Max	-87, -82	-97, -91	-98, -89	-98, -82

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Overall

Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=12)	SM-AHN (N=54)	MCL (N=17)	All AdvSM (N=83)
Percent Change from Baseline to Cycle 36 Day 1				
n	2	4	0	6
Mean (StdDev)	-89.2 (1.96)	-94.9 (2.43)		-93.0 (3.61)
Median	-89.2	-94.1		-93.2
Min, Max	-91, -88	-98, -93		-98, -88
Percent Change from Baseline to Cycle 42 Day 1				
n	1	3	1	5
Mean (StdDev)	-87.8 (-)	-93.7 (4.75)	-97.0 (-)	-93.2 (4.75)
Median	-87.8	-94.7	-97.0	-94.7
Min, Max	-88, -88	-98, -89	-97, -97	-98, -88
Percent Change from Baseline to Cycle 48 Day 1				
n	1	0	1	2
Mean (StdDev)	-90.0 (-)		-97.0 (-)	-93.5 (4.96)
Median	-90.0		-97.0	-93.5
Min, Max	-90, -90		-97, -97	-97, -90

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg

Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=2)	SM-AHN (N=3)	MCL (N=1)	All AdvSM (N=6)
Baseline				
n	2	3	1	6
Mean (StdDev)	779.7 (897.53)	569.5 (892.44)	226.6 (-)	582.4 (721.58)
Median	779.7	55.9	226.6	185.8
Min, Max	145, 1414	53, 1600	227, 227	53, 1600
Percent Change from Baseline to Cycle 1 Day 15				
n	2	3	1	6
Mean (StdDev)	-73.2 (22.53)	-38.3 (36.82)	-41.1 (-)	-50.4 (30.94)
Median	-73.2	-57.0	-41.1	-57.2
Min, Max	-89, -57	-62, 4	-41, -41	-89, 4
Percent Change from Baseline to Cycle 2 Day 1				
n	1	3	1	5
Mean (StdDev)	-70.1 (-)	-54.2 (47.57)	-62.1 (-)	-59.0 (34.38)
Median	-70.1	-76.1	-62.1	-70.1
Min, Max	-70, -70	-87, 0	-62, -62	-87, 0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=2)	SM-AHN (N=3)	MCL (N=1)	All AdvSM (N=6)
Percent Change from Baseline to Cycle 3 Day 1				
n	1	3	1	5
Mean (StdDev)	-73.5 (-)	-44.6 (58.94)	-72.3 (-)	-55.9 (44.46)
Median	-73.5	-66.0	-72.3	-72.3
Min, Max	-73, -73	-90, 22	-72, -72	-90, 22
Percent Change from Baseline to Cycle 5 Day 1				
n	1	2	1	4
Mean (StdDev)	-84.2 (-)	-30.5 (80.56)	-60.9 (-)	-51.5 (53.32)
Median	-84.2	-30.5	-60.9	-72.5
Min, Max	-84, -84	-87, 26	-61, -61	-87, 26
Percent Change from Baseline to Cycle 7 Day 1				
n	1	3	1	5
Mean (StdDev)	-82.5 (-)	-42.7 (39.94)	-56.0 (-)	-53.3 (33.12)
Median	-82.5	-52.5	-56.0	-56.0
Min, Max	-82, -82	-77, 1	-56, -56	-82, 1
Percent Change from Baseline to Cycle 11 Day 1				
n	1	3	1	5
Mean (StdDev)	-81.1 (-)	-55.0 (20.44)	-67.0 (-)	-62.6 (18.51)
Median	-81.1	-54.2	-67.0	-67.0
Min, Max	-81, -81	-76, -35	-67, -67	-81, -35

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=2)	SM-AHN (N=3)	MCL (N=1)	All AdvSM (N=6)
Percent Change from Baseline to Cycle 18 Day 1				
n	1	2	1	4
Mean (StdDev)	-90.8 (-)	-89.3 (5.93)	-83.8 (-)	-88.3 (4.61)
Median	-90.8	-89.3	-83.8	-88.0
Min, Max	-91, -91	-94, -85	-84, -84	-94, -84
Percent Change from Baseline to Cycle 24 Day 1				
n	1	2	1	4
Mean (StdDev)	-80.3 (-)	-91.4 (5.49)	-82.7 (-)	-86.4 (6.59)
Median	-80.3	-91.4	-82.7	-85.1
Min, Max	-80, -80	-95, -87	-83, -83	-95, -80
Percent Change from Baseline to Cycle 30 Day 1				
n	1	2	1	4
Mean (StdDev)	-81.8 (-)	-94.3 (2.89)	-88.6 (-)	-89.8 (6.18)
Median	-81.8	-94.3	-88.6	-90.4
Min, Max	-82, -82	-96, -92	-89, -89	-96, -82
Percent Change from Baseline to Cycle 36 Day 1				
n	1	2	0	3
Mean (StdDev)	-87.8 (-)	-94.1 (1.05)		-92.0 (3.70)
Median	-87.8	-94.1		-93.4
Min, Max	-88, -88	-95, -93		-95, -88

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=2)	SM-AHN (N=3)	MCL (N=1)	All AdvSM (N=6)
Percent Change from Baseline to Cycle 42 Day 1				
n	1	2	1	4
Mean (StdDev)	-87.8 (-)	-91.6 (4.33)	-97.0 (-)	-92.0 (4.56)
Median	-87.8	-91.6	-97.0	-91.6
Min, Max	-88, -88	-95, -89	-97, -97	-97, -88
Percent Change from Baseline to Cycle 48 Day 1				
n	1	0	1	2
Mean (StdDev)	-90.0 (-)		-97.0 (-)	-93.5 (4.96)
Median	-90.0		-97.0	-93.5
Min, Max	-90, -90		-97, -97	-97, -90

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=7)	SM-AHN (N=37)	MCL (N=14)	All AdvSM (N=58)
Baseline				
n	7	37	14	58
Mean (StdDev)	360.2 (496.20)	350.8 (318.53)	473.3 (382.43)	381.5 (355.09)
Median	145.0	262.0	329.6	303.6
Min, Max	20, 1414	41, 1600	31, 1600	20, 1600
Percent Change from Baseline to Cycle 1 Day 15				
n	7	33	13	53
Mean (StdDev)	-72.0 (12.75)	-60.4 (26.59)	-60.5 (20.19)	-62.0 (23.74)
Median	-68.3	-69.5	-68.5	-68.5
Min, Max	-89, -57	-94, 4	-82, -7	-94, 4
Percent Change from Baseline to Cycle 2 Day 1				
n	5	32	14	51
Mean (StdDev)	-71.0 (24.63)	-69.1 (28.66)	-65.5 (20.74)	-68.3 (25.94)
Median	-73.9	-78.6	-71.5	-73.9
Min, Max	-93, -30	-99, 0	-90, -9	-99, 0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg

Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=7)	SM-AHN (N=37)	MCL (N=14)	All AdvSM (N=58)
Percent Change from Baseline to Cycle 3 Day 1				
n	6	28	12	46
Mean (StdDev)	-77.7 (17.62)	-65.6 (38.73)	-65.7 (25.72)	-67.2 (33.37)
Median	-79.0	-80.2	-75.3	-76.1
Min, Max	-97, -48	-99, 28	-91, -6	-99, 28
Percent Change from Baseline to Cycle 5 Day 1				
n	2	6	5	13
Mean (StdDev)	-77.3 (9.78)	-14.4 (88.65)	-76.4 (19.16)	-47.9 (66.69)
Median	-77.3	-30.5	-86.9	-84.2
Min, Max	-84, -70	-94, 116	-96, -51	-96, 116
Percent Change from Baseline to Cycle 7 Day 1				
n	2	22	7	31
Mean (StdDev)	-55.7 (37.86)	-40.5 (163.58)	-77.4 (18.68)	-49.8 (138.18)
Median	-55.7	-82.8	-87.6	-82.5
Min, Max	-82, -29	-99, 682	-93, -48	-99, 682
Percent Change from Baseline to Cycle 11 Day 1				
n	1	13	5	19
Mean (StdDev)	-81.1 (-)	-77.4 (21.45)	-85.7 (12.38)	-79.8 (18.83)
Median	-81.1	-80.9	-91.4	-81.1
Min, Max	-81, -81	-98, -35	-96, -67	-98, -35

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=7)	SM-AHN (N=37)	MCL (N=14)	All AdvSM (N=58)
Percent Change from Baseline to Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		-77.1 (-)	-90.4 (-)	-83.7 (9.39)
Median		-77.1	-90.4	-83.7
Min, Max		-77, -77	-90, -90	-90, -77
Percent Change from Baseline to Cycle 18 Day 1				
n	1	2	2	5
Mean (StdDev)	-90.8 (-)	-89.3 (5.93)	-90.3 (9.23)	-90.0 (5.52)
Median	-90.8	-89.3	-90.3	-90.8
Min, Max	-91, -91	-94, -85	-97, -84	-97, -84
Percent Change from Baseline to Cycle 24 Day 1				
n	1	3	1	5
Mean (StdDev)	-80.3 (-)	-92.3 (4.22)	-82.7 (-)	-88.0 (6.69)
Median	-80.3	-94.2	-82.7	-87.5
Min, Max	-80, -80	-95, -87	-83, -83	-95, -80
Percent Change from Baseline to Cycle 30 Day 1				
n	1	3	1	5
Mean (StdDev)	-81.8 (-)	-95.2 (2.55)	-88.6 (-)	-91.2 (6.25)
Median	-81.8	-96.4	-88.6	-92.3
Min, Max	-82, -82	-97, -92	-89, -89	-97, -82

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=7)	SM-AHN (N=37)	MCL (N=14)	All AdvSM (N=58)
Percent Change from Baseline to Cycle 36 Day 1				
n	1	3	0	4
Mean (StdDev)	-87.8 (-)	-95.6 (2.58)		-93.6 (4.39)
Median	-87.8	-94.9		-94.1
Min, Max	-88, -88	-98, -93		-98, -88
Percent Change from Baseline to Cycle 42 Day 1				
n	1	3	1	5
Mean (StdDev)	-87.8 (-)	-93.7 (4.75)	-97.0 (-)	-93.2 (4.75)
Median	-87.8	-94.7	-97.0	-94.7
Min, Max	-88, -88	-98, -89	-97, -97	-98, -88
Percent Change from Baseline to Cycle 48 Day 1				
n	1	0	1	2
Mean (StdDev)	-90.0 (-)		-97.0 (-)	-93.5 (4.96)
Median	-90.0		-97.0	-93.5
Min, Max	-90, -90		-97, -97	-97, -90

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas
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Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=5)	SM-AHN (N=34)	MCL (N=13)	All AdvSM (N=52)
Baseline				
n	5	34	13	52
Mean (StdDev)	192.4 (211.55)	331.5 (240.17)	492.3 (391.13)	358.4 (290.83)
Median	90.2	266.0	334.0	312.0
Min, Max	20, 492	41, 856	31, 1600	20, 1600
Percent Change from Baseline to Cycle 1 Day 15				
n	5	30	12	47
Mean (StdDev)	-71.6 (10.77)	-62.6 (25.12)	-62.1 (20.20)	-63.4 (22.66)
Median	-68.3	-72.0	-68.5	-68.9
Min, Max	-87, -60	-94, -9	-82, -7	-94, -7
Percent Change from Baseline to Cycle 2 Day 1				
n	4	29	13	46
Mean (StdDev)	-71.3 (28.43)	-70.7 (26.86)	-65.7 (21.57)	-69.3 (25.14)
Median	-80.8	-81.2	-71.6	-74.7
Min, Max	-93, -30	-99, -9	-90, -9	-99, -9

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=5)	SM-AHN (N=34)	MCL (N=13)	All AdvSM (N=52)
Percent Change from Baseline to Cycle 3 Day 1				
n	5	25	11	41
Mean (StdDev)	-78.6 (19.56)	-68.1 (36.56)	-65.1 (26.89)	-68.5 (32.20)
Median	-84.6	-84.4	-76.0	-79.1
Min, Max	-97, -48	-99, 28	-91, -6	-99, 28
Percent Change from Baseline to Cycle 5 Day 1				
n	1	4	4	9
Mean (StdDev)	-70.4 (-)	-6.4 (103.32)	-80.3 (19.72)	-46.3 (74.80)
Median	-70.4	-24.1	-86.9	-86.9
Min, Max	-70, -70	-94, 116	-96, -51	-96, 116
Percent Change from Baseline to Cycle 7 Day 1				
n	1	19	6	26
Mean (StdDev)	-28.9 (-)	-40.1 (176.19)	-81.0 (17.67)	-49.1 (150.78)
Median	-28.9	-87.9	-89.4	-87.8
Min, Max	-29, -29	-99, 682	-93, -48	-99, 682
Percent Change from Baseline to Cycle 11 Day 1				
n	0	10	4	14
Mean (StdDev)		-84.2 (17.40)	-90.4 (7.61)	-86.0 (15.21)
Median		-93.1	-93.0	-93.1
Min, Max		-98, -44	-96, -79	-98, -44

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.

Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas
Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=5)	SM-AHN (N=34)	MCL (N=13)	All AdvSM (N=52)
Percent Change from Baseline to Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		-77.1 (-)	-90.4 (-)	-83.7 (9.39)
Median		-77.1	-90.4	-83.7
Min, Max		-77, -77	-90, -90	-90, -77
Percent Change from Baseline to Cycle 18 Day 1				
n	0	0	1	1
Mean (StdDev)			-96.9 (-)	-96.9 (-)
Median			-96.9	-96.9
Min, Max			-97, -97	-97, -97
Percent Change from Baseline to Cycle 24 Day 1				
n	0	1	0	1
Mean (StdDev)		-94.2 (-)		-94.2 (-)
Median		-94.2		-94.2
Min, Max		-94, -94		-94, -94
Percent Change from Baseline to Cycle 30 Day 1				
n	0	1	0	1
Mean (StdDev)		-97.0 (-)		-97.0 (-)
Median		-97.0		-97.0
Min, Max		-97, -97		-97, -97

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=5)	SM-AHN (N=34)	MCL (N=13)	All AdvSM (N=52)
Percent Change from Baseline to Cycle 36 Day 1				
n	0	1	0	1
Mean (StdDev)		-98.4 (-)		-98.4 (-)
Median		-98.4		-98.4
Min, Max		-98, -98		-98, -98
Percent Change from Baseline to Cycle 42 Day 1				
n	0	1	0	1
Mean (StdDev)		-97.9 (-)		-97.9 (-)
Median		-97.9		-97.9
Min, Max		-98, -98		-98, -98

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Baseline				
n	4	13	3	20
Mean (StdDev)	330.8 (123.55)	286.9 (184.33)	400.7 (311.31)	312.7 (189.26)
Median	313.8	367.4	227.1	313.8
Min, Max	205, 491	21, 631	215, 760	21, 760
Percent Change from Baseline to Cycle 1 Day 15				
n	3	13	3	19
Mean (StdDev)	-75.4 (11.68)	-66.8 (15.95)	-73.3 (15.22)	-69.2 (14.96)
Median	-74.8	-66.2	-71.7	-68.8
Min, Max	-87, -64	-90, -41	-89, -59	-90, -41
Percent Change from Baseline to Cycle 2 Day 1				
n	4	13	3	20
Mean (StdDev)	-81.1 (10.94)	-73.8 (21.08)	-72.7 (25.17)	-75.1 (19.38)
Median	-81.3	-80.9	-79.3	-80.1
Min, Max	-94, -68	-97, -40	-94, -45	-97, -40

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Percent Change from Baseline to Cycle 3 Day 1				
n	3	13	3	19
Mean (StdDev)	-85.9 (9.15)	-78.3 (20.99)	-80.9 (18.47)	-79.9 (18.68)
Median	-81.2	-87.9	-85.3	-85.3
Min, Max	-96, -80	-99, -40	-97, -61	-99, -40
Percent Change from Baseline to Cycle 5 Day 1				
n	3	13	3	19
Mean (StdDev)	-89.4 (1.91)	-81.7 (18.91)	-86.2 (6.31)	-83.6 (15.89)
Median	-90.2	-94.1	-86.9	-90.2
Min, Max	-91, -87	-98, -52	-92, -80	-98, -52
Percent Change from Baseline to Cycle 7 Day 1				
n	3	8	2	13
Mean (StdDev)	-93.0 (4.16)	-83.1 (17.32)	-51.1 (60.78)	-80.5 (25.95)
Median	-91.3	-93.0	-51.1	-91.3
Min, Max	-98, -90	-98, -56	-94, -8	-98, -8
Percent Change from Baseline to Cycle 11 Day 1				
n	3	7	2	12
Mean (StdDev)	-92.7 (4.88)	-84.9 (16.95)	-38.4 (82.58)	-79.1 (33.96)
Median	-90.4	-96.4	-38.4	-93.4
Min, Max	-98, -89	-99, -58	-97, 20	-99, 20

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Percent Change from Baseline to Cycle 18 Day 1				
n	2	6	1	9
Mean (StdDev)	-92.8 (3.23)	-87.8 (11.30)	-97.4 (-)	-90.0 (9.67)
Median	-92.8	-91.0	-97.4	-95.1
Min, Max	-95, -91	-99, -71	-97, -97	-99, -71
Percent Change from Baseline to Cycle 24 Day 1				
n	2	4	1	7
Mean (StdDev)	-92.0 (6.65)	-84.8 (17.01)	-97.3 (-)	-88.7 (13.34)
Median	-92.0	-89.4	-97.3	-95.5
Min, Max	-97, -87	-99, -61	-97, -97	-99, -61
Percent Change from Baseline to Cycle 30 Day 1				
n	1	0	1	2
Mean (StdDev)	-86.8 (-)		-98.0 (-)	-92.4 (7.98)
Median	-86.8		-98.0	-92.4
Min, Max	-87, -87		-98, -98	-98, -87
Percent Change from Baseline to Cycle 36 Day 1				
n	1	0	0	1
Mean (StdDev)	-90.6 (-)			-90.6 (-)
Median	-90.6			-90.6
Min, Max	-91, -91			-91, -91

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=9)	SM-AHN (N=47)	MCL (N=16)	All AdvSM (N=72)
Baseline				
n	9	47	16	72
Mean (StdDev)	253.9 (182.81)	319.2 (225.06)	475.1 (369.69)	345.7 (266.02)
Median	270.5	270.0	329.6	312.0
Min, Max	20, 492	21, 856	31, 1600	20, 1600
Percent Change from Baseline to Cycle 1 Day 15				
n	8	43	15	66
Mean (StdDev)	-73.0 (10.45)	-63.9 (22.63)	-64.4 (19.36)	-65.1 (20.79)
Median	-71.6	-69.5	-68.6	-68.8
Min, Max	-87, -60	-94, -9	-89, -7	-94, -7
Percent Change from Baseline to Cycle 2 Day 1				
n	8	42	16	66
Mean (StdDev)	-76.2 (20.62)	-71.6 (25.00)	-67.0 (21.55)	-71.1 (23.55)
Median	-81.3	-81.0	-71.8	-77.7
Min, Max	-94, -30	-99, -9	-94, -9	-99, -9

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=9)	SM-AHN (N=47)	MCL (N=16)	All AdvSM (N=72)
Percent Change from Baseline to Cycle 3 Day 1				
n	8	38	14	60
Mean (StdDev)	-81.3 (16.02)	-71.6 (32.15)	-68.5 (25.58)	-72.1 (28.95)
Median	-82.9	-85.5	-77.6	-82.4
Min, Max	-97, -48	-99, 28	-97, -6	-99, 28
Percent Change from Baseline to Cycle 5 Day 1				
n	4	17	7	28
Mean (StdDev)	-84.7 (9.66)	-64.0 (57.92)	-82.8 (14.75)	-71.7 (46.27)
Median	-88.7	-90.3	-86.9	-87.2
Min, Max	-91, -70	-98, 116	-96, -51	-98, 116
Percent Change from Baseline to Cycle 7 Day 1				
n	4	27	8	39
Mean (StdDev)	-77.0 (32.23)	-52.9 (148.23)	-73.5 (30.69)	-59.6 (124.07)
Median	-90.7	-90.2	-89.4	-90.2
Min, Max	-98, -29	-99, 682	-94, -8	-99, 682
Percent Change from Baseline to Cycle 11 Day 1				
n	3	17	6	26
Mean (StdDev)	-92.7 (4.88)	-84.5 (16.68)	-73.1 (46.03)	-82.8 (25.30)
Median	-90.4	-93.2	-93.0	-93.1
Min, Max	-98, -89	-99, -44	-97, 20	-99, 20

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=9)	SM-AHN (N=47)	MCL (N=16)	All AdvSM (N=72)
Percent Change from Baseline to Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		-77.1 (-)	-90.4 (-)	-83.7 (9.39)
Median		-77.1	-90.4	-83.7
Min, Max		-77, -77	-90, -90	-90, -77
Percent Change from Baseline to Cycle 18 Day 1				
n	2	6	2	10
Mean (StdDev)	-92.8 (3.23)	-87.8 (11.30)	-97.1 (0.38)	-90.7 (9.37)
Median	-92.8	-91.0	-97.1	-95.3
Min, Max	-95, -91	-99, -71	-97, -97	-99, -71
Percent Change from Baseline to Cycle 24 Day 1				
n	2	5	1	8
Mean (StdDev)	-92.0 (6.65)	-86.7 (15.32)	-97.3 (-)	-89.4 (12.51)
Median	-92.0	-94.2	-97.3	-94.9
Min, Max	-97, -87	-99, -61	-97, -97	-99, -61
Percent Change from Baseline to Cycle 30 Day 1				
n	1	1	1	3
Mean (StdDev)	-86.8 (-)	-97.0 (-)	-98.0 (-)	-93.9 (6.23)
Median	-86.8	-97.0	-98.0	-97.0
Min, Max	-87, -87	-97, -97	-98, -98	-98, -87

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=9)	SM-AHN (N=47)	MCL (N=16)	All AdvSM (N=72)
Percent Change from Baseline to Cycle 36 Day 1				
n	1	1	0	2
Mean (StdDev)	-90.6 (-)	-98.4 (-)		-94.5 (5.50)
Median	-90.6	-98.4		-94.5
Min, Max	-91, -91	-98, -98		-98, -91
Percent Change from Baseline to Cycle 42 Day 1				
n	0	1	0	1
Mean (StdDev)		-97.9 (-)		-97.9 (-)
Median		-97.9		-97.9
Min, Max		-98, -98		-98, -98

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Baseline				
n	1	4	0	5
Mean (StdDev)	31.2 (-)	127.3 (69.95)		108.1 (74.28)
Median	31.2	151.0		130.0
Min, Max	31, 31	28, 180		28, 180
Percent Change from Baseline to Cycle 1 Day 15				
n	1	4	0	5
Mean (StdDev)	-66.7 (-)	-83.7 (3.67)		-80.3 (8.24)
Median	-66.7	-84.2		-81.9
Min, Max	-67, -67	-87, -79		-87, -67
Percent Change from Baseline to Cycle 2 Day 1				
n	1	3	0	4
Mean (StdDev)	-81.1 (-)	-90.1 (0.67)		-87.8 (4.53)
Median	-81.1	-90.2		-89.8
Min, Max	-81, -81	-91, -89		-91, -81

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Percent Change from Baseline to Cycle 3 Day 1				
n	1	2	0	3
Mean (StdDev)	-84.9 (-)	-93.8 (3.55)		-90.9 (5.71)
Median	-84.9	-93.8		-91.3
Min, Max	-85, -85	-96, -91		-96, -85
Percent Change from Baseline to Cycle 5 Day 1				
n	1	3	0	4
Mean (StdDev)	-88.1 (-)	-81.9 (19.47)		-83.4 (16.20)
Median	-88.1	-91.6		-89.9
Min, Max	-88, -88	-95, -59		-95, -59
Percent Change from Baseline to Cycle 7 Day 1				
n	1	2	0	3
Mean (StdDev)	-85.3 (-)	-86.9 (5.66)		-86.4 (4.11)
Median	-85.3	-86.9		-85.3
Min, Max	-85, -85	-91, -83		-91, -83
Percent Change from Baseline to Cycle 11 Day 1				
n	0	1	0	1
Mean (StdDev)		-63.7 (-)		-63.7 (-)
Median		-63.7		-63.7
Min, Max		-64, -64		-64, -64

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.6.2
Summary of Serum Tryptase Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg				
Serum Tryptase (ug/L) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Percent Change from Baseline to Cycle 24 Day 1				
n	0	1	0	1
Mean (StdDev)		-97.7 (-)		-97.7 (-)
Median		-97.7		-97.7
Min, Max		-98, -98		-98, -98
Percent Change from Baseline to Cycle 30 Day 1				
n	0	1	0	1
Mean (StdDev)		-91.3 (-)		-91.3 (-)
Median		-91.3		-91.3
Min, Max		-91, -91		-91, -91
Percent Change from Baseline to Cycle 36 Day 1				
n	0	1	0	1
Mean (StdDev)		-93.1 (-)		-93.1 (-)
Median		-93.1		-93.1
Min, Max		-93, -93		-93, -93

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-serum-pchg-advsm.sas Date: 19:34/27SEP2021

Table 99.2.6.3.1b
Summary of Serum Tryptase Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101 & 200 mg Dose Group

Prior antineoplastic therapy = Yes						
Serum Tryptase Best Response	ASM (N=1) n (%)	SM-AHN (N=7) n (%)	MCL (N=4) n (%)	All AdvSM (N=12) n (%)	ISM/SSM (N=1) n (%)	All Patients (N=13) n (%)
Patients with baseline serum tryptase assessment	1	7	4	12	1	13
Patients achieved serum tryptase < 20 ng/mL (CR)	1 (100.0)	5 (71.4)	1 (25.0)	7 (58.3)	1 (100.0)	8 (61.5)
Patients achieved >= 50 % reduction from baseline	1 (100.0)	6 (85.7)	4 (100.0)	11 (91.7)	1 (100.0)	12 (92.3)
Patients achieved >= 50 % reduction from baseline for at least 2 cycles (PR)	1 (100.0)	4 (57.1)	3 (75.0)	8 (66.7)	1 (100.0)	9 (69.2)
Patients with serum tryptase >= 40 ng/mL	0	7	4	11	0	11
Patients achieved serum tryptase < 20 ng/mL (CR)	0	5 (71.4)	1 (25.0)	6 (54.5)	0	6 (54.5)
Patients achieved >= 50 % reduction from baseline	0	6 (85.7)	4 (100.0)	10 (90.9)	0	10 (90.9)
Patients achieved >= 50 % reduction from baseline for at least 2 cycles (PR)	0	4 (57.1)	3 (75.0)	7 (63.6)	0	7 (63.6)

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. If a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/EMA_D120/t99.2.6.3.1b-serum-resp-nat.sas Date: 10:50/04AUG2021

Table 99.2.6.3.1b
Summary of Serum Tryptase Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101 & <=200 mg Dose Group

Prior antineoplastic therapy = Yes

Serum Tryptase Best Response	ASM (N=2) n (%)	SM-AHN (N=9) n (%)	MCL (N=5) n (%)	All AdvSM (N=16) n (%)	ISM/SSM (N=4) n (%)	All Patients (N=20) n (%)
Patients with baseline serum tryptase assessment	2	9	5	16	4	20
Patients achieved serum tryptase < 20 ng/mL (CR)	1 (50.0)	7 (77.8)	2 (40.0)	10 (62.5)	4 (100.0)	14 (70.0)
Patients achieved >= 50 % reduction from baseline	2 (100.0)	8 (88.9)	5 (100.0)	15 (93.8)	4 (100.0)	19 (95.0)
Patients achieved >= 50 % reduction from baseline for at least 2 cycles (PR)	2 (100.0)	6 (66.7)	4 (80.0)	12 (75.0)	4 (100.0)	16 (80.0)
Patients with serum tryptase >= 40 ng/mL	1	9	5	15	3	18
Patients achieved serum tryptase < 20 ng/mL (CR)	0	7 (77.8)	2 (40.0)	9 (60.0)	3 (100.0)	12 (66.7)
Patients achieved >= 50 % reduction from baseline	1 (100.0)	8 (88.9)	5 (100.0)	14 (93.3)	3 (100.0)	17 (94.4)
Patients achieved >= 50 % reduction from baseline for at least 2 cycles (PR)	1 (100.0)	6 (66.7)	4 (80.0)	11 (73.3)	3 (100.0)	14 (77.8)

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. If a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
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Table 99.2.6.3.1b
Summary of Serum Tryptase Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101 & All Dose Groups

Prior antineoplastic therapy = Yes

Serum Tryptase Best Response	ASM (N=7) n (%)	SM-AHN (N=26) n (%)	MCL (N=8) n (%)	All AdvSM (N=41) n (%)	ISM/SSM (N=9) n (%)	All Patients (N=50) n (%)
Patients with baseline serum tryptase assessment	7	26	8	41	9	50
Patients achieved serum tryptase < 20 ng/mL (CR)	5 (71.4)	21 (80.8)	3 (37.5)	29 (70.7)	8 (88.9)	37 (74.0)
Patients achieved >= 50 % reduction from baseline	7 (100.0)	25 (96.2)	8 (100.0)	40 (97.6)	9 (100.0)	49 (98.0)
Patients achieved >= 50 % reduction from baseline for at least 2 cycles (PR)	7 (100.0)	23 (88.5)	7 (87.5)	37 (90.2)	8 (88.9)	45 (90.0)
Patients with serum tryptase >= 40 ng/mL	5	24	8	37	7	44
Patients achieved serum tryptase < 20 ng/mL (CR)	3 (60.0)	19 (79.2)	3 (37.5)	25 (67.6)	6 (85.7)	31 (70.5)
Patients achieved >= 50 % reduction from baseline	5 (100.0)	23 (95.8)	8 (100.0)	36 (97.3)	7 (100.0)	43 (97.7)
Patients achieved >= 50 % reduction from baseline for at least 2 cycles (PR)	5 (100.0)	21 (87.5)	7 (87.5)	33 (89.2)	6 (85.7)	39 (88.6)

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. If a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
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Table 99.2.6.3.1b
Summary of Serum Tryptase Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101 & 200 mg Dose Group

Prior antineoplastic therapy = No						
Serum Tryptase Best Response	ASM (N=0) n (%)	SM-AHN (N=6) n (%)	MCL (N=2) n (%)	All AdvSM (N=8) n (%)	ISM/SSM (N=0) n (%)	All Patients (N=8) n (%)
Patients with baseline serum tryptase assessment	0	6	2	8	0	8
Patients achieved serum tryptase < 20 ng/mL (CR)	0	3 (50.0)	2 (100.0)	5 (62.5)	0	5 (62.5)
Patients achieved >= 50 % reduction from baseline	0	6 (100.0)	2 (100.0)	8 (100.0)	0	8 (100.0)
Patients achieved >= 50 % reduction from baseline for at least 2 cycles (PR)	0	4 (66.7)	2 (100.0)	6 (75.0)	0	6 (75.0)
Patients with serum tryptase >= 40 ng/mL	0	6	2	8	0	8
Patients achieved serum tryptase < 20 ng/mL (CR)	0	3 (50.0)	2 (100.0)	5 (62.5)	0	5 (62.5)
Patients achieved >= 50 % reduction from baseline	0	6 (100.0)	2 (100.0)	8 (100.0)	0	8 (100.0)
Patients achieved >= 50 % reduction from baseline for at least 2 cycles (PR)	0	4 (66.7)	2 (100.0)	6 (75.0)	0	6 (75.0)

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. If a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
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Table 99.2.6.3.1b
Summary of Serum Tryptase Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101 & <=200 mg Dose Group

Prior antineoplastic therapy = No

Serum Tryptase Best Response	ASM (N=0) n (%)	SM-AHN (N=11) n (%)	MCL (N=2) n (%)	All AdvSM (N=13) n (%)	ISM/SSM (N=2) n (%)	All Patients (N=15) n (%)
Patients with baseline serum tryptase assessment	0	11	2	13	2	15
Patients achieved serum tryptase < 20 ng/mL (CR)	0	7 (63.6)	2 (100.0)	9 (69.2)	2 (100.0)	11 (73.3)
Patients achieved >= 50 % reduction from baseline	0	11 (100.0)	2 (100.0)	13 (100.0)	2 (100.0)	15 (100.0)
Patients achieved >= 50 % reduction from baseline for at least 2 cycles (PR)	0	9 (81.8)	2 (100.0)	11 (84.6)	2 (100.0)	13 (86.7)
Patients with serum tryptase >= 40 ng/mL	0	11	2	13	2	15
Patients achieved serum tryptase < 20 ng/mL (CR)	0	7 (63.6)	2 (100.0)	9 (69.2)	2 (100.0)	11 (73.3)
Patients achieved >= 50 % reduction from baseline	0	11 (100.0)	2 (100.0)	13 (100.0)	2 (100.0)	15 (100.0)
Patients achieved >= 50 % reduction from baseline for at least 2 cycles (PR)	0	9 (81.8)	2 (100.0)	11 (84.6)	2 (100.0)	13 (86.7)

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. If a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
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Table 99.2.6.3.1b
Summary of Serum Tryptase Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101 & All Dose Groups

Prior antineoplastic therapy = No

Serum Tryptase Best Response	ASM (N=1) n (%)	SM-AHN (N=22) n (%)	MCL (N=5) n (%)	All AdvSM (N=28) n (%)	ISM/SSM (N=7) n (%)	All Patients (N=35) n (%)
Patients with baseline serum tryptase assessment	1	22	5	28	7	35
Patients achieved serum tryptase < 20 ng/mL (CR)	1 (100.0)	17 (77.3)	4 (80.0)	22 (78.6)	7 (100.0)	29 (82.9)
Patients achieved >= 50 % reduction from baseline	1 (100.0)	22 (100.0)	5 (100.0)	28 (100.0)	7 (100.0)	35 (100.0)
Patients achieved >= 50 % reduction from baseline for at least 2 cycles (PR)	1 (100.0)	20 (90.9)	5 (100.0)	26 (92.9)	7 (100.0)	33 (94.3)
Patients with serum tryptase >= 40 ng/mL	1	20	5	26	6	32
Patients achieved serum tryptase < 20 ng/mL (CR)	1 (100.0)	15 (75.0)	4 (80.0)	20 (76.9)	6 (100.0)	26 (81.3)
Patients achieved >= 50 % reduction from baseline	1 (100.0)	20 (100.0)	5 (100.0)	26 (100.0)	6 (100.0)	32 (100.0)
Patients achieved >= 50 % reduction from baseline for at least 2 cycles (PR)	1 (100.0)	18 (90.0)	5 (100.0)	24 (92.3)	6 (100.0)	30 (93.8)

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. If a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
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Table 99.2.6.3.1b
Summary of Serum Tryptase Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2202 & 200 mg Dose Group

Prior antineoplastic therapy = Yes

Serum Tryptase Best Response	ASM (N=4) n (%)	SM-AHN (N=27) n (%)	MCL (N=9) n (%)	All AdvSM (N=40) n (%)
Patients with baseline serum tryptase assessment	4	27	9	40
Patients achieved serum tryptase < 20 ng/mL (CR)	2 (50.0)	10 (37.0)	1 (11.1)	13 (32.5)
Patients achieved >= 50 % reduction from baseline	4 (100.0)	22 (81.5)	8 (88.9)	34 (85.0)
Patients achieved >= 50 % reduction from baseline for at least 2 cycles (PR)	1 (25.0)	12 (44.4)	3 (33.3)	16 (40.0)
Patients with serum tryptase >= 40 ng/mL	3	27	8	38
Patients achieved serum tryptase < 20 ng/mL (CR)	1 (33.3)	10 (37.0)	0	11 (28.9)
Patients achieved >= 50 % reduction from baseline	3 (100.0)	22 (81.5)	7 (87.5)	32 (84.2)
Patients achieved >= 50 % reduction from baseline for at least 2 cycles (PR)	0	12 (44.4)	3 (37.5)	15 (39.5)

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. If a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.

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Table 99.2.6.3.1b
Summary of Serum Tryptase Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2202 & <=200 mg Dose Group

Prior antineoplastic therapy = Yes				
Serum Tryptase Best Response	ASM (N=5) n (%)	SM-AHN (N=28) n (%)	MCL (N=9) n (%)	All AdvSM (N=42) n (%)
Patients with baseline serum tryptase assessment	5	28	9	42
Patients achieved serum tryptase < 20 ng/mL (CR)	3 (60.0)	10 (35.7)	1 (11.1)	14 (33.3)
Patients achieved >= 50 % reduction from baseline	5 (100.0)	23 (82.1)	8 (88.9)	36 (85.7)
Patients achieved >= 50 % reduction from baseline for at least 2 cycles (PR)	1 (20.0)	13 (46.4)	3 (33.3)	17 (40.5)
Patients with serum tryptase >= 40 ng/mL	4	28	8	40
Patients achieved serum tryptase < 20 ng/mL (CR)	2 (50.0)	10 (35.7)	0	12 (30.0)
Patients achieved >= 50 % reduction from baseline	4 (100.0)	23 (82.1)	7 (87.5)	34 (85.0)
Patients achieved >= 50 % reduction from baseline for at least 2 cycles (PR)	0	13 (46.4)	3 (37.5)	16 (40.0)

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. If a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
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Table 99.2.6.3.1b
Summary of Serum Tryptase Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2202 & All Dose Groups

Prior antineoplastic therapy = Yes				
Serum Tryptase Best Response	ASM (N=5) n (%)	SM-AHN (N=28) n (%)	MCL (N=9) n (%)	All AdvSM (N=42) n (%)
Patients with baseline serum tryptase assessment	5	28	9	42
Patients achieved serum tryptase < 20 ng/mL (CR)	3 (60.0)	10 (35.7)	1 (11.1)	14 (33.3)
Patients achieved >= 50 % reduction from baseline	5 (100.0)	23 (82.1)	8 (88.9)	36 (85.7)
Patients achieved >= 50 % reduction from baseline for at least 2 cycles (PR)	1 (20.0)	13 (46.4)	3 (33.3)	17 (40.5)
Patients with serum tryptase >= 40 ng/mL	4	28	8	40
Patients achieved serum tryptase < 20 ng/mL (CR)	2 (50.0)	10 (35.7)	0	12 (30.0)
Patients achieved >= 50 % reduction from baseline	4 (100.0)	23 (82.1)	7 (87.5)	34 (85.0)
Patients achieved >= 50 % reduction from baseline for at least 2 cycles (PR)	0	13 (46.4)	3 (37.5)	16 (40.0)

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. If a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
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Table 99.2.6.3.1b
Summary of Serum Tryptase Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2202 & 200 mg Dose Group

Prior antineoplastic therapy = No

Serum Tryptase Best Response	ASM (N=4) n (%)	SM-AHN (N=15) n (%)	MCL (N=1) n (%)	All AdvSM (N=20) n (%)
Patients with baseline serum tryptase assessment	4	15	1	20
Patients achieved serum tryptase < 20 ng/mL (CR)	2 (50.0)	9 (60.0)	0	11 (55.0)
Patients achieved >= 50 % reduction from baseline	3 (75.0)	14 (93.3)	1 (100.0)	18 (90.0)
Patients achieved >= 50 % reduction from baseline for at least 2 cycles (PR)	1 (25.0)	8 (53.3)	0	9 (45.0)
Patients with serum tryptase >= 40 ng/mL	4	14	1	19
Patients achieved serum tryptase < 20 ng/mL (CR)	2 (50.0)	8 (57.1)	0	10 (52.6)
Patients achieved >= 50 % reduction from baseline	3 (75.0)	13 (92.9)	1 (100.0)	17 (89.5)
Patients achieved >= 50 % reduction from baseline for at least 2 cycles (PR)	1 (25.0)	7 (50.0)	0	8 (42.1)

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. If a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
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Table 99.2.6.3.1b
Summary of Serum Tryptase Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2202 & <=200 mg Dose Group

Prior antineoplastic therapy = No				
Serum Tryptase Best Response	ASM (N=4) n (%)	SM-AHN (N=15) n (%)	MCL (N=1) n (%)	All AdvSM (N=20) n (%)
Patients with baseline serum tryptase assessment	4	15	1	20
Patients achieved serum tryptase < 20 ng/mL (CR)	2 (50.0)	9 (60.0)	0	11 (55.0)
Patients achieved >= 50 % reduction from baseline	3 (75.0)	14 (93.3)	1 (100.0)	18 (90.0)
Patients achieved >= 50 % reduction from baseline for at least 2 cycles (PR)	1 (25.0)	8 (53.3)	0	9 (45.0)
Patients with serum tryptase >= 40 ng/mL	4	14	1	19
Patients achieved serum tryptase < 20 ng/mL (CR)	2 (50.0)	8 (57.1)	0	10 (52.6)
Patients achieved >= 50 % reduction from baseline	3 (75.0)	13 (92.9)	1 (100.0)	17 (89.5)
Patients achieved >= 50 % reduction from baseline for at least 2 cycles (PR)	1 (25.0)	7 (50.0)	0	8 (42.1)

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. If a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
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Table 99.2.6.3.1b
Summary of Serum Tryptase Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2202 & All Dose Groups

Prior antineoplastic therapy = No				
Serum Tryptase Best Response	ASM (N=4) n (%)	SM-AHN (N=15) n (%)	MCL (N=1) n (%)	All AdvSM (N=20) n (%)
Patients with baseline serum tryptase assessment	4	15	1	20
Patients achieved serum tryptase < 20 ng/mL (CR)	2 (50.0)	9 (60.0)	0	11 (55.0)
Patients achieved >= 50 % reduction from baseline	3 (75.0)	14 (93.3)	1 (100.0)	18 (90.0)
Patients achieved >= 50 % reduction from baseline for at least 2 cycles (PR)	1 (25.0)	8 (53.3)	0	9 (45.0)
Patients with serum tryptase >= 40 ng/mL	4	14	1	19
Patients achieved serum tryptase < 20 ng/mL (CR)	2 (50.0)	8 (57.1)	0	10 (52.6)
Patients achieved >= 50 % reduction from baseline	3 (75.0)	13 (92.9)	1 (100.0)	17 (89.5)
Patients achieved >= 50 % reduction from baseline for at least 2 cycles (PR)	1 (25.0)	7 (50.0)	0	8 (42.1)

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. If a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
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Table 99.2.6.3.1b
Summary of Serum Tryptase Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101/2202 & 200 mg Dose Group

Prior antineoplastic therapy = Yes

Serum Tryptase Best Response	ASM (N=5) n (%)	SM-AHN (N=34) n (%)	MCL (N=13) n (%)	All AdvSM (N=52) n (%)	ISM/SSM (N=1) n (%)	All Patients (N=53) n (%)
Patients with baseline serum tryptase assessment	5	34	13	52	1	53
Patients achieved serum tryptase < 20 ng/mL (CR)	3 (60.0)	15 (44.1)	2 (15.4)	20 (38.5)	1 (100.0)	21 (39.6)
Patients achieved >= 50 % reduction from baseline	5 (100.0)	28 (82.4)	12 (92.3)	45 (86.5)	1 (100.0)	46 (86.8)
Patients achieved >= 50 % reduction from baseline for at least 2 cycles (PR)	2 (40.0)	16 (47.1)	6 (46.2)	24 (46.2)	1 (100.0)	25 (47.2)
Patients with serum tryptase >= 40 ng/mL	3	34	12	49	0	49
Patients achieved serum tryptase < 20 ng/mL (CR)	1 (33.3)	15 (44.1)	1 (8.3)	17 (34.7)	0	17 (34.7)
Patients achieved >= 50 % reduction from baseline	3 (100.0)	28 (82.4)	11 (91.7)	42 (85.7)	0	42 (85.7)
Patients achieved >= 50 % reduction from baseline for at least 2 cycles (PR)	0	16 (47.1)	6 (50.0)	22 (44.9)	0	22 (44.9)

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. If a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
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Table 99.2.6.3.1b
Summary of Serum Tryptase Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101/2202 & <=200 mg Dose Group

Prior antineoplastic therapy = Yes

Serum Tryptase Best Response	ASM (N=7) n (%)	SM-AHN (N=37) n (%)	MCL (N=14) n (%)	All AdvSM (N=58) n (%)	ISM/SSM (N=4) n (%)	All Patients (N=62) n (%)
Patients with baseline serum tryptase assessment	7	37	14	58	4	62
Patients achieved serum tryptase < 20 ng/mL (CR)	4 (57.1)	17 (45.9)	3 (21.4)	24 (41.4)	4 (100.0)	28 (45.2)
Patients achieved >= 50 % reduction from baseline	7 (100.0)	31 (83.8)	13 (92.9)	51 (87.9)	4 (100.0)	55 (88.7)
Patients achieved >= 50 % reduction from baseline for at least 2 cycles (PR)	3 (42.9)	19 (51.4)	7 (50.0)	29 (50.0)	4 (100.0)	33 (53.2)
Patients with serum tryptase >= 40 ng/mL	5	37	13	55	3	58
Patients achieved serum tryptase < 20 ng/mL (CR)	2 (40.0)	17 (45.9)	2 (15.4)	21 (38.2)	3 (100.0)	24 (41.4)
Patients achieved >= 50 % reduction from baseline	5 (100.0)	31 (83.8)	12 (92.3)	48 (87.3)	3 (100.0)	51 (87.9)
Patients achieved >= 50 % reduction from baseline for at least 2 cycles (PR)	1 (20.0)	19 (51.4)	7 (53.8)	27 (49.1)	3 (100.0)	30 (51.7)

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. If a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
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Table 99.2.6.3.1b
Summary of Serum Tryptase Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101/2202 & All Dose Groups

Prior antineoplastic therapy = Yes

Serum Tryptase Best Response	ASM (N=12) n (%)	SM-AHN (N=54) n (%)	MCL (N=17) n (%)	All AdvSM (N=83) n (%)	ISM/SSM (N=9) n (%)	All Patients (N=92) n (%)
Patients with baseline serum tryptase assessment	12	54	17	83	9	92
Patients achieved serum tryptase < 20 ng/mL (CR)	8 (66.7)	31 (57.4)	4 (23.5)	43 (51.8)	8 (88.9)	51 (55.4)
Patients achieved >= 50 % reduction from baseline	12 (100.0)	48 (88.9)	16 (94.1)	76 (91.6)	9 (100.0)	85 (92.4)
Patients achieved >= 50 % reduction from baseline for at least 2 cycles (PR)	8 (66.7)	36 (66.7)	10 (58.8)	54 (65.1)	8 (88.9)	62 (67.4)
Patients with serum tryptase >= 40 ng/mL	9	52	16	77	7	84
Patients achieved serum tryptase < 20 ng/mL (CR)	5 (55.6)	29 (55.8)	3 (18.8)	37 (48.1)	6 (85.7)	43 (51.2)
Patients achieved >= 50 % reduction from baseline	9 (100.0)	46 (88.5)	15 (93.8)	70 (90.9)	7 (100.0)	77 (91.7)
Patients achieved >= 50 % reduction from baseline for at least 2 cycles (PR)	5 (55.6)	34 (65.4)	10 (62.5)	49 (63.6)	6 (85.7)	55 (65.5)

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. If a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
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Table 99.2.6.3.1b
Summary of Serum Tryptase Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101/2202 & 200 mg Dose Group

Prior antineoplastic therapy = No

Serum Tryptase Best Response	ASM (N=4) n (%)	SM-AHN (N=21) n (%)	MCL (N=3) n (%)	All AdvSM (N=28) n (%)	ISM/SSM (N=0) n (%)	All Patients (N=28) n (%)
Patients with baseline serum tryptase assessment	4	21	3	28	0	28
Patients achieved serum tryptase < 20 ng/mL (CR)	2 (50.0)	12 (57.1)	2 (66.7)	16 (57.1)	0	16 (57.1)
Patients achieved >= 50 % reduction from baseline	3 (75.0)	20 (95.2)	3 (100.0)	26 (92.9)	0	26 (92.9)
Patients achieved >= 50 % reduction from baseline for at least 2 cycles (PR)	1 (25.0)	12 (57.1)	2 (66.7)	15 (53.6)	0	15 (53.6)
Patients with serum tryptase >= 40 ng/mL	4	20	3	27	0	27
Patients achieved serum tryptase < 20 ng/mL (CR)	2 (50.0)	11 (55.0)	2 (66.7)	15 (55.6)	0	15 (55.6)
Patients achieved >= 50 % reduction from baseline	3 (75.0)	19 (95.0)	3 (100.0)	25 (92.6)	0	25 (92.6)
Patients achieved >= 50 % reduction from baseline for at least 2 cycles (PR)	1 (25.0)	11 (55.0)	2 (66.7)	14 (51.9)	0	14 (51.9)

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. If a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/EMA_D120/t99.2.6.3.1b-serum-resp-nat.sas Date: 10:50/04AUG2021

Table 99.2.6.3.1b
Summary of Serum Tryptase Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101/2202 & <=200 mg Dose Group

Prior antineoplastic therapy = No

Serum Tryptase Best Response	ASM (N=4) n (%)	SM-AHN (N=26) n (%)	MCL (N=3) n (%)	All AdvSM (N=33) n (%)	ISM/SSM (N=2) n (%)	All Patients (N=35) n (%)
Patients with baseline serum tryptase assessment	4	26	3	33	2	35
Patients achieved serum tryptase < 20 ng/mL (CR)	2 (50.0)	16 (61.5)	2 (66.7)	20 (60.6)	2 (100.0)	22 (62.9)
Patients achieved >= 50 % reduction from baseline	3 (75.0)	25 (96.2)	3 (100.0)	31 (93.9)	2 (100.0)	33 (94.3)
Patients achieved >= 50 % reduction from baseline for at least 2 cycles (PR)	1 (25.0)	17 (65.4)	2 (66.7)	20 (60.6)	2 (100.0)	22 (62.9)
Patients with serum tryptase >= 40 ng/mL	4	25	3	32	2	34
Patients achieved serum tryptase < 20 ng/mL (CR)	2 (50.0)	15 (60.0)	2 (66.7)	19 (59.4)	2 (100.0)	21 (61.8)
Patients achieved >= 50 % reduction from baseline	3 (75.0)	24 (96.0)	3 (100.0)	30 (93.8)	2 (100.0)	32 (94.1)
Patients achieved >= 50 % reduction from baseline for at least 2 cycles (PR)	1 (25.0)	16 (64.0)	2 (66.7)	19 (59.4)	2 (100.0)	21 (61.8)

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. If a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/EMA_D120/t99.2.6.3.1b-serum-resp-nat.sas Date: 10:50/04AUG2021

Table 99.2.6.3.1b
Summary of Serum Tryptase Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101/2202 & All Dose Groups

Prior antineoplastic therapy = No						
Serum Tryptase Best Response	ASM (N=5) n (%)	SM-AHN (N=37) n (%)	MCL (N=6) n (%)	All AdvSM (N=48) n (%)	ISM/SSM (N=7) n (%)	All Patients (N=55) n (%)
Patients with baseline serum tryptase assessment	5	37	6	48	7	55
Patients achieved serum tryptase < 20 ng/mL (CR)	3 (60.0)	26 (70.3)	4 (66.7)	33 (68.8)	7 (100.0)	40 (72.7)
Patients achieved >= 50 % reduction from baseline	4 (80.0)	36 (97.3)	6 (100.0)	46 (95.8)	7 (100.0)	53 (96.4)
Patients achieved >= 50 % reduction from baseline for at least 2 cycles (PR)	2 (40.0)	28 (75.7)	5 (83.3)	35 (72.9)	7 (100.0)	42 (76.4)
Patients with serum tryptase >= 40 ng/mL	5	34	6	45	6	51
Patients achieved serum tryptase < 20 ng/mL (CR)	3 (60.0)	23 (67.6)	4 (66.7)	30 (66.7)	6 (100.0)	36 (70.6)
Patients achieved >= 50 % reduction from baseline	4 (80.0)	33 (97.1)	6 (100.0)	43 (95.6)	6 (100.0)	49 (96.1)
Patients achieved >= 50 % reduction from baseline for at least 2 cycles (PR)	2 (40.0)	25 (73.5)	5 (83.3)	32 (71.1)	6 (100.0)	38 (74.5)

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. If a patient does not have serum tryptase measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days after Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/EMA_D120/t99.2.6.3.1b-serum-resp-nat.sas Date: 10:50/04AUG2021

Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Overall

D816V Mutation (%) Allele Fraction	ASM (N=7)	SM-AHN (N=26)	MCL (N=8)	All AdvSM (N=41)
Baseline				
n	7	26	7	40
Mean (StdDev)	2.7 (4.33)	26.5 (20.55)	5.5 (9.86)	18.7 (20.17)
Median	1.4	24.8	0.1	11.5
Min, Max	0, 12	0, 80	0, 27	0, 80
Cycle 1 Day 15				
n	6	26	8	40
Mean (StdDev)	2.1 (3.35)	23.9 (18.96)	4.4 (7.94)	16.7 (18.48)
Median	0.6	21.3	0.6	8.2
Min, Max	0, 9	0, 68	0, 23	0, 68
Cycle 2 Day 1				
n	7	25	7	39
Mean (StdDev)	1.4 (2.05)	21.0 (18.78)	3.9 (7.76)	14.4 (17.70)
Median	0.7	16.1	0.5	4.5
Min, Max	0, 6	0, 51	0, 21	0, 51

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-advsm.sas Date: 19:33/27SEP2021

Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Overall				
D816V Mutation (%) Allele Fraction	ASM (N=7)	SM-AHN (N=26)	MCL (N=8)	All AdvSM (N=41)
Cycle 3 Day 1				
n	5	23	6	34
Mean (StdDev)	1.1 (1.85)	18.1 (17.09)	3.1 (5.60)	12.9 (16.04)
Median	0.5	17.4	0.4	3.8
Min, Max	0, 4	0, 47	0, 14	0, 47
Cycle 5 Day 1				
n	6	22	8	36
Mean (StdDev)	0.7 (0.99)	14.7 (16.40)	1.8 (3.63)	9.5 (14.41)
Median	0.3	7.8	0.2	2.5
Min, Max	0, 2	0, 46	0, 11	0, 46
Cycle 7 Day 1				
n	5	16	7	28
Mean (StdDev)	0.8 (0.88)	14.5 (18.03)	1.8 (3.50)	8.9 (15.07)
Median	0.5	5.1	0.3	1.5
Min, Max	0, 2	0, 48	0, 10	0, 48
Cycle 11 Day 1				
n	4	13	5	22
Mean (StdDev)	1.2 (1.24)	8.2 (14.06)	0.5 (0.63)	5.2 (11.28)
Median	1.0	1.0	0.3	0.7
Min, Max	0, 3	0, 35	0, 2	0, 35

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-advsm.sas Date: 19:33/27SEP2021

Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Overall				
D816V Mutation (%) Allele Fraction	ASM (N=7)	SM-AHN (N=26)	MCL (N=8)	All AdvSM (N=41)
Cycle 18 Day 1				
n	3	8	3	14
Mean (StdDev)	1.5 (1.15)	0.9 (2.14)	0.2 (0.23)	0.9 (1.70)
Median	1.5	0.1	0.2	0.2
Min, Max	0, 3	0, 6	0, 0	0, 6
Cycle 24 Day 1				
n	3	9	2	14
Mean (StdDev)	1.4 (0.70)	0.2 (0.35)	0.2 (0.28)	0.5 (0.65)
Median	1.8	0.1	0.2	0.2
Min, Max	1, 2	0, 1	0, 0	0, 2
Cycle 30 Day 1				
n	2	4	2	8
Mean (StdDev)	0.7 (0.26)	0.1 (0.16)	0.1 (0.13)	0.2 (0.30)
Median	0.7	0.0	0.1	0.1
Min, Max	0, 1	0, 0	0, 0	0, 1
Cycle 36 Day 1				
n	2	4	0	6
Mean (StdDev)	0.4 (0.12)	0.0 (0.03)		0.2 (0.21)
Median	0.4	0.0		0.1
Min, Max	0, 1	0, 0		0, 1

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-advsm.sas Date: 19:33/27SEP2021

Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Overall				
D816V Mutation (%) Allele Fraction	ASM (N=7)	SM-AHN (N=26)	MCL (N=8)	All AdvSM (N=41)
Cycle 42 Day 1				
n	1	3	1	5
Mean (StdDev)	0.4 (-)	0.0 (0.03)	0.1 (-)	0.1 (0.15)
Median	0.4	0.0	0.1	0.1
Min, Max	0, 0	0, 0	0, 0	0, 0
Cycle 48 Day 1				
n	1	0	1	2
Mean (StdDev)	0.5 (-)		0.1 (-)	0.3 (0.30)
Median	0.5		0.1	0.3
Min, Max	1, 1		0, 0	0, 1

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-advsm.sas Date: 19:33/27SEP2021

Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <200 mg				
D816V Mutation (%) Allele Fraction	ASM (N=1)	SM-AHN (N=2)	MCL (N=1)	All AdvSM (N=4)
Baseline				
n	1	2	0	3
Mean (StdDev)	3.1 (-)	24.7 (30.58)		17.5 (24.95)
Median	3.1	24.7		3.1
Min, Max	3, 3	3, 46		3, 46
Cycle 1 Day 15				
n	1	2	1	4
Mean (StdDev)	2.8 (-)	22.9 (28.60)	1.3 (-)	12.5 (20.44)
Median	2.8	22.9	1.3	2.7
Min, Max	3, 3	3, 43	1, 1	1, 43
Cycle 2 Day 1				
n	1	2	0	3
Mean (StdDev)	2.1 (-)	22.0 (28.89)		15.4 (23.42)
Median	2.1	22.0		2.1
Min, Max	2, 2	2, 42		2, 42

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-advsm.sas Date: 19:33/27SEP2021

Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <200 mg				
D816V Mutation (%) Allele Fraction	ASM (N=1)	SM-AHN (N=2)	MCL (N=1)	All AdvSM (N=4)
Cycle 3 Day 1				
n	0	2	0	2
Mean (StdDev)		22.2 (30.30)		22.2 (30.30)
Median		22.2		22.2
Min, Max		1, 44		1, 44
Cycle 5 Day 1				
n	1	2	1	4
Mean (StdDev)	1.4 (-)	18.8 (25.85)	0.9 (-)	10.0 (18.10)
Median	1.4	18.8	0.9	1.1
Min, Max	1, 1	1, 37	1, 1	1, 37
Cycle 7 Day 1				
n	1	2	1	4
Mean (StdDev)	1.1 (-)	20.7 (28.47)	0.9 (-)	10.8 (19.99)
Median	1.1	20.7	0.9	1.0
Min, Max	1, 1	1, 41	1, 1	1, 41
Cycle 11 Day 1				
n	1	2	1	4
Mean (StdDev)	1.3 (-)	14.3 (19.68)	0.7 (-)	7.6 (13.71)
Median	1.3	14.3	0.7	1.0
Min, Max	1, 1	0, 28	1, 1	0, 28

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-advsm.sas Date: 19:33/27SEP2021

Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <200 mg				
D816V Mutation (%) Allele Fraction	ASM (N=1)	SM-AHN (N=2)	MCL (N=1)	All AdvSM (N=4)
Cycle 18 Day 1				
n	1	2	1	4
Mean (StdDev)	1.5 (-)	3.2 (4.32)	0.5 (-)	2.1 (2.82)
Median	1.5	3.2	0.5	1.0
Min, Max	2, 2	0, 6	0, 0	0, 6
Cycle 24 Day 1				
n	1	2	1	4
Mean (StdDev)	1.8 (-)	0.6 (0.72)	0.4 (-)	0.8 (0.76)
Median	1.8	0.6	0.4	0.8
Min, Max	2, 2	0, 1	0, 0	0, 2
Cycle 30 Day 1				
n	1	2	1	4
Mean (StdDev)	0.8 (-)	0.2 (0.21)	0.2 (-)	0.4 (0.35)
Median	0.8	0.2	0.2	0.3
Min, Max	1, 1	0, 0	0, 0	0, 1
Cycle 36 Day 1				
n	1	2	0	3
Mean (StdDev)	0.5 (-)	0.1 (0.04)		0.2 (0.26)
Median	0.5	0.1		0.1
Min, Max	1, 1	0, 0		0, 1

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-advsm.sas Date: 19:33/27SEP2021

Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <200 mg				
D816V Mutation (%) Allele Fraction	ASM (N=1)	SM-AHN (N=2)	MCL (N=1)	All AdvSM (N=4)
Cycle 42 Day 1				
n	1	2	1	4
Mean (StdDev)	0.4 (-)	0.1 (0.03)	0.1 (-)	0.2 (0.16)
Median	0.4	0.1	0.1	0.1
Min, Max	0, 0	0, 0	0, 0	0, 0
Cycle 48 Day 1				
n	1	0	1	2
Mean (StdDev)	0.5 (-)		0.1 (-)	0.3 (0.30)
Median	0.5		0.1	0.3
Min, Max	1, 1		0, 0	0, 1

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-advsm.sas Date: 19:33/27SEP2021

Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <300 mg				
D816V Mutation (%) Allele Fraction	ASM (N=2)	SM-AHN (N=9)	MCL (N=5)	All AdvSM (N=16)
Baseline				
n	2	9	4	15
Mean (StdDev)	1.6 (2.18)	21.5 (20.64)	9.6 (11.90)	15.7 (18.29)
Median	1.6	12.9	5.8	6.7
Min, Max	0, 3	0, 46	0, 27	0, 46
Cycle 1 Day 15				
n	2	9	5	16
Mean (StdDev)	1.4 (1.95)	18.8 (19.19)	7.0 (9.36)	12.9 (16.44)
Median	1.4	12.7	3.5	4.8
Min, Max	0, 3	0, 44	0, 23	0, 44
Cycle 2 Day 1				
n	2	9	4	15
Mean (StdDev)	1.1 (1.49)	17.1 (19.36)	6.9 (9.67)	12.2 (16.60)
Median	1.1	5.2	2.9	4.2
Min, Max	0, 2	0, 44	0, 21	0, 44

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-advsm.sas Date: 19:33/27SEP2021

Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <300 mg				
D816V Mutation (%) Allele Fraction	ASM (N=2)	SM-AHN (N=9)	MCL (N=5)	All AdvSM (N=16)
Cycle 3 Day 1				
n	1	8	4	13
Mean (StdDev)	0.0 (-)	16.6 (18.80)	4.7 (6.54)	11.6 (16.14)
Median	0.0	10.3	2.2	1.3
Min, Max	0, 0	0, 44	0, 14	0, 44
Cycle 5 Day 1				
n	2	6	5	13
Mean (StdDev)	0.7 (0.95)	23.2 (20.01)	2.9 (4.37)	11.9 (17.09)
Median	0.7	25.5	0.9	2.5
Min, Max	0, 1	1, 46	0, 11	0, 46
Cycle 7 Day 1				
n	1	6	5	12
Mean (StdDev)	1.1 (-)	21.4 (21.17)	2.5 (4.02)	11.8 (17.58)
Median	1.1	19.5	0.9	1.5
Min, Max	1, 1	0, 48	0, 10	0, 48
Cycle 11 Day 1				
n	1	5	3	9
Mean (StdDev)	1.3 (-)	13.1 (16.80)	0.8 (0.62)	7.7 (13.51)
Median	1.3	2.6	0.7	1.3
Min, Max	1, 1	0, 35	0, 2	0, 35

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-advsm.sas Date: 19:33/27SEP2021

Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <300 mg				
D816V Mutation (%) Allele Fraction	ASM (N=2)	SM-AHN (N=9)	MCL (N=5)	All AdvSM (N=16)
Cycle 18 Day 1				
n	1	2	2	5
Mean (StdDev)	1.5 (-)	3.2 (4.32)	0.3 (0.22)	1.7 (2.59)
Median	1.5	3.2	0.3	0.5
Min, Max	2, 2	0, 6	0, 0	0, 6
Cycle 24 Day 1				
n	1	3	1	5
Mean (StdDev)	1.8 (-)	0.4 (0.61)	0.4 (-)	0.7 (0.76)
Median	1.8	0.1	0.4	0.4
Min, Max	2, 2	0, 1	0, 0	0, 2
Cycle 30 Day 1				
n	1	3	1	5
Mean (StdDev)	0.8 (-)	0.1 (0.18)	0.2 (-)	0.3 (0.34)
Median	0.8	0.0	0.2	0.2
Min, Max	1, 1	0, 0	0, 0	0, 1
Cycle 36 Day 1				
n	1	3	0	4
Mean (StdDev)	0.5 (-)	0.0 (0.04)		0.2 (0.23)
Median	0.5	0.0		0.1
Min, Max	1, 1	0, 0		0, 1

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-advsm.sas Date: 19:33/27SEP2021

Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <300 mg				
D816V Mutation (%) Allele Fraction	ASM (N=2)	SM-AHN (N=9)	MCL (N=5)	All AdvSM (N=16)
Cycle 42 Day 1				
n	1	3	1	5
Mean (StdDev)	0.4 (-)	0.0 (0.03)	0.1 (-)	0.1 (0.15)
Median	0.4	0.0	0.1	0.1
Min, Max	0, 0	0, 0	0, 0	0, 0
Cycle 48 Day 1				
n	1	0	1	2
Mean (StdDev)	0.5 (-)		0.1 (-)	0.3 (0.30)
Median	0.5		0.1	0.3
Min, Max	1, 1		0, 0	0, 1

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-advsm.sas Date: 19:33/27SEP2021

Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg				
D816V Mutation (%) Allele Fraction	ASM (N=1)	SM-AHN (N=7)	MCL (N=4)	All AdvSM (N=12)
Baseline				
n	1	7	4	12
Mean (StdDev)	0.0 (-)	20.6 (20.19)	9.6 (11.90)	15.2 (17.65)
Median	0.0	12.9	5.8	7.0
Min, Max	0, 0	0, 44	0, 27	0, 44
Cycle 1 Day 15				
n	1	7	4	12
Mean (StdDev)	0.0 (-)	17.6 (18.65)	8.4 (10.16)	13.1 (15.95)
Median	0.0	12.7	5.3	6.6
Min, Max	0, 0	0, 44	0, 23	0, 44
Cycle 2 Day 1				
n	1	7	4	12
Mean (StdDev)	0.0 (-)	15.7 (18.72)	6.9 (9.67)	11.4 (15.73)
Median	0.0	5.2	2.9	4.5
Min, Max	0, 0	0, 44	0, 21	0, 44

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-advsm.sas Date: 19:33/27SEP2021

Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg				
D816V Mutation (%) Allele Fraction	ASM (N=1)	SM-AHN (N=7)	MCL (N=4)	All AdvSM (N=12)
Cycle 3 Day 1				
n	1	6	4	11
Mean (StdDev)	0.0 (-)	14.7 (17.15)	4.7 (6.54)	9.7 (13.94)
Median	0.0	10.3	2.2	1.3
Min, Max	0, 0	0, 41	0, 14	0, 41
Cycle 5 Day 1				
n	1	4	4	9
Mean (StdDev)	0.0 (-)	25.4 (20.62)	3.4 (4.87)	12.8 (17.68)
Median	0.0	26.5	1.6	2.8
Min, Max	0, 0	3, 46	0, 11	0, 46
Cycle 7 Day 1				
n	0	4	4	8
Mean (StdDev)		21.7 (21.83)	3.0 (4.51)	12.3 (17.71)
Median		19.5	1.1	5.0
Min, Max		0, 48	0, 10	0, 48
Cycle 11 Day 1				
n	0	3	2	5
Mean (StdDev)		12.4 (19.20)	0.9 (0.86)	7.8 (14.97)
Median		2.6	0.9	1.5
Min, Max		0, 35	0, 2	0, 35

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-advsm.sas Date: 19:33/27SEP2021

Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg				
D816V Mutation (%) Allele Fraction	ASM (N=1)	SM-AHN (N=7)	MCL (N=4)	All AdvSM (N=12)
Cycle 18 Day 1				
n	0	0	1	1
Mean (StdDev)			0.2 (-)	0.2 (-)
Median			0.2	0.2
Min, Max			0, 0	0, 0
Cycle 24 Day 1				
n	0	1	0	1
Mean (StdDev)		0.0 (-)		0.0 (-)
Median		0.0		0.0
Min, Max		0, 0		0, 0
Cycle 30 Day 1				
n	0	1	0	1
Mean (StdDev)		0.0 (-)		0.0 (-)
Median		0.0		0.0
Min, Max		0, 0		0, 0
Cycle 36 Day 1				
n	0	1	0	1
Mean (StdDev)		0.0 (-)		0.0 (-)
Median		0.0		0.0
Min, Max		0, 0		0, 0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-advsm.sas Date: 19:33/27SEP2021

Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg				
D816V Mutation (%) Allele Fraction	ASM (N=1)	SM-AHN (N=7)	MCL (N=4)	All AdvSM (N=12)
Cycle 42 Day 1				
n	0	1	0	1
Mean (StdDev)		0.0 (-)		0.0 (-)
Median		0.0		0.0
Min, Max		0, 0		0, 0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-advsm.sas Date: 19:33/27SEP2021

Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 300 mg				
D816V Mutation (%) Allele Fraction	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Baseline				
n	4	13	3	20
Mean (StdDev)	3.5 (5.80)	33.1 (21.42)	0.0 (0.03)	22.2 (22.96)
Median	0.9	37.4	0.0	15.7
Min, Max	0, 12	0, 80	0, 0	0, 80
Cycle 1 Day 15				
n	3	13	3	19
Mean (StdDev)	2.9 (4.93)	29.0 (18.89)	0.0 (0.01)	20.3 (20.34)
Median	0.1	27.7	0.0	17.5
Min, Max	0, 9	0, 68	0, 0	0, 68
Cycle 2 Day 1				
n	4	13	3	20
Mean (StdDev)	1.7 (2.71)	26.4 (18.69)	0.0 (0.01)	17.5 (19.42)
Median	0.5	30.5	0.0	7.6
Min, Max	0, 6	0, 51	0, 0	0, 51

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-advsm.sas Date: 19:33/27SEP2021

Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 300 mg				
D816V Mutation (%) Allele Fraction	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Cycle 3 Day 1				
n	3	13	2	18
Mean (StdDev)	1.6 (2.38)	20.9 (17.17)	0.0 (0.03)	15.3 (17.12)
Median	0.5	22.3	0.0	6.6
Min, Max	0, 4	0, 47	0, 0	0, 47
Cycle 5 Day 1				
n	3	13	3	19
Mean (StdDev)	0.9 (1.37)	13.3 (15.23)	0.0 (0.02)	9.3 (13.88)
Median	0.2	8.1	0.0	2.5
Min, Max	0, 2	0, 45	0, 0	0, 45
Cycle 7 Day 1				
n	3	8	2	13
Mean (StdDev)	0.8 (1.21)	12.1 (17.14)	0.0 (0.01)	7.6 (14.35)
Median	0.2	4.6	0.0	0.4
Min, Max	0, 2	0, 43	0, 0	0, 43
Cycle 11 Day 1				
n	3	7	2	12
Mean (StdDev)	1.2 (1.51)	5.7 (13.13)	0.0 (0.01)	3.6 (10.05)
Median	0.7	0.7	0.0	0.6
Min, Max	0, 3	0, 35	0, 0	0, 35

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-advsm.sas Date: 19:33/27SEP2021

Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 300 mg				
D816V Mutation (%) Allele Fraction	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Cycle 18 Day 1				
n	2	6	1	9
Mean (StdDev)	1.5 (1.62)	0.2 (0.25)	0.0 (-)	0.5 (0.85)
Median	1.5	0.1	0.0	0.1
Min, Max	0, 3	0, 1	0, 0	0, 3
Cycle 24 Day 1				
n	2	4	1	7
Mean (StdDev)	1.2 (0.87)	0.1 (0.14)	0.0 (-)	0.4 (0.64)
Median	1.2	0.1	0.0	0.2
Min, Max	1, 2	0, 0	0, 0	0, 2
Cycle 30 Day 1				
n	1	0	1	2
Mean (StdDev)	0.5 (-)		0.0 (-)	0.3 (0.31)
Median	0.5		0.0	0.3
Min, Max	0, 0		0, 0	0, 0
Cycle 36 Day 1				
n	1	0	0	1
Mean (StdDev)	0.3 (-)			0.3 (-)
Median	0.3			0.3
Min, Max	0, 0			0, 0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-advsm.sas Date: 19:33/27SEP2021

Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg				
D816V Mutation (%) Allele Fraction	ASM (N=5)	SM-AHN (N=20)	MCL (N=7)	All AdvSM (N=32)
Baseline				
n	5	20	7	32
Mean (StdDev)	2.8 (5.26)	28.7 (21.35)	5.5 (9.86)	19.6 (21.11)
Median	0.1	31.6	0.1	11.5
Min, Max	0, 12	0, 80	0, 27	0, 80
Cycle 1 Day 15				
n	4	20	7	31
Mean (StdDev)	2.2 (4.28)	25.0 (19.13)	4.8 (8.46)	17.5 (18.82)
Median	0.0	21.3	0.0	9.5
Min, Max	0, 9	0, 68	0, 23	0, 68
Cycle 2 Day 1				
n	5	20	7	32
Mean (StdDev)	1.3 (2.46)	22.7 (18.94)	3.9 (7.76)	15.2 (18.10)
Median	0.1	17.5	0.5	5.0
Min, Max	0, 6	0, 51	0, 21	0, 51

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-advsm.sas Date: 19:33/27SEP2021

Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg				
D816V Mutation (%) Allele Fraction	ASM (N=5)	SM-AHN (N=20)	MCL (N=7)	All AdvSM (N=32)
Cycle 3 Day 1				
n	4	19	6	29
Mean (StdDev)	1.2 (2.10)	18.9 (16.94)	3.1 (5.60)	13.2 (15.97)
Median	0.2	19.2	0.4	3.7
Min, Max	0, 4	0, 47	0, 14	0, 47
Cycle 5 Day 1				
n	4	17	7	28
Mean (StdDev)	0.7 (1.20)	16.2 (16.79)	2.0 (3.90)	10.4 (14.96)
Median	0.1	10.2	0.0	2.6
Min, Max	0, 2	0, 46	0, 11	0, 46
Cycle 7 Day 1				
n	3	12	6	21
Mean (StdDev)	0.8 (1.21)	15.3 (18.43)	2.0 (3.81)	9.4 (15.46)
Median	0.2	6.9	0.1	1.9
Min, Max	0, 2	0, 48	0, 10	0, 48
Cycle 11 Day 1				
n	3	10	4	17
Mean (StdDev)	1.2 (1.51)	7.7 (14.40)	0.5 (0.72)	4.8 (11.37)
Median	0.7	0.8	0.2	0.7
Min, Max	0, 3	0, 35	0, 2	0, 35

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-advsm.sas Date: 19:33/27SEP2021

Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg				
D816V Mutation (%) Allele Fraction	ASM (N=5)	SM-AHN (N=20)	MCL (N=7)	All AdvSM (N=32)
Cycle 18 Day 1				
n	2	6	2	10
Mean (StdDev)	1.5 (1.62)	0.2 (0.25)	0.1 (0.09)	0.4 (0.81)
Median	1.5	0.1	0.1	0.1
Min, Max	0, 3	0, 1	0, 0	0, 3
Cycle 24 Day 1				
n	2	5	1	8
Mean (StdDev)	1.2 (0.87)	0.1 (0.13)	0.0 (-)	0.4 (0.61)
Median	1.2	0.1	0.0	0.1
Min, Max	1, 2	0, 0	0, 0	0, 2
Cycle 30 Day 1				
n	1	1	1	3
Mean (StdDev)	0.5 (-)	0.0 (-)	0.0 (-)	0.2 (0.26)
Median	0.5	0.0	0.0	0.0
Min, Max	0, 0	0, 0	0, 0	0, 0
Cycle 36 Day 1				
n	1	1	0	2
Mean (StdDev)	0.3 (-)	0.0 (-)		0.2 (0.23)
Median	0.3	0.0		0.2
Min, Max	0, 0	0, 0		0, 0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-advsm.sas Date: 19:33/27SEP2021

Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg				
D816V Mutation (%) Allele Fraction	ASM (N=5)	SM-AHN (N=20)	MCL (N=7)	All AdvSM (N=32)
Cycle 42 Day 1				
n	0	1	0	1
Mean (StdDev)		0.0 (-)		0.0 (-)
Median		0.0		0.0
Min, Max		0, 0		0, 0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-advsm.sas Date: 19:33/27SEP2021

Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 400 mg				
D816V Mutation (%) Allele Fraction	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Baseline				
n	1	4	0	5
Mean (StdDev)	1.4 (-)	16.6 (12.42)		13.6 (12.71)
Median	1.4	18.6		14.5
Min, Max	1, 1	0, 29		0, 29
Cycle 1 Day 15				
n	1	4	0	5
Mean (StdDev)	1.2 (-)	18.6 (19.01)		15.1 (18.22)
Median	1.2	19.1		4.4
Min, Max	1, 1	0, 36		0, 36
Cycle 2 Day 1				
n	1	3	0	4
Mean (StdDev)	0.7 (-)	9.5 (13.39)		7.3 (11.79)
Median	0.7	3.6		2.1
Min, Max	1, 1	0, 25		0, 25

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-advsm.sas Date: 19:33/27SEP2021

Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 400 mg				
D816V Mutation (%) Allele Fraction	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Cycle 3 Day 1				
n	1	2	0	3
Mean (StdDev)	0.5 (-)	6.1 (3.28)		4.2 (3.97)
Median	0.5	6.1		3.8
Min, Max	1, 1	4, 8		1, 8
Cycle 5 Day 1				
n	1	3	0	4
Mean (StdDev)	0.3 (-)	3.4 (2.96)		2.6 (2.87)
Median	0.3	4.5		2.4
Min, Max	0, 0	0, 6		0, 6
Cycle 7 Day 1				
n	1	2	0	3
Mean (StdDev)	0.5 (-)	3.5 (1.36)		2.5 (1.98)
Median	0.5	3.5		2.5
Min, Max	0, 0	2, 4		0, 4
Cycle 11 Day 1				
n	0	1	0	1
Mean (StdDev)		1.7 (-)		1.7 (-)
Median		1.7		1.7
Min, Max		2, 2		2, 2

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-advsm.sas Date: 19:33/27SEP2021

Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 400 mg				
D816V Mutation (%) Allele Fraction	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Cycle 24 Day 1				
n	0	2	0	2
Mean (StdDev)		0.0 (0.01)		0.0 (0.01)
Median		0.0		0.0
Min, Max		0, 0		0, 0
Cycle 30 Day 1				
n	0	1	0	1
Mean (StdDev)		0.0 (-)		0.0 (-)
Median		0.0		0.0
Min, Max		0, 0		0, 0
Cycle 36 Day 1				
n	0	1	0	1
Mean (StdDev)		0.0 (-)		0.0 (-)
Median		0.0		0.0
Min, Max		0, 0		0, 0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2202

Overall				
D816V Mutation (%) Allele Fraction	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Baseline				
n	5	28	9	42
Mean (StdDev)	10.0 (16.83)	23.8 (16.91)	23.6 (18.27)	22.1 (17.36)
Median	3.8	22.4	31.1	22.4
Min, Max	0, 40	1, 47	0, 42	0, 47
Cycle 1 Day 15				
n	5	24	8	37
Mean (StdDev)	9.1 (16.01)	22.2 (14.14)	18.9 (16.57)	19.7 (15.15)
Median	2.8	23.4	22.8	20.0
Min, Max	0, 38	1, 44	0, 37	0, 44
Cycle 2 Day 1				
n	3	23	8	34
Mean (StdDev)	1.3 (1.56)	19.2 (14.08)	13.4 (13.13)	16.2 (14.04)
Median	0.9	18.6	12.5	14.9
Min, Max	0, 3	0, 44	0, 31	0, 44

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-advsm.sas Date: 19:33/27SEP2021

Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2202

Overall				
D816V Mutation (%) Allele Fraction	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Cycle 3 Day 1				
n	4	20	6	30
Mean (StdDev)	9.3 (16.45)	15.8 (15.14)	18.6 (16.10)	15.5 (15.17)
Median	1.7	11.1	22.1	11.1
Min, Max	0, 34	0, 47	0, 40	0, 47
Cycle 7 Day 1				
n	1	15	2	18
Mean (StdDev)	3.3 (-)	13.9 (15.02)	12.0 (16.92)	13.1 (14.45)
Median	3.3	8.6	12.0	6.1
Min, Max	3, 3	0, 46	0, 24	0, 46
Cycle 11 Day 1				
n	0	7	2	9
Mean (StdDev)		12.5 (14.20)	14.1 (19.89)	12.9 (14.19)
Median		4.7	14.1	4.7
Min, Max		0, 37	0, 28	0, 37
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		35.9 (-)		35.9 (-)
Median		35.9		35.9
Min, Max		36, 36		36, 36

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-advsm.sas Date: 19:33/27SEP2021

Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2202

Starting Dose: 200 mg				
D816V Mutation (%) Allele Fraction	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Baseline				
n	4	27	9	40
Mean (StdDev)	11.5 (19.02)	23.3 (17.02)	23.6 (18.27)	22.2 (17.39)
Median	3.0	19.7	31.1	22.4
Min, Max	0, 40	1, 47	0, 42	0, 47
Cycle 1 Day 15				
n	4	23	8	35
Mean (StdDev)	10.7 (18.03)	21.7 (14.26)	18.9 (16.57)	19.8 (15.14)
Median	2.6	21.9	22.8	20.0
Min, Max	0, 38	1, 44	0, 37	0, 44
Cycle 2 Day 1				
n	3	22	8	33
Mean (StdDev)	1.3 (1.56)	18.6 (14.13)	13.4 (13.13)	15.8 (13.98)
Median	0.9	16.8	12.5	14.8
Min, Max	0, 3	0, 44	0, 31	0, 44

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-advsm.sas Date: 19:33/27SEP2021

Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2202

Starting Dose: 200 mg				
D816V Mutation (%) Allele Fraction	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Cycle 3 Day 1				
n	4	19	6	29
Mean (StdDev)	9.3 (16.45)	15.1 (15.29)	18.6 (16.10)	15.1 (15.27)
Median	1.7	10.7	22.1	10.7
Min, Max	0, 34	0, 47	0, 40	0, 47
Cycle 7 Day 1				
n	1	14	2	17
Mean (StdDev)	3.3 (-)	13.2 (15.33)	12.0 (16.92)	12.5 (14.65)
Median	3.3	6.1	12.0	3.7
Min, Max	3, 3	0, 46	0, 24	0, 46
Cycle 11 Day 1				
n	0	6	2	8
Mean (StdDev)		10.4 (14.27)	14.1 (19.89)	11.3 (14.32)
Median		3.7	14.1	3.7
Min, Max		0, 37	0, 28	0, 37
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		35.9 (-)		35.9 (-)
Median		35.9		35.9
Min, Max		36, 36		36, 36

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-advsm.sas Date: 19:33/27SEP2021

Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Overall

D816V Mutation (%) Allele Fraction	ASM (N=12)	SM-AHN (N=54)	MCL (N=17)	All AdvSM (N=83)
Baseline				
n	12	54	16	82
Mean (StdDev)	5.7 (11.28)	25.1 (18.62)	15.7 (17.39)	20.4 (18.75)
Median	2.0	23.9	5.8	16.5
Min, Max	0, 40	0, 80	0, 42	0, 80
Cycle 1 Day 15				
n	11	50	16	77
Mean (StdDev)	5.3 (11.03)	23.1 (16.68)	11.6 (14.61)	18.1 (16.92)
Median	1.9	23.0	2.4	17.0
Min, Max	0, 38	0, 68	0, 37	0, 68
Cycle 2 Day 1				
n	10	48	15	73
Mean (StdDev)	1.3 (1.83)	20.1 (16.55)	9.0 (11.66)	15.3 (16.01)
Median	0.8	17.4	1.6	8.1
Min, Max	0, 6	0, 51	0, 31	0, 51

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Overall

D816V Mutation (%) Allele Fraction	ASM (N=12)	SM-AHN (N=54)	MCL (N=17)	All AdvSM (N=83)
Cycle 3 Day 1				
n	9	43	12	64
Mean (StdDev)	4.7 (11.05)	17.0 (16.07)	10.9 (14.07)	14.1 (15.57)
Median	0.5	11.5	2.2	7.8
Min, Max	0, 34	0, 47	0, 40	0, 47
Cycle 5 Day 1				
n	6	22	8	36
Mean (StdDev)	0.7 (0.99)	14.7 (16.40)	1.8 (3.63)	9.5 (14.41)
Median	0.3	7.8	0.2	2.5
Min, Max	0, 2	0, 46	0, 11	0, 46
Cycle 7 Day 1				
n	6	31	9	46
Mean (StdDev)	1.2 (1.30)	14.2 (16.37)	4.1 (8.08)	10.5 (14.82)
Median	0.8	5.8	0.3	2.4
Min, Max	0, 3	0, 48	0, 24	0, 48
Cycle 11 Day 1				
n	4	20	7	31
Mean (StdDev)	1.2 (1.24)	9.7 (13.89)	4.4 (10.51)	7.4 (12.46)
Median	1.0	1.9	0.3	1.0
Min, Max	0, 3	0, 37	0, 28	0, 37

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Overall				
D816V Mutation (%) Allele Fraction	ASM (N=12)	SM-AHN (N=54)	MCL (N=17)	All AdvSM (N=83)
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		35.9 (-)		35.9 (-)
Median		35.9		35.9
Min, Max		36, 36		36, 36
Cycle 18 Day 1				
n	3	8	3	14
Mean (StdDev)	1.5 (1.15)	0.9 (2.14)	0.2 (0.23)	0.9 (1.70)
Median	1.5	0.1	0.2	0.2
Min, Max	0, 3	0, 6	0, 0	0, 6
Cycle 24 Day 1				
n	3	9	2	14
Mean (StdDev)	1.4 (0.70)	0.2 (0.35)	0.2 (0.28)	0.5 (0.65)
Median	1.8	0.1	0.2	0.2
Min, Max	1, 2	0, 1	0, 0	0, 2
Cycle 30 Day 1				
n	2	4	2	8
Mean (StdDev)	0.7 (0.26)	0.1 (0.16)	0.1 (0.13)	0.2 (0.30)
Median	0.7	0.0	0.1	0.1
Min, Max	0, 1	0, 0	0, 0	0, 1

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Overall

D816V Mutation (%) Allele Fraction	ASM (N=12)	SM-AHN (N=54)	MCL (N=17)	All AdvSM (N=83)
Cycle 36 Day 1				
n	2	4	0	6
Mean (StdDev)	0.4 (0.12)	0.0 (0.03)		0.2 (0.21)
Median	0.4	0.0		0.1
Min, Max	0, 1	0, 0		0, 1
Cycle 42 Day 1				
n	1	3	1	5
Mean (StdDev)	0.4 (-)	0.0 (0.03)	0.1 (-)	0.1 (0.15)
Median	0.4	0.0	0.1	0.1
Min, Max	0, 0	0, 0	0, 0	0, 0
Cycle 48 Day 1				
n	1	0	1	2
Mean (StdDev)	0.5 (-)		0.1 (-)	0.3 (0.30)
Median	0.5		0.1	0.3
Min, Max	1, 1		0, 0	0, 1

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-advsm.sas Date: 19:33/27SEP2021

Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg				
D816V Mutation (%) Allele Fraction	ASM (N=2)	SM-AHN (N=3)	MCL (N=1)	All AdvSM (N=6)
Baseline				
n	2	3	0	5
Mean (StdDev)	3.5 (0.50)	28.9 (22.80)		18.7 (21.29)
Median	3.5	37.2		3.8
Min, Max	3, 4	3, 46		3, 46
Cycle 1 Day 15				
n	2	3	1	6
Mean (StdDev)	2.8 (0.05)	26.4 (21.10)	1.3 (-)	14.3 (18.76)
Median	2.8	33.3	1.3	2.8
Min, Max	3, 3	3, 43	1, 1	1, 43
Cycle 2 Day 1				
n	1	3	0	4
Mean (StdDev)	2.1 (-)	25.2 (21.19)		19.4 (20.80)
Median	2.1	31.7		16.9
Min, Max	2, 2	2, 42		2, 42

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-advsm.sas Date: 19:33/27SEP2021

Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg				
D816V Mutation (%) Allele Fraction	ASM (N=2)	SM-AHN (N=3)	MCL (N=1)	All AdvSM (N=6)
Cycle 3 Day 1				
n	0	3	0	3
Mean (StdDev)		23.9 (21.64)		23.9 (21.64)
Median		27.4		27.4
Min, Max		1, 44		1, 44
Cycle 5 Day 1				
n	1	2	1	4
Mean (StdDev)	1.4 (-)	18.8 (25.85)	0.9 (-)	10.0 (18.10)
Median	1.4	18.8	0.9	1.1
Min, Max	1, 1	1, 37	1, 1	1, 37
Cycle 7 Day 1				
n	1	3	1	5
Mean (StdDev)	1.1 (-)	21.7 (20.21)	0.9 (-)	13.4 (18.24)
Median	1.1	23.7	0.9	1.1
Min, Max	1, 1	1, 41	1, 1	1, 41
Cycle 11 Day 1				
n	1	3	1	5
Mean (StdDev)	1.3 (-)	18.0 (15.31)	0.7 (-)	11.2 (14.28)
Median	1.3	25.4	0.7	1.3
Min, Max	1, 1	0, 28	1, 1	0, 28

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg				
D816V Mutation (%) Allele Fraction	ASM (N=2)	SM-AHN (N=3)	MCL (N=1)	All AdvSM (N=6)
Cycle 18 Day 1				
n	1	2	1	4
Mean (StdDev)	1.5 (-)	3.2 (4.32)	0.5 (-)	2.1 (2.82)
Median	1.5	3.2	0.5	1.0
Min, Max	2, 2	0, 6	0, 0	0, 6
Cycle 24 Day 1				
n	1	2	1	4
Mean (StdDev)	1.8 (-)	0.6 (0.72)	0.4 (-)	0.8 (0.76)
Median	1.8	0.6	0.4	0.8
Min, Max	2, 2	0, 1	0, 0	0, 2
Cycle 30 Day 1				
n	1	2	1	4
Mean (StdDev)	0.8 (-)	0.2 (0.21)	0.2 (-)	0.4 (0.35)
Median	0.8	0.2	0.2	0.3
Min, Max	1, 1	0, 0	0, 0	0, 1
Cycle 36 Day 1				
n	1	2	0	3
Mean (StdDev)	0.5 (-)	0.1 (0.04)		0.2 (0.26)
Median	0.5	0.1		0.1
Min, Max	1, 1	0, 0		0, 1

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg				
D816V Mutation (%) Allele Fraction	ASM (N=2)	SM-AHN (N=3)	MCL (N=1)	All AdvSM (N=6)
Cycle 42 Day 1				
n	1	2	1	4
Mean (StdDev)	0.4 (-)	0.1 (0.03)	0.1 (-)	0.2 (0.16)
Median	0.4	0.1	0.1	0.1
Min, Max	0, 0	0, 0	0, 0	0, 0
Cycle 48 Day 1				
n	1	0	1	2
Mean (StdDev)	0.5 (-)		0.1 (-)	0.3 (0.30)
Median	0.5		0.1	0.3
Min, Max	1, 1		0, 0	0, 1

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-advsm.sas Date: 19:33/27SEP2021

Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg				
D816V Mutation (%) Allele Fraction	ASM (N=7)	SM-AHN (N=37)	MCL (N=14)	All AdvSM (N=58)
Baseline				
n	7	37	13	57
Mean (StdDev)	7.6 (14.36)	23.2 (17.61)	19.3 (17.40)	20.4 (17.68)
Median	3.1	19.7	26.3	18.4
Min, Max	0, 40	0, 47	0, 42	0, 47
Cycle 1 Day 15				
n	7	33	13	53
Mean (StdDev)	6.9 (13.63)	21.3 (15.44)	14.3 (15.02)	17.7 (15.71)
Median	2.8	20.0	7.1	17.0
Min, Max	0, 38	0, 44	0, 37	0, 44
Cycle 2 Day 1				
n	5	32	12	49
Mean (StdDev)	1.2 (1.34)	18.6 (15.44)	11.2 (12.06)	15.0 (14.81)
Median	0.9	15.5	6.1	9.2
Min, Max	0, 3	0, 44	0, 31	0, 44

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg				
D816V Mutation (%) Allele Fraction	ASM (N=7)	SM-AHN (N=37)	MCL (N=14)	All AdvSM (N=58)
Cycle 3 Day 1				
n	5	28	10	43
Mean (StdDev)	7.5 (14.84)	16.0 (15.90)	13.0 (14.51)	14.3 (15.38)
Median	0.8	11.1	8.9	8.4
Min, Max	0, 34	0, 47	0, 40	0, 47
Cycle 5 Day 1				
n	2	6	5	13
Mean (StdDev)	0.7 (0.95)	23.2 (20.01)	2.9 (4.37)	11.9 (17.09)
Median	0.7	25.5	0.9	2.5
Min, Max	0, 1	1, 46	0, 11	0, 46
Cycle 7 Day 1				
n	2	21	7	30
Mean (StdDev)	2.2 (1.59)	16.0 (16.79)	5.2 (8.94)	12.6 (15.50)
Median	2.2	8.6	0.9	3.5
Min, Max	1, 3	0, 48	0, 24	0, 48
Cycle 11 Day 1				
n	1	12	5	18
Mean (StdDev)	1.3 (-)	12.8 (14.59)	6.2 (12.33)	10.3 (13.70)
Median	1.3	3.7	0.7	2.1
Min, Max	1, 1	0, 37	0, 28	0, 37

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg				
D816V Mutation (%) Allele Fraction	ASM (N=7)	SM-AHN (N=37)	MCL (N=14)	All AdvSM (N=58)
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		35.9 (-)		35.9 (-)
Median		35.9		35.9
Min, Max		36, 36		36, 36
Cycle 18 Day 1				
n	1	2	2	5
Mean (StdDev)	1.5 (-)	3.2 (4.32)	0.3 (0.22)	1.7 (2.59)
Median	1.5	3.2	0.3	0.5
Min, Max	2, 2	0, 6	0, 0	0, 6
Cycle 24 Day 1				
n	1	3	1	5
Mean (StdDev)	1.8 (-)	0.4 (0.61)	0.4 (-)	0.7 (0.76)
Median	1.8	0.1	0.4	0.4
Min, Max	2, 2	0, 1	0, 0	0, 2
Cycle 30 Day 1				
n	1	3	1	5
Mean (StdDev)	0.8 (-)	0.1 (0.18)	0.2 (-)	0.3 (0.34)
Median	0.8	0.0	0.2	0.2
Min, Max	1, 1	0, 0	0, 0	0, 1

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-advsm.sas Date: 19:33/27SEP2021

Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg				
D816V Mutation (%) Allele Fraction	ASM (N=7)	SM-AHN (N=37)	MCL (N=14)	All AdvSM (N=58)
Cycle 36 Day 1				
n	1	3	0	4
Mean (StdDev)	0.5 (-)	0.0 (0.04)		0.2 (0.23)
Median	0.5	0.0		0.1
Min, Max	1, 1	0, 0		0, 1
Cycle 42 Day 1				
n	1	3	1	5
Mean (StdDev)	0.4 (-)	0.0 (0.03)	0.1 (-)	0.1 (0.15)
Median	0.4	0.0	0.1	0.1
Min, Max	0, 0	0, 0	0, 0	0, 0
Cycle 48 Day 1				
n	1	0	1	2
Mean (StdDev)	0.5 (-)		0.1 (-)	0.3 (0.30)
Median	0.5		0.1	0.3
Min, Max	1, 1		0, 0	0, 1

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg				
D816V Mutation (%) Allele Fraction	ASM (N=5)	SM-AHN (N=34)	MCL (N=13)	All AdvSM (N=52)
Baseline				
n	5	34	13	52
Mean (StdDev)	9.2 (17.25)	22.7 (17.42)	19.3 (17.40)	20.6 (17.53)
Median	2.2	19.6	26.3	18.9
Min, Max	0, 40	0, 47	0, 42	0, 47
Cycle 1 Day 15				
n	5	30	12	47
Mean (StdDev)	8.6 (16.33)	20.8 (15.14)	15.4 (15.15)	18.1 (15.46)
Median	1.9	19.1	12.9	17.1
Min, Max	0, 38	0, 44	0, 37	0, 44
Cycle 2 Day 1				
n	4	29	12	45
Mean (StdDev)	1.0 (1.43)	17.9 (15.05)	11.2 (12.06)	14.6 (14.41)
Median	0.4	15.0	6.1	9.2
Min, Max	0, 3	0, 44	0, 31	0, 44

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg				
D816V Mutation (%) Allele Fraction	ASM (N=5)	SM-AHN (N=34)	MCL (N=13)	All AdvSM (N=52)
Cycle 3 Day 1				
n	5	25	10	40
Mean (StdDev)	7.5 (14.84)	15.0 (15.39)	13.0 (14.51)	13.6 (14.93)
Median	0.8	10.7	8.9	7.9
Min, Max	0, 34	0, 47	0, 40	0, 47
Cycle 5 Day 1				
n	1	4	4	9
Mean (StdDev)	0.0 (-)	25.4 (20.62)	3.4 (4.87)	12.8 (17.68)
Median	0.0	26.5	1.6	2.8
Min, Max	0, 0	3, 46	0, 11	0, 46
Cycle 7 Day 1				
n	1	18	6	25
Mean (StdDev)	3.3 (-)	15.1 (16.65)	6.0 (9.56)	12.4 (15.31)
Median	3.3	8.3	1.1	3.7
Min, Max	3, 3	0, 48	0, 24	0, 48
Cycle 11 Day 1				
n	0	9	4	13
Mean (StdDev)		11.0 (14.85)	7.5 (13.80)	10.0 (14.05)
Median		2.7	0.9	2.6
Min, Max		0, 37	0, 28	0, 37

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg				
D816V Mutation (%) Allele Fraction	ASM (N=5)	SM-AHN (N=34)	MCL (N=13)	All AdvSM (N=52)
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		35.9 (-)		35.9 (-)
Median		35.9		35.9
Min, Max		36, 36		36, 36
Cycle 18 Day 1				
n	0	0	1	1
Mean (StdDev)			0.2 (-)	0.2 (-)
Median			0.2	0.2
Min, Max			0, 0	0, 0
Cycle 24 Day 1				
n	0	1	0	1
Mean (StdDev)		0.0 (-)		0.0 (-)
Median		0.0		0.0
Min, Max		0, 0		0, 0
Cycle 30 Day 1				
n	0	1	0	1
Mean (StdDev)		0.0 (-)		0.0 (-)
Median		0.0		0.0
Min, Max		0, 0		0, 0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-advsm.sas Date: 19:33/27SEP2021

Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg				
D816V Mutation (%) Allele Fraction	ASM (N=5)	SM-AHN (N=34)	MCL (N=13)	All AdvSM (N=52)
Cycle 36 Day 1				
n	0	1	0	1
Mean (StdDev)		0.0 (-)		0.0 (-)
Median		0.0		0.0
Min, Max		0, 0		0, 0
Cycle 42 Day 1				
n	0	1	0	1
Mean (StdDev)		0.0 (-)		0.0 (-)
Median		0.0		0.0
Min, Max		0, 0		0, 0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-advsm.sas Date: 19:33/27SEP2021

Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg				
D816V Mutation (%) Allele Fraction	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Baseline				
n	4	13	3	20
Mean (StdDev)	3.5 (5.80)	33.1 (21.42)	0.0 (0.03)	22.2 (22.96)
Median	0.9	37.4	0.0	15.7
Min, Max	0, 12	0, 80	0, 0	0, 80
Cycle 1 Day 15				
n	3	13	3	19
Mean (StdDev)	2.9 (4.93)	29.0 (18.89)	0.0 (0.01)	20.3 (20.34)
Median	0.1	27.7	0.0	17.5
Min, Max	0, 9	0, 68	0, 0	0, 68
Cycle 2 Day 1				
n	4	13	3	20
Mean (StdDev)	1.7 (2.71)	26.4 (18.69)	0.0 (0.01)	17.5 (19.42)
Median	0.5	30.5	0.0	7.6
Min, Max	0, 6	0, 51	0, 0	0, 51

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg				
D816V Mutation (%) Allele Fraction	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Cycle 3 Day 1				
n	3	13	2	18
Mean (StdDev)	1.6 (2.38)	20.9 (17.17)	0.0 (0.03)	15.3 (17.12)
Median	0.5	22.3	0.0	6.6
Min, Max	0, 4	0, 47	0, 0	0, 47
Cycle 5 Day 1				
n	3	13	3	19
Mean (StdDev)	0.9 (1.37)	13.3 (15.23)	0.0 (0.02)	9.3 (13.88)
Median	0.2	8.1	0.0	2.5
Min, Max	0, 2	0, 45	0, 0	0, 45
Cycle 7 Day 1				
n	3	8	2	13
Mean (StdDev)	0.8 (1.21)	12.1 (17.14)	0.0 (0.01)	7.6 (14.35)
Median	0.2	4.6	0.0	0.4
Min, Max	0, 2	0, 43	0, 0	0, 43
Cycle 11 Day 1				
n	3	7	2	12
Mean (StdDev)	1.2 (1.51)	5.7 (13.13)	0.0 (0.01)	3.6 (10.05)
Median	0.7	0.7	0.0	0.6
Min, Max	0, 3	0, 35	0, 0	0, 35

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg				
D816V Mutation (%) Allele Fraction	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Cycle 18 Day 1				
n	2	6	1	9
Mean (StdDev)	1.5 (1.62)	0.2 (0.25)	0.0 (-)	0.5 (0.85)
Median	1.5	0.1	0.0	0.1
Min, Max	0, 3	0, 1	0, 0	0, 3
Cycle 24 Day 1				
n	2	4	1	7
Mean (StdDev)	1.2 (0.87)	0.1 (0.14)	0.0 (-)	0.4 (0.64)
Median	1.2	0.1	0.0	0.2
Min, Max	1, 2	0, 0	0, 0	0, 2
Cycle 30 Day 1				
n	1	0	1	2
Mean (StdDev)	0.5 (-)		0.0 (-)	0.3 (0.31)
Median	0.5		0.0	0.3
Min, Max	0, 0		0, 0	0, 0
Cycle 36 Day 1				
n	1	0	0	1
Mean (StdDev)	0.3 (-)			0.3 (-)
Median	0.3			0.3
Min, Max	0, 0			0, 0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg				
D816V Mutation (%) Allele Fraction	ASM (N=9)	SM-AHN (N=47)	MCL (N=16)	All AdvSM (N=72)
Baseline				
n	9	47	16	72
Mean (StdDev)	6.7 (13.06)	25.6 (18.96)	15.7 (17.39)	21.0 (19.03)
Median	1.8	25.1	5.8	18.8
Min, Max	0, 40	0, 80	0, 42	0, 80
Cycle 1 Day 15				
n	8	43	15	66
Mean (StdDev)	6.4 (12.96)	23.3 (16.58)	12.3 (14.86)	18.7 (16.88)
Median	1.0	21.9	3.5	17.3
Min, Max	0, 38	0, 68	0, 37	0, 68
Cycle 2 Day 1				
n	8	42	15	65
Mean (StdDev)	1.3 (2.04)	20.5 (16.52)	9.0 (11.66)	15.5 (16.02)
Median	0.5	17.4	1.6	9.2
Min, Max	0, 6	0, 51	0, 31	0, 51

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg				
D816V Mutation (%) Allele Fraction	ASM (N=9)	SM-AHN (N=47)	MCL (N=16)	All AdvSM (N=72)
Cycle 3 Day 1				
n	8	38	12	58
Mean (StdDev)	5.3 (11.69)	17.0 (16.03)	10.9 (14.07)	14.1 (15.51)
Median	0.6	13.0	2.2	7.9
Min, Max	0, 34	0, 47	0, 40	0, 47
Cycle 5 Day 1				
n	4	17	7	28
Mean (StdDev)	0.7 (1.20)	16.2 (16.79)	2.0 (3.90)	10.4 (14.96)
Median	0.1	10.2	0.0	2.6
Min, Max	0, 2	0, 46	0, 11	0, 46
Cycle 7 Day 1				
n	4	26	8	38
Mean (StdDev)	1.4 (1.60)	14.2 (16.52)	4.5 (8.54)	10.8 (14.98)
Median	1.2	6.9	0.2	2.9
Min, Max	0, 3	0, 48	0, 24	0, 48
Cycle 11 Day 1				
n	3	16	6	25
Mean (StdDev)	1.2 (1.51)	8.7 (13.93)	5.0 (11.37)	6.9 (12.47)
Median	0.7	1.6	0.2	0.9
Min, Max	0, 3	0, 37	0, 28	0, 37

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg				
D816V Mutation (%) Allele Fraction	ASM (N=9)	SM-AHN (N=47)	MCL (N=16)	All AdvSM (N=72)
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		35.9 (-)		35.9 (-)
Median		35.9		35.9
Min, Max		36, 36		36, 36
Cycle 18 Day 1				
n	2	6	2	10
Mean (StdDev)	1.5 (1.62)	0.2 (0.25)	0.1 (0.09)	0.4 (0.81)
Median	1.5	0.1	0.1	0.1
Min, Max	0, 3	0, 1	0, 0	0, 3
Cycle 24 Day 1				
n	2	5	1	8
Mean (StdDev)	1.2 (0.87)	0.1 (0.13)	0.0 (-)	0.4 (0.61)
Median	1.2	0.1	0.0	0.1
Min, Max	1, 2	0, 0	0, 0	0, 2
Cycle 30 Day 1				
n	1	1	1	3
Mean (StdDev)	0.5 (-)	0.0 (-)	0.0 (-)	0.2 (0.26)
Median	0.5	0.0	0.0	0.0
Min, Max	0, 0	0, 0	0, 0	0, 0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg				
D816V Mutation (%) Allele Fraction	ASM (N=9)	SM-AHN (N=47)	MCL (N=16)	All AdvSM (N=72)
Cycle 36 Day 1				
n	1	1	0	2
Mean (StdDev)	0.3 (-)	0.0 (-)		0.2 (0.23)
Median	0.3	0.0		0.2
Min, Max	0, 0	0, 0		0, 0
Cycle 42 Day 1				
n	0	1	0	1
Mean (StdDev)		0.0 (-)		0.0 (-)
Median		0.0		0.0
Min, Max		0, 0		0, 0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg				
D816V Mutation (%) Allele Fraction	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Baseline				
n	1	4	0	5
Mean (StdDev)	1.4 (-)	16.6 (12.42)		13.6 (12.71)
Median	1.4	18.6		14.5
Min, Max	1, 1	0, 29		0, 29
Cycle 1 Day 15				
n	1	4	0	5
Mean (StdDev)	1.2 (-)	18.6 (19.01)		15.1 (18.22)
Median	1.2	19.1		4.4
Min, Max	1, 1	0, 36		0, 36
Cycle 2 Day 1				
n	1	3	0	4
Mean (StdDev)	0.7 (-)	9.5 (13.39)		7.3 (11.79)
Median	0.7	3.6		2.1
Min, Max	1, 1	0, 25		0, 25

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg				
D816V Mutation (%) Allele Fraction	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Cycle 3 Day 1				
n	1	2	0	3
Mean (StdDev)	0.5 (-)	6.1 (3.28)		4.2 (3.97)
Median	0.5	6.1		3.8
Min, Max	1, 1	4, 8		1, 8
Cycle 5 Day 1				
n	1	3	0	4
Mean (StdDev)	0.3 (-)	3.4 (2.96)		2.6 (2.87)
Median	0.3	4.5		2.4
Min, Max	0, 0	0, 6		0, 6
Cycle 7 Day 1				
n	1	2	0	3
Mean (StdDev)	0.5 (-)	3.5 (1.36)		2.5 (1.98)
Median	0.5	3.5		2.5
Min, Max	0, 0	2, 4		0, 4
Cycle 11 Day 1				
n	0	1	0	1
Mean (StdDev)		1.7 (-)		1.7 (-)
Median		1.7		1.7
Min, Max		2, 2		2, 2

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.1
Summary of KIT D816V Mutation Allele Fraction in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg				
D816V Mutation (%) Allele Fraction	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Cycle 24 Day 1				
n	0	2	0	2
Mean (StdDev)		0.0 (0.01)		0.0 (0.01)
Median		0.0		0.0
Min, Max		0, 0		0, 0
Cycle 30 Day 1				
n	0	1	0	1
Mean (StdDev)		0.0 (-)		0.0 (-)
Median		0.0		0.0
Min, Max		0, 0		0, 0
Cycle 36 Day 1				
n	0	1	0	1
Mean (StdDev)		0.0 (-)		0.0 (-)
Median		0.0		0.0
Min, Max		0, 0		0, 0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-advsm.sas Date: 19:33/27SEP2021

Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Overall				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=7)	SM-AHN (N=26)	MCL (N=8)	All AdvSM (N=41)
Baseline				
n	7	26	7	40
Mean (StdDev)	2.7 (4.33)	26.5 (20.55)	5.5 (9.86)	18.7 (20.17)
Median	1.4	24.8	0.1	11.5
Min, Max	0, 12	0, 80	0, 27	0, 80
Percent Change from Baseline to Cycle 1 Day 15				
n	3	24	3	30
Mean (StdDev)	-20.1 (9.11)	-13.3 (24.95)	-12.3 (7.93)	-13.9 (22.54)
Median	-20.1	-11.9	-14.5	-12.6
Min, Max	-29, -11	-70, 60	-19, -4	-70, 60
Percent Change from Baseline to Cycle 2 Day 1				
n	4	23	3	30
Mean (StdDev)	-46.6 (10.14)	-31.3 (28.22)	-41.9 (20.26)	-34.4 (26.02)
Median	-50.5	-30.1	-42.7	-34.4
Min, Max	-53, -32	-82, 10	-62, -21	-82, 10

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Overall

D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=7)	SM-AHN (N=26)	MCL (N=8)	All AdvSM (N=41)
Percent Change from Baseline to Cycle 3 Day 1				
n	3	21	3	27
Mean (StdDev)	-67.8 (6.08)	-47.5 (28.84)	-60.0 (20.28)	-51.2 (26.94)
Median	-64.6	-47.0	-49.3	-50.3
Min, Max	-75, -64	-89, -3	-83, -47	-89, -3
Percent Change from Baseline to Cycle 5 Day 1				
n	4	21	3	28
Mean (StdDev)	-76.1 (13.72)	-58.7 (34.99)	-71.3 (16.40)	-62.5 (31.54)
Median	-79.4	-72.7	-62.7	-73.5
Min, Max	-89, -57	-98, 8	-90, -61	-98, 8
Percent Change from Baseline to Cycle 7 Day 1				
n	4	14	3	21
Mean (StdDev)	-75.7 (10.79)	-60.0 (38.89)	-77.4 (14.96)	-65.4 (32.96)
Median	-74.9	-82.0	-74.1	-81.8
Min, Max	-88, -65	-98, 8	-94, -64	-98, 8
Percent Change from Baseline to Cycle 11 Day 1				
n	3	11	2	16
Mean (StdDev)	-65.3 (9.39)	-75.5 (34.43)	-86.2 (9.63)	-75.0 (29.05)
Median	-61.5	-92.4	-86.2	-90.0
Min, Max	-76, -59	-100, -5	-93, -79	-100, -5

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Overall

D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=7)	SM-AHN (N=26)	MCL (N=8)	All AdvSM (N=41)
Percent Change from Baseline to Cycle 18 Day 1				
n	3	7	1	11
Mean (StdDev)	-69.7 (15.55)	-97.0 (4.73)	-96.5 (-)	-89.5 (14.94)
Median	-78.0	-98.6	-96.5	-96.7
Min, Max	-79, -52	-100, -87	-96, -96	-100, -52
Percent Change from Baseline to Cycle 24 Day 1				
n	3	8	0	11
Mean (StdDev)	-65.0 (21.42)	-98.5 (1.55)		-89.4 (18.37)
Median	-67.6	-98.9		-97.6
Min, Max	-85, -42	-100, -95		-100, -42
Percent Change from Baseline to Cycle 30 Day 1				
n	2	3	0	5
Mean (StdDev)	-73.4 (0.53)	-97.9 (2.14)		-88.1 (13.54)
Median	-73.4	-99.0		-95.5
Min, Max	-74, -73	-99, -95		-99, -73
Percent Change from Baseline to Cycle 36 Day 1				
n	2	3	0	5
Mean (StdDev)	-82.7 (1.67)	-98.2 (2.40)		-92.0 (8.68)
Median	-82.7	-99.3		-95.5
Min, Max	-84, -82	-100, -95		-100, -82

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Overall

D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=7)	SM-AHN (N=26)	MCL (N=8)	All AdvSM (N=41)
Percent Change from Baseline to Cycle 42 Day 1				
n	1	2	0	3
Mean (StdDev)	-87.5 (-)	-99.4 (0.59)		-95.4 (6.93)
Median	-87.5	-99.4		-99.0
Min, Max	-87, -87	-100, -99		-100, -87
Percent Change from Baseline to Cycle 48 Day 1				
n	1	0	0	1
Mean (StdDev)	-82.6 (-)			-82.6 (-)
Median	-82.6			-82.6
Min, Max	-83, -83			-83, -83

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <200 mg				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=1)	SM-AHN (N=2)	MCL (N=1)	All AdvSM (N=4)
Baseline				
n	1	2	0	3
Mean (StdDev)	3.1 (-)	24.7 (30.58)		17.5 (24.95)
Median	3.1	24.7		3.1
Min, Max	3, 3	3, 46		3, 46
Percent Change from Baseline to Cycle 1 Day 15				
n	1	2	0	3
Mean (StdDev)	-10.9 (-)	-9.8 (4.15)		-10.2 (3.00)
Median	-10.9	-9.8		-10.9
Min, Max	-11, -11	-13, -7		-13, -7
Percent Change from Baseline to Cycle 2 Day 1				
n	1	2	0	3
Mean (StdDev)	-31.8 (-)	-29.0 (29.05)		-29.9 (20.61)
Median	-31.8	-29.0		-31.8
Min, Max	-32, -32	-50, -8		-50, -8

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <200 mg				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=1)	SM-AHN (N=2)	MCL (N=1)	All AdvSM (N=4)
Percent Change from Baseline to Cycle 3 Day 1				
n	0	2	0	2
Mean (StdDev)		-40.6 (49.20)		-40.6 (49.20)
Median		-40.6		-40.6
Min, Max		-75, -6		-75, -6
Percent Change from Baseline to Cycle 5 Day 1				
n	1	2	0	3
Mean (StdDev)	-56.6 (-)	-51.1 (44.14)		-52.9 (31.37)
Median	-56.6	-51.1		-56.6
Min, Max	-57, -57	-82, -20		-82, -20
Percent Change from Baseline to Cycle 7 Day 1				
n	1	2	0	3
Mean (StdDev)	-65.3 (-)	-47.1 (49.79)		-53.1 (36.74)
Median	-65.3	-47.1		-65.3
Min, Max	-65, -65	-82, -12		-82, -12
Percent Change from Baseline to Cycle 11 Day 1				
n	1	2	0	3
Mean (StdDev)	-58.5 (-)	-63.5 (34.49)		-61.8 (24.56)
Median	-58.5	-63.5		-58.5
Min, Max	-59, -59	-88, -39		-88, -39

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <200 mg				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=1)	SM-AHN (N=2)	MCL (N=1)	All AdvSM (N=4)
Percent Change from Baseline to Cycle 18 Day 1				
n	1	2	0	3
Mean (StdDev)	-51.8 (-)	-91.7 (7.17)		-78.4 (23.58)
Median	-51.8	-91.7		-86.6
Min, Max	-52, -52	-97, -87		-97, -52
Percent Change from Baseline to Cycle 24 Day 1				
n	1	2	0	3
Mean (StdDev)	-42.4 (-)	-97.5 (0.17)		-79.1 (31.79)
Median	-42.4	-97.5		-97.4
Min, Max	-42, -42	-98, -97		-98, -42
Percent Change from Baseline to Cycle 30 Day 1				
n	1	2	0	3
Mean (StdDev)	-73.0 (-)	-99.2 (0.19)		-90.4 (15.10)
Median	-73.0	-99.2		-99.0
Min, Max	-73, -73	-99, -99		-99, -73
Percent Change from Baseline to Cycle 36 Day 1				
n	1	2	0	3
Mean (StdDev)	-83.9 (-)	-99.6 (0.34)		-94.4 (9.05)
Median	-83.9	-99.6		-99.3
Min, Max	-84, -84	-100, -99		-100, -84

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <200 mg				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=1)	SM-AHN (N=2)	MCL (N=1)	All AdvSM (N=4)
Percent Change from Baseline to Cycle 42 Day 1				
n	1	2	0	3
Mean (StdDev)	-87.5 (-)	-99.4 (0.59)		-95.4 (6.93)
Median	-87.5	-99.4		-99.0
Min, Max	-87, -87	-100, -99		-100, -87
Percent Change from Baseline to Cycle 48 Day 1				
n	1	0	0	1
Mean (StdDev)	-82.6 (-)			-82.6 (-)
Median	-82.6			-82.6
Min, Max	-83, -83			-83, -83

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <300 mg				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=2)	SM-AHN (N=9)	MCL (N=5)	All AdvSM (N=16)
Baseline				
n	2	9	4	15
Mean (StdDev)	1.6 (2.18)	21.5 (20.64)	9.6 (11.90)	15.7 (18.29)
Median	1.6	12.9	5.8	6.7
Min, Max	0, 3	0, 46	0, 27	0, 46
Percent Change from Baseline to Cycle 1 Day 15				
n	1	8	3	12
Mean (StdDev)	-10.9 (-)	-15.9 (19.28)	-12.3 (7.93)	-14.6 (15.87)
Median	-10.9	-8.3	-14.5	-10.3
Min, Max	-11, -11	-50, -1	-19, -4	-50, -1
Percent Change from Baseline to Cycle 2 Day 1				
n	1	8	3	12
Mean (StdDev)	-31.8 (-)	-31.9 (23.44)	-41.9 (20.26)	-34.4 (21.08)
Median	-31.8	-35.6	-42.7	-37.3
Min, Max	-32, -32	-60, 0	-62, -21	-62, 0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <300 mg				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=2)	SM-AHN (N=9)	MCL (N=5)	All AdvSM (N=16)
Percent Change from Baseline to Cycle 3 Day 1				
n	0	7	3	10
Mean (StdDev)		-46.7 (31.32)	-60.0 (20.28)	-50.7 (28.04)
Median		-47.0	-49.3	-48.3
Min, Max		-81, -6	-83, -47	-83, -6
Percent Change from Baseline to Cycle 5 Day 1				
n	1	6	3	10
Mean (StdDev)	-56.6 (-)	-36.8 (39.31)	-71.3 (16.40)	-49.1 (34.48)
Median	-56.6	-41.3	-62.7	-61.8
Min, Max	-57, -57	-82, 8	-90, -61	-90, 8
Percent Change from Baseline to Cycle 7 Day 1				
n	1	5	3	9
Mean (StdDev)	-65.3 (-)	-36.4 (42.52)	-77.4 (14.96)	-53.3 (37.05)
Median	-65.3	-14.4	-74.1	-65.3
Min, Max	-65, -65	-82, 8	-94, -64	-94, 8
Percent Change from Baseline to Cycle 11 Day 1				
n	1	4	2	7
Mean (StdDev)	-58.5 (-)	-56.4 (42.33)	-86.2 (9.63)	-65.2 (33.42)
Median	-58.5	-63.5	-86.2	-79.4
Min, Max	-59, -59	-94, -5	-93, -79	-94, -5

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <300 mg				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=2)	SM-AHN (N=9)	MCL (N=5)	All AdvSM (N=16)
Percent Change from Baseline to Cycle 18 Day 1				
n	1	2	1	4
Mean (StdDev)	-51.8 (-)	-91.7 (7.17)	-96.5 (-)	-82.9 (21.28)
Median	-51.8	-91.7	-96.5	-91.5
Min, Max	-52, -52	-97, -87	-96, -96	-97, -52
Percent Change from Baseline to Cycle 24 Day 1				
n	1	2	0	3
Mean (StdDev)	-42.4 (-)	-97.5 (0.17)		-79.1 (31.79)
Median	-42.4	-97.5		-97.4
Min, Max	-42, -42	-98, -97		-98, -42
Percent Change from Baseline to Cycle 30 Day 1				
n	1	2	0	3
Mean (StdDev)	-73.0 (-)	-99.2 (0.19)		-90.4 (15.10)
Median	-73.0	-99.2		-99.0
Min, Max	-73, -73	-99, -99		-99, -73
Percent Change from Baseline to Cycle 36 Day 1				
n	1	2	0	3
Mean (StdDev)	-83.9 (-)	-99.6 (0.34)		-94.4 (9.05)
Median	-83.9	-99.6		-99.3
Min, Max	-84, -84	-100, -99		-100, -84

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <300 mg				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=2)	SM-AHN (N=9)	MCL (N=5)	All AdvSM (N=16)
Percent Change from Baseline to Cycle 42 Day 1				
n	1	2	0	3
Mean (StdDev)	-87.5 (-)	-99.4 (0.59)		-95.4 (6.93)
Median	-87.5	-99.4		-99.0
Min, Max	-87, -87	-100, -99		-100, -87
Percent Change from Baseline to Cycle 48 Day 1				
n	1	0	0	1
Mean (StdDev)	-82.6 (-)			-82.6 (-)
Median	-82.6			-82.6
Min, Max	-83, -83			-83, -83

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=1)	SM-AHN (N=7)	MCL (N=4)	All AdvSM (N=12)
Baseline				
n	1	7	4	12
Mean (StdDev)	0.0 (-)	20.6 (20.19)	9.6 (11.90)	15.2 (17.65)
Median	0.0	12.9	5.8	7.0
Min, Max	0, 0	0, 44	0, 27	0, 44
Percent Change from Baseline to Cycle 1 Day 15				
n	0	6	3	9
Mean (StdDev)		-17.9 (22.30)	-12.3 (7.93)	-16.1 (18.29)
Median		-6.4	-14.5	-9.7
Min, Max		-50, -1	-19, -4	-50, -1
Percent Change from Baseline to Cycle 2 Day 1				
n	0	6	3	9
Mean (StdDev)		-32.9 (24.41)	-41.9 (20.26)	-35.9 (22.25)
Median		-35.6	-42.7	-42.7
Min, Max		-60, 0	-62, -21	-62, 0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=1)	SM-AHN (N=7)	MCL (N=4)	All AdvSM (N=12)
Percent Change from Baseline to Cycle 3 Day 1				
n	0	5	3	8
Mean (StdDev)		-49.2 (28.97)	-60.0 (20.28)	-53.3 (25.07)
Median		-47.0	-49.3	-48.3
Min, Max		-81, -7	-83, -47	-83, -7
Percent Change from Baseline to Cycle 5 Day 1				
n	0	4	3	7
Mean (StdDev)		-29.7 (41.49)	-71.3 (16.40)	-47.5 (38.01)
Median		-29.3	-62.7	-62.6
Min, Max		-68, 8	-90, -61	-90, 8
Percent Change from Baseline to Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		-29.3 (46.77)	-77.4 (14.96)	-53.3 (40.70)
Median		-14.4	-74.1	-69.2
Min, Max		-82, 8	-94, -64	-94, 8
Percent Change from Baseline to Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		-49.3 (63.14)	-86.2 (9.63)	-67.8 (42.57)
Median		-49.3	-86.2	-86.2
Min, Max		-94, -5	-93, -79	-94, -5

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=1)	SM-AHN (N=7)	MCL (N=4)	All AdvSM (N=12)
Percent Change from Baseline to Cycle 18 Day 1				
n	0	0	1	1
Mean (StdDev)			-96.5 (-)	-96.5 (-)
Median			-96.5	-96.5
Min, Max			-96, -96	-96, -96

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 300 mg				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Baseline				
n	4	13	3	20
Mean (StdDev)	3.5 (5.80)	33.1 (21.42)	0.0 (0.03)	22.2 (22.96)
Median	0.9	37.4	0.0	15.7
Min, Max	0, 12	0, 80	0, 0	0, 80
Percent Change from Baseline to Cycle 1 Day 15				
n	1	12	0	13
Mean (StdDev)	-29.1 (-)	-12.4 (8.74)		-13.6 (9.58)
Median	-29.1	-12.8		-13.2
Min, Max	-29, -29	-26, 1		-29, 1
Percent Change from Baseline to Cycle 2 Day 1				
n	2	12	0	14
Mean (StdDev)	-50.5 (3.51)	-26.4 (25.62)		-29.9 (25.16)
Median	-50.5	-23.1		-31.1
Min, Max	-53, -48	-72, 3		-72, 3

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 300 mg				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Percent Change from Baseline to Cycle 3 Day 1				
n	2	12	0	14
Mean (StdDev)	-69.5 (7.62)	-44.5 (29.68)		-48.1 (28.85)
Median	-69.5	-39.1		-46.4
Min, Max	-75, -64	-89, -3		-89, -3
Percent Change from Baseline to Cycle 5 Day 1				
n	2	12	0	14
Mean (StdDev)	-84.3 (6.46)	-64.8 (33.07)		-67.5 (31.29)
Median	-84.3	-78.1		-80.8
Min, Max	-89, -80	-98, -7		-98, -7
Percent Change from Baseline to Cycle 7 Day 1				
n	2	7	0	9
Mean (StdDev)	-84.8 (4.16)	-70.6 (36.37)		-73.7 (32.15)
Median	-84.8	-87.5		-87.5
Min, Max	-88, -82	-98, -12		-98, -12
Percent Change from Baseline to Cycle 11 Day 1				
n	2	6	0	8
Mean (StdDev)	-68.8 (10.32)	-85.5 (28.77)		-81.3 (25.81)
Median	-68.8	-97.6		-94.7
Min, Max	-76, -61	-100, -27		-100, -27

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 300 mg				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Percent Change from Baseline to Cycle 18 Day 1				
n	2	5	0	7
Mean (StdDev)	-78.7 (0.92)	-99.1 (1.00)		-93.3 (10.00)
Median	-78.7	-99.6		-98.6
Min, Max	-79, -78	-100, -98		-100, -78
Percent Change from Baseline to Cycle 24 Day 1				
n	2	4	0	6
Mean (StdDev)	-76.3 (12.34)	-99.4 (0.51)		-91.7 (13.12)
Median	-76.3	-99.3		-98.9
Min, Max	-85, -68	-100, -99		-100, -68
Percent Change from Baseline to Cycle 30 Day 1				
n	1	0	0	1
Mean (StdDev)	-73.7 (-)			-73.7 (-)
Median	-73.7			-73.7
Min, Max	-74, -74			-74, -74
Percent Change from Baseline to Cycle 36 Day 1				
n	1	0	0	1
Mean (StdDev)	-81.6 (-)			-81.6 (-)
Median	-81.6			-81.6
Min, Max	-82, -82			-82, -82

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=5)	SM-AHN (N=20)	MCL (N=7)	All AdvSM (N=32)
Baseline				
n	5	20	7	32
Mean (StdDev)	2.8 (5.26)	28.7 (21.35)	5.5 (9.86)	19.6 (21.11)
Median	0.1	31.6	0.1	11.5
Min, Max	0, 12	0, 80	0, 27	0, 80
Percent Change from Baseline to Cycle 1 Day 15				
n	1	18	3	22
Mean (StdDev)	-29.1 (-)	-14.2 (14.25)	-12.3 (7.93)	-14.6 (13.46)
Median	-29.1	-11.9	-14.5	-12.8
Min, Max	-29, -29	-50, 1	-19, -4	-50, 1
Percent Change from Baseline to Cycle 2 Day 1				
n	2	18	3	23
Mean (StdDev)	-50.5 (3.51)	-28.6 (24.69)	-41.9 (20.26)	-32.2 (23.73)
Median	-50.5	-29.3	-42.7	-32.1
Min, Max	-53, -48	-72, 3	-62, -21	-72, 3

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=5)	SM-AHN (N=20)	MCL (N=7)	All AdvSM (N=32)
Percent Change from Baseline to Cycle 3 Day 1				
n	2	17	3	22
Mean (StdDev)	-69.5 (7.62)	-45.9 (28.65)	-60.0 (20.28)	-50.0 (27.04)
Median	-69.5	-42.4	-49.3	-48.3
Min, Max	-75, -64	-89, -3	-83, -47	-89, -3
Percent Change from Baseline to Cycle 5 Day 1				
n	2	16	3	21
Mean (StdDev)	-84.3 (6.46)	-56.0 (37.32)	-71.3 (16.40)	-60.9 (34.11)
Median	-84.3	-70.5	-62.7	-72.7
Min, Max	-89, -80	-98, 8	-90, -61	-98, 8
Percent Change from Baseline to Cycle 7 Day 1				
n	2	10	3	15
Mean (StdDev)	-84.8 (4.16)	-58.2 (42.01)	-77.4 (14.96)	-65.6 (35.90)
Median	-84.8	-83.1	-74.1	-81.8
Min, Max	-88, -82	-98, 8	-94, -64	-98, 8
Percent Change from Baseline to Cycle 11 Day 1				
n	2	8	2	12
Mean (StdDev)	-68.8 (10.32)	-76.4 (37.96)	-86.2 (9.63)	-76.8 (31.03)
Median	-68.8	-95.7	-86.2	-92.5
Min, Max	-76, -61	-100, -5	-93, -79	-100, -5

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=5)	SM-AHN (N=20)	MCL (N=7)	All AdvSM (N=32)
Percent Change from Baseline to Cycle 18 Day 1				
n	2	5	1	8
Mean (StdDev)	-78.7 (0.92)	-99.1 (1.00)	-96.5 (-)	-93.7 (9.33)
Median	-78.7	-99.6	-96.5	-98.1
Min, Max	-79, -78	-100, -98	-96, -96	-100, -78
Percent Change from Baseline to Cycle 24 Day 1				
n	2	4	0	6
Mean (StdDev)	-76.3 (12.34)	-99.4 (0.51)		-91.7 (13.12)
Median	-76.3	-99.3		-98.9
Min, Max	-85, -68	-100, -99		-100, -68
Percent Change from Baseline to Cycle 30 Day 1				
n	1	0	0	1
Mean (StdDev)	-73.7 (-)			-73.7 (-)
Median	-73.7			-73.7
Min, Max	-74, -74			-74, -74
Percent Change from Baseline to Cycle 36 Day 1				
n	1	0	0	1
Mean (StdDev)	-81.6 (-)			-81.6 (-)
Median	-81.6			-81.6
Min, Max	-82, -82			-82, -82

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 400 mg				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Baseline				
n	1	4	0	5
Mean (StdDev)	1.4 (-)	16.6 (12.42)		13.6 (12.71)
Median	1.4	18.6		14.5
Min, Max	1, 1	0, 29		0, 29
Percent Change from Baseline to Cycle 1 Day 15				
n	1	4	0	5
Mean (StdDev)	-20.1 (-)	-10.7 (59.94)		-12.6 (52.08)
Median	-20.1	-16.7		-20.1
Min, Max	-20, -20	-70, 60		-70, 60
Percent Change from Baseline to Cycle 2 Day 1				
n	1	3	0	4
Mean (StdDev)	-53.5 (-)	-49.1 (51.08)		-50.2 (41.77)
Median	-53.5	-75.3		-64.4
Min, Max	-53, -53	-82, 10		-82, 10

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 400 mg				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Percent Change from Baseline to Cycle 3 Day 1				
n	1	2	0	3
Mean (StdDev)	-64.6 (-)	-68.5 (7.95)		-67.2 (6.05)
Median	-64.6	-68.5		-64.6
Min, Max	-65, -65	-74, -63		-74, -63
Percent Change from Baseline to Cycle 5 Day 1				
n	1	3	0	4
Mean (StdDev)	-79.2 (-)	-78.3 (11.39)		-78.5 (9.31)
Median	-79.2	-75.2		-77.2
Min, Max	-79, -79	-91, -69		-91, -69
Percent Change from Baseline to Cycle 7 Day 1				
n	1	2	0	3
Mean (StdDev)	-68.1 (-)	-81.6 (1.69)		-77.1 (7.93)
Median	-68.1	-81.6		-80.4
Min, Max	-68, -68	-83, -80		-83, -68
Percent Change from Baseline to Cycle 11 Day 1				
n	0	1	0	1
Mean (StdDev)		-92.4 (-)		-92.4 (-)
Median		-92.4		-92.4
Min, Max		-92, -92		-92, -92

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 400 mg				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Percent Change from Baseline to Cycle 24 Day 1				
n	0	2	0	2
Mean (StdDev)		-97.7 (3.12)		-97.7 (3.12)
Median		-97.7		-97.7
Min, Max		-100, -95		-100, -95
Percent Change from Baseline to Cycle 30 Day 1				
n	0	1	0	1
Mean (StdDev)		-95.5 (-)		-95.5 (-)
Median		-95.5		-95.5
Min, Max		-95, -95		-95, -95
Percent Change from Baseline to Cycle 36 Day 1				
n	0	1	0	1
Mean (StdDev)		-95.5 (-)		-95.5 (-)
Median		-95.5		-95.5
Min, Max		-95, -95		-95, -95

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2202

Overall				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Baseline				
n	5	28	9	42
Mean (StdDev)	10.0 (16.83)	23.8 (16.91)	23.6 (18.27)	22.1 (17.36)
Median	3.8	22.4	31.1	22.4
Min, Max	0, 40	1, 47	0, 42	0, 47
Percent Change from Baseline to Cycle 1 Day 15				
n	4	24	7	35
Mean (StdDev)	-15.0 (8.35)	-13.5 (16.21)	-11.2 (29.83)	-13.2 (18.50)
Median	-14.4	-12.5	-18.2	-12.8
Min, Max	-26, -6	-43, 35	-50, 43	-50, 43
Percent Change from Baseline to Cycle 2 Day 1				
n	2	23	7	32
Mean (StdDev)	-40.8 (27.12)	-33.1 (23.94)	-44.0 (14.76)	-36.0 (22.25)
Median	-40.8	-25.1	-42.9	-31.2
Min, Max	-60, -22	-88, 12	-69, -27	-88, 12

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2202

Overall

D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Percent Change from Baseline to Cycle 3 Day 1				
n	3	20	5	28
Mean (StdDev)	-37.7 (25.10)	-47.4 (28.27)	-30.6 (23.16)	-43.4 (27.10)
Median	-33.5	-45.2	-37.4	-39.8
Min, Max	-65, -15	-90, 7	-49, 9	-90, 9
Percent Change from Baseline to Cycle 7 Day 1				
n	1	15	2	18
Mean (StdDev)	-14.2 (-)	-59.0 (36.51)	-34.6 (8.55)	-53.8 (35.52)
Median	-14.2	-81.0	-34.6	-44.7
Min, Max	-14, -14	-99, -2	-41, -29	-99, -2
Percent Change from Baseline to Cycle 11 Day 1				
n	0	7	2	9
Mean (StdDev)		-66.5 (33.78)	-22.3 (11.28)	-56.7 (35.40)
Median		-89.2	-22.3	-52.2
Min, Max		-99, -14	-30, -14	-99, -14
Percent Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		-15.3 (-)		-15.3 (-)
Median		-15.3		-15.3
Min, Max		-15, -15		-15, -15

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2202

Starting Dose: 200 mg				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Baseline				
n	4	27	9	40
Mean (StdDev)	11.5 (19.02)	23.3 (17.02)	23.6 (18.27)	22.2 (17.39)
Median	3.0	19.7	31.1	22.4
Min, Max	0, 40	1, 47	0, 42	0, 47
Percent Change from Baseline to Cycle 1 Day 15				
n	3	23	7	33
Mean (StdDev)	-11.5 (5.40)	-13.6 (16.56)	-11.2 (29.83)	-12.9 (18.93)
Median	-12.6	-12.8	-18.2	-12.8
Min, Max	-16, -6	-43, 35	-50, 43	-50, 43
Percent Change from Baseline to Cycle 2 Day 1				
n	2	22	7	31
Mean (StdDev)	-40.8 (27.12)	-33.9 (24.16)	-44.0 (14.76)	-36.7 (22.27)
Median	-40.8	-28.0	-42.9	-31.5
Min, Max	-60, -22	-88, 12	-69, -27	-88, 12

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2202

Starting Dose: 200 mg				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Percent Change from Baseline to Cycle 3 Day 1				
n	3	19	5	27
Mean (StdDev)	-37.7 (25.10)	-48.5 (28.59)	-30.6 (23.16)	-44.0 (27.40)
Median	-33.5	-48.8	-37.4	-41.6
Min, Max	-65, -15	-90, 7	-49, 9	-90, 9
Percent Change from Baseline to Cycle 7 Day 1				
n	1	14	2	17
Mean (StdDev)	-14.2 (-)	-60.7 (37.32)	-34.6 (8.55)	-54.9 (36.34)
Median	-14.2	-82.9	-34.6	-48.8
Min, Max	-14, -14	-99, -2	-41, -29	-99, -2
Percent Change from Baseline to Cycle 11 Day 1				
n	0	6	2	8
Mean (StdDev)		-72.3 (32.99)	-22.3 (11.28)	-59.8 (36.51)
Median		-89.4	-22.3	-70.7
Min, Max		-99, -14	-30, -14	-99, -14
Percent Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		-15.3 (-)		-15.3 (-)
Median		-15.3		-15.3
Min, Max		-15, -15		-15, -15

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Overall				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=12)	SM-AHN (N=54)	MCL (N=17)	All AdvSM (N=83)
Baseline				
n	12	54	16	82
Mean (StdDev)	5.7 (11.28)	25.1 (18.62)	15.7 (17.39)	20.4 (18.75)
Median	2.0	23.9	5.8	16.5
Min, Max	0, 40	0, 80	0, 42	0, 80
Percent Change from Baseline to Cycle 1 Day 15				
n	7	48	10	65
Mean (StdDev)	-17.2 (8.36)	-13.4 (20.81)	-11.5 (24.64)	-13.5 (20.30)
Median	-16.2	-12.3	-16.3	-12.8
Min, Max	-29, -6	-70, 60	-50, 43	-70, 60
Percent Change from Baseline to Cycle 2 Day 1				
n	6	46	10	62
Mean (StdDev)	-44.7 (14.75)	-32.2 (25.89)	-43.4 (15.41)	-35.2 (23.96)
Median	-50.5	-29.3	-42.8	-31.7
Min, Max	-60, -22	-88, 12	-69, -21	-88, 12

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Overall

D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=12)	SM-AHN (N=54)	MCL (N=17)	All AdvSM (N=83)
Percent Change from Baseline to Cycle 3 Day 1				
n	6	41	8	55
Mean (StdDev)	-52.8 (23.22)	-47.5 (28.20)	-41.6 (25.60)	-47.2 (27.06)
Median	-64.3	-47.0	-45.1	-47.4
Min, Max	-75, -15	-90, 7	-83, 9	-90, 9
Percent Change from Baseline to Cycle 5 Day 1				
n	4	21	3	28
Mean (StdDev)	-76.1 (13.72)	-58.7 (34.99)	-71.3 (16.40)	-62.5 (31.54)
Median	-79.4	-72.7	-62.7	-73.5
Min, Max	-89, -57	-98, 8	-90, -61	-98, 8
Percent Change from Baseline to Cycle 7 Day 1				
n	5	29	5	39
Mean (StdDev)	-63.4 (29.06)	-59.5 (37.00)	-60.3 (26.05)	-60.1 (34.22)
Median	-68.1	-81.8	-64.3	-80.4
Min, Max	-88, -14	-99, 8	-94, -29	-99, 8
Percent Change from Baseline to Cycle 11 Day 1				
n	3	18	4	25
Mean (StdDev)	-65.3 (9.39)	-72.0 (33.47)	-54.2 (37.88)	-68.4 (32.02)
Median	-61.5	-89.9	-54.8	-87.9
Min, Max	-76, -59	-100, -5	-93, -14	-100, -5

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Overall				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=12)	SM-AHN (N=54)	MCL (N=17)	All AdvSM (N=83)
Percent Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		-15.3 (-)		-15.3 (-)
Median		-15.3		-15.3
Min, Max		-15, -15		-15, -15
Percent Change from Baseline to Cycle 18 Day 1				
n	3	7	1	11
Mean (StdDev)	-69.7 (15.55)	-97.0 (4.73)	-96.5 (-)	-89.5 (14.94)
Median	-78.0	-98.6	-96.5	-96.7
Min, Max	-79, -52	-100, -87	-96, -96	-100, -52
Percent Change from Baseline to Cycle 24 Day 1				
n	3	8	0	11
Mean (StdDev)	-65.0 (21.42)	-98.5 (1.55)		-89.4 (18.37)
Median	-67.6	-98.9		-97.6
Min, Max	-85, -42	-100, -95		-100, -42
Percent Change from Baseline to Cycle 30 Day 1				
n	2	3	0	5
Mean (StdDev)	-73.4 (0.53)	-97.9 (2.14)		-88.1 (13.54)
Median	-73.4	-99.0		-95.5
Min, Max	-74, -73	-99, -95		-99, -73

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Overall				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=12)	SM-AHN (N=54)	MCL (N=17)	All AdvSM (N=83)
Percent Change from Baseline to Cycle 36 Day 1				
n	2	3	0	5
Mean (StdDev)	-82.7 (1.67)	-98.2 (2.40)		-92.0 (8.68)
Median	-82.7	-99.3		-95.5
Min, Max	-84, -82	-100, -95		-100, -82
Percent Change from Baseline to Cycle 42 Day 1				
n	1	2	0	3
Mean (StdDev)	-87.5 (-)	-99.4 (0.59)		-95.4 (6.93)
Median	-87.5	-99.4		-99.0
Min, Max	-87, -87	-100, -99		-100, -87
Percent Change from Baseline to Cycle 48 Day 1				
n	1	0	0	1
Mean (StdDev)	-82.6 (-)			-82.6 (-)
Median	-82.6			-82.6
Min, Max	-83, -83			-83, -83

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=2)	SM-AHN (N=3)	MCL (N=1)	All AdvSM (N=6)
Baseline				
n	2	3	0	5
Mean (StdDev)	3.5 (0.50)	28.9 (22.80)		18.7 (21.29)
Median	3.5	37.2		3.8
Min, Max	3, 4	3, 46		3, 46
Percent Change from Baseline to Cycle 1 Day 15				
n	2	3	0	5
Mean (StdDev)	-18.3 (10.41)	-10.1 (2.96)		-13.4 (7.20)
Median	-18.3	-10.5		-10.9
Min, Max	-26, -11	-13, -7		-26, -7
Percent Change from Baseline to Cycle 2 Day 1				
n	1	3	0	4
Mean (StdDev)	-31.8 (-)	-24.2 (22.11)		-26.1 (18.45)
Median	-31.8	-14.8		-23.3
Min, Max	-32, -32	-50, -8		-50, -8

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=2)	SM-AHN (N=3)	MCL (N=1)	All AdvSM (N=6)
Percent Change from Baseline to Cycle 3 Day 1				
n	0	3	0	3
Mean (StdDev)		-35.8 (35.76)		-35.8 (35.76)
Median		-26.3		-26.3
Min, Max		-75, -6		-75, -6
Percent Change from Baseline to Cycle 5 Day 1				
n	1	2	0	3
Mean (StdDev)	-56.6 (-)	-51.1 (44.14)		-52.9 (31.37)
Median	-56.6	-51.1		-56.6
Min, Max	-57, -57	-82, -20		-82, -20
Percent Change from Baseline to Cycle 7 Day 1				
n	1	3	0	4
Mean (StdDev)	-65.3 (-)	-43.5 (35.75)		-48.9 (31.16)
Median	-65.3	-36.3		-50.8
Min, Max	-65, -65	-82, -12		-82, -12
Percent Change from Baseline to Cycle 11 Day 1				
n	1	3	0	4
Mean (StdDev)	-58.5 (-)	-52.9 (30.46)		-54.3 (25.03)
Median	-58.5	-39.1		-48.8
Min, Max	-59, -59	-88, -32		-88, -32

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=2)	SM-AHN (N=3)	MCL (N=1)	All AdvSM (N=6)
Percent Change from Baseline to Cycle 18 Day 1				
n	1	2	0	3
Mean (StdDev)	-51.8 (-)	-91.7 (7.17)		-78.4 (23.58)
Median	-51.8	-91.7		-86.6
Min, Max	-52, -52	-97, -87		-97, -52
Percent Change from Baseline to Cycle 24 Day 1				
n	1	2	0	3
Mean (StdDev)	-42.4 (-)	-97.5 (0.17)		-79.1 (31.79)
Median	-42.4	-97.5		-97.4
Min, Max	-42, -42	-98, -97		-98, -42
Percent Change from Baseline to Cycle 30 Day 1				
n	1	2	0	3
Mean (StdDev)	-73.0 (-)	-99.2 (0.19)		-90.4 (15.10)
Median	-73.0	-99.2		-99.0
Min, Max	-73, -73	-99, -99		-99, -73
Percent Change from Baseline to Cycle 36 Day 1				
n	1	2	0	3
Mean (StdDev)	-83.9 (-)	-99.6 (0.34)		-94.4 (9.05)
Median	-83.9	-99.6		-99.3
Min, Max	-84, -84	-100, -99		-100, -84

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=2)	SM-AHN (N=3)	MCL (N=1)	All AdvSM (N=6)
Percent Change from Baseline to Cycle 42 Day 1				
n	1	2	0	3
Mean (StdDev)	-87.5 (-)	-99.4 (0.59)		-95.4 (6.93)
Median	-87.5	-99.4		-99.0
Min, Max	-87, -87	-100, -99		-100, -87
Percent Change from Baseline to Cycle 48 Day 1				
n	1	0	0	1
Mean (StdDev)	-82.6 (-)			-82.6 (-)
Median	-82.6			-82.6
Min, Max	-83, -83			-83, -83

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=7)	SM-AHN (N=37)	MCL (N=14)	All AdvSM (N=58)
Baseline				
n	7	37	13	57
Mean (StdDev)	7.6 (14.36)	23.2 (17.61)	19.3 (17.40)	20.4 (17.68)
Median	3.1	19.7	26.3	18.4
Min, Max	0, 40	0, 47	0, 42	0, 47
Percent Change from Baseline to Cycle 1 Day 15				
n	5	32	10	47
Mean (StdDev)	-14.2 (7.46)	-14.1 (16.73)	-11.5 (24.64)	-13.6 (17.70)
Median	-12.6	-11.3	-16.3	-12.6
Min, Max	-26, -6	-50, 35	-50, 43	-50, 43
Percent Change from Baseline to Cycle 2 Day 1				
n	3	31	10	44
Mean (StdDev)	-37.8 (19.87)	-32.8 (23.43)	-43.4 (15.41)	-35.5 (21.70)
Median	-31.8	-28.4	-42.8	-31.6
Min, Max	-60, -22	-88, 12	-69, -21	-88, 12

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=7)	SM-AHN (N=37)	MCL (N=14)	All AdvSM (N=58)
Percent Change from Baseline to Cycle 3 Day 1				
n	3	27	8	38
Mean (StdDev)	-37.7 (25.10)	-47.2 (28.47)	-41.6 (25.60)	-45.3 (27.16)
Median	-33.5	-47.0	-45.1	-44.9
Min, Max	-65, -15	-90, 7	-83, 9	-90, 9
Percent Change from Baseline to Cycle 5 Day 1				
n	1	6	3	10
Mean (StdDev)	-56.6 (-)	-36.8 (39.31)	-71.3 (16.40)	-49.1 (34.48)
Median	-56.6	-41.3	-62.7	-61.8
Min, Max	-57, -57	-82, 8	-90, -61	-90, 8
Percent Change from Baseline to Cycle 7 Day 1				
n	2	20	5	27
Mean (StdDev)	-39.7 (36.13)	-53.4 (38.26)	-60.3 (26.05)	-53.6 (35.32)
Median	-39.7	-64.9	-64.3	-64.3
Min, Max	-65, -14	-99, 8	-94, -29	-99, 8
Percent Change from Baseline to Cycle 11 Day 1				
n	1	11	4	16
Mean (StdDev)	-58.5 (-)	-62.9 (35.33)	-54.2 (37.88)	-60.4 (33.68)
Median	-58.5	-87.9	-54.8	-68.9
Min, Max	-59, -59	-99, -5	-93, -14	-99, -5

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg

D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=7)	SM-AHN (N=37)	MCL (N=14)	All AdvSM (N=58)
Percent Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		-15.3 (-)		-15.3 (-)
Median		-15.3		-15.3
Min, Max		-15, -15		-15, -15
Percent Change from Baseline to Cycle 18 Day 1				
n	1	2	1	4
Mean (StdDev)	-51.8 (-)	-91.7 (7.17)	-96.5 (-)	-82.9 (21.28)
Median	-51.8	-91.7	-96.5	-91.5
Min, Max	-52, -52	-97, -87	-96, -96	-97, -52
Percent Change from Baseline to Cycle 24 Day 1				
n	1	2	0	3
Mean (StdDev)	-42.4 (-)	-97.5 (0.17)		-79.1 (31.79)
Median	-42.4	-97.5		-97.4
Min, Max	-42, -42	-98, -97		-98, -42
Percent Change from Baseline to Cycle 30 Day 1				
n	1	2	0	3
Mean (StdDev)	-73.0 (-)	-99.2 (0.19)		-90.4 (15.10)
Median	-73.0	-99.2		-99.0
Min, Max	-73, -73	-99, -99		-99, -73

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=7)	SM-AHN (N=37)	MCL (N=14)	All AdvSM (N=58)
Percent Change from Baseline to Cycle 36 Day 1				
n	1	2	0	3
Mean (StdDev)	-83.9 (-)	-99.6 (0.34)		-94.4 (9.05)
Median	-83.9	-99.6		-99.3
Min, Max	-84, -84	-100, -99		-100, -84
Percent Change from Baseline to Cycle 42 Day 1				
n	1	2	0	3
Mean (StdDev)	-87.5 (-)	-99.4 (0.59)		-95.4 (6.93)
Median	-87.5	-99.4		-99.0
Min, Max	-87, -87	-100, -99		-100, -87
Percent Change from Baseline to Cycle 48 Day 1				
n	1	0	0	1
Mean (StdDev)	-82.6 (-)			-82.6 (-)
Median	-82.6			-82.6
Min, Max	-83, -83			-83, -83

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=5)	SM-AHN (N=34)	MCL (N=13)	All AdvSM (N=52)
Baseline				
n	5	34	13	52
Mean (StdDev)	9.2 (17.25)	22.7 (17.42)	19.3 (17.40)	20.6 (17.53)
Median	2.2	19.6	26.3	18.9
Min, Max	0, 40	0, 47	0, 42	0, 47
Percent Change from Baseline to Cycle 1 Day 15				
n	3	29	10	42
Mean (StdDev)	-11.5 (5.40)	-14.5 (17.53)	-11.5 (24.64)	-13.6 (18.62)
Median	-12.6	-12.1	-16.3	-12.7
Min, Max	-16, -6	-50, 35	-50, 43	-50, 43
Percent Change from Baseline to Cycle 2 Day 1				
n	2	28	10	40
Mean (StdDev)	-40.8 (27.12)	-33.7 (23.76)	-43.4 (15.41)	-36.5 (21.98)
Median	-40.8	-29.6	-42.8	-31.6
Min, Max	-60, -22	-88, 12	-69, -21	-88, 12

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=5)	SM-AHN (N=34)	MCL (N=13)	All AdvSM (N=52)
Percent Change from Baseline to Cycle 3 Day 1				
n	3	24	8	35
Mean (StdDev)	-37.7 (25.10)	-48.7 (28.03)	-41.6 (25.60)	-46.1 (26.82)
Median	-33.5	-47.9	-45.1	-47.0
Min, Max	-65, -15	-90, 7	-83, 9	-90, 9
Percent Change from Baseline to Cycle 5 Day 1				
n	0	4	3	7
Mean (StdDev)		-29.7 (41.49)	-71.3 (16.40)	-47.5 (38.01)
Median		-29.3	-62.7	-62.6
Min, Max		-68, 8	-90, -61	-90, 8
Percent Change from Baseline to Cycle 7 Day 1				
n	1	17	5	23
Mean (StdDev)	-14.2 (-)	-55.1 (39.46)	-60.3 (26.05)	-54.5 (36.57)
Median	-14.2	-81.0	-64.3	-64.3
Min, Max	-14, -14	-99, 8	-94, -29	-99, 8
Percent Change from Baseline to Cycle 11 Day 1				
n	0	8	4	12
Mean (StdDev)		-66.6 (38.21)	-54.2 (37.88)	-62.5 (36.85)
Median		-89.4	-54.8	-84.3
Min, Max		-99, -5	-93, -14	-99, -5

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=5)	SM-AHN (N=34)	MCL (N=13)	All AdvSM (N=52)
Percent Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		-15.3 (-)		-15.3 (-)
Median		-15.3		-15.3
Min, Max		-15, -15		-15, -15
Percent Change from Baseline to Cycle 18 Day 1				
n	0	0	1	1
Mean (StdDev)			-96.5 (-)	-96.5 (-)
Median			-96.5	-96.5
Min, Max			-96, -96	-96, -96

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Baseline				
n	4	13	3	20
Mean (StdDev)	3.5 (5.80)	33.1 (21.42)	0.0 (0.03)	22.2 (22.96)
Median	0.9	37.4	0.0	15.7
Min, Max	0, 12	0, 80	0, 0	0, 80
Percent Change from Baseline to Cycle 1 Day 15				
n	1	12	0	13
Mean (StdDev)	-29.1 (-)	-12.4 (8.74)		-13.6 (9.58)
Median	-29.1	-12.8		-13.2
Min, Max	-29, -29	-26, 1		-29, 1
Percent Change from Baseline to Cycle 2 Day 1				
n	2	12	0	14
Mean (StdDev)	-50.5 (3.51)	-26.4 (25.62)		-29.9 (25.16)
Median	-50.5	-23.1		-31.1
Min, Max	-53, -48	-72, 3		-72, 3

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Percent Change from Baseline to Cycle 3 Day 1				
n	2	12	0	14
Mean (StdDev)	-69.5 (7.62)	-44.5 (29.68)		-48.1 (28.85)
Median	-69.5	-39.1		-46.4
Min, Max	-75, -64	-89, -3		-89, -3
Percent Change from Baseline to Cycle 5 Day 1				
n	2	12	0	14
Mean (StdDev)	-84.3 (6.46)	-64.8 (33.07)		-67.5 (31.29)
Median	-84.3	-78.1		-80.8
Min, Max	-89, -80	-98, -7		-98, -7
Percent Change from Baseline to Cycle 7 Day 1				
n	2	7	0	9
Mean (StdDev)	-84.8 (4.16)	-70.6 (36.37)		-73.7 (32.15)
Median	-84.8	-87.5		-87.5
Min, Max	-88, -82	-98, -12		-98, -12
Percent Change from Baseline to Cycle 11 Day 1				
n	2	6	0	8
Mean (StdDev)	-68.8 (10.32)	-85.5 (28.77)		-81.3 (25.81)
Median	-68.8	-97.6		-94.7
Min, Max	-76, -61	-100, -27		-100, -27

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Percent Change from Baseline to Cycle 18 Day 1				
n	2	5	0	7
Mean (StdDev)	-78.7 (0.92)	-99.1 (1.00)		-93.3 (10.00)
Median	-78.7	-99.6		-98.6
Min, Max	-79, -78	-100, -98		-100, -78
Percent Change from Baseline to Cycle 24 Day 1				
n	2	4	0	6
Mean (StdDev)	-76.3 (12.34)	-99.4 (0.51)		-91.7 (13.12)
Median	-76.3	-99.3		-98.9
Min, Max	-85, -68	-100, -99		-100, -68
Percent Change from Baseline to Cycle 30 Day 1				
n	1	0	0	1
Mean (StdDev)	-73.7 (-)			-73.7 (-)
Median	-73.7			-73.7
Min, Max	-74, -74			-74, -74
Percent Change from Baseline to Cycle 36 Day 1				
n	1	0	0	1
Mean (StdDev)	-81.6 (-)			-81.6 (-)
Median	-81.6			-81.6
Min, Max	-82, -82			-82, -82

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=9)	SM-AHN (N=47)	MCL (N=16)	All AdvSM (N=72)
Baseline				
n	9	47	16	72
Mean (StdDev)	6.7 (13.06)	25.6 (18.96)	15.7 (17.39)	21.0 (19.03)
Median	1.8	25.1	5.8	18.8
Min, Max	0, 40	0, 80	0, 42	0, 80
Percent Change from Baseline to Cycle 1 Day 15				
n	4	41	10	55
Mean (StdDev)	-15.9 (9.88)	-13.9 (15.40)	-11.5 (24.64)	-13.6 (16.84)
Median	-14.4	-12.5	-16.3	-12.8
Min, Max	-29, -6	-50, 35	-50, 43	-50, 43
Percent Change from Baseline to Cycle 2 Day 1				
n	4	40	10	54
Mean (StdDev)	-45.7 (16.75)	-31.5 (24.24)	-43.4 (15.41)	-34.8 (22.79)
Median	-50.5	-29.3	-42.8	-31.6
Min, Max	-60, -22	-88, 12	-69, -21	-88, 12

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=9)	SM-AHN (N=47)	MCL (N=16)	All AdvSM (N=72)
Percent Change from Baseline to Cycle 3 Day 1				
n	5	36	8	49
Mean (StdDev)	-50.4 (25.14)	-47.3 (28.24)	-41.6 (25.60)	-46.7 (27.12)
Median	-64.1	-44.7	-45.1	-47.0
Min, Max	-75, -15	-90, 7	-83, 9	-90, 9
Percent Change from Baseline to Cycle 5 Day 1				
n	2	16	3	21
Mean (StdDev)	-84.3 (6.46)	-56.0 (37.32)	-71.3 (16.40)	-60.9 (34.11)
Median	-84.3	-70.5	-62.7	-72.7
Min, Max	-89, -80	-98, 8	-90, -61	-98, 8
Percent Change from Baseline to Cycle 7 Day 1				
n	3	24	5	32
Mean (StdDev)	-61.2 (40.86)	-59.6 (38.46)	-60.3 (26.05)	-59.9 (35.96)
Median	-81.8	-83.1	-64.3	-81.4
Min, Max	-88, -14	-99, 8	-94, -29	-99, 8
Percent Change from Baseline to Cycle 11 Day 1				
n	2	14	4	20
Mean (StdDev)	-68.8 (10.32)	-74.7 (34.62)	-54.2 (37.88)	-70.0 (33.48)
Median	-68.8	-91.2	-54.8	-89.4
Min, Max	-76, -61	-100, -5	-93, -14	-100, -5

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=9)	SM-AHN (N=47)	MCL (N=16)	All AdvSM (N=72)
Percent Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		-15.3 (-)		-15.3 (-)
Median		-15.3		-15.3
Min, Max		-15, -15		-15, -15
Percent Change from Baseline to Cycle 18 Day 1				
n	2	5	1	8
Mean (StdDev)	-78.7 (0.92)	-99.1 (1.00)	-96.5 (-)	-93.7 (9.33)
Median	-78.7	-99.6	-96.5	-98.1
Min, Max	-79, -78	-100, -98	-96, -96	-100, -78
Percent Change from Baseline to Cycle 24 Day 1				
n	2	4	0	6
Mean (StdDev)	-76.3 (12.34)	-99.4 (0.51)		-91.7 (13.12)
Median	-76.3	-99.3		-98.9
Min, Max	-85, -68	-100, -99		-100, -68
Percent Change from Baseline to Cycle 30 Day 1				
n	1	0	0	1
Mean (StdDev)	-73.7 (-)			-73.7 (-)
Median	-73.7			-73.7
Min, Max	-74, -74			-74, -74

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=9)	SM-AHN (N=47)	MCL (N=16)	All AdvSM (N=72)
Percent Change from Baseline to Cycle 36 Day 1				
n	1	0	0	1
Mean (StdDev)	-81.6 (-)			-81.6 (-)
Median	-81.6			-81.6
Min, Max	-82, -82			-82, -82

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-mut-bd-pchg-advsm.sas Date: 19:34/27SEP2021

Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Baseline				
n	1	4	0	5
Mean (StdDev)	1.4 (-)	16.6 (12.42)		13.6 (12.71)
Median	1.4	18.6		14.5
Min, Max	1, 1	0, 29		0, 29
Percent Change from Baseline to Cycle 1 Day 15				
n	1	4	0	5
Mean (StdDev)	-20.1 (-)	-10.7 (59.94)		-12.6 (52.08)
Median	-20.1	-16.7		-20.1
Min, Max	-20, -20	-70, 60		-70, 60
Percent Change from Baseline to Cycle 2 Day 1				
n	1	3	0	4
Mean (StdDev)	-53.5 (-)	-49.1 (51.08)		-50.2 (41.77)
Median	-53.5	-75.3		-64.4
Min, Max	-53, -53	-82, 10		-82, 10

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Percent Change from Baseline to Cycle 3 Day 1				
n	1	2	0	3
Mean (StdDev)	-64.6 (-)	-68.5 (7.95)		-67.2 (6.05)
Median	-64.6	-68.5		-64.6
Min, Max	-65, -65	-74, -63		-74, -63
Percent Change from Baseline to Cycle 5 Day 1				
n	1	3	0	4
Mean (StdDev)	-79.2 (-)	-78.3 (11.39)		-78.5 (9.31)
Median	-79.2	-75.2		-77.2
Min, Max	-79, -79	-91, -69		-91, -69
Percent Change from Baseline to Cycle 7 Day 1				
n	1	2	0	3
Mean (StdDev)	-68.1 (-)	-81.6 (1.69)		-77.1 (7.93)
Median	-68.1	-81.6		-80.4
Min, Max	-68, -68	-83, -80		-83, -68
Percent Change from Baseline to Cycle 11 Day 1				
n	0	1	0	1
Mean (StdDev)		-92.4 (-)		-92.4 (-)
Median		-92.4		-92.4
Min, Max		-92, -92		-92, -92

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 35.2.7.2
Summary of KIT D816V Mutation Allele Fraction Percent Change from Baseline in Blood
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg				
D816V Mutation (%) Allele Fraction Percent Change from Baseline	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Percent Change from Baseline to Cycle 24 Day 1				
n	0	2	0	2
Mean (StdDev)		-97.7 (3.12)		-97.7 (3.12)
Median		-97.7		-97.7
Min, Max		-100, -95		-100, -95
Percent Change from Baseline to Cycle 30 Day 1				
n	0	1	0	1
Mean (StdDev)		-95.5 (-)		-95.5 (-)
Median		-95.5		-95.5
Min, Max		-95, -95		-95, -95
Percent Change from Baseline to Cycle 36 Day 1				
n	0	1	0	1
Mean (StdDev)		-95.5 (-)		-95.5 (-)
Median		-95.5		-95.5
Min, Max		-95, -95		-95, -95

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. In study 2101, if a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Blueprint Medicines Corporation
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Data cutoff: 2101 - 27MAY2020, 2202 - 23JUN2020

Table 99.2.7.3.1b
Summary of KIT D816V Mutation Allele Fraction Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101 & 200 mg Dose Group

Prior antineoplastic therapy = Yes

D816V Mutation Allele Fraction Best Response	ASM (N=1) n (%)	SM-AHN (N=7) n (%)	MCL (N=4) n (%)	All AdvSM (N=12) n (%)	ISM/SSM (N=1) n (%)	All Patients (N=13) n (%)
Patients with Baseline Assessment in Blood	1	7	4	12	1	13
Patients with MAF < 0.17%	0	1 (14.3)	1 (25.0)	2 (16.7)	0	2 (15.4)
Patients with MAF < 1%	0	1 (14.3)	1 (25.0)	2 (16.7)	0	2 (15.4)
>= 50% reduction from baseline	0	5 (71.4)	3 (75.0)	8 (66.7)	0	8 (61.5)
>= 50% reduction from baseline for at least 2 cycles	0	2 (28.6)	3 (75.0)	5 (41.7)	0	5 (38.5)
Patients with Baseline >=1% Assessment in Blood	0	5	3	8	0	8
Patients with MAF < 0.17%	0	0	1 (33.3)	1 (12.5)	0	1 (12.5)
Patients with MAF < 1%	0	0	1 (33.3)	1 (12.5)	0	1 (12.5)
>= 50% reduction from baseline	0	4 (80.0)	3 (100.0)	7 (87.5)	0	7 (87.5)
>= 50% reduction from baseline for at least 2 cycles	0	2 (40.0)	3 (100.0)	5 (62.5)	0	5 (62.5)
Patients with Baseline Assessment in Bone Marrow	1	6	4	11	1	12
Patients with MAF < 0.17%	0	0	0	0	0	0
Patients with MAF < 1%	0	2 (33.3)	1 (25.0)	3 (27.3)	0	3 (25.0)
>= 50% reduction from baseline	0	2 (33.3)	4 (100.0)	6 (54.5)	0	6 (50.0)
>= 50% reduction from baseline for at least 2 cycles	0	2 (33.3)	3 (75.0)	5 (45.5)	0	5 (41.7)
Patients with Baseline >=1% Assessment in Bone marrow	0	4	4	8	0	8
Patients with MAF < 0.17%	0	0	0	0	0	0
Patients with MAF < 1%	0	1 (25.0)	1 (25.0)	2 (25.0)	0	2 (25.0)
>= 50% reduction from baseline	0	2 (50.0)	4 (100.0)	6 (75.0)	0	6 (75.0)
>= 50% reduction from baseline for at least 2 cycles	0	2 (50.0)	3 (75.0)	5 (62.5)	0	5 (62.5)

Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. If a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 99.2.7.3.1b
Summary of KIT D816V Mutation Allele Fraction Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101 & <=200 mg Dose Group

Prior antineoplastic therapy = Yes

D816V Mutation Allele Fraction Best Response	ASM (N=2) n (%)	SM-AHN (N=9) n (%)	MCL (N=5) n (%)	All AdvSM (N=16) n (%)	ISM/SSM (N=4) n (%)	All Patients (N=20) n (%)
Patients with Baseline Assessment in Blood	2	9	4	15	4	19
Patients with MAF < 0.17%	0	3 (33.3)	1 (25.0)	4 (26.7)	0	4 (21.1)
Patients with MAF < 1%	1 (50.0)	3 (33.3)	1 (25.0)	5 (33.3)	1 (25.0)	6 (31.6)
>= 50% reduction from baseline	1 (50.0)	7 (77.8)	3 (75.0)	11 (73.3)	2 (50.0)	13 (68.4)
>= 50% reduction from baseline for at least 2 cycles	1 (50.0)	4 (44.4)	3 (75.0)	8 (53.3)	2 (50.0)	10 (52.6)
Patients with Baseline >=1% Assessment in Blood	1	7	3	11	2	13
Patients with MAF < 0.17%	0	2 (28.6)	1 (33.3)	3 (27.3)	0	3 (23.1)
Patients with MAF < 1%	1 (100.0)	2 (28.6)	1 (33.3)	4 (36.4)	1 (50.0)	5 (38.5)
>= 50% reduction from baseline	1 (100.0)	6 (85.7)	3 (100.0)	10 (90.9)	2 (100.0)	12 (92.3)
>= 50% reduction from baseline for at least 2 cycles	1 (100.0)	4 (57.1)	3 (100.0)	8 (72.7)	2 (100.0)	10 (76.9)
Patients with Baseline Assessment in Bone Marrow	2	8	5	15	4	19
Patients with MAF < 0.17%	0	2 (25.0)	1 (20.0)	3 (20.0)	1 (25.0)	4 (21.1)
Patients with MAF < 1%	1 (50.0)	4 (50.0)	2 (40.0)	7 (46.7)	2 (50.0)	9 (47.4)
>= 50% reduction from baseline	1 (50.0)	4 (50.0)	5 (100.0)	10 (66.7)	3 (75.0)	13 (68.4)
>= 50% reduction from baseline for at least 2 cycles	1 (50.0)	4 (50.0)	4 (80.0)	9 (60.0)	3 (75.0)	12 (63.2)
Patients with Baseline >=1% Assessment in Bone marrow	1	6	5	12	2	14
Patients with MAF < 0.17%	0	2 (33.3)	1 (20.0)	3 (25.0)	0	3 (21.4)
Patients with MAF < 1%	1 (100.0)	3 (50.0)	2 (40.0)	6 (50.0)	1 (50.0)	7 (50.0)
>= 50% reduction from baseline	1 (100.0)	4 (66.7)	5 (100.0)	10 (83.3)	2 (100.0)	12 (85.7)
>= 50% reduction from baseline for at least 2 cycles	1 (100.0)	4 (66.7)	4 (80.0)	9 (75.0)	2 (100.0)	11 (78.6)

Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. If a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.

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Table 99.2.7.3.1b
Summary of KIT D816V Mutation Allele Fraction Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101 & All Dose Groups

Prior antineoplastic therapy = Yes

D816V Mutation Allele Fraction Best Response	ASM (N=7) n (%)	SM-AHN (N=26) n (%)	MCL (N=8) n (%)	All AdvSM (N=41) n (%)	ISM/SSM (N=9) n (%)	All Patients (N=50) n (%)
Patients with Baseline Assessment in Blood	7	26	7	40	9	49
Patients with MAF < 0.17%	0	9 (34.6)	1 (14.3)	10 (25.0)	2 (22.2)	12 (24.5)
Patients with MAF < 1%	3 (42.9)	12 (46.2)	1 (14.3)	16 (40.0)	4 (44.4)	20 (40.8)
>= 50% reduction from baseline	4 (57.1)	20 (76.9)	3 (42.9)	27 (67.5)	6 (66.7)	33 (67.3)
>= 50% reduction from baseline for at least 2 cycles	4 (57.1)	17 (65.4)	3 (42.9)	24 (60.0)	6 (66.7)	30 (61.2)
Patients with Baseline >=1% Assessment in Blood	4	22	3	29	4	33
Patients with MAF < 0.17%	0	7 (31.8)	1 (33.3)	8 (27.6)	0	8 (24.2)
Patients with MAF < 1%	3 (75.0)	10 (45.5)	1 (33.3)	14 (48.3)	2 (50.0)	16 (48.5)
>= 50% reduction from baseline	4 (100.0)	18 (81.8)	3 (100.0)	25 (86.2)	4 (100.0)	29 (87.9)
>= 50% reduction from baseline for at least 2 cycles	4 (100.0)	16 (72.7)	3 (100.0)	23 (79.3)	4 (100.0)	27 (81.8)
Patients with Baseline Assessment in Bone Marrow	6	24	8	38	8	46
Patients with MAF < 0.17%	1 (16.7)	7 (29.2)	3 (37.5)	11 (28.9)	2 (25.0)	13 (28.3)
Patients with MAF < 1%	4 (66.7)	12 (50.0)	4 (50.0)	20 (52.6)	4 (50.0)	24 (52.2)
>= 50% reduction from baseline	4 (66.7)	16 (66.7)	7 (87.5)	27 (71.1)	5 (62.5)	32 (69.6)
>= 50% reduction from baseline for at least 2 cycles	4 (66.7)	14 (58.3)	6 (75.0)	24 (63.2)	4 (50.0)	28 (60.9)
Patients with Baseline >=1% Assessment in Bone marrow	3	20	7	30	3	33
Patients with MAF < 0.17%	0	6 (30.0)	3 (42.9)	9 (30.0)	0	9 (27.3)
Patients with MAF < 1%	3 (100.0)	10 (50.0)	4 (57.1)	17 (56.7)	1 (33.3)	18 (54.5)
>= 50% reduction from baseline	3 (100.0)	15 (75.0)	7 (100.0)	25 (83.3)	3 (100.0)	28 (84.8)
>= 50% reduction from baseline for at least 2 cycles	3 (100.0)	13 (65.0)	6 (85.7)	22 (73.3)	2 (66.7)	24 (72.7)

Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. If a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.

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Table 99.2.7.3.1b
Summary of KIT D816V Mutation Allele Fraction Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101 & 200 mg Dose Group

Prior antineoplastic therapy = No

D816V Mutation Allele Fraction Best Response	ASM (N=0) n (%)	SM-AHN (N=6) n (%)	MCL (N=2) n (%)	All AdvSM (N=8) n (%)	ISM/SSM (N=0) n (%)	All Patients (N=8) n (%)
Patients with Baseline Assessment in Blood	0	6	2	8	0	8
Patients with MAF < 0.17%	0	2 (33.3)	0	2 (25.0)	0	2 (25.0)
Patients with MAF < 1%	0	2 (33.3)	2 (100.0)	4 (50.0)	0	4 (50.0)
>= 50% reduction from baseline	0	5 (83.3)	2 (100.0)	7 (87.5)	0	7 (87.5)
>= 50% reduction from baseline for at least 2 cycles	0	4 (66.7)	2 (100.0)	6 (75.0)	0	6 (75.0)
Patients with Baseline >=1% Assessment in Blood	0	6	2	8	0	8
Patients with MAF < 0.17%	0	2 (33.3)	0	2 (25.0)	0	2 (25.0)
Patients with MAF < 1%	0	2 (33.3)	2 (100.0)	4 (50.0)	0	4 (50.0)
>= 50% reduction from baseline	0	5 (83.3)	2 (100.0)	7 (87.5)	0	7 (87.5)
>= 50% reduction from baseline for at least 2 cycles	0	4 (66.7)	2 (100.0)	6 (75.0)	0	6 (75.0)
Patients with Baseline Assessment in Bone Marrow	0	5	2	7	0	7
Patients with MAF < 0.17%	0	1 (20.0)	0	1 (14.3)	0	1 (14.3)
Patients with MAF < 1%	0	2 (40.0)	0	2 (28.6)	0	2 (28.6)
>= 50% reduction from baseline	0	5 (100.0)	2 (100.0)	7 (100.0)	0	7 (100.0)
>= 50% reduction from baseline for at least 2 cycles	0	2 (40.0)	1 (50.0)	3 (42.9)	0	3 (42.9)
Patients with Baseline >=1% Assessment in Bone marrow	0	5	2	7	0	7
Patients with MAF < 0.17%	0	1 (20.0)	0	1 (14.3)	0	1 (14.3)
Patients with MAF < 1%	0	2 (40.0)	0	2 (28.6)	0	2 (28.6)
>= 50% reduction from baseline	0	5 (100.0)	2 (100.0)	7 (100.0)	0	7 (100.0)
>= 50% reduction from baseline for at least 2 cycles	0	2 (40.0)	1 (50.0)	3 (42.9)	0	3 (42.9)

Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. If a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.

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Table 99.2.7.3.1b
Summary of KIT D816V Mutation Allele Fraction Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101 & <=200 mg Dose Group

Prior antineoplastic therapy = No

D816V Mutation Allele Fraction Best Response	ASM (N=0) n (%)	SM-AHN (N=11) n (%)	MCL (N=2) n (%)	All AdvSM (N=13) n (%)	ISM/SSM (N=2) n (%)	All Patients (N=15) n (%)
Patients with Baseline Assessment in Blood	0	11	2	13	2	15
Patients with MAF < 0.17%	0	4 (36.4)	0	4 (30.8)	1 (50.0)	5 (33.3)
Patients with MAF < 1%	0	5 (45.5)	2 (100.0)	7 (53.8)	1 (50.0)	8 (53.3)
>= 50% reduction from baseline	0	10 (90.9)	2 (100.0)	12 (92.3)	2 (100.0)	14 (93.3)
>= 50% reduction from baseline for at least 2 cycles	0	9 (81.8)	2 (100.0)	11 (84.6)	2 (100.0)	13 (86.7)
Patients with Baseline >=1% Assessment in Blood	0	10	2	12	1	13
Patients with MAF < 0.17%	0	3 (30.0)	0	3 (25.0)	0	3 (23.1)
Patients with MAF < 1%	0	4 (40.0)	2 (100.0)	6 (50.0)	0	6 (46.2)
>= 50% reduction from baseline	0	9 (90.0)	2 (100.0)	11 (91.7)	1 (100.0)	12 (92.3)
>= 50% reduction from baseline for at least 2 cycles	0	8 (80.0)	2 (100.0)	10 (83.3)	1 (100.0)	11 (84.6)
Patients with Baseline Assessment in Bone Marrow	0	9	2	11	2	13
Patients with MAF < 0.17%	0	2 (22.2)	0	2 (18.2)	1 (50.0)	3 (23.1)
Patients with MAF < 1%	0	5 (55.6)	0	5 (45.5)	1 (50.0)	6 (46.2)
>= 50% reduction from baseline	0	9 (100.0)	2 (100.0)	11 (100.0)	2 (100.0)	13 (100.0)
>= 50% reduction from baseline for at least 2 cycles	0	5 (55.6)	1 (50.0)	6 (54.5)	2 (100.0)	8 (61.5)
Patients with Baseline >=1% Assessment in Bone marrow	0	9	2	11	1	12
Patients with MAF < 0.17%	0	2 (22.2)	0	2 (18.2)	0	2 (16.7)
Patients with MAF < 1%	0	5 (55.6)	0	5 (45.5)	0	5 (41.7)
>= 50% reduction from baseline	0	9 (100.0)	2 (100.0)	11 (100.0)	1 (100.0)	12 (100.0)
>= 50% reduction from baseline for at least 2 cycles	0	5 (55.6)	1 (50.0)	6 (54.5)	1 (100.0)	7 (58.3)

Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. If a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.

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Table 99.2.7.3.1b
Summary of KIT D816V Mutation Allele Fraction Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101 & All Dose Groups

Prior antineoplastic therapy = No

D816V Mutation Allele Fraction Best Response	ASM (N=1) n (%)	SM-AHN (N=22) n (%)	MCL (N=5) n (%)	All AdvSM (N=28) n (%)	ISM/SSM (N=7) n (%)	All Patients (N=35) n (%)
Patients with Baseline Assessment in Blood	1	22	4	27	7	34
Patients with MAF < 0.17%	1 (100.0)	8 (36.4)	1 (25.0)	10 (37.0)	4 (57.1)	14 (41.2)
Patients with MAF < 1%	1 (100.0)	12 (54.5)	3 (75.0)	16 (59.3)	5 (71.4)	21 (61.8)
>= 50% reduction from baseline	1 (100.0)	18 (81.8)	4 (100.0)	23 (85.2)	7 (100.0)	30 (88.2)
>= 50% reduction from baseline for at least 2 cycles	1 (100.0)	17 (77.3)	4 (100.0)	22 (81.5)	7 (100.0)	29 (85.3)
Patients with Baseline >=1% Assessment in Blood	1	19	4	24	3	27
Patients with MAF < 0.17%	1 (100.0)	6 (31.6)	1 (25.0)	8 (33.3)	0	8 (29.6)
Patients with MAF < 1%	1 (100.0)	10 (52.6)	3 (75.0)	14 (58.3)	1 (33.3)	15 (55.6)
>= 50% reduction from baseline	1 (100.0)	16 (84.2)	4 (100.0)	21 (87.5)	3 (100.0)	24 (88.9)
>= 50% reduction from baseline for at least 2 cycles	1 (100.0)	15 (78.9)	4 (100.0)	20 (83.3)	3 (100.0)	23 (85.2)
Patients with Baseline Assessment in Bone Marrow	1	20	5	26	7	33
Patients with MAF < 0.17%	1 (100.0)	7 (35.0)	0	8 (30.8)	4 (57.1)	12 (36.4)
Patients with MAF < 1%	1 (100.0)	13 (65.0)	3 (60.0)	17 (65.4)	5 (71.4)	22 (66.7)
>= 50% reduction from baseline	1 (100.0)	18 (90.0)	5 (100.0)	24 (92.3)	7 (100.0)	31 (93.9)
>= 50% reduction from baseline for at least 2 cycles	1 (100.0)	14 (70.0)	3 (60.0)	18 (69.2)	7 (100.0)	25 (75.8)
Patients with Baseline >=1% Assessment in Bone marrow	1	19	5	25	4	29
Patients with MAF < 0.17%	1 (100.0)	6 (31.6)	0	7 (28.0)	1 (25.0)	8 (27.6)
Patients with MAF < 1%	1 (100.0)	12 (63.2)	3 (60.0)	16 (64.0)	2 (50.0)	18 (62.1)
>= 50% reduction from baseline	1 (100.0)	17 (89.5)	5 (100.0)	23 (92.0)	4 (100.0)	27 (93.1)
>= 50% reduction from baseline for at least 2 cycles	1 (100.0)	13 (68.4)	3 (60.0)	17 (68.0)	4 (100.0)	21 (72.4)

Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. If a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.

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Table 99.2.7.3.1b
Summary of KIT D816V Mutation Allele Fraction Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2202 & 200 mg Dose Group

Prior antineoplastic therapy = Yes

D816V Mutation Allele Fraction Best Response	ASM (N=4) n (%)	SM-AHN (N=27) n (%)	MCL (N=9) n (%)	All AdvSM (N=40) n (%)
Patients with Baseline Assessment in Blood	4	27	9	40
Patients with MAF < 0.17%	0	4 (14.8)	2 (22.2)	6 (15.0)
Patients with MAF < 1%	1 (25.0)	7 (25.9)	2 (22.2)	10 (25.0)
>= 50% reduction from baseline	1 (25.0)	14 (51.9)	3 (33.3)	18 (45.0)
>= 50% reduction from baseline for at least 2 cycles	0	9 (33.3)	0	9 (22.5)
Patients with Baseline >=1% Assessment in Blood	3	25	6	34
Patients with MAF < 0.17%	0	2 (8.0)	0	2 (5.9)
Patients with MAF < 1%	1 (33.3)	5 (20.0)	0	6 (17.6)
>= 50% reduction from baseline	1 (33.3)	12 (48.0)	2 (33.3)	15 (44.1)
>= 50% reduction from baseline for at least 2 cycles	0	9 (36.0)	0	9 (26.5)
Patients with Baseline Assessment in Bone Marrow	0	0	0	0
Patients with MAF < 0.17%	0	0	0	0
Patients with MAF < 1%	0	0	0	0
>= 50% reduction from baseline	0	0	0	0
>= 50% reduction from baseline for at least 2 cycles	0	0	0	0
Patients with Baseline >=1% Assessment in Bone marrow	0	0	0	0
Patients with MAF < 0.17%	0	0	0	0
Patients with MAF < 1%	0	0	0	0
>= 50% reduction from baseline	0	0	0	0
>= 50% reduction from baseline for at least 2 cycles	0	0	0	0

Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. If a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.

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Table 99.2.7.3.1b
Summary of KIT D816V Mutation Allele Fraction Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2202 & <=200 mg Dose Group

Prior antineoplastic therapy = Yes

D816V Mutation Allele Fraction Best Response	ASM (N=5) n (%)	SM-AHN (N=28) n (%)	MCL (N=9) n (%)	All AdvSM (N=42) n (%)
Patients with Baseline Assessment in Blood	5	28	9	42
Patients with MAF < 0.17%	0	4 (14.3)	2 (22.2)	6 (14.3)
Patients with MAF < 1%	1 (20.0)	7 (25.0)	2 (22.2)	10 (23.8)
>= 50% reduction from baseline	1 (20.0)	14 (50.0)	3 (33.3)	18 (42.9)
>= 50% reduction from baseline for at least 2 cycles	0	9 (32.1)	0	9 (21.4)
Patients with Baseline >=1% Assessment in Blood	4	26	6	36
Patients with MAF < 0.17%	0	2 (7.7)	0	2 (5.6)
Patients with MAF < 1%	1 (25.0)	5 (19.2)	0	6 (16.7)
>= 50% reduction from baseline	1 (25.0)	12 (46.2)	2 (33.3)	15 (41.7)
>= 50% reduction from baseline for at least 2 cycles	0	9 (34.6)	0	9 (25.0)
Patients with Baseline Assessment in Bone Marrow	0	0	0	0
Patients with MAF < 0.17%	0	0	0	0
Patients with MAF < 1%	0	0	0	0
>= 50% reduction from baseline	0	0	0	0
>= 50% reduction from baseline for at least 2 cycles	0	0	0	0
Patients with Baseline >=1% Assessment in Bone marrow	0	0	0	0
Patients with MAF < 0.17%	0	0	0	0
Patients with MAF < 1%	0	0	0	0
>= 50% reduction from baseline	0	0	0	0
>= 50% reduction from baseline for at least 2 cycles	0	0	0	0

Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. If a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 99.2.7.3.1b
Summary of KIT D816V Mutation Allele Fraction Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2202 & All Dose Groups

Prior antineoplastic therapy = Yes

D816V Mutation Allele Fraction Best Response	ASM (N=5) n (%)	SM-AHN (N=28) n (%)	MCL (N=9) n (%)	All AdvSM (N=42) n (%)
Patients with Baseline Assessment in Blood	5	28	9	42
Patients with MAF < 0.17%	0	4 (14.3)	2 (22.2)	6 (14.3)
Patients with MAF < 1%	1 (20.0)	7 (25.0)	2 (22.2)	10 (23.8)
>= 50% reduction from baseline	1 (20.0)	14 (50.0)	3 (33.3)	18 (42.9)
>= 50% reduction from baseline for at least 2 cycles	0	9 (32.1)	0	9 (21.4)
Patients with Baseline >=1% Assessment in Blood	4	26	6	36
Patients with MAF < 0.17%	0	2 (7.7)	0	2 (5.6)
Patients with MAF < 1%	1 (25.0)	5 (19.2)	0	6 (16.7)
>= 50% reduction from baseline	1 (25.0)	12 (46.2)	2 (33.3)	15 (41.7)
>= 50% reduction from baseline for at least 2 cycles	0	9 (34.6)	0	9 (25.0)
Patients with Baseline Assessment in Bone Marrow	0	0	0	0
Patients with MAF < 0.17%	0	0	0	0
Patients with MAF < 1%	0	0	0	0
>= 50% reduction from baseline	0	0	0	0
>= 50% reduction from baseline for at least 2 cycles	0	0	0	0
Patients with Baseline >=1% Assessment in Bone marrow	0	0	0	0
Patients with MAF < 0.17%	0	0	0	0
Patients with MAF < 1%	0	0	0	0
>= 50% reduction from baseline	0	0	0	0
>= 50% reduction from baseline for at least 2 cycles	0	0	0	0

Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. If a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.

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Table 99.2.7.3.1b
Summary of KIT D816V Mutation Allele Fraction Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2202 & 200 mg Dose Group

Prior antineoplastic therapy = No				
D816V Mutation Allele Fraction Best Response	ASM (N=4) n (%)	SM-AHN (N=15) n (%)	MCL (N=1) n (%)	All AdvSM (N=20) n (%)
Patients with Baseline Assessment in Blood	4	15	1	20
Patients with MAF < 0.17%	0	3 (20.0)	0	3 (15.0)
Patients with MAF < 1%	1 (25.0)	8 (53.3)	0	9 (45.0)
>= 50% reduction from baseline	3 (75.0)	12 (80.0)	0	15 (75.0)
>= 50% reduction from baseline for at least 2 cycles	1 (25.0)	6 (40.0)	0	7 (35.0)
Patients with Baseline >=1% Assessment in Blood	3	12	1	16
Patients with MAF < 0.17%	0	1 (8.3)	0	1 (6.3)
Patients with MAF < 1%	1 (33.3)	6 (50.0)	0	7 (43.8)
>= 50% reduction from baseline	3 (100.0)	10 (83.3)	0	13 (81.3)
>= 50% reduction from baseline for at least 2 cycles	1 (33.3)	5 (41.7)	0	6 (37.5)
Patients with Baseline Assessment in Bone Marrow	0	0	0	0
Patients with MAF < 0.17%	0	0	0	0
Patients with MAF < 1%	0	0	0	0
>= 50% reduction from baseline	0	0	0	0
>= 50% reduction from baseline for at least 2 cycles	0	0	0	0
Patients with Baseline >=1% Assessment in Bone marrow	0	0	0	0
Patients with MAF < 0.17%	0	0	0	0
Patients with MAF < 1%	0	0	0	0
>= 50% reduction from baseline	0	0	0	0
>= 50% reduction from baseline for at least 2 cycles	0	0	0	0

Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. If a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.

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Table 99.2.7.3.1b
Summary of KIT D816V Mutation Allele Fraction Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2202 & <=200 mg Dose Group

Prior antineoplastic therapy = No

D816V Mutation Allele Fraction Best Response	ASM (N=4) n (%)	SM-AHN (N=15) n (%)	MCL (N=1) n (%)	All AdvSM (N=20) n (%)
Patients with Baseline Assessment in Blood	4	15	1	20
Patients with MAF < 0.17%	0	3 (20.0)	0	3 (15.0)
Patients with MAF < 1%	1 (25.0)	8 (53.3)	0	9 (45.0)
>= 50% reduction from baseline	3 (75.0)	12 (80.0)	0	15 (75.0)
>= 50% reduction from baseline for at least 2 cycles	1 (25.0)	6 (40.0)	0	7 (35.0)
Patients with Baseline >=1% Assessment in Blood	3	12	1	16
Patients with MAF < 0.17%	0	1 (8.3)	0	1 (6.3)
Patients with MAF < 1%	1 (33.3)	6 (50.0)	0	7 (43.8)
>= 50% reduction from baseline	3 (100.0)	10 (83.3)	0	13 (81.3)
>= 50% reduction from baseline for at least 2 cycles	1 (33.3)	5 (41.7)	0	6 (37.5)
Patients with Baseline Assessment in Bone Marrow	0	0	0	0
Patients with MAF < 0.17%	0	0	0	0
Patients with MAF < 1%	0	0	0	0
>= 50% reduction from baseline	0	0	0	0
>= 50% reduction from baseline for at least 2 cycles	0	0	0	0
Patients with Baseline >=1% Assessment in Bone marrow	0	0	0	0
Patients with MAF < 0.17%	0	0	0	0
Patients with MAF < 1%	0	0	0	0
>= 50% reduction from baseline	0	0	0	0
>= 50% reduction from baseline for at least 2 cycles	0	0	0	0

Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. If a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/EMA_D120/t99.2.7.3.1b-mut-resp-pant.sas Date: 10:51/04AUG2021

Table 99.2.7.3.1b
Summary of KIT D816V Mutation Allele Fraction Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2202 & All Dose Groups

Prior antineoplastic therapy = No

D816V Mutation Allele Fraction Best Response	ASM (N=4) n (%)	SM-AHN (N=15) n (%)	MCL (N=1) n (%)	All AdvSM (N=20) n (%)
Patients with Baseline Assessment in Blood	4	15	1	20
Patients with MAF < 0.17%	0	3 (20.0)	0	3 (15.0)
Patients with MAF < 1%	1 (25.0)	8 (53.3)	0	9 (45.0)
>= 50% reduction from baseline	3 (75.0)	12 (80.0)	0	15 (75.0)
>= 50% reduction from baseline for at least 2 cycles	1 (25.0)	6 (40.0)	0	7 (35.0)
Patients with Baseline >=1% Assessment in Blood	3	12	1	16
Patients with MAF < 0.17%	0	1 (8.3)	0	1 (6.3)
Patients with MAF < 1%	1 (33.3)	6 (50.0)	0	7 (43.8)
>= 50% reduction from baseline	3 (100.0)	10 (83.3)	0	13 (81.3)
>= 50% reduction from baseline for at least 2 cycles	1 (33.3)	5 (41.7)	0	6 (37.5)
Patients with Baseline Assessment in Bone Marrow	0	0	0	0
Patients with MAF < 0.17%	0	0	0	0
Patients with MAF < 1%	0	0	0	0
>= 50% reduction from baseline	0	0	0	0
>= 50% reduction from baseline for at least 2 cycles	0	0	0	0
Patients with Baseline >=1% Assessment in Bone marrow	0	0	0	0
Patients with MAF < 0.17%	0	0	0	0
Patients with MAF < 1%	0	0	0	0
>= 50% reduction from baseline	0	0	0	0
>= 50% reduction from baseline for at least 2 cycles	0	0	0	0

Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. If a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.

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Table 99.2.7.3.1b
Summary of KIT D816V Mutation Allele Fraction Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101/2202 & 200 mg Dose Group

Prior antineoplastic therapy = Yes

D816V Mutation Allele Fraction Best Response	ASM (N=5) n (%)	SM-AHN (N=34) n (%)	MCL (N=13) n (%)	All AdvSM (N=52) n (%)	ISM/SSM (N=1) n (%)	All Patients (N=53) n (%)
Patients with Baseline Assessment in Blood	5	34	13	52	1	53
Patients with MAF < 0.17%	0	5 (14.7)	3 (23.1)	8 (15.4)	0	8 (15.1)
Patients with MAF < 1%	1 (20.0)	8 (23.5)	3 (23.1)	12 (23.1)	0	12 (22.6)
>= 50% reduction from baseline	1 (20.0)	19 (55.9)	6 (46.2)	26 (50.0)	0	26 (49.1)
>= 50% reduction from baseline for at least 2 cycles	0	11 (32.4)	3 (23.1)	14 (26.9)	0	14 (26.4)
Patients with Baseline >=1% Assessment in Blood	3	30	9	42	0	42
Patients with MAF < 0.17%	0	2 (6.7)	1 (11.1)	3 (7.1)	0	3 (7.1)
Patients with MAF < 1%	1 (33.3)	5 (16.7)	1 (11.1)	7 (16.7)	0	7 (16.7)
>= 50% reduction from baseline	1 (33.3)	16 (53.3)	5 (55.6)	22 (52.4)	0	22 (52.4)
>= 50% reduction from baseline for at least 2 cycles	0	11 (36.7)	3 (33.3)	14 (33.3)	0	14 (33.3)
Patients with Baseline Assessment in Bone Marrow	1	6	4	11	1	12
Patients with MAF < 0.17%	0	0	0	0	0	0
Patients with MAF < 1%	0	2 (33.3)	1 (25.0)	3 (27.3)	0	3 (25.0)
>= 50% reduction from baseline	0	2 (33.3)	4 (100.0)	6 (54.5)	0	6 (50.0)
>= 50% reduction from baseline for at least 2 cycles	0	2 (33.3)	3 (75.0)	5 (45.5)	0	5 (41.7)
Patients with Baseline >=1% Assessment in Bone marrow	0	4	4	8	0	8
Patients with MAF < 0.17%	0	0	0	0	0	0
Patients with MAF < 1%	0	1 (25.0)	1 (25.0)	2 (25.0)	0	2 (25.0)
>= 50% reduction from baseline	0	2 (50.0)	4 (100.0)	6 (75.0)	0	6 (75.0)
>= 50% reduction from baseline for at least 2 cycles	0	2 (50.0)	3 (75.0)	5 (62.5)	0	5 (62.5)

Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. If a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.

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Table 99.2.7.3.1b
Summary of KIT D816V Mutation Allele Fraction Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101/2202 & <=200 mg Dose Group

Prior antineoplastic therapy = Yes

D816V Mutation Allele Fraction Best Response	ASM (N=7) n (%)	SM-AHN (N=37) n (%)	MCL (N=14) n (%)	All AdvSM (N=58) n (%)	ISM/SSM (N=4) n (%)	All Patients (N=62) n (%)
Patients with Baseline Assessment in Blood	7	37	13	57	4	61
Patients with MAF < 0.17%	0	7 (18.9)	3 (23.1)	10 (17.5)	0	10 (16.4)
Patients with MAF < 1%	2 (28.6)	10 (27.0)	3 (23.1)	15 (26.3)	1 (25.0)	16 (26.2)
>= 50% reduction from baseline	2 (28.6)	21 (56.8)	6 (46.2)	29 (50.9)	2 (50.0)	31 (50.8)
>= 50% reduction from baseline for at least 2 cycles	1 (14.3)	13 (35.1)	3 (23.1)	17 (29.8)	2 (50.0)	19 (31.1)
Patients with Baseline >=1% Assessment in Blood	5	33	9	47	2	49
Patients with MAF < 0.17%	0	4 (12.1)	1 (11.1)	5 (10.6)	0	5 (10.2)
Patients with MAF < 1%	2 (40.0)	7 (21.2)	1 (11.1)	10 (21.3)	1 (50.0)	11 (22.4)
>= 50% reduction from baseline	2 (40.0)	18 (54.5)	5 (55.6)	25 (53.2)	2 (100.0)	27 (55.1)
>= 50% reduction from baseline for at least 2 cycles	1 (20.0)	13 (39.4)	3 (33.3)	17 (36.2)	2 (100.0)	19 (38.8)
Patients with Baseline Assessment in Bone Marrow	2	8	5	15	4	19
Patients with MAF < 0.17%	0	2 (25.0)	1 (20.0)	3 (20.0)	1 (25.0)	4 (21.1)
Patients with MAF < 1%	1 (50.0)	4 (50.0)	2 (40.0)	7 (46.7)	2 (50.0)	9 (47.4)
>= 50% reduction from baseline	1 (50.0)	4 (50.0)	5 (100.0)	10 (66.7)	3 (75.0)	13 (68.4)
>= 50% reduction from baseline for at least 2 cycles	1 (50.0)	4 (50.0)	4 (80.0)	9 (60.0)	3 (75.0)	12 (63.2)
Patients with Baseline >=1% Assessment in Bone marrow	1	6	5	12	2	14
Patients with MAF < 0.17%	0	2 (33.3)	1 (20.0)	3 (25.0)	0	3 (21.4)
Patients with MAF < 1%	1 (100.0)	3 (50.0)	2 (40.0)	6 (50.0)	1 (50.0)	7 (50.0)
>= 50% reduction from baseline	1 (100.0)	4 (66.7)	5 (100.0)	10 (83.3)	2 (100.0)	12 (85.7)
>= 50% reduction from baseline for at least 2 cycles	1 (100.0)	4 (66.7)	4 (80.0)	9 (75.0)	2 (100.0)	11 (78.6)

Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. If a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.

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Table 99.2.7.3.1b
Summary of KIT D816V Mutation Allele Fraction Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101/2202 & All Dose Groups

Prior antineoplastic therapy = Yes

D816V Mutation Allele Fraction Best Response	ASM (N=12) n (%)	SM-AHN (N=54) n (%)	MCL (N=17) n (%)	All AdvSM (N=83) n (%)	ISM/SSM (N=9) n (%)	All Patients (N=92) n (%)
Patients with Baseline Assessment in Blood	12	54	16	82	9	91
Patients with MAF < 0.17%	0	13 (24.1)	3 (18.8)	16 (19.5)	2 (22.2)	18 (19.8)
Patients with MAF < 1%	4 (33.3)	19 (35.2)	3 (18.8)	26 (31.7)	4 (44.4)	30 (33.0)
>= 50% reduction from baseline	5 (41.7)	34 (63.0)	6 (37.5)	45 (54.9)	6 (66.7)	51 (56.0)
>= 50% reduction from baseline for at least 2 cycles	4 (33.3)	26 (48.1)	3 (18.8)	33 (40.2)	6 (66.7)	39 (42.9)
Patients with Baseline >=1% Assessment in Blood	8	48	9	65	4	69
Patients with MAF < 0.17%	0	9 (18.8)	1 (11.1)	10 (15.4)	0	10 (14.5)
Patients with MAF < 1%	4 (50.0)	15 (31.3)	1 (11.1)	20 (30.8)	2 (50.0)	22 (31.9)
>= 50% reduction from baseline	5 (62.5)	30 (62.5)	5 (55.6)	40 (61.5)	4 (100.0)	44 (63.8)
>= 50% reduction from baseline for at least 2 cycles	4 (50.0)	25 (52.1)	3 (33.3)	32 (49.2)	4 (100.0)	36 (52.2)
Patients with Baseline Assessment in Bone Marrow	6	24	8	38	8	46
Patients with MAF < 0.17%	1 (16.7)	7 (29.2)	3 (37.5)	11 (28.9)	2 (25.0)	13 (28.3)
Patients with MAF < 1%	4 (66.7)	12 (50.0)	4 (50.0)	20 (52.6)	4 (50.0)	24 (52.2)
>= 50% reduction from baseline	4 (66.7)	16 (66.7)	7 (87.5)	27 (71.1)	5 (62.5)	32 (69.6)
>= 50% reduction from baseline for at least 2 cycles	4 (66.7)	14 (58.3)	6 (75.0)	24 (63.2)	4 (50.0)	28 (60.9)
Patients with Baseline >=1% Assessment in Bone marrow	3	20	7	30	3	33
Patients with MAF < 0.17%	0	6 (30.0)	3 (42.9)	9 (30.0)	0	9 (27.3)
Patients with MAF < 1%	3 (100.0)	10 (50.0)	4 (57.1)	17 (56.7)	1 (33.3)	18 (54.5)
>= 50% reduction from baseline	3 (100.0)	15 (75.0)	7 (100.0)	25 (83.3)	3 (100.0)	28 (84.8)
>= 50% reduction from baseline for at least 2 cycles	3 (100.0)	13 (65.0)	6 (85.7)	22 (73.3)	2 (66.7)	24 (72.7)

Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. If a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.

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Table 99.2.7.3.1b
Summary of KIT D816V Mutation Allele Fraction Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101/2202 & 200 mg Dose Group

Prior antineoplastic therapy = No

D816V Mutation Allele Fraction Best Response	ASM (N=4) n (%)	SM-AHN (N=21) n (%)	MCL (N=3) n (%)	All AdvSM (N=28) n (%)	ISM/SSM (N=0) n (%)	All Patients (N=28) n (%)
Patients with Baseline Assessment in Blood	4	21	3	28	0	28
Patients with MAF < 0.17%	0	5 (23.8)	0	5 (17.9)	0	5 (17.9)
Patients with MAF < 1%	1 (25.0)	10 (47.6)	2 (66.7)	13 (46.4)	0	13 (46.4)
>= 50% reduction from baseline	3 (75.0)	17 (81.0)	2 (66.7)	22 (78.6)	0	22 (78.6)
>= 50% reduction from baseline for at least 2 cycles	1 (25.0)	10 (47.6)	2 (66.7)	13 (46.4)	0	13 (46.4)
Patients with Baseline >=1% Assessment in Blood	3	18	3	24	0	24
Patients with MAF < 0.17%	0	3 (16.7)	0	3 (12.5)	0	3 (12.5)
Patients with MAF < 1%	1 (33.3)	8 (44.4)	2 (66.7)	11 (45.8)	0	11 (45.8)
>= 50% reduction from baseline	3 (100.0)	15 (83.3)	2 (66.7)	20 (83.3)	0	20 (83.3)
>= 50% reduction from baseline for at least 2 cycles	1 (33.3)	9 (50.0)	2 (66.7)	12 (50.0)	0	12 (50.0)
Patients with Baseline Assessment in Bone Marrow	0	5	2	7	0	7
Patients with MAF < 0.17%	0	1 (20.0)	0	1 (14.3)	0	1 (14.3)
Patients with MAF < 1%	0	2 (40.0)	0	2 (28.6)	0	2 (28.6)
>= 50% reduction from baseline	0	5 (100.0)	2 (100.0)	7 (100.0)	0	7 (100.0)
>= 50% reduction from baseline for at least 2 cycles	0	2 (40.0)	1 (50.0)	3 (42.9)	0	3 (42.9)
Patients with Baseline >=1% Assessment in Bone marrow	0	5	2	7	0	7
Patients with MAF < 0.17%	0	1 (20.0)	0	1 (14.3)	0	1 (14.3)
Patients with MAF < 1%	0	2 (40.0)	0	2 (28.6)	0	2 (28.6)
>= 50% reduction from baseline	0	5 (100.0)	2 (100.0)	7 (100.0)	0	7 (100.0)
>= 50% reduction from baseline for at least 2 cycles	0	2 (40.0)	1 (50.0)	3 (42.9)	0	3 (42.9)

Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. If a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.
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Table 99.2.7.3.1b
Summary of KIT D816V Mutation Allele Fraction Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101/2202 & <=200 mg Dose Group

Prior antineoplastic therapy = No

D816V Mutation Allele Fraction Best Response	ASM (N=4) n (%)	SM-AHN (N=26) n (%)	MCL (N=3) n (%)	All AdvSM (N=33) n (%)	ISM/SSM (N=2) n (%)	All Patients (N=35) n (%)
Patients with Baseline Assessment in Blood	4	26	3	33	2	35
Patients with MAF < 0.17%	0	7 (26.9)	0	7 (21.2)	1 (50.0)	8 (22.9)
Patients with MAF < 1%	1 (25.0)	13 (50.0)	2 (66.7)	16 (48.5)	1 (50.0)	17 (48.6)
>= 50% reduction from baseline	3 (75.0)	22 (84.6)	2 (66.7)	27 (81.8)	2 (100.0)	29 (82.9)
>= 50% reduction from baseline for at least 2 cycles	1 (25.0)	15 (57.7)	2 (66.7)	18 (54.5)	2 (100.0)	20 (57.1)
Patients with Baseline >=1% Assessment in Blood	3	22	3	28	1	29
Patients with MAF < 0.17%	0	4 (18.2)	0	4 (14.3)	0	4 (13.8)
Patients with MAF < 1%	1 (33.3)	10 (45.5)	2 (66.7)	13 (46.4)	0	13 (44.8)
>= 50% reduction from baseline	3 (100.0)	19 (86.4)	2 (66.7)	24 (85.7)	1 (100.0)	25 (86.2)
>= 50% reduction from baseline for at least 2 cycles	1 (33.3)	13 (59.1)	2 (66.7)	16 (57.1)	1 (100.0)	17 (58.6)
Patients with Baseline Assessment in Bone Marrow	0	9	2	11	2	13
Patients with MAF < 0.17%	0	2 (22.2)	0	2 (18.2)	1 (50.0)	3 (23.1)
Patients with MAF < 1%	0	5 (55.6)	0	5 (45.5)	1 (50.0)	6 (46.2)
>= 50% reduction from baseline	0	9 (100.0)	2 (100.0)	11 (100.0)	2 (100.0)	13 (100.0)
>= 50% reduction from baseline for at least 2 cycles	0	5 (55.6)	1 (50.0)	6 (54.5)	2 (100.0)	8 (61.5)
Patients with Baseline >=1% Assessment in Bone marrow	0	9	2	11	1	12
Patients with MAF < 0.17%	0	2 (22.2)	0	2 (18.2)	0	2 (16.7)
Patients with MAF < 1%	0	5 (55.6)	0	5 (45.5)	0	5 (41.7)
>= 50% reduction from baseline	0	9 (100.0)	2 (100.0)	11 (100.0)	1 (100.0)	12 (100.0)
>= 50% reduction from baseline for at least 2 cycles	0	5 (55.6)	1 (50.0)	6 (54.5)	1 (100.0)	7 (58.3)

Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. If a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.

Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/EMA_D120/t99.2.7.3.1b-mut-resp-pant.sas Date: 10:51/04AUG2021

Table 99.2.7.3.1b
Summary of KIT D816V Mutation Allele Fraction Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101/2202 & All Dose Groups

Prior antineoplastic therapy = No

D816V Mutation Allele Fraction Best Response	ASM (N=5) n (%)	SM-AHN (N=37) n (%)	MCL (N=6) n (%)	All AdvSM (N=48) n (%)	ISM/SSM (N=7) n (%)	All Patients (N=55) n (%)
Patients with Baseline Assessment in Blood	5	37	5	47	7	54
Patients with MAF < 0.17%	1 (20.0)	11 (29.7)	1 (20.0)	13 (27.7)	4 (57.1)	17 (31.5)
Patients with MAF < 1%	2 (40.0)	20 (54.1)	3 (60.0)	25 (53.2)	5 (71.4)	30 (55.6)
>= 50% reduction from baseline	4 (80.0)	30 (81.1)	4 (80.0)	38 (80.9)	7 (100.0)	45 (83.3)
>= 50% reduction from baseline for at least 2 cycles	2 (40.0)	23 (62.2)	4 (80.0)	29 (61.7)	7 (100.0)	36 (66.7)
Patients with Baseline >=1% Assessment in Blood	4	31	5	40	3	43
Patients with MAF < 0.17%	1 (25.0)	7 (22.6)	1 (20.0)	9 (22.5)	0	9 (20.9)
Patients with MAF < 1%	2 (50.0)	16 (51.6)	3 (60.0)	21 (52.5)	1 (33.3)	22 (51.2)
>= 50% reduction from baseline	4 (100.0)	26 (83.9)	4 (80.0)	34 (85.0)	3 (100.0)	37 (86.0)
>= 50% reduction from baseline for at least 2 cycles	2 (50.0)	20 (64.5)	4 (80.0)	26 (65.0)	3 (100.0)	29 (67.4)
Patients with Baseline Assessment in Bone Marrow	1	20	5	26	7	33
Patients with MAF < 0.17%	1 (100.0)	7 (35.0)	0	8 (30.8)	4 (57.1)	12 (36.4)
Patients with MAF < 1%	1 (100.0)	13 (65.0)	3 (60.0)	17 (65.4)	5 (71.4)	22 (66.7)
>= 50% reduction from baseline	1 (100.0)	18 (90.0)	5 (100.0)	24 (92.3)	7 (100.0)	31 (93.9)
>= 50% reduction from baseline for at least 2 cycles	1 (100.0)	14 (70.0)	3 (60.0)	18 (69.2)	7 (100.0)	25 (75.8)
Patients with Baseline >=1% Assessment in Bone marrow	1	19	5	25	4	29
Patients with MAF < 0.17%	1 (100.0)	6 (31.6)	0	7 (28.0)	1 (25.0)	8 (27.6)
Patients with MAF < 1%	1 (100.0)	12 (63.2)	3 (60.0)	16 (64.0)	2 (50.0)	18 (62.1)
>= 50% reduction from baseline	1 (100.0)	17 (89.5)	5 (100.0)	23 (92.0)	4 (100.0)	27 (93.1)
>= 50% reduction from baseline for at least 2 cycles	1 (100.0)	13 (68.4)	3 (60.0)	17 (68.0)	4 (100.0)	21 (72.4)

Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. If a patient does not have Mutation Allele Fraction measurement on Cycle 1 Day 1 or earlier, the closest on treatment measurement within 3 days of Day 1 of avapritinib is considered as baseline assessment.

Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/EMA_D120/t99.2.7.3.1b-mut-resp-pant.sas Date: 10:51/04AUG2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Overall
Organ = Spleen

Volume (mL)	ASM (N=7)	SM-AHN (N=26)	MCL (N=8)	All AdvSM (N=41)
Baseline				
n	6	25	7	38
Mean (StdDev)	725.22 (615.037)	1060.21 (501.440)	868.82 (535.191)	972.06 (527.077)
Median	524.39	1120.69	688.48	862.44
Min, Max	163.4, 1922.7	298.5, 2262.7	257.8, 1940.9	163.4, 2262.7
Cycle 3 Day 1				
n	6	23	6	35
Mean (StdDev)	463.44 (365.008)	617.57 (285.451)	578.06 (357.793)	584.38 (307.369)
Median	383.80	607.84	523.75	541.87
Min, Max	94.6, 1162.3	196.8, 1239.8	201.9, 1257.9	94.6, 1257.9
Cycle 5 Day 1				
n	5	21	7	33
Mean (StdDev)	540.60 (531.415)	601.42 (280.712)	487.55 (165.900)	568.05 (303.276)
Median	389.95	617.66	506.90	590.45
Min, Max	96.5, 1460.7	184.5, 1294.0	189.2, 647.0	96.5, 1460.7
Cycle 7 Day 1				
n	4	18	5	27
Mean (StdDev)	494.06 (435.988)	593.48 (203.562)	409.63 (153.584)	544.71 (241.260)
Median	368.40	564.76	369.21	522.69
Min, Max	120.5, 1119.0	140.8, 971.9	258.6, 613.2	120.5, 1119.0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Overall
Organ = Spleen

Volume (mL)	ASM (N=7)	SM-AHN (N=26)	MCL (N=8)	All AdvSM (N=41)
Cycle 11 Day 1				
n	3	12	4	19
Mean (StdDev)	514.91 (473.360)	527.56 (239.869)	489.23 (148.195)	517.49 (252.912)
Median	365.51	451.65	441.39	427.43
Min, Max	134.3, 1044.9	136.0, 1073.3	379.4, 694.7	134.3, 1073.3
Cycle 18 Day 1				
n	2	9	2	13
Mean (StdDev)	273.64 (78.001)	508.38 (144.717)	340.69 (10.508)	446.46 (155.551)
Median	273.64	573.32	340.69	385.20
Min, Max	218.5, 328.8	277.3, 689.2	333.3, 348.1	218.5, 689.2
Cycle 24 Day 1				
n	2	9	1	12
Mean (StdDev)	303.59 (123.680)	548.32 (206.804)	353.28 (-)	491.28 (208.070)
Median	303.59	611.44	353.28	471.09
Min, Max	216.1, 391.0	252.3, 823.7	353.3, 353.3	216.1, 823.7
Cycle 30 Day 1				
n	1	4	1	6
Mean (StdDev)	316.97 (-)	598.35 (226.043)	238.39 (-)	491.46 (242.273)
Median	316.97	543.93	238.39	419.10
Min, Max	317.0, 317.0	416.7, 888.9	238.4, 238.4	238.4, 888.9

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Overall
Organ = Spleen

Volume (mL)	ASM (N=7)	SM-AHN (N=26)	MCL (N=8)	All AdvSM (N=41)
Cycle 36 Day 1				
n	1	4	1	6
Mean (StdDev)	310.12 (-)	574.64 (240.080)	276.98 (-)	480.94 (236.140)
Median	310.12	521.85	276.98	401.14
Min, Max	310.1, 310.1	352.2, 902.6	277.0, 277.0	277.0, 902.6
Cycle 42 Day 1				
n	0	3	1	4
Mean (StdDev)		478.63 (130.745)	204.10 (-)	410.00 (173.889)
Median		424.70	204.10	404.09
Min, Max		383.5, 627.7	204.1, 204.1	204.1, 627.7
Cycle 48 Day 1				
n	0	0	1	1
Mean (StdDev)			172.80 (-)	172.80 (-)
Median			172.80	172.80
Min, Max			172.8, 172.8	172.8, 172.8

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Overall
Organ = Liver

Volume (mL)	ASM (N=7)	SM-AHN (N=26)	MCL (N=8)	All AdvSM (N=41)
Baseline				
n	7	26	8	41
Mean (StdDev)	2283.11 (793.529)	2332.67 (547.909)	2345.83 (617.874)	2326.77 (591.032)
Median	2349.73	2233.18	2220.45	2285.21
Min, Max	1019.9, 3603.1	1436.4, 3624.1	1435.8, 3437.5	1019.9, 3624.1
Cycle 3 Day 1				
n	6	24	7	37
Mean (StdDev)	1987.39 (854.616)	2039.19 (531.963)	1951.71 (528.871)	2014.24 (574.586)
Median	1893.12	1983.87	1841.37	1973.06
Min, Max	1017.4, 3507.4	1284.5, 3519.1	1330.7, 2617.1	1017.4, 3519.1
Cycle 5 Day 1				
n	6	22	8	36
Mean (StdDev)	2104.20 (685.669)	1969.84 (547.122)	1851.60 (404.725)	1965.96 (534.606)
Median	2139.30	1901.97	1941.25	1960.91
Min, Max	1039.9, 3098.8	1127.1, 3615.9	1295.4, 2357.8	1039.9, 3615.9
Cycle 7 Day 1				
n	5	19	6	30
Mean (StdDev)	1880.51 (533.254)	1975.61 (547.037)	1762.24 (377.522)	1917.08 (506.923)
Median	2134.58	1948.43	1723.89	1955.79
Min, Max	993.2, 2328.3	1231.1, 3549.6	1402.7, 2255.4	993.2, 3549.6

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Overall
Organ = Liver

Volume (mL)	ASM (N=7)	SM-AHN (N=26)	MCL (N=8)	All AdvSM (N=41)
Cycle 11 Day 1				
n	3	13	5	21
Mean (StdDev)	1762.30 (152.191)	2084.24 (500.725)	1766.69 (425.804)	1962.64 (462.865)
Median	1758.77	2107.40	1838.21	1916.22
Min, Max	1611.9, 1916.2	1174.6, 3135.2	1344.8, 2388.2	1174.6, 3135.2
Cycle 18 Day 1				
n	3	10	3	16
Mean (StdDev)	1802.15 (162.584)	1947.28 (419.109)	1501.98 (457.391)	1836.57 (409.399)
Median	1761.70	1814.74	1292.81	1803.58
Min, Max	1663.6, 1981.1	1478.1, 2939.6	1186.6, 2026.6	1186.6, 2939.6
Cycle 24 Day 1				
n	3	9	2	14
Mean (StdDev)	1851.65 (218.266)	1995.68 (437.106)	1304.90 (45.057)	1866.14 (430.336)
Median	1909.57	1945.43	1304.90	1898.26
Min, Max	1610.3, 2035.1	1380.4, 2910.2	1273.0, 1336.8	1273.0, 2910.2
Cycle 30 Day 1				
n	2	4	2	8
Mean (StdDev)	1552.16 (5.883)	2238.70 (463.433)	1290.13 (77.768)	1829.92 (541.934)
Median	1552.16	2150.81	1290.13	1667.06
Min, Max	1548.0, 1556.3	1777.8, 2875.4	1235.1, 1345.1	1235.1, 2875.4

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Overall
Organ = Liver

Volume (mL)	ASM (N=7)	SM-AHN (N=26)	MCL (N=8)	All AdvSM (N=41)
Cycle 36 Day 1				
n	2	4	1	7
Mean (StdDev)	1618.72 (2.489)	2139.75 (415.115)	1286.99 (-)	1869.06 (460.835)
Median	1618.72	2059.09	1286.99	1732.26
Min, Max	1617.0, 1620.5	1732.3, 2708.6	1287.0, 1287.0	1287.0, 2708.6
Cycle 42 Day 1				
n	0	3	1	4
Mean (StdDev)		1811.53 (212.694)	1314.94 (-)	1687.38 (303.000)
Median		1820.09	1314.94	1707.39
Min, Max		1594.7, 2019.8	1314.9, 1314.9	1314.9, 2019.8
Cycle 48 Day 1				
n	1	0	1	2
Mean (StdDev)	1727.89 (-)		1093.73 (-)	1410.81 (448.419)
Median	1727.89		1093.73	1410.81
Min, Max	1727.9, 1727.9		1093.7, 1093.7	1093.7, 1727.9

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <200 mg
Organ = Spleen

Volume (mL)	ASM (N=1)	SM-AHN (N=2)	MCL (N=1)	All AdvSM (N=4)
Baseline				
n	0	2	1	3
Mean (StdDev)		886.08 (673.788)	580.85 (-)	784.34 (507.986)
Median		886.08	580.85	580.85
Min, Max		409.6, 1362.5	580.9, 580.9	409.6, 1362.5
Cycle 3 Day 1				
n	0	2	1	3
Mean (StdDev)		615.25 (499.797)	554.17 (-)	594.89 (355.165)
Median		615.25	554.17	554.17
Min, Max		261.8, 968.7	554.2, 554.2	261.8, 968.7
Cycle 5 Day 1				
n	0	2	1	3
Mean (StdDev)		608.28 (485.860)	590.45 (-)	602.33 (343.709)
Median		608.28	590.45	590.45
Min, Max		264.7, 951.8	590.5, 590.5	264.7, 951.8
Cycle 7 Day 1				
n	0	2	1	3
Mean (StdDev)		687.09 (313.517)	613.22 (-)	662.47 (225.755)
Median		687.09	613.22	613.22
Min, Max		465.4, 908.8	613.2, 613.2	465.4, 908.8

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <200 mg
Organ = Spleen

Volume (mL)	ASM (N=1)	SM-AHN (N=2)	MCL (N=1)	All AdvSM (N=4)
Cycle 11 Day 1				
n	0	2	1	3
Mean (StdDev)		582.81 (236.626)	500.65 (-)	555.42 (173.914)
Median		582.81	500.65	500.65
Min, Max		415.5, 750.1	500.7, 500.7	415.5, 750.1
Cycle 18 Day 1				
n	0	2	1	3
Mean (StdDev)		530.35 (224.612)	333.26 (-)	464.65 (195.379)
Median		530.35	333.26	371.52
Min, Max		371.5, 689.2	333.3, 333.3	333.3, 689.2
Cycle 24 Day 1				
n	0	2	1	3
Mean (StdDev)		541.28 (322.709)	353.28 (-)	478.61 (252.690)
Median		541.28	353.28	353.28
Min, Max		313.1, 769.5	353.3, 353.3	313.1, 769.5
Cycle 30 Day 1				
n	0	2	1	3
Mean (StdDev)		541.53 (176.529)	238.39 (-)	440.48 (214.969)
Median		541.53	238.39	416.70
Min, Max		416.7, 666.4	238.4, 238.4	238.4, 666.4

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <200 mg
Organ = Spleen

Volume (mL)	ASM (N=1)	SM-AHN (N=2)	MCL (N=1)	All AdvSM (N=4)
Cycle 36 Day 1				
n	0	2	1	3
Mean (StdDev)		472.95 (170.710)	276.98 (-)	407.63 (165.446)
Median		472.95	276.98	352.24
Min, Max		352.2, 593.7	277.0, 277.0	277.0, 593.7
Cycle 42 Day 1				
n	0	2	1	3
Mean (StdDev)		505.59 (172.704)	204.10 (-)	405.09 (212.631)
Median		505.59	204.10	383.47
Min, Max		383.5, 627.7	204.1, 204.1	204.1, 627.7
Cycle 48 Day 1				
n	0	0	1	1
Mean (StdDev)			172.80 (-)	172.80 (-)
Median			172.80	172.80
Min, Max			172.8, 172.8	172.8, 172.8

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas
Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <200 mg
Organ = Liver

Volume (mL)	ASM (N=1)	SM-AHN (N=2)	MCL (N=1)	All AdvSM (N=4)
Baseline				
n	1	2	1	4
Mean (StdDev)	2373.51 (-)	2317.88 (193.358)	1435.80 (-)	2111.27 (464.682)
Median	2373.51	2317.88	1435.80	2277.33
Min, Max	2373.5, 2373.5	2181.2, 2454.6	1435.8, 1435.8	1435.8, 2454.6
Cycle 3 Day 1				
n	1	2	1	4
Mean (StdDev)	2107.61 (-)	2099.55 (178.877)	1330.66 (-)	1909.34 (399.389)
Median	2107.61	2099.55	1330.66	2040.34
Min, Max	2107.6, 2107.6	1973.1, 2226.0	1330.7, 1330.7	1330.7, 2226.0
Cycle 5 Day 1				
n	1	2	1	4
Mean (StdDev)	1966.19 (-)	1969.40 (284.144)	1431.57 (-)	1834.14 (314.552)
Median	1966.19	1969.40	1431.57	1867.34
Min, Max	1966.2, 1966.2	1768.5, 2170.3	1431.6, 1431.6	1431.6, 2170.3
Cycle 7 Day 1				
n	1	2	1	4
Mean (StdDev)	1789.11 (-)	2220.84 (385.239)	1419.11 (-)	1912.47 (446.172)
Median	1789.11	2220.84	1419.11	1868.77
Min, Max	1789.1, 1789.1	1948.4, 2493.2	1419.1, 1419.1	1419.1, 2493.2

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <200 mg
Organ = Liver

Volume (mL)	ASM (N=1)	SM-AHN (N=2)	MCL (N=1)	All AdvSM (N=4)
Cycle 11 Day 1				
n	1	2	1	4
Mean (StdDev)	1611.90 (-)	2189.47 (98.592)	1344.84 (-)	1833.92 (428.578)
Median	1611.90	2189.47	1344.84	1865.83
Min, Max	1611.9, 1611.9	2119.8, 2259.2	1344.8, 1344.8	1344.8, 2259.2
Cycle 18 Day 1				
n	1	2	1	4
Mean (StdDev)	1663.61 (-)	1909.16 (148.507)	1186.58 (-)	1667.13 (351.261)
Median	1663.61	1909.16	1186.58	1733.88
Min, Max	1663.6, 1663.6	1804.2, 2014.2	1186.6, 1186.6	1186.6, 2014.2
Cycle 24 Day 1				
n	1	2	1	4
Mean (StdDev)	1610.27 (-)	1786.44 (574.171)	1336.76 (-)	1629.98 (393.700)
Median	1610.27	1786.44	1336.76	1495.36
Min, Max	1610.3, 1610.3	1380.4, 2192.4	1336.8, 1336.8	1336.8, 2192.4
Cycle 30 Day 1				
n	1	2	1	4
Mean (StdDev)	1548.00 (-)	2001.48 (316.331)	1235.14 (-)	1696.53 (416.732)
Median	1548.00	2001.48	1235.14	1662.90
Min, Max	1548.0, 1548.0	1777.8, 2225.2	1235.1, 1235.1	1235.1, 2225.2

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <200 mg
Organ = Liver

Volume (mL)	ASM (N=1)	SM-AHN (N=2)	MCL (N=1)	All AdvSM (N=4)
Cycle 36 Day 1				
n	1	2	1	4
Mean (StdDev)	1620.48 (-)	1938.02 (290.989)	1286.99 (-)	1695.88 (353.466)
Median	1620.48	1938.02	1286.99	1676.37
Min, Max	1620.5, 1620.5	1732.3, 2143.8	1287.0, 1287.0	1287.0, 2143.8
Cycle 42 Day 1				
n	0	2	1	3
Mean (StdDev)		1807.25 (300.612)	1314.94 (-)	1643.14 (354.925)
Median		1807.25	1314.94	1594.68
Min, Max		1594.7, 2019.8	1314.9, 1314.9	1314.9, 2019.8
Cycle 48 Day 1				
n	1	0	1	2
Mean (StdDev)	1727.89 (-)		1093.73 (-)	1410.81 (448.419)
Median	1727.89		1093.73	1410.81
Min, Max	1727.9, 1727.9		1093.7, 1093.7	1093.7, 1727.9

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <300 mg
Organ = Spleen

Volume (mL)	ASM (N=2)	SM-AHN (N=9)	MCL (N=5)	All AdvSM (N=16)
Baseline				
n	1	9	5	15
Mean (StdDev)	508.66 (-)	899.42 (393.875)	776.61 (195.827)	832.43 (333.305)
Median	508.66	875.83	688.48	810.35
Min, Max	508.7, 508.7	298.5, 1362.5	580.9, 1082.0	298.5, 1362.5
Cycle 3 Day 1				
n	1	8	4	13
Mean (StdDev)	444.37 (-)	554.88 (250.489)	502.16 (66.716)	530.16 (197.474)
Median	444.37	582.32	523.75	541.87
Min, Max	444.4, 444.4	238.9, 968.7	407.0, 554.2	238.9, 968.7
Cycle 5 Day 1				
n	1	7	5	13
Mean (StdDev)	449.24 (-)	596.89 (244.735)	516.07 (109.277)	554.45 (191.090)
Median	449.24	599.60	506.90	582.65
Min, Max	449.2, 449.2	264.7, 951.8	364.4, 647.0	264.7, 951.8
Cycle 7 Day 1				
n	0	7	4	11
Mean (StdDev)		624.58 (159.519)	447.38 (148.153)	560.14 (172.756)
Median		578.62	445.95	547.36
Min, Max		465.4, 908.8	284.4, 613.2	284.4, 908.8

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <300 mg
Organ = Spleen

Volume (mL)	ASM (N=2)	SM-AHN (N=9)	MCL (N=5)	All AdvSM (N=16)
Cycle 11 Day 1				
n	0	5	3	8
Mean (StdDev)		514.12 (160.890)	420.73 (69.223)	479.10 (136.003)
Median		427.43	382.12	421.46
Min, Max		367.7, 750.1	379.4, 500.7	367.7, 750.1
Cycle 18 Day 1				
n	0	3	2	5
Mean (StdDev)		499.31 (167.675)	340.69 (10.508)	435.86 (147.082)
Median		437.24	340.69	371.52
Min, Max		371.5, 689.2	333.3, 348.1	333.3, 689.2
Cycle 24 Day 1				
n	0	3	1	4
Mean (StdDev)		544.57 (228.261)	353.28 (-)	496.75 (209.483)
Median		551.14	353.28	452.21
Min, Max		313.1, 769.5	353.3, 353.3	313.1, 769.5
Cycle 30 Day 1				
n	0	3	1	4
Mean (StdDev)		501.52 (142.770)	238.39 (-)	435.74 (175.778)
Median		421.50	238.39	419.10
Min, Max		416.7, 666.4	238.4, 238.4	238.4, 666.4

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <300 mg
Organ = Spleen

Volume (mL)	ASM (N=2)	SM-AHN (N=9)	MCL (N=5)	All AdvSM (N=16)
Cycle 36 Day 1				
n	0	3	1	4
Mean (StdDev)		465.31 (121.433)	276.98 (-)	418.23 (136.740)
Median		450.03	276.98	401.14
Min, Max		352.2, 593.7	277.0, 277.0	277.0, 593.7
Cycle 42 Day 1				
n	0	3	1	4
Mean (StdDev)		478.63 (130.745)	204.10 (-)	410.00 (173.889)
Median		424.70	204.10	404.09
Min, Max		383.5, 627.7	204.1, 204.1	204.1, 627.7
Cycle 48 Day 1				
n	0	0	1	1
Mean (StdDev)			172.80 (-)	172.80 (-)
Median			172.80	172.80
Min, Max			172.8, 172.8	172.8, 172.8

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <300 mg
Organ = Liver

Volume (mL)	ASM (N=2)	SM-AHN (N=9)	MCL (N=5)	All AdvSM (N=16)
Baseline				
n	2	9	5	16
Mean (StdDev)	2988.28 (869.416)	2215.54 (285.564)	2499.23 (758.054)	2400.79 (562.994)
Median	2988.28	2181.15	2566.01	2329.36
Min, Max	2373.5, 3603.1	1764.2, 2731.4	1435.8, 3437.5	1435.8, 3603.1
Cycle 3 Day 1				
n	2	8	4	14
Mean (StdDev)	2807.52 (989.815)	2041.19 (325.384)	2042.42 (574.919)	2151.02 (534.797)
Median	2807.52	1983.87	2110.96	2051.14
Min, Max	2107.6, 3507.4	1594.4, 2651.4	1330.7, 2617.1	1330.7, 3507.4
Cycle 5 Day 1				
n	2	7	5	14
Mean (StdDev)	2532.50 (800.876)	2024.56 (373.121)	2002.97 (369.144)	2089.41 (436.880)
Median	2532.50	2018.74	2160.89	2089.82
Min, Max	1966.2, 3098.8	1492.8, 2654.6	1431.6, 2357.8	1431.6, 3098.8
Cycle 7 Day 1				
n	1	7	4	12
Mean (StdDev)	1789.11 (-)	2071.10 (401.399)	1927.27 (357.790)	1999.65 (363.291)
Median	1789.11	1963.15	2017.29	1974.62
Min, Max	1789.1, 1789.1	1406.6, 2563.8	1419.1, 2255.4	1406.6, 2563.8

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <300 mg
Organ = Liver

Volume (mL)	ASM (N=2)	SM-AHN (N=9)	MCL (N=5)	All AdvSM (N=16)
Cycle 11 Day 1				
n	1	5	3	9
Mean (StdDev)	1611.90 (-)	2164.53 (259.680)	1686.07 (296.094)	1943.64 (353.221)
Median	1611.90	2119.75	1838.21	1875.17
Min, Max	1611.9, 1611.9	1848.2, 2546.0	1344.8, 1875.2	1344.8, 2546.0
Cycle 18 Day 1				
n	1	3	2	6
Mean (StdDev)	1663.61 (-)	1881.22 (115.627)	1606.57 (593.956)	1753.40 (309.746)
Median	1663.61	1825.33	1606.57	1814.74
Min, Max	1663.6, 1663.6	1804.2, 2014.2	1186.6, 2026.6	1186.6, 2026.6
Cycle 24 Day 1				
n	1	3	1	5
Mean (StdDev)	1610.27 (-)	1839.44 (416.247)	1336.76 (-)	1693.07 (368.987)
Median	1610.27	1945.43	1336.76	1610.27
Min, Max	1610.3, 1610.3	1380.4, 2192.4	1336.8, 1336.8	1336.8, 2192.4
Cycle 30 Day 1				
n	1	3	1	5
Mean (StdDev)	1548.00 (-)	2026.47 (227.829)	1235.14 (-)	1772.51 (398.896)
Median	1548.00	2076.45	1235.14	1777.80
Min, Max	1548.0, 1548.0	1777.8, 2225.2	1235.1, 1235.1	1235.1, 2225.2

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <300 mg
Organ = Liver

Volume (mL)	ASM (N=2)	SM-AHN (N=9)	MCL (N=5)	All AdvSM (N=16)
Cycle 36 Day 1				
n	1	3	1	5
Mean (StdDev)	1620.48 (-)	1950.15 (206.829)	1286.99 (-)	1751.58 (330.482)
Median	1620.48	1974.40	1286.99	1732.26
Min, Max	1620.5, 1620.5	1732.3, 2143.8	1287.0, 1287.0	1287.0, 2143.8
Cycle 42 Day 1				
n	0	3	1	4
Mean (StdDev)		1811.53 (212.694)	1314.94 (-)	1687.38 (303.000)
Median		1820.09	1314.94	1707.39
Min, Max		1594.7, 2019.8	1314.9, 1314.9	1314.9, 2019.8
Cycle 48 Day 1				
n	1	0	1	2
Mean (StdDev)	1727.89 (-)		1093.73 (-)	1410.81 (448.419)
Median	1727.89		1093.73	1410.81
Min, Max	1727.9, 1727.9		1093.7, 1093.7	1093.7, 1727.9

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg
Organ = Spleen

Volume (mL)	ASM (N=1)	SM-AHN (N=7)	MCL (N=4)	All AdvSM (N=12)
Baseline				
n	1	7	4	12
Mean (StdDev)	508.66 (-)	903.23 (362.090)	825.55 (187.519)	844.46 (306.077)
Median	508.66	875.83	768.77	829.70
Min, Max	508.7, 508.7	298.5, 1245.1	682.7, 1082.0	298.5, 1245.1
Cycle 3 Day 1				
n	1	6	3	10
Mean (StdDev)	444.37 (-)	534.76 (189.578)	484.82 (69.808)	510.74 (148.820)
Median	444.37	582.32	505.62	523.75
Min, Max	444.4, 444.4	238.9, 741.8	407.0, 541.9	238.9, 741.8
Cycle 5 Day 1				
n	1	5	4	10
Mean (StdDev)	449.24 (-)	592.34 (175.321)	497.47 (116.691)	540.08 (146.427)
Median	449.24	599.60	489.25	544.78
Min, Max	449.2, 449.2	334.0, 827.8	364.4, 647.0	334.0, 827.8
Cycle 7 Day 1				
n	0	5	3	8
Mean (StdDev)		599.57 (104.213)	392.10 (120.783)	521.77 (147.999)
Median		578.62	369.21	535.03
Min, Max		475.0, 749.5	284.4, 522.7	284.4, 749.5

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg
Organ = Spleen

Volume (mL)	ASM (N=1)	SM-AHN (N=7)	MCL (N=4)	All AdvSM (N=12)
Cycle 11 Day 1				
n	0	3	2	5
Mean (StdDev)		468.32 (126.138)	380.78 (1.902)	433.30 (101.269)
Median		427.43	380.78	382.12
Min, Max		367.7, 609.8	379.4, 382.1	367.7, 609.8
Cycle 18 Day 1				
n	0	1	1	2
Mean (StdDev)		437.24 (-)	348.12 (-)	392.68 (63.017)
Median		437.24	348.12	392.68
Min, Max		437.2, 437.2	348.1, 348.1	348.1, 437.2
Cycle 24 Day 1				
n	0	1	0	1
Mean (StdDev)		551.14 (-)		551.14 (-)
Median		551.14		551.14
Min, Max		551.1, 551.1		551.1, 551.1
Cycle 30 Day 1				
n	0	1	0	1
Mean (StdDev)		421.50 (-)		421.50 (-)
Median		421.50		421.50
Min, Max		421.5, 421.5		421.5, 421.5

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg
Organ = Spleen

Volume (mL)	ASM (N=1)	SM-AHN (N=7)	MCL (N=4)	All AdvSM (N=12)
Cycle 36 Day 1				
n	0	1	0	1
Mean (StdDev)		450.03 (-)		450.03 (-)
Median		450.03		450.03
Min, Max		450.0, 450.0		450.0, 450.0
Cycle 42 Day 1				
n	0	1	0	1
Mean (StdDev)		424.70 (-)		424.70 (-)
Median		424.70		424.70
Min, Max		424.7, 424.7		424.7, 424.7

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg
Organ = Liver

Volume (mL)	ASM (N=1)	SM-AHN (N=7)	MCL (N=4)	All AdvSM (N=12)
Baseline				
n	1	7	4	12
Mean (StdDev)	3603.05 (-)	2186.30 (313.065)	2765.09 (543.133)	2497.29 (576.794)
Median	3603.05	2067.41	2734.69	2337.74
Min, Max	3603.1, 3603.1	1764.2, 2731.4	2153.5, 3437.5	1764.2, 3603.1
Cycle 3 Day 1				
n	1	6	3	10
Mean (StdDev)	3507.42 (-)	2021.74 (374.178)	2279.67 (397.576)	2247.69 (568.867)
Median	3507.42	1960.34	2380.54	2104.48
Min, Max	3507.4, 3507.4	1594.4, 2651.4	1841.4, 2617.1	1594.4, 3507.4
Cycle 5 Day 1				
n	1	5	4	10
Mean (StdDev)	3098.80 (-)	2046.62 (431.874)	2145.82 (213.654)	2191.52 (449.629)
Median	3098.80	2018.74	2187.47	2187.47
Min, Max	3098.8, 3098.8	1492.8, 2654.6	1850.6, 2357.8	1492.8, 3098.8
Cycle 7 Day 1				
n	0	5	3	8
Mean (StdDev)		2011.20 (434.608)	2096.65 (140.965)	2043.25 (339.951)
Median		1963.15	2048.48	2017.29
Min, Max		1406.6, 2563.8	1986.1, 2255.4	1406.6, 2563.8

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg
Organ = Liver

Volume (mL)	ASM (N=1)	SM-AHN (N=7)	MCL (N=4)	All AdvSM (N=12)
Cycle 11 Day 1				
n	0	3	2	5
Mean (StdDev)		2147.91 (359.126)	1856.69 (26.135)	2031.42 (300.165)
Median		2049.54	1856.69	1875.17
Min, Max		1848.2, 2546.0	1838.2, 1875.2	1838.2, 2546.0
Cycle 18 Day 1				
n	0	1	1	2
Mean (StdDev)		1825.33 (-)	2026.56 (-)	1925.95 (142.291)
Median		1825.33	2026.56	1925.95
Min, Max		1825.3, 1825.3	2026.6, 2026.6	1825.3, 2026.6
Cycle 24 Day 1				
n	0	1	0	1
Mean (StdDev)		1945.43 (-)		1945.43 (-)
Median		1945.43		1945.43
Min, Max		1945.4, 1945.4		1945.4, 1945.4
Cycle 30 Day 1				
n	0	1	0	1
Mean (StdDev)		2076.45 (-)		2076.45 (-)
Median		2076.45		2076.45
Min, Max		2076.5, 2076.5		2076.5, 2076.5

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg
Organ = Liver

Volume (mL)	ASM (N=1)	SM-AHN (N=7)	MCL (N=4)	All AdvSM (N=12)
Cycle 36 Day 1				
n	0	1	0	1
Mean (StdDev)		1974.40 (-)		1974.40 (-)
Median		1974.40		1974.40
Min, Max		1974.4, 1974.4		1974.4, 1974.4
Cycle 42 Day 1				
n	0	1	0	1
Mean (StdDev)		1820.09 (-)		1820.09 (-)
Median		1820.09		1820.09
Min, Max		1820.1, 1820.1		1820.1, 1820.1

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 300 mg
Organ = Spleen

Volume (mL)	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Baseline				
n	4	12	2	18
Mean (StdDev)	919.82 (677.582)	1181.24 (549.211)	1099.34 (1190.124)	1114.05 (609.591)
Median	638.71	1147.89	1099.34	1092.31
Min, Max	479.2, 1922.7	359.4, 2262.7	257.8, 1940.9	257.8, 2262.7
Cycle 3 Day 1				
n	4	12	2	18
Mean (StdDev)	560.43 (405.010)	617.24 (315.071)	729.87 (746.719)	617.13 (358.094)
Median	383.80	609.39	729.87	547.78
Min, Max	311.8, 1162.3	196.8, 1239.8	201.9, 1257.9	196.8, 1257.9
Cycle 5 Day 1				
n	3	11	2	16
Mean (StdDev)	719.09 (643.603)	547.49 (263.408)	416.26 (321.154)	563.26 (341.001)
Median	389.95	631.85	416.26	619.24
Min, Max	306.6, 1460.7	184.5, 1108.6	189.2, 643.4	184.5, 1460.7
Cycle 7 Day 1				
n	3	9	1	13
Mean (StdDev)	618.59 (438.270)	531.87 (222.472)	258.62 (-)	530.87 (270.389)
Median	433.90	500.35	258.62	473.73
Min, Max	302.9, 1119.0	140.8, 971.9	258.6, 258.6	140.8, 1119.0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 300 mg
Organ = Spleen

Volume (mL)	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Cycle 11 Day 1				
n	3	5	1	9
Mean (StdDev)	514.91 (473.360)	425.04 (210.321)	694.72 (-)	484.96 (293.624)
Median	365.51	411.27	694.72	411.27
Min, Max	134.3, 1044.9	136.0, 722.6	694.7, 694.7	134.3, 1044.9
Cycle 18 Day 1				
n	2	5	0	7
Mean (StdDev)	273.64 (78.001)	500.83 (163.221)		435.92 (176.251)
Median	273.64	575.47		385.20
Min, Max	218.5, 328.8	277.3, 669.5		218.5, 669.5
Cycle 24 Day 1				
n	2	4	0	6
Mean (StdDev)	303.59 (123.680)	581.86 (238.971)		489.10 (240.778)
Median	303.59	625.71		501.24
Min, Max	216.1, 391.0	252.3, 823.7		216.1, 823.7
Cycle 30 Day 1				
n	1	0	0	1
Mean (StdDev)	316.97 (-)			316.97 (-)
Median	316.97			316.97
Min, Max	317.0, 317.0			317.0, 317.0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 300 mg
Organ = Spleen

Volume (mL)	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Cycle 36 Day 1				
n	1	0	0	1
Mean (StdDev)	310.12 (-)			310.12 (-)
Median	310.12			310.12
Min, Max	310.1, 310.1			310.1, 310.1

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 300 mg
Organ = Liver

Volume (mL)	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Baseline				
n	4	13	3	20
Mean (StdDev)	2246.32 (377.128)	2276.97 (657.353)	2090.15 (173.239)	2242.82 (550.463)
Median	2184.95	2112.93	2020.24	2070.22
Min, Max	1885.0, 2730.4	1436.4, 3624.1	1962.8, 2287.4	1436.4, 3624.1
Cycle 3 Day 1				
n	3	13	3	19
Mean (StdDev)	1763.95 (343.722)	1940.55 (650.332)	1830.77 (552.197)	1895.33 (577.936)
Median	1678.63	1800.88	1623.02	1787.96
Min, Max	1470.9, 2142.3	1284.5, 3519.1	1412.6, 2456.7	1284.5, 3519.1
Cycle 5 Day 1				
n	3	12	3	18
Mean (StdDev)	2173.43 (312.539)	1865.65 (674.977)	1599.32 (384.737)	1872.56 (594.042)
Median	2312.41	1637.80	1470.70	1696.62
Min, Max	1815.5, 2392.4	1127.1, 3615.9	1295.4, 2031.9	1127.1, 3615.9
Cycle 7 Day 1				
n	3	10	2	15
Mean (StdDev)	2206.75 (105.913)	1868.42 (676.249)	1432.17 (41.748)	1877.92 (589.350)
Median	2157.33	1602.29	1432.17	1620.40
Min, Max	2134.6, 2328.3	1231.1, 3549.6	1402.7, 1461.7	1231.1, 3549.6

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 300 mg
Organ = Liver

Volume (mL)	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Cycle 11 Day 1				
n	2	6	2	10
Mean (StdDev)	1837.50 (111.334)	1929.46 (695.147)	1887.62 (707.920)	1902.70 (571.834)
Median	1837.50	1878.83	1887.62	1837.50
Min, Max	1758.8, 1916.2	1174.6, 3135.2	1387.0, 2388.2	1174.6, 3135.2
Cycle 18 Day 1				
n	2	6	1	9
Mean (StdDev)	1871.42 (155.168)	1923.06 (532.830)	1292.81 (-)	1841.56 (472.544)
Median	1871.42	1789.39	1292.81	1775.76
Min, Max	1761.7, 1981.1	1478.1, 2939.6	1292.8, 1292.8	1292.8, 2939.6
Cycle 24 Day 1				
n	2	4	1	7
Mean (StdDev)	1972.35 (88.777)	2091.78 (583.860)	1273.04 (-)	1940.69 (511.473)
Median	1972.35	1945.40	1273.04	1909.57
Min, Max	1909.6, 2035.1	1566.1, 2910.2	1273.0, 1273.0	1273.0, 2910.2
Cycle 30 Day 1				
n	1	0	1	2
Mean (StdDev)	1556.32 (-)		1345.12 (-)	1450.72 (149.341)
Median	1556.32		1345.12	1450.72
Min, Max	1556.3, 1556.3		1345.1, 1345.1	1345.1, 1556.3

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 300 mg
Organ = Liver

Volume (mL)	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Cycle 36 Day 1				
n	1	0	0	1
Mean (StdDev)	1616.96 (-)			1616.96 (-)
Median	1616.96			1616.96
Min, Max	1617.0, 1617.0			1617.0, 1617.0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg
Organ = Spleen

Volume (mL)	ASM (N=5)	SM-AHN (N=20)	MCL (N=7)	All AdvSM (N=32)
Baseline				
n	5	19	6	30
Mean (StdDev)	837.59 (614.938)	1078.82 (497.009)	916.81 (569.531)	1006.21 (520.975)
Median	540.12	1120.69	768.77	958.12
Min, Max	479.2, 1922.7	298.5, 2262.7	257.8, 1940.9	257.8, 2262.7
Cycle 3 Day 1				
n	5	18	5	28
Mean (StdDev)	537.21 (354.568)	589.75 (276.413)	582.84 (399.810)	579.13 (301.356)
Median	436.66	582.55	505.62	540.09
Min, Max	311.8, 1162.3	196.8, 1239.8	201.9, 1257.9	196.8, 1257.9
Cycle 5 Day 1				
n	4	16	6	26
Mean (StdDev)	651.63 (542.545)	561.51 (234.336)	470.40 (174.805)	554.35 (278.604)
Median	419.60	612.15	489.25	591.13
Min, Max	306.6, 1460.7	184.5, 1108.6	189.2, 647.0	184.5, 1460.7
Cycle 7 Day 1				
n	3	14	4	21
Mean (StdDev)	618.59 (438.270)	556.05 (186.902)	358.73 (119.079)	527.40 (227.053)
Median	433.90	549.13	326.81	500.35
Min, Max	302.9, 1119.0	140.8, 971.9	258.6, 522.7	140.8, 1119.0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg
Organ = Spleen

Volume (mL)	ASM (N=5)	SM-AHN (N=20)	MCL (N=7)	All AdvSM (N=32)
Cycle 11 Day 1				
n	3	8	3	14
Mean (StdDev)	514.91 (473.360)	441.27 (174.140)	485.42 (181.261)	466.51 (238.476)
Median	365.51	419.35	382.12	396.70
Min, Max	134.3, 1044.9	136.0, 722.6	379.4, 694.7	134.3, 1044.9
Cycle 18 Day 1				
n	2	6	1	9
Mean (StdDev)	273.64 (78.001)	490.23 (148.280)	348.12 (-)	426.31 (155.429)
Median	273.64	506.36	348.12	385.20
Min, Max	218.5, 328.8	277.3, 669.5	348.1, 348.1	218.5, 669.5
Cycle 24 Day 1				
n	2	5	0	7
Mean (StdDev)	303.59 (123.680)	575.72 (207.411)		497.97 (221.046)
Median	303.59	611.44		551.14
Min, Max	216.1, 391.0	252.3, 823.7		216.1, 823.7
Cycle 30 Day 1				
n	1	1	0	2
Mean (StdDev)	316.97 (-)	421.50 (-)		369.24 (73.914)
Median	316.97	421.50		369.24
Min, Max	317.0, 317.0	421.5, 421.5		317.0, 421.5

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg
Organ = Spleen

Volume (mL)	ASM (N=5)	SM-AHN (N=20)	MCL (N=7)	All AdvSM (N=32)
Cycle 36 Day 1				
n	1	1	0	2
Mean (StdDev)	310.12 (-)	450.03 (-)		380.08 (98.931)
Median	310.12	450.03		380.08
Min, Max	310.1, 310.1	450.0, 450.0		310.1, 450.0
Cycle 42 Day 1				
n	0	1	0	1
Mean (StdDev)		424.70 (-)		424.70 (-)
Median		424.70		424.70
Min, Max		424.7, 424.7		424.7, 424.7

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg
Organ = Liver

Volume (mL)	ASM (N=5)	SM-AHN (N=20)	MCL (N=7)	All AdvSM (N=32)
Baseline				
n	5	20	7	32
Mean (StdDev)	2517.67 (689.065)	2245.23 (553.021)	2475.83 (536.335)	2338.24 (565.185)
Median	2349.73	2090.17	2287.42	2219.34
Min, Max	1885.0, 3603.1	1436.4, 3624.1	1962.8, 3437.5	1436.4, 3624.1
Cycle 3 Day 1				
n	4	19	6	29
Mean (StdDev)	2199.82 (915.796)	1966.19 (567.758)	2055.22 (495.629)	2016.83 (589.736)
Median	1910.47	1868.20	2110.96	1868.20
Min, Max	1470.9, 3507.4	1284.5, 3519.1	1412.6, 2617.1	1284.5, 3519.1
Cycle 5 Day 1				
n	4	17	7	28
Mean (StdDev)	2404.78 (528.390)	1918.88 (605.866)	1911.61 (396.860)	1986.47 (560.178)
Median	2352.40	1714.31	2031.89	1903.12
Min, Max	1815.5, 3098.8	1127.1, 3615.9	1295.4, 2357.8	1127.1, 3615.9
Cycle 7 Day 1				
n	3	15	5	23
Mean (StdDev)	2206.75 (105.913)	1916.01 (593.976)	1830.86 (377.932)	1935.42 (514.085)
Median	2157.33	1811.01	1986.09	1963.15
Min, Max	2134.6, 2328.3	1231.1, 3549.6	1402.7, 2255.4	1231.1, 3549.6

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg
Organ = Liver

Volume (mL)	ASM (N=5)	SM-AHN (N=20)	MCL (N=7)	All AdvSM (N=32)
Cycle 11 Day 1				
n	2	9	4	15
Mean (StdDev)	1837.50 (111.334)	2002.28 (588.380)	1872.15 (409.386)	1945.61 (489.794)
Median	1837.50	2049.54	1856.69	1875.17
Min, Max	1758.8, 1916.2	1174.6, 3135.2	1387.0, 2388.2	1174.6, 3135.2
Cycle 18 Day 1				
n	2	7	2	11
Mean (StdDev)	1871.42 (155.168)	1909.10 (487.806)	1659.69 (518.840)	1856.90 (426.413)
Median	1871.42	1803.01	1659.69	1803.01
Min, Max	1761.7, 1981.1	1478.1, 2939.6	1292.8, 2026.6	1292.8, 2939.6
Cycle 24 Day 1				
n	2	5	1	8
Mean (StdDev)	1972.35 (88.777)	2062.51 (509.856)	1273.04 (-)	1941.28 (473.535)
Median	1972.35	1945.43	1273.04	1927.50
Min, Max	1909.6, 2035.1	1566.1, 2910.2	1273.0, 1273.0	1273.0, 2910.2
Cycle 30 Day 1				
n	1	1	1	3
Mean (StdDev)	1556.32 (-)	2076.45 (-)	1345.12 (-)	1659.30 (376.383)
Median	1556.32	2076.45	1345.12	1556.32
Min, Max	1556.3, 1556.3	2076.5, 2076.5	1345.1, 1345.1	1345.1, 2076.5

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg
Organ = Liver

Volume (mL)	ASM (N=5)	SM-AHN (N=20)	MCL (N=7)	All AdvSM (N=32)
Cycle 36 Day 1				
n	1	1	0	2
Mean (StdDev)	1616.96 (-)	1974.40 (-)		1795.68 (252.748)
Median	1616.96	1974.40		1795.68
Min, Max	1617.0, 1617.0	1974.4, 1974.4		1617.0, 1974.4
Cycle 42 Day 1				
n	0	1	0	1
Mean (StdDev)		1820.09 (-)		1820.09 (-)
Median		1820.09		1820.09
Min, Max		1820.1, 1820.1		1820.1, 1820.1

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 400 mg
Organ = Spleen

Volume (mL)	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Baseline				
n	1	4	0	5
Mean (StdDev)	163.41 (-)	1058.92 (596.395)		879.82 (653.569)
Median	163.41	1008.52		580.47
Min, Max	163.4, 163.4	521.8, 1696.9		163.4, 1696.9
Cycle 3 Day 1				
n	1	3	0	4
Mean (StdDev)	94.57 (-)	786.10 (269.052)		613.22 (409.651)
Median	94.57	849.67		670.32
Min, Max	94.6, 94.6	491.0, 1017.7		94.6, 1017.7
Cycle 5 Day 1				
n	1	3	0	4
Mean (StdDev)	96.49 (-)	809.71 (424.554)		631.40 (497.327)
Median	96.49	633.75		567.59
Min, Max	96.5, 96.5	501.4, 1294.0		96.5, 1294.0
Cycle 7 Day 1				
n	1	2	0	3
Mean (StdDev)	120.47 (-)	761.90 (241.159)		548.09 (407.702)
Median	120.47	761.90		591.37
Min, Max	120.5, 120.5	591.4, 932.4		120.5, 932.4

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 400 mg
Organ = Spleen

Volume (mL)	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Cycle 11 Day 1				
n	0	2	0	2
Mean (StdDev)		817.45 (361.805)		817.45 (361.805)
Median		817.45		817.45
Min, Max		561.6, 1073.3		561.6, 1073.3
Cycle 18 Day 1				
n	0	1	0	1
Mean (StdDev)		573.32 (-)		573.32 (-)
Median		573.32		573.32
Min, Max		573.3, 573.3		573.3, 573.3
Cycle 24 Day 1				
n	0	2	0	2
Mean (StdDev)		486.87 (233.494)		486.87 (233.494)
Median		486.87		486.87
Min, Max		321.8, 652.0		321.8, 652.0
Cycle 30 Day 1				
n	0	1	0	1
Mean (StdDev)		888.85 (-)		888.85 (-)
Median		888.85		888.85
Min, Max		888.9, 888.9		888.9, 888.9

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 400 mg
Organ = Spleen

Volume (mL)	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Cycle 36 Day 1				
n	0	1	0	1
Mean (StdDev)		902.61 (-)		902.61 (-)
Median		902.61		902.61
Min, Max		902.6, 902.6		902.6, 902.6

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 400 mg
Organ = Liver

Volume (mL)	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Baseline				
n	1	4	0	5
Mean (StdDev)	1019.93 (-)	2777.23 (487.520)		2425.77 (892.121)
Median	1019.93	2791.67		2682.43
Min, Max	1019.9, 1019.9	2176.1, 3349.5		1019.9, 3349.5
Cycle 3 Day 1				
n	1	3	0	4
Mean (StdDev)	1017.42 (-)	2461.29 (125.135)		2100.32 (729.129)
Median	1017.42	2520.49		2419.02
Min, Max	1017.4, 1017.4	2317.5, 2545.8		1017.4, 2545.8
Cycle 5 Day 1				
n	1	3	0	4
Mean (StdDev)	1039.92 (-)	2258.95 (136.662)		1954.20 (619.646)
Median	1039.92	2299.86		2203.19
Min, Max	1039.9, 1039.9	2106.5, 2370.5		1039.9, 2370.5
Cycle 7 Day 1				
n	1	2	0	3
Mean (StdDev)	993.18 (-)	2177.33 (209.396)		1782.61 (699.516)
Median	993.18	2177.33		2029.26
Min, Max	993.2, 993.2	2029.3, 2325.4		993.2, 2325.4

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 400 mg
Organ = Liver

Volume (mL)	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Cycle 11 Day 1				
n	0	2	0	2
Mean (StdDev)		2347.83 (88.848)		2347.83 (88.848)
Median		2347.83		2347.83
Min, Max		2285.0, 2410.7		2285.0, 2410.7
Cycle 18 Day 1				
n	0	1	0	1
Mean (StdDev)		2290.76 (-)		2290.76 (-)
Median		2290.76		2290.76
Min, Max		2290.8, 2290.8		2290.8, 2290.8
Cycle 24 Day 1				
n	0	2	0	2
Mean (StdDev)		2037.87 (213.447)		2037.87 (213.447)
Median		2037.87		2037.87
Min, Max		1886.9, 2188.8		1886.9, 2188.8
Cycle 30 Day 1				
n	0	1	0	1
Mean (StdDev)		2875.39 (-)		2875.39 (-)
Median		2875.39		2875.39
Min, Max		2875.4, 2875.4		2875.4, 2875.4

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 400 mg
Organ = Liver

Volume (mL)	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Cycle 36 Day 1				
n	0	1	0	1
Mean (StdDev)		2708.57 (-)		2708.57 (-)
Median		2708.57		2708.57
Min, Max		2708.6, 2708.6		2708.6, 2708.6

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2202

Overall
Organ = Spleen

Volume (mL)	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Baseline				
n	5	28	9	42
Mean (StdDev)	641.10 (467.460)	983.64 (507.650)	1213.12 (645.927)	992.04 (546.109)
Median	651.85	823.26	1166.99	766.96
Min, Max	44.2, 1321.6	449.5, 2600.8	367.4, 2270.0	44.2, 2600.8
Cycle 3 Day 1				
n	4	19	6	29
Mean (StdDev)	465.99 (170.543)	815.16 (430.645)	729.86 (348.525)	749.35 (398.145)
Median	407.71	709.66	690.23	662.06
Min, Max	332.9, 715.6	343.8, 1788.5	397.8, 1384.1	332.9, 1788.5
Cycle 7 Day 1				
n	1	13	2	16
Mean (StdDev)	392.79 (-)	629.44 (401.455)	492.76 (170.278)	597.57 (368.791)
Median	392.79	429.73	492.76	424.06
Min, Max	392.8, 392.8	348.1, 1702.8	372.4, 613.2	348.1, 1702.8
Cycle 11 Day 1				
n	0	8	1	9
Mean (StdDev)		539.34 (345.162)	353.71 (-)	518.71 (328.745)
Median		410.14	353.71	381.16
Min, Max		292.9, 1338.0	353.7, 353.7	292.9, 1338.0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2202

Overall
Organ = Spleen

Volume (mL)	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		713.44 (-)	329.23 (-)	521.34 (271.677)
Median		713.44	329.23	521.34
Min, Max		713.4, 713.4	329.2, 329.2	329.2, 713.4

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2202

Overall
Organ = Liver

Volume (mL)	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Baseline				
n	5	28	9	42
Mean (StdDev)	2019.15 (291.817)	2480.12 (423.795)	3001.19 (680.274)	2536.90 (546.893)
Median	2101.22	2462.19	3141.41	2462.19
Min, Max	1671.6, 2289.8	1707.4, 3311.1	1660.5, 4020.8	1660.5, 4020.8
Cycle 3 Day 1				
n	4	19	6	29
Mean (StdDev)	1688.04 (238.489)	2169.80 (378.969)	2704.58 (402.287)	2213.99 (468.760)
Median	1591.99	2183.03	2795.97	2183.03
Min, Max	1531.2, 2037.0	1433.4, 2974.6	2137.1, 3130.4	1433.4, 3130.4
Cycle 7 Day 1				
n	1	13	2	16
Mean (StdDev)	1782.23 (-)	1972.46 (367.694)	2460.52 (993.428)	2021.58 (453.379)
Median	1782.23	1824.99	2460.52	1813.27
Min, Max	1782.2, 1782.2	1436.2, 2830.5	1758.1, 3163.0	1436.2, 3163.0
Cycle 11 Day 1				
n	0	8	1	9
Mean (StdDev)		1832.17 (302.532)	1694.08 (-)	1816.83 (286.712)
Median		1840.29	1694.08	1815.15
Min, Max		1294.2, 2279.1	1694.1, 1694.1	1294.2, 2279.1

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2202

Overall
Organ = Liver

Volume (mL)	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		1867.29 (-)	1486.28 (-)	1676.79 (269.415)
Median		1867.29	1486.28	1676.79
Min, Max		1867.3, 1867.3	1486.3, 1486.3	1486.3, 1867.3

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2202

Starting Dose: 200 mg
Organ = Spleen

Volume (mL)	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Baseline				
n	4	27	9	40
Mean (StdDev)	790.33 (378.001)	977.28 (516.182)	1213.12 (645.927)	1011.65 (537.971)
Median	702.10	719.85	1166.99	766.96
Min, Max	435.6, 1321.6	449.5, 2600.8	367.4, 2270.0	367.4, 2600.8
Cycle 3 Day 1				
n	4	18	6	28
Mean (StdDev)	465.99 (170.543)	789.25 (427.612)	729.86 (348.525)	730.34 (391.818)
Median	407.71	643.62	690.23	619.82
Min, Max	332.9, 715.6	343.8, 1788.5	397.8, 1384.1	332.9, 1788.5
Cycle 7 Day 1				
n	1	12	2	15
Mean (StdDev)	392.79 (-)	576.73 (369.337)	492.76 (170.278)	553.27 (334.790)
Median	392.79	424.06	492.76	418.39
Min, Max	392.8, 392.8	348.1, 1702.8	372.4, 613.2	348.1, 1702.8
Cycle 11 Day 1				
n	0	7	1	8
Mean (StdDev)		425.24 (132.271)	353.71 (-)	416.30 (125.044)
Median		381.16	353.71	370.30
Min, Max		292.9, 681.4	353.7, 353.7	292.9, 681.4

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2202

Starting Dose: 200 mg
Organ = Spleen

Volume (mL)	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		713.44 (-)	329.23 (-)	521.34 (271.677)
Median		713.44	329.23	521.34
Min, Max		713.4, 713.4	329.2, 329.2	329.2, 713.4

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2202

Starting Dose: 200 mg
Organ = Liver

Volume (mL)	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Baseline				
n	4	27	9	40
Mean (StdDev)	1953.70 (291.521)	2449.34 (398.705)	3001.19 (680.274)	2523.95 (545.168)
Median	1926.67	2453.43	3141.41	2462.19
Min, Max	1671.6, 2289.8	1707.4, 3239.5	1660.5, 4020.8	1660.5, 4020.8
Cycle 3 Day 1				
n	4	18	6	28
Mean (StdDev)	1688.04 (238.489)	2151.08 (380.812)	2704.58 (402.287)	2203.54 (473.907)
Median	1591.99	2121.39	2795.97	2160.07
Min, Max	1531.2, 2037.0	1433.4, 2974.6	2137.1, 3130.4	1433.4, 3130.4
Cycle 7 Day 1				
n	1	12	2	15
Mean (StdDev)	1782.23 (-)	1941.60 (366.037)	2460.52 (993.428)	2000.16 (460.840)
Median	1782.23	1813.27	2460.52	1801.55
Min, Max	1782.2, 1782.2	1436.2, 2830.5	1758.1, 3163.0	1436.2, 3163.0
Cycle 11 Day 1				
n	0	7	1	8
Mean (StdDev)		1768.33 (262.177)	1694.08 (-)	1759.05 (244.144)
Median		1815.15	1694.08	1779.14
Min, Max		1294.2, 2144.9	1694.1, 1694.1	1294.2, 2144.9

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2202

Starting Dose: 200 mg
Organ = Liver

Volume (mL)	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		1867.29 (-)	1486.28 (-)	1676.79 (269.415)
Median		1867.29	1486.28	1676.79
Min, Max		1867.3, 1867.3	1486.3, 1486.3	1486.3, 1867.3

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Overall
Organ = Spleen

Volume (mL)	ASM (N=12)	SM-AHN (N=54)	MCL (N=17)	All AdvSM (N=83)
Baseline				
n	11	53	16	80
Mean (StdDev)	686.98 (527.705)	1019.76 (501.348)	1062.49 (606.801)	982.55 (533.849)
Median	540.12	1030.73	815.31	829.70
Min, Max	44.2, 1922.7	298.5, 2600.8	257.8, 2270.0	44.2, 2600.8
Cycle 3 Day 1				
n	10	42	12	64
Mean (StdDev)	464.46 (289.333)	706.96 (367.490)	653.96 (345.958)	659.13 (358.178)
Median	407.71	634.69	548.02	556.48
Min, Max	94.6, 1162.3	196.8, 1788.5	201.9, 1384.1	94.6, 1788.5
Cycle 5 Day 1				
n	5	21	7	33
Mean (StdDev)	540.60 (531.415)	601.42 (280.712)	487.55 (165.900)	568.05 (303.276)
Median	389.95	617.66	506.90	590.45
Min, Max	96.5, 1460.7	184.5, 1294.0	189.2, 647.0	96.5, 1460.7
Cycle 7 Day 1				
n	5	31	7	43
Mean (StdDev)	473.81 (380.283)	608.56 (297.108)	433.38 (149.007)	564.38 (292.018)
Median	392.79	547.36	372.35	500.35
Min, Max	120.5, 1119.0	140.8, 1702.8	258.6, 613.2	120.5, 1702.8

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Overall
Organ = Spleen

Volume (mL)	ASM (N=12)	SM-AHN (N=54)	MCL (N=17)	All AdvSM (N=83)
Cycle 11 Day 1				
n	3	20	5	28
Mean (StdDev)	514.91 (473.360)	532.27 (277.918)	462.13 (141.931)	517.88 (273.249)
Median	365.51	433.27	382.12	421.46
Min, Max	134.3, 1044.9	136.0, 1338.0	353.7, 694.7	134.3, 1338.0
Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		713.44 (-)	329.23 (-)	521.34 (271.677)
Median		713.44	329.23	521.34
Min, Max		713.4, 713.4	329.2, 329.2	329.2, 713.4
Cycle 18 Day 1				
n	2	9	2	13
Mean (StdDev)	273.64 (78.001)	508.38 (144.717)	340.69 (10.508)	446.46 (155.551)
Median	273.64	573.32	340.69	385.20
Min, Max	218.5, 328.8	277.3, 689.2	333.3, 348.1	218.5, 689.2
Cycle 24 Day 1				
n	2	9	1	12
Mean (StdDev)	303.59 (123.680)	548.32 (206.804)	353.28 (-)	491.28 (208.070)
Median	303.59	611.44	353.28	471.09
Min, Max	216.1, 391.0	252.3, 823.7	353.3, 353.3	216.1, 823.7

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Overall
Organ = Spleen

Volume (mL)	ASM (N=12)	SM-AHN (N=54)	MCL (N=17)	All AdvSM (N=83)
Cycle 30 Day 1				
n	1	4	1	6
Mean (StdDev)	316.97 (-)	598.35 (226.043)	238.39 (-)	491.46 (242.273)
Median	316.97	543.93	238.39	419.10
Min, Max	317.0, 317.0	416.7, 888.9	238.4, 238.4	238.4, 888.9
Cycle 36 Day 1				
n	1	4	1	6
Mean (StdDev)	310.12 (-)	574.64 (240.080)	276.98 (-)	480.94 (236.140)
Median	310.12	521.85	276.98	401.14
Min, Max	310.1, 310.1	352.2, 902.6	277.0, 277.0	277.0, 902.6
Cycle 42 Day 1				
n	0	3	1	4
Mean (StdDev)		478.63 (130.745)	204.10 (-)	410.00 (173.889)
Median		424.70	204.10	404.09
Min, Max		383.5, 627.7	204.1, 204.1	204.1, 627.7
Cycle 48 Day 1				
n	0	0	1	1
Mean (StdDev)			172.80 (-)	172.80 (-)
Median			172.80	172.80
Min, Max			172.8, 172.8	172.8, 172.8

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Overall
Organ = Liver

Volume (mL)	ASM (N=12)	SM-AHN (N=54)	MCL (N=17)	All AdvSM (N=83)
Baseline				
n	12	54	17	83
Mean (StdDev)	2173.13 (626.823)	2409.13 (488.500)	2692.79 (715.614)	2433.10 (575.428)
Median	2191.09	2406.85	2903.36	2361.64
Min, Max	1019.9, 3603.1	1436.4, 3624.1	1435.8, 4020.8	1019.9, 4020.8
Cycle 3 Day 1				
n	10	43	13	66
Mean (StdDev)	1867.65 (669.788)	2096.90 (469.920)	2299.19 (599.906)	2102.01 (536.178)
Median	1662.21	2052.60	2380.54	2053.87
Min, Max	1017.4, 3507.4	1284.5, 3519.1	1330.7, 3130.4	1017.4, 3519.1
Cycle 5 Day 1				
n	6	22	8	36
Mean (StdDev)	2104.20 (685.669)	1969.84 (547.122)	1851.60 (404.725)	1965.96 (534.606)
Median	2139.30	1901.97	1941.25	1960.91
Min, Max	1039.9, 3098.8	1127.1, 3615.9	1295.4, 2357.8	1039.9, 3615.9
Cycle 7 Day 1				
n	6	32	8	46
Mean (StdDev)	1864.13 (478.642)	1974.33 (475.495)	1936.81 (589.299)	1953.43 (486.470)
Median	1961.85	1906.54	1872.08	1906.54
Min, Max	993.2, 2328.3	1231.1, 3549.6	1402.7, 3163.0	993.2, 3549.6

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Overall
Organ = Liver

Volume (mL)	ASM (N=12)	SM-AHN (N=54)	MCL (N=17)	All AdvSM (N=83)
Cycle 11 Day 1				
n	3	21	6	30
Mean (StdDev)	1762.30 (152.191)	1988.21 (445.199)	1754.59 (382.003)	1918.90 (418.390)
Median	1758.77	2049.54	1766.15	1870.30
Min, Max	1611.9, 1916.2	1174.6, 3135.2	1344.8, 2388.2	1174.6, 3135.2
Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		1867.29 (-)	1486.28 (-)	1676.79 (269.415)
Median		1867.29	1486.28	1676.79
Min, Max		1867.3, 1867.3	1486.3, 1486.3	1486.3, 1867.3
Cycle 18 Day 1				
n	3	10	3	16
Mean (StdDev)	1802.15 (162.584)	1947.28 (419.109)	1501.98 (457.391)	1836.57 (409.399)
Median	1761.70	1814.74	1292.81	1803.58
Min, Max	1663.6, 1981.1	1478.1, 2939.6	1186.6, 2026.6	1186.6, 2939.6
Cycle 24 Day 1				
n	3	9	2	14
Mean (StdDev)	1851.65 (218.266)	1995.68 (437.106)	1304.90 (45.057)	1866.14 (430.336)
Median	1909.57	1945.43	1304.90	1898.26
Min, Max	1610.3, 2035.1	1380.4, 2910.2	1273.0, 1336.8	1273.0, 2910.2

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Overall
Organ = Liver

Volume (mL)	ASM (N=12)	SM-AHN (N=54)	MCL (N=17)	All AdvSM (N=83)
Cycle 30 Day 1				
n	2	4	2	8
Mean (StdDev)	1552.16 (5.883)	2238.70 (463.433)	1290.13 (77.768)	1829.92 (541.934)
Median	1552.16	2150.81	1290.13	1667.06
Min, Max	1548.0, 1556.3	1777.8, 2875.4	1235.1, 1345.1	1235.1, 2875.4
Cycle 36 Day 1				
n	2	4	1	7
Mean (StdDev)	1618.72 (2.489)	2139.75 (415.115)	1286.99 (-)	1869.06 (460.835)
Median	1618.72	2059.09	1286.99	1732.26
Min, Max	1617.0, 1620.5	1732.3, 2708.6	1287.0, 1287.0	1287.0, 2708.6
Cycle 42 Day 1				
n	0	3	1	4
Mean (StdDev)		1811.53 (212.694)	1314.94 (-)	1687.38 (303.000)
Median		1820.09	1314.94	1707.39
Min, Max		1594.7, 2019.8	1314.9, 1314.9	1314.9, 2019.8
Cycle 48 Day 1				
n	1	0	1	2
Mean (StdDev)	1727.89 (-)		1093.73 (-)	1410.81 (448.419)
Median	1727.89		1093.73	1410.81
Min, Max	1727.9, 1727.9		1093.7, 1093.7	1093.7, 1727.9

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg
Organ = Spleen

Volume (mL)	ASM (N=2)	SM-AHN (N=3)	MCL (N=1)	All AdvSM (N=6)
Baseline				
n	1	3	1	5
Mean (StdDev)	44.16 (-)	975.86 (501.173)	580.85 (-)	710.52 (541.851)
Median	44.16	1155.41	580.85	580.85
Min, Max	44.2, 44.2	409.6, 1362.5	580.9, 580.9	44.2, 1362.5
Cycle 3 Day 1				
n	0	3	1	4
Mean (StdDev)		837.39 (522.430)	554.17 (-)	766.58 (449.453)
Median		968.66	554.17	761.42
Min, Max		261.8, 1281.7	554.2, 554.2	261.8, 1281.7
Cycle 5 Day 1				
n	0	2	1	3
Mean (StdDev)		608.28 (485.860)	590.45 (-)	602.33 (343.709)
Median		608.28	590.45	590.45
Min, Max		264.7, 951.8	590.5, 590.5	264.7, 951.8
Cycle 7 Day 1				
n	0	3	1	4
Mean (StdDev)		878.73 (399.154)	613.22 (-)	812.35 (351.909)
Median		908.78	613.22	761.00
Min, Max		465.4, 1262.0	613.2, 613.2	465.4, 1262.0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg
Organ = Spleen

Volume (mL)	ASM (N=2)	SM-AHN (N=3)	MCL (N=1)	All AdvSM (N=6)
Cycle 11 Day 1				
n	0	3	1	4
Mean (StdDev)		834.54 (467.012)	500.65 (-)	751.07 (416.258)
Median		750.13	500.65	625.39
Min, Max		415.5, 1338.0	500.7, 500.7	415.5, 1338.0
Cycle 18 Day 1				
n	0	2	1	3
Mean (StdDev)		530.35 (224.612)	333.26 (-)	464.65 (195.379)
Median		530.35	333.26	371.52
Min, Max		371.5, 689.2	333.3, 333.3	333.3, 689.2
Cycle 24 Day 1				
n	0	2	1	3
Mean (StdDev)		541.28 (322.709)	353.28 (-)	478.61 (252.690)
Median		541.28	353.28	353.28
Min, Max		313.1, 769.5	353.3, 353.3	313.1, 769.5
Cycle 30 Day 1				
n	0	2	1	3
Mean (StdDev)		541.53 (176.529)	238.39 (-)	440.48 (214.969)
Median		541.53	238.39	416.70
Min, Max		416.7, 666.4	238.4, 238.4	238.4, 666.4

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg
Organ = Spleen

Volume (mL)	ASM (N=2)	SM-AHN (N=3)	MCL (N=1)	All AdvSM (N=6)
Cycle 36 Day 1				
n	0	2	1	3
Mean (StdDev)		472.95 (170.710)	276.98 (-)	407.63 (165.446)
Median		472.95	276.98	352.24
Min, Max		352.2, 593.7	277.0, 277.0	277.0, 593.7
Cycle 42 Day 1				
n	0	2	1	3
Mean (StdDev)		505.59 (172.704)	204.10 (-)	405.09 (212.631)
Median		505.59	204.10	383.47
Min, Max		383.5, 627.7	204.1, 204.1	204.1, 627.7
Cycle 48 Day 1				
n	0	0	1	1
Mean (StdDev)			172.80 (-)	172.80 (-)
Median			172.80	172.80
Min, Max			172.8, 172.8	172.8, 172.8

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg
Organ = Liver

Volume (mL)	ASM (N=2)	SM-AHN (N=3)	MCL (N=1)	All AdvSM (N=6)
Baseline				
n	2	3	1	6
Mean (StdDev)	2327.23 (65.450)	2648.96 (589.530)	1435.80 (-)	2339.52 (600.607)
Median	2327.23	2454.60	1435.80	2327.23
Min, Max	2281.0, 2373.5	2181.2, 3311.1	1435.8, 1435.8	1435.8, 3311.1
Cycle 3 Day 1				
n	1	3	1	5
Mean (StdDev)	2107.61 (-)	2235.26 (266.940)	1330.66 (-)	2028.81 (437.037)
Median	2107.61	2226.03	1330.66	2107.61
Min, Max	2107.6, 2107.6	1973.1, 2506.7	1330.7, 1330.7	1330.7, 2506.7
Cycle 5 Day 1				
n	1	2	1	4
Mean (StdDev)	1966.19 (-)	1969.40 (284.144)	1431.57 (-)	1834.14 (314.552)
Median	1966.19	1969.40	1431.57	1867.34
Min, Max	1966.2, 1966.2	1768.5, 2170.3	1431.6, 1431.6	1431.6, 2170.3
Cycle 7 Day 1				
n	1	3	1	5
Mean (StdDev)	1789.11 (-)	2261.49 (281.358)	1419.11 (-)	1998.54 (431.667)
Median	1789.11	2342.79	1419.11	1948.43
Min, Max	1789.1, 1789.1	1948.4, 2493.2	1419.1, 1419.1	1419.1, 2493.2

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg
Organ = Liver

Volume (mL)	ASM (N=2)	SM-AHN (N=3)	MCL (N=1)	All AdvSM (N=6)
Cycle 11 Day 1				
n	1	3	1	5
Mean (StdDev)	1611.90 (-)	2219.34 (86.817)	1344.84 (-)	1922.95 (421.181)
Median	1611.90	2259.18	1344.84	2119.75
Min, Max	1611.9, 1611.9	2119.8, 2279.1	1344.8, 1344.8	1344.8, 2279.1
Cycle 18 Day 1				
n	1	2	1	4
Mean (StdDev)	1663.61 (-)	1909.16 (148.507)	1186.58 (-)	1667.13 (351.261)
Median	1663.61	1909.16	1186.58	1733.88
Min, Max	1663.6, 1663.6	1804.2, 2014.2	1186.6, 1186.6	1186.6, 2014.2
Cycle 24 Day 1				
n	1	2	1	4
Mean (StdDev)	1610.27 (-)	1786.44 (574.171)	1336.76 (-)	1629.98 (393.700)
Median	1610.27	1786.44	1336.76	1495.36
Min, Max	1610.3, 1610.3	1380.4, 2192.4	1336.8, 1336.8	1336.8, 2192.4
Cycle 30 Day 1				
n	1	2	1	4
Mean (StdDev)	1548.00 (-)	2001.48 (316.331)	1235.14 (-)	1696.53 (416.732)
Median	1548.00	2001.48	1235.14	1662.90
Min, Max	1548.0, 1548.0	1777.8, 2225.2	1235.1, 1235.1	1235.1, 2225.2

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg
Organ = Liver

Volume (mL)	ASM (N=2)	SM-AHN (N=3)	MCL (N=1)	All AdvSM (N=6)
Cycle 36 Day 1				
n	1	2	1	4
Mean (StdDev)	1620.48 (-)	1938.02 (290.989)	1286.99 (-)	1695.88 (353.466)
Median	1620.48	1938.02	1286.99	1676.37
Min, Max	1620.5, 1620.5	1732.3, 2143.8	1287.0, 1287.0	1287.0, 2143.8
Cycle 42 Day 1				
n	0	2	1	3
Mean (StdDev)		1807.25 (300.612)	1314.94 (-)	1643.14 (354.925)
Median		1807.25	1314.94	1594.68
Min, Max		1594.7, 2019.8	1314.9, 1314.9	1314.9, 2019.8
Cycle 48 Day 1				
n	1	0	1	2
Mean (StdDev)	1727.89 (-)		1093.73 (-)	1410.81 (448.419)
Median	1727.89		1093.73	1410.81
Min, Max	1727.9, 1727.9		1093.7, 1093.7	1093.7, 1727.9

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg
Organ = Spleen

Volume (mL)	ASM (N=7)	SM-AHN (N=37)	MCL (N=14)	All AdvSM (N=58)
Baseline				
n	6	37	14	57
Mean (StdDev)	619.03 (421.590)	963.16 (478.642)	1057.22 (561.839)	950.04 (501.150)
Median	580.26	875.83	815.31	781.57
Min, Max	44.2, 1321.6	298.5, 2600.8	367.4, 2270.0	44.2, 2600.8
Cycle 3 Day 1				
n	5	27	10	42
Mean (StdDev)	461.66 (148.011)	738.04 (399.942)	638.78 (287.737)	681.51 (360.818)
Median	422.22	607.84	548.02	556.48
Min, Max	332.9, 715.6	238.9, 1788.5	397.8, 1384.1	238.9, 1788.5
Cycle 5 Day 1				
n	1	7	5	13
Mean (StdDev)	449.24 (-)	596.89 (244.735)	516.07 (109.277)	554.45 (191.090)
Median	449.24	599.60	506.90	582.65
Min, Max	449.2, 449.2	264.7, 951.8	364.4, 647.0	264.7, 951.8
Cycle 7 Day 1				
n	1	20	6	27
Mean (StdDev)	392.79 (-)	627.74 (331.407)	462.51 (139.705)	582.32 (300.492)
Median	392.79	533.93	447.52	520.50
Min, Max	392.8, 392.8	348.1, 1702.8	284.4, 613.2	284.4, 1702.8

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg
Organ = Spleen

Volume (mL)	ASM (N=7)	SM-AHN (N=37)	MCL (N=14)	All AdvSM (N=58)
Cycle 11 Day 1				
n	0	13	4	17
Mean (StdDev)		529.64 (279.800)	403.98 (65.708)	500.07 (250.089)
Median		427.43	380.78	415.49
Min, Max		292.9, 1338.0	353.7, 500.7	292.9, 1338.0
Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		713.44 (-)	329.23 (-)	521.34 (271.677)
Median		713.44	329.23	521.34
Min, Max		713.4, 713.4	329.2, 329.2	329.2, 713.4
Cycle 18 Day 1				
n	0	3	2	5
Mean (StdDev)		499.31 (167.675)	340.69 (10.508)	435.86 (147.082)
Median		437.24	340.69	371.52
Min, Max		371.5, 689.2	333.3, 348.1	333.3, 689.2
Cycle 24 Day 1				
n	0	3	1	4
Mean (StdDev)		544.57 (228.261)	353.28 (-)	496.75 (209.483)
Median		551.14	353.28	452.21
Min, Max		313.1, 769.5	353.3, 353.3	313.1, 769.5

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg
Organ = Spleen

Volume (mL)	ASM (N=7)	SM-AHN (N=37)	MCL (N=14)	All AdvSM (N=58)
Cycle 30 Day 1				
n	0	3	1	4
Mean (StdDev)		501.52 (142.770)	238.39 (-)	435.74 (175.778)
Median		421.50	238.39	419.10
Min, Max		416.7, 666.4	238.4, 238.4	238.4, 666.4
Cycle 36 Day 1				
n	0	3	1	4
Mean (StdDev)		465.31 (121.433)	276.98 (-)	418.23 (136.740)
Median		450.03	276.98	401.14
Min, Max		352.2, 593.7	277.0, 277.0	277.0, 593.7
Cycle 42 Day 1				
n	0	3	1	4
Mean (StdDev)		478.63 (130.745)	204.10 (-)	410.00 (173.889)
Median		424.70	204.10	404.09
Min, Max		383.5, 627.7	204.1, 204.1	204.1, 627.7
Cycle 48 Day 1				
n	0	0	1	1
Mean (StdDev)			172.80 (-)	172.80 (-)
Median			172.80	172.80
Min, Max			172.8, 172.8	172.8, 172.8

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg
Organ = Liver

Volume (mL)	ASM (N=7)	SM-AHN (N=37)	MCL (N=14)	All AdvSM (N=58)
Baseline				
n	7	37	14	58
Mean (StdDev)	2296.04 (637.475)	2415.76 (407.513)	2821.92 (723.807)	2499.35 (549.831)
Median	2280.95	2390.27	2919.56	2411.39
Min, Max	1671.6, 3603.1	1707.4, 3311.1	1435.8, 4020.8	1435.8, 4020.8
Cycle 3 Day 1				
n	6	27	10	43
Mean (StdDev)	2061.20 (751.178)	2131.69 (362.647)	2439.72 (563.036)	2193.49 (485.704)
Median	1841.40	2059.75	2498.82	2137.11
Min, Max	1531.2, 3507.4	1433.4, 2974.6	1330.7, 3130.4	1330.7, 3507.4
Cycle 5 Day 1				
n	2	7	5	14
Mean (StdDev)	2532.50 (800.876)	2024.56 (373.121)	2002.97 (369.144)	2089.41 (436.880)
Median	2532.50	2018.74	2160.89	2089.82
Min, Max	1966.2, 3098.8	1492.8, 2654.6	1431.6, 2357.8	1431.6, 3098.8
Cycle 7 Day 1				
n	2	20	6	28
Mean (StdDev)	1785.67 (4.865)	2006.98 (372.289)	2105.02 (591.622)	2012.18 (409.985)
Median	1785.67	1954.30	2017.29	1954.30
Min, Max	1782.2, 1789.1	1406.6, 2830.5	1419.1, 3163.0	1406.6, 3163.0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg
Organ = Liver

Volume (mL)	ASM (N=7)	SM-AHN (N=37)	MCL (N=14)	All AdvSM (N=58)
Cycle 11 Day 1				
n	1	13	4	18
Mean (StdDev)	1611.90 (-)	1960.00 (322.787)	1688.08 (241.793)	1880.24 (318.832)
Median	1611.90	1887.00	1766.15	1856.82
Min, Max	1611.9, 1611.9	1294.2, 2546.0	1344.8, 1875.2	1294.2, 2546.0
Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		1867.29 (-)	1486.28 (-)	1676.79 (269.415)
Median		1867.29	1486.28	1676.79
Min, Max		1867.3, 1867.3	1486.3, 1486.3	1486.3, 1867.3
Cycle 18 Day 1				
n	1	3	2	6
Mean (StdDev)	1663.61 (-)	1881.22 (115.627)	1606.57 (593.956)	1753.40 (309.746)
Median	1663.61	1825.33	1606.57	1814.74
Min, Max	1663.6, 1663.6	1804.2, 2014.2	1186.6, 2026.6	1186.6, 2026.6
Cycle 24 Day 1				
n	1	3	1	5
Mean (StdDev)	1610.27 (-)	1839.44 (416.247)	1336.76 (-)	1693.07 (368.987)
Median	1610.27	1945.43	1336.76	1610.27
Min, Max	1610.3, 1610.3	1380.4, 2192.4	1336.8, 1336.8	1336.8, 2192.4

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg
Organ = Liver

Volume (mL)	ASM (N=7)	SM-AHN (N=37)	MCL (N=14)	All AdvSM (N=58)
Cycle 30 Day 1				
n	1	3	1	5
Mean (StdDev)	1548.00 (-)	2026.47 (227.829)	1235.14 (-)	1772.51 (398.896)
Median	1548.00	2076.45	1235.14	1777.80
Min, Max	1548.0, 1548.0	1777.8, 2225.2	1235.1, 1235.1	1235.1, 2225.2
Cycle 36 Day 1				
n	1	3	1	5
Mean (StdDev)	1620.48 (-)	1950.15 (206.829)	1286.99 (-)	1751.58 (330.482)
Median	1620.48	1974.40	1286.99	1732.26
Min, Max	1620.5, 1620.5	1732.3, 2143.8	1287.0, 1287.0	1287.0, 2143.8
Cycle 42 Day 1				
n	0	3	1	4
Mean (StdDev)		1811.53 (212.694)	1314.94 (-)	1687.38 (303.000)
Median		1820.09	1314.94	1707.39
Min, Max		1594.7, 2019.8	1314.9, 1314.9	1314.9, 2019.8
Cycle 48 Day 1				
n	1	0	1	2
Mean (StdDev)	1727.89 (-)		1093.73 (-)	1410.81 (448.419)
Median	1727.89		1093.73	1410.81
Min, Max	1727.9, 1727.9		1093.7, 1093.7	1093.7, 1727.9

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg
Organ = Spleen

Volume (mL)	ASM (N=5)	SM-AHN (N=34)	MCL (N=13)	All AdvSM (N=52)
Baseline				
n	5	34	13	52
Mean (StdDev)	734.00 (350.759)	962.03 (484.445)	1093.87 (567.100)	973.07 (496.569)
Median	651.85	843.09	849.05	795.96
Min, Max	435.6, 1321.6	298.5, 2600.8	367.4, 2270.0	298.5, 2600.8
Cycle 3 Day 1				
n	5	24	9	38
Mean (StdDev)	461.66 (148.011)	725.62 (394.507)	648.18 (303.558)	672.55 (356.399)
Median	422.22	592.71	541.87	556.48
Min, Max	332.9, 715.6	238.9, 1788.5	397.8, 1384.1	238.9, 1788.5
Cycle 5 Day 1				
n	1	5	4	10
Mean (StdDev)	449.24 (-)	592.34 (175.321)	497.47 (116.691)	540.08 (146.427)
Median	449.24	599.60	489.25	544.78
Min, Max	449.2, 449.2	334.0, 827.8	364.4, 647.0	334.0, 827.8
Cycle 7 Day 1				
n	1	17	5	23
Mean (StdDev)	392.79 (-)	583.45 (310.824)	432.36 (132.598)	542.31 (280.234)
Median	392.79	520.50	372.35	474.99
Min, Max	392.8, 392.8	348.1, 1702.8	284.4, 613.2	284.4, 1702.8

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg
Organ = Spleen

Volume (mL)	ASM (N=5)	SM-AHN (N=34)	MCL (N=13)	All AdvSM (N=52)
Cycle 11 Day 1				
n	0	10	3	13
Mean (StdDev)		438.17 (125.030)	371.75 (15.684)	422.84 (112.310)
Median		404.30	379.43	381.16
Min, Max		292.9, 681.4	353.7, 382.1	292.9, 681.4
Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		713.44 (-)	329.23 (-)	521.34 (271.677)
Median		713.44	329.23	521.34
Min, Max		713.4, 713.4	329.2, 329.2	329.2, 713.4
Cycle 18 Day 1				
n	0	1	1	2
Mean (StdDev)		437.24 (-)	348.12 (-)	392.68 (63.017)
Median		437.24	348.12	392.68
Min, Max		437.2, 437.2	348.1, 348.1	348.1, 437.2
Cycle 24 Day 1				
n	0	1	0	1
Mean (StdDev)		551.14 (-)		551.14 (-)
Median		551.14		551.14
Min, Max		551.1, 551.1		551.1, 551.1

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg
Organ = Spleen

Volume (mL)	ASM (N=5)	SM-AHN (N=34)	MCL (N=13)	All AdvSM (N=52)
Cycle 30 Day 1				
n	0	1	0	1
Mean (StdDev)		421.50 (-)		421.50 (-)
Median		421.50		421.50
Min, Max		421.5, 421.5		421.5, 421.5
Cycle 36 Day 1				
n	0	1	0	1
Mean (StdDev)		450.03 (-)		450.03 (-)
Median		450.03		450.03
Min, Max		450.0, 450.0		450.0, 450.0
Cycle 42 Day 1				
n	0	1	0	1
Mean (StdDev)		424.70 (-)		424.70 (-)
Median		424.70		424.70
Min, Max		424.7, 424.7		424.7, 424.7

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg
Organ = Liver

Volume (mL)	ASM (N=5)	SM-AHN (N=34)	MCL (N=13)	All AdvSM (N=52)
Baseline				
n	5	34	13	52
Mean (StdDev)	2283.57 (779.621)	2395.19 (393.345)	2928.55 (628.592)	2517.79 (546.957)
Median	2101.22	2375.96	2932.82	2442.97
Min, Max	1671.6, 3603.1	1707.4, 3239.5	1660.5, 4020.8	1660.5, 4020.8
Cycle 3 Day 1				
n	5	24	9	38
Mean (StdDev)	2051.91 (839.457)	2118.74 (375.362)	2562.94 (431.047)	2215.16 (492.943)
Median	1645.79	2057.44	2617.09	2160.07
Min, Max	1531.2, 3507.4	1433.4, 2974.6	1841.4, 3130.4	1433.4, 3507.4
Cycle 5 Day 1				
n	1	5	4	10
Mean (StdDev)	3098.80 (-)	2046.62 (431.874)	2145.82 (213.654)	2191.52 (449.629)
Median	3098.80	2018.74	2187.47	2187.47
Min, Max	3098.8, 3098.8	1492.8, 2654.6	1850.6, 2357.8	1492.8, 3098.8
Cycle 7 Day 1				
n	1	17	5	23
Mean (StdDev)	1782.23 (-)	1962.07 (374.704)	2242.20 (544.408)	2015.15 (415.160)
Median	1782.23	1864.64	2048.48	1960.16
Min, Max	1782.2, 1782.2	1406.6, 2830.5	1758.1, 3163.0	1406.6, 3163.0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg
Organ = Liver

Volume (mL)	ASM (N=5)	SM-AHN (N=34)	MCL (N=13)	All AdvSM (N=52)
Cycle 11 Day 1				
n	0	10	3	13
Mean (StdDev)		1882.20 (328.792)	1802.49 (95.684)	1863.81 (289.527)
Median		1856.82	1838.21	1848.22
Min, Max		1294.2, 2546.0	1694.1, 1875.2	1294.2, 2546.0
Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		1867.29 (-)	1486.28 (-)	1676.79 (269.415)
Median		1867.29	1486.28	1676.79
Min, Max		1867.3, 1867.3	1486.3, 1486.3	1486.3, 1867.3
Cycle 18 Day 1				
n	0	1	1	2
Mean (StdDev)		1825.33 (-)	2026.56 (-)	1925.95 (142.291)
Median		1825.33	2026.56	1925.95
Min, Max		1825.3, 1825.3	2026.6, 2026.6	1825.3, 2026.6
Cycle 24 Day 1				
n	0	1	0	1
Mean (StdDev)		1945.43 (-)		1945.43 (-)
Median		1945.43		1945.43
Min, Max		1945.4, 1945.4		1945.4, 1945.4

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg
Organ = Liver

Volume (mL)	ASM (N=5)	SM-AHN (N=34)	MCL (N=13)	All AdvSM (N=52)
Cycle 30 Day 1				
n	0	1	0	1
Mean (StdDev)		2076.45 (-)		2076.45 (-)
Median		2076.45		2076.45
Min, Max		2076.5, 2076.5		2076.5, 2076.5
Cycle 36 Day 1				
n	0	1	0	1
Mean (StdDev)		1974.40 (-)		1974.40 (-)
Median		1974.40		1974.40
Min, Max		1974.4, 1974.4		1974.4, 1974.4
Cycle 42 Day 1				
n	0	1	0	1
Mean (StdDev)		1820.09 (-)		1820.09 (-)
Median		1820.09		1820.09
Min, Max		1820.1, 1820.1		1820.1, 1820.1

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg
Organ = Spleen

Volume (mL)	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Baseline				
n	4	12	2	18
Mean (StdDev)	919.82 (677.582)	1181.24 (549.211)	1099.34 (1190.124)	1114.05 (609.591)
Median	638.71	1147.89	1099.34	1092.31
Min, Max	479.2, 1922.7	359.4, 2262.7	257.8, 1940.9	257.8, 2262.7
Cycle 3 Day 1				
n	4	12	2	18
Mean (StdDev)	560.43 (405.010)	617.24 (315.071)	729.87 (746.719)	617.13 (358.094)
Median	383.80	609.39	729.87	547.78
Min, Max	311.8, 1162.3	196.8, 1239.8	201.9, 1257.9	196.8, 1257.9
Cycle 5 Day 1				
n	3	11	2	16
Mean (StdDev)	719.09 (643.603)	547.49 (263.408)	416.26 (321.154)	563.26 (341.001)
Median	389.95	631.85	416.26	619.24
Min, Max	306.6, 1460.7	184.5, 1108.6	189.2, 643.4	184.5, 1460.7
Cycle 7 Day 1				
n	3	9	1	13
Mean (StdDev)	618.59 (438.270)	531.87 (222.472)	258.62 (-)	530.87 (270.389)
Median	433.90	500.35	258.62	473.73
Min, Max	302.9, 1119.0	140.8, 971.9	258.6, 258.6	140.8, 1119.0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg
Organ = Spleen

Volume (mL)	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Cycle 11 Day 1				
n	3	5	1	9
Mean (StdDev)	514.91 (473.360)	425.04 (210.321)	694.72 (-)	484.96 (293.624)
Median	365.51	411.27	694.72	411.27
Min, Max	134.3, 1044.9	136.0, 722.6	694.7, 694.7	134.3, 1044.9
Cycle 18 Day 1				
n	2	5	0	7
Mean (StdDev)	273.64 (78.001)	500.83 (163.221)		435.92 (176.251)
Median	273.64	575.47		385.20
Min, Max	218.5, 328.8	277.3, 669.5		218.5, 669.5
Cycle 24 Day 1				
n	2	4	0	6
Mean (StdDev)	303.59 (123.680)	581.86 (238.971)		489.10 (240.778)
Median	303.59	625.71		501.24
Min, Max	216.1, 391.0	252.3, 823.7		216.1, 823.7
Cycle 30 Day 1				
n	1	0	0	1
Mean (StdDev)	316.97 (-)			316.97 (-)
Median	316.97			316.97
Min, Max	317.0, 317.0			317.0, 317.0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg
Organ = Spleen

Volume (mL)	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Cycle 36 Day 1				
n	1	0	0	1
Mean (StdDev)	310.12 (-)			310.12 (-)
Median	310.12			310.12
Min, Max	310.1, 310.1			310.1, 310.1

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg
Organ = Liver

Volume (mL)	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Baseline				
n	4	13	3	20
Mean (StdDev)	2246.32 (377.128)	2276.97 (657.353)	2090.15 (173.239)	2242.82 (550.463)
Median	2184.95	2112.93	2020.24	2070.22
Min, Max	1885.0, 2730.4	1436.4, 3624.1	1962.8, 2287.4	1436.4, 3624.1
Cycle 3 Day 1				
n	3	13	3	19
Mean (StdDev)	1763.95 (343.722)	1940.55 (650.332)	1830.77 (552.197)	1895.33 (577.936)
Median	1678.63	1800.88	1623.02	1787.96
Min, Max	1470.9, 2142.3	1284.5, 3519.1	1412.6, 2456.7	1284.5, 3519.1
Cycle 5 Day 1				
n	3	12	3	18
Mean (StdDev)	2173.43 (312.539)	1865.65 (674.977)	1599.32 (384.737)	1872.56 (594.042)
Median	2312.41	1637.80	1470.70	1696.62
Min, Max	1815.5, 2392.4	1127.1, 3615.9	1295.4, 2031.9	1127.1, 3615.9
Cycle 7 Day 1				
n	3	10	2	15
Mean (StdDev)	2206.75 (105.913)	1868.42 (676.249)	1432.17 (41.748)	1877.92 (589.350)
Median	2157.33	1602.29	1432.17	1620.40
Min, Max	2134.6, 2328.3	1231.1, 3549.6	1402.7, 1461.7	1231.1, 3549.6

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg
Organ = Liver

Volume (mL)	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Cycle 11 Day 1				
n	2	6	2	10
Mean (StdDev)	1837.50 (111.334)	1929.46 (695.147)	1887.62 (707.920)	1902.70 (571.834)
Median	1837.50	1878.83	1887.62	1837.50
Min, Max	1758.8, 1916.2	1174.6, 3135.2	1387.0, 2388.2	1174.6, 3135.2
Cycle 18 Day 1				
n	2	6	1	9
Mean (StdDev)	1871.42 (155.168)	1923.06 (532.830)	1292.81 (-)	1841.56 (472.544)
Median	1871.42	1789.39	1292.81	1775.76
Min, Max	1761.7, 1981.1	1478.1, 2939.6	1292.8, 1292.8	1292.8, 2939.6
Cycle 24 Day 1				
n	2	4	1	7
Mean (StdDev)	1972.35 (88.777)	2091.78 (583.860)	1273.04 (-)	1940.69 (511.473)
Median	1972.35	1945.40	1273.04	1909.57
Min, Max	1909.6, 2035.1	1566.1, 2910.2	1273.0, 1273.0	1273.0, 2910.2
Cycle 30 Day 1				
n	1	0	1	2
Mean (StdDev)	1556.32 (-)		1345.12 (-)	1450.72 (149.341)
Median	1556.32		1345.12	1450.72
Min, Max	1556.3, 1556.3		1345.1, 1345.1	1345.1, 1556.3

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg
Organ = Liver

Volume (mL)	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Cycle 36 Day 1				
n	1	0	0	1
Mean (StdDev)	1616.96 (-)			1616.96 (-)
Median	1616.96			1616.96
Min, Max	1617.0, 1617.0			1617.0, 1617.0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg
Organ = Spleen

Volume (mL)	ASM (N=9)	SM-AHN (N=47)	MCL (N=16)	All AdvSM (N=72)
Baseline				
n	9	46	15	70
Mean (StdDev)	816.58 (493.230)	1019.22 (505.279)	1094.60 (613.868)	1009.32 (526.936)
Median	651.85	1024.58	849.05	862.44
Min, Max	435.6, 1922.7	298.5, 2600.8	257.8, 2270.0	257.8, 2600.8
Cycle 3 Day 1				
n	9	36	11	56
Mean (StdDev)	505.56 (274.181)	689.50 (368.997)	663.03 (361.343)	654.74 (354.637)
Median	422.22	592.71	541.87	556.48
Min, Max	311.8, 1162.3	196.8, 1788.5	201.9, 1384.1	196.8, 1788.5
Cycle 5 Day 1				
n	4	16	6	26
Mean (StdDev)	651.63 (542.545)	561.51 (234.336)	470.40 (174.805)	554.35 (278.604)
Median	419.60	612.15	489.25	591.13
Min, Max	306.6, 1460.7	184.5, 1108.6	189.2, 647.0	184.5, 1460.7
Cycle 7 Day 1				
n	4	26	6	36
Mean (StdDev)	562.14 (375.234)	565.60 (279.814)	403.41 (138.192)	538.18 (272.874)
Median	413.35	510.43	370.78	474.36
Min, Max	302.9, 1119.0	140.8, 1702.8	258.6, 613.2	140.8, 1702.8

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg
Organ = Spleen

Volume (mL)	ASM (N=9)	SM-AHN (N=47)	MCL (N=16)	All AdvSM (N=72)
Cycle 11 Day 1				
n	3	15	4	22
Mean (StdDev)	514.91 (473.360)	433.79 (150.761)	452.50 (161.990)	448.25 (202.556)
Median	365.51	411.27	380.78	381.64
Min, Max	134.3, 1044.9	136.0, 722.6	353.7, 694.7	134.3, 1044.9
Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		713.44 (-)	329.23 (-)	521.34 (271.677)
Median		713.44	329.23	521.34
Min, Max		713.4, 713.4	329.2, 329.2	329.2, 713.4
Cycle 18 Day 1				
n	2	6	1	9
Mean (StdDev)	273.64 (78.001)	490.23 (148.280)	348.12 (-)	426.31 (155.429)
Median	273.64	506.36	348.12	385.20
Min, Max	218.5, 328.8	277.3, 669.5	348.1, 348.1	218.5, 669.5
Cycle 24 Day 1				
n	2	5	0	7
Mean (StdDev)	303.59 (123.680)	575.72 (207.411)		497.97 (221.046)
Median	303.59	611.44		551.14
Min, Max	216.1, 391.0	252.3, 823.7		216.1, 823.7

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg
Organ = Spleen

Volume (mL)	ASM (N=9)	SM-AHN (N=47)	MCL (N=16)	All AdvSM (N=72)
Cycle 30 Day 1				
n	1	1	0	2
Mean (StdDev)	316.97 (-)	421.50 (-)		369.24 (73.914)
Median	316.97	421.50		369.24
Min, Max	317.0, 317.0	421.5, 421.5		317.0, 421.5
Cycle 36 Day 1				
n	1	1	0	2
Mean (StdDev)	310.12 (-)	450.03 (-)		380.08 (98.931)
Median	310.12	450.03		380.08
Min, Max	310.1, 310.1	450.0, 450.0		310.1, 450.0
Cycle 42 Day 1				
n	0	1	0	1
Mean (StdDev)		424.70 (-)		424.70 (-)
Median		424.70		424.70
Min, Max		424.7, 424.7		424.7, 424.7

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg
Organ = Liver

Volume (mL)	ASM (N=9)	SM-AHN (N=47)	MCL (N=16)	All AdvSM (N=72)
Baseline				
n	9	47	16	72
Mean (StdDev)	2267.02 (598.017)	2362.49 (476.002)	2771.35 (659.035)	2441.41 (557.998)
Median	2101.22	2361.64	2904.83	2355.69
Min, Max	1671.6, 3603.1	1436.4, 3624.1	1660.5, 4020.8	1436.4, 4020.8
Cycle 3 Day 1				
n	8	37	12	57
Mean (StdDev)	1943.93 (677.234)	2056.14 (488.295)	2379.90 (547.924)	2108.55 (539.486)
Median	1662.21	2003.30	2418.63	2037.01
Min, Max	1470.9, 3507.4	1284.5, 3519.1	1412.6, 3130.4	1284.5, 3519.1
Cycle 5 Day 1				
n	4	17	7	28
Mean (StdDev)	2404.78 (528.390)	1918.88 (605.866)	1911.61 (396.860)	1986.47 (560.178)
Median	2352.40	1714.31	2031.89	1903.12
Min, Max	1815.5, 3098.8	1127.1, 3615.9	1295.4, 2357.8	1127.1, 3615.9
Cycle 7 Day 1				
n	4	27	7	38
Mean (StdDev)	2100.62 (229.200)	1927.38 (496.816)	2010.76 (595.066)	1960.98 (488.393)
Median	2145.96	1811.01	1986.09	1844.82
Min, Max	1782.2, 2328.3	1231.1, 3549.6	1402.7, 3163.0	1231.1, 3549.6

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg
Organ = Liver

Volume (mL)	ASM (N=9)	SM-AHN (N=47)	MCL (N=16)	All AdvSM (N=72)
Cycle 11 Day 1				
n	2	16	5	23
Mean (StdDev)	1837.50 (111.334)	1899.92 (475.917)	1836.54 (363.372)	1880.72 (424.125)
Median	1837.50	1856.82	1838.21	1848.22
Min, Max	1758.8, 1916.2	1174.6, 3135.2	1387.0, 2388.2	1174.6, 3135.2
Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		1867.29 (-)	1486.28 (-)	1676.79 (269.415)
Median		1867.29	1486.28	1676.79
Min, Max		1867.3, 1867.3	1486.3, 1486.3	1486.3, 1867.3
Cycle 18 Day 1				
n	2	7	2	11
Mean (StdDev)	1871.42 (155.168)	1909.10 (487.806)	1659.69 (518.840)	1856.90 (426.413)
Median	1871.42	1803.01	1659.69	1803.01
Min, Max	1761.7, 1981.1	1478.1, 2939.6	1292.8, 2026.6	1292.8, 2939.6
Cycle 24 Day 1				
n	2	5	1	8
Mean (StdDev)	1972.35 (88.777)	2062.51 (509.856)	1273.04 (-)	1941.28 (473.535)
Median	1972.35	1945.43	1273.04	1927.50
Min, Max	1909.6, 2035.1	1566.1, 2910.2	1273.0, 1273.0	1273.0, 2910.2

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg
Organ = Liver

Volume (mL)	ASM (N=9)	SM-AHN (N=47)	MCL (N=16)	All AdvSM (N=72)
Cycle 30 Day 1				
n	1	1	1	3
Mean (StdDev)	1556.32 (-)	2076.45 (-)	1345.12 (-)	1659.30 (376.383)
Median	1556.32	2076.45	1345.12	1556.32
Min, Max	1556.3, 1556.3	2076.5, 2076.5	1345.1, 1345.1	1345.1, 2076.5
Cycle 36 Day 1				
n	1	1	0	2
Mean (StdDev)	1616.96 (-)	1974.40 (-)		1795.68 (252.748)
Median	1616.96	1974.40		1795.68
Min, Max	1617.0, 1617.0	1974.4, 1974.4		1617.0, 1974.4
Cycle 42 Day 1				
n	0	1	0	1
Mean (StdDev)		1820.09 (-)		1820.09 (-)
Median		1820.09		1820.09
Min, Max		1820.1, 1820.1		1820.1, 1820.1

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg
Organ = Spleen

Volume (mL)	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Baseline				
n	1	4	0	5
Mean (StdDev)	163.41 (-)	1058.92 (596.395)		879.82 (653.569)
Median	163.41	1008.52		580.47
Min, Max	163.4, 163.4	521.8, 1696.9		163.4, 1696.9
Cycle 3 Day 1				
n	1	3	0	4
Mean (StdDev)	94.57 (-)	786.10 (269.052)		613.22 (409.651)
Median	94.57	849.67		670.32
Min, Max	94.6, 94.6	491.0, 1017.7		94.6, 1017.7
Cycle 5 Day 1				
n	1	3	0	4
Mean (StdDev)	96.49 (-)	809.71 (424.554)		631.40 (497.327)
Median	96.49	633.75		567.59
Min, Max	96.5, 96.5	501.4, 1294.0		96.5, 1294.0
Cycle 7 Day 1				
n	1	2	0	3
Mean (StdDev)	120.47 (-)	761.90 (241.159)		548.09 (407.702)
Median	120.47	761.90		591.37
Min, Max	120.5, 120.5	591.4, 932.4		120.5, 932.4

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg
Organ = Spleen

Volume (mL)	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Cycle 11 Day 1				
n	0	2	0	2
Mean (StdDev)		817.45 (361.805)		817.45 (361.805)
Median		817.45		817.45
Min, Max		561.6, 1073.3		561.6, 1073.3
Cycle 18 Day 1				
n	0	1	0	1
Mean (StdDev)		573.32 (-)		573.32 (-)
Median		573.32		573.32
Min, Max		573.3, 573.3		573.3, 573.3
Cycle 24 Day 1				
n	0	2	0	2
Mean (StdDev)		486.87 (233.494)		486.87 (233.494)
Median		486.87		486.87
Min, Max		321.8, 652.0		321.8, 652.0
Cycle 30 Day 1				
n	0	1	0	1
Mean (StdDev)		888.85 (-)		888.85 (-)
Median		888.85		888.85
Min, Max		888.9, 888.9		888.9, 888.9

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg
Organ = Spleen

Volume (mL)	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Cycle 36 Day 1				
n	0	1	0	1
Mean (StdDev)		902.61 (-)		902.61 (-)
Median		902.61		902.61
Min, Max		902.6, 902.6		902.6, 902.6

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg
Organ = Liver

Volume (mL)	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Baseline				
n	1	4	0	5
Mean (StdDev)	1019.93 (-)	2777.23 (487.520)		2425.77 (892.121)
Median	1019.93	2791.67		2682.43
Min, Max	1019.9, 1019.9	2176.1, 3349.5		1019.9, 3349.5
Cycle 3 Day 1				
n	1	3	0	4
Mean (StdDev)	1017.42 (-)	2461.29 (125.135)		2100.32 (729.129)
Median	1017.42	2520.49		2419.02
Min, Max	1017.4, 1017.4	2317.5, 2545.8		1017.4, 2545.8
Cycle 5 Day 1				
n	1	3	0	4
Mean (StdDev)	1039.92 (-)	2258.95 (136.662)		1954.20 (619.646)
Median	1039.92	2299.86		2203.19
Min, Max	1039.9, 1039.9	2106.5, 2370.5		1039.9, 2370.5
Cycle 7 Day 1				
n	1	2	0	3
Mean (StdDev)	993.18 (-)	2177.33 (209.396)		1782.61 (699.516)
Median	993.18	2177.33		2029.26
Min, Max	993.2, 993.2	2029.3, 2325.4		993.2, 2325.4

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg
Organ = Liver

Volume (mL)	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Cycle 11 Day 1				
n	0	2	0	2
Mean (StdDev)		2347.83 (88.848)		2347.83 (88.848)
Median		2347.83		2347.83
Min, Max		2285.0, 2410.7		2285.0, 2410.7
Cycle 18 Day 1				
n	0	1	0	1
Mean (StdDev)		2290.76 (-)		2290.76 (-)
Median		2290.76		2290.76
Min, Max		2290.8, 2290.8		2290.8, 2290.8
Cycle 24 Day 1				
n	0	2	0	2
Mean (StdDev)		2037.87 (213.447)		2037.87 (213.447)
Median		2037.87		2037.87
Min, Max		1886.9, 2188.8		1886.9, 2188.8
Cycle 30 Day 1				
n	0	1	0	1
Mean (StdDev)		2875.39 (-)		2875.39 (-)
Median		2875.39		2875.39
Min, Max		2875.4, 2875.4		2875.4, 2875.4

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.1
Summary of Spleen and Liver Volume
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg
Organ = Liver

Volume (mL)	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Cycle 36 Day 1				
n	0	1	0	1
Mean (StdDev)		2708.57 (-)		2708.57 (-)
Median		2708.57		2708.57
Min, Max		2708.6, 2708.6		2708.6, 2708.6

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Overall
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=7)	SM-AHN (N=26)	MCL (N=8)	All AdvSM (N=41)
Baseline				
n	6	25	7	38
Mean (StdDev)	725.22 (615.037)	1060.21 (501.440)	868.82 (535.191)	972.06 (527.077)
Median	524.39	1120.69	688.48	862.44
Min, Max	163.4, 1922.7	298.5, 2262.7	257.8, 1940.9	163.4, 2262.7
Percent change from Baseline to Cycle 3 Day 1				
n	6	23	6	35
Mean (StdDev)	-34.72 (11.609)	-41.03 (16.414)	-27.24 (14.221)	-37.59 (15.883)
Median	-40.16	-44.63	-28.44	-40.45
Min, Max	-42.3, -12.6	-75.9, -2.9	-40.9, -4.6	-75.9, -2.9
Percent change from Baseline to Cycle 5 Day 1				
n	5	21	7	33
Mean (StdDev)	-31.96 (14.151)	-38.51 (23.759)	-34.98 (23.252)	-36.77 (22.035)
Median	-36.01	-46.23	-26.62	-39.35
Min, Max	-47.1, -11.7	-82.3, 11.9	-66.9, 1.7	-82.3, 11.9
Percent change from Baseline to Cycle 7 Day 1				
n	4	18	5	27
Mean (StdDev)	-34.11 (21.166)	-38.03 (38.115)	-28.42 (32.885)	-35.67 (34.384)
Median	-34.04	-51.36	-23.44	-41.80
Min, Max	-58.9, -9.5	-76.2, 83.4	-65.9, 5.6	-76.2, 83.4

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Overall
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=7)	SM-AHN (N=26)	MCL (N=8)	All AdvSM (N=41)
Percent change from Baseline to Cycle 11 Day 1				
n	3	12	4	19
Mean (StdDev)	-50.39 (29.321)	-42.04 (26.776)	-46.74 (23.999)	-44.35 (25.310)
Median	-45.65	-38.34	-54.12	-44.95
Min, Max	-81.8, -23.7	-74.4, 1.4	-64.9, -13.8	-81.8, 1.4
Percent change from Baseline to Cycle 18 Day 1				
n	2	9	2	13
Mean (StdDev)	-50.88 (27.564)	-40.61 (29.495)	-55.23 (17.819)	-44.44 (26.590)
Median	-50.88	-46.75	-55.23	-46.75
Min, Max	-70.4, -31.4	-81.3, -1.2	-67.8, -42.6	-81.3, -1.2
Percent change from Baseline to Cycle 24 Day 1				
n	2	9	1	12
Mean (StdDev)	-44.54 (36.975)	-37.00 (34.880)	-39.18 (-)	-38.44 (31.900)
Median	-44.54	-26.50	-39.18	-32.84
Min, Max	-70.7, -18.4	-83.0, 12.3	-39.2, -39.2	-83.0, 12.3
Percent change from Baseline to Cycle 30 Day 1				
n	1	4	1	6
Mean (StdDev)	-33.85 (-)	-7.23 (45.809)	-58.96 (-)	-20.29 (41.609)
Median	-33.85	-15.48	-58.96	-33.27
Min, Max	-33.9, -33.9	-51.1, 53.1	-59.0, -59.0	-59.0, 53.1

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Overall
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=7)	SM-AHN (N=26)	MCL (N=8)	All AdvSM (N=41)
Percent change from Baseline to Cycle 36 Day 1				
n	1	4	1	6
Mean (StdDev)	-35.28 (-)	-10.77 (47.568)	-52.31 (-)	-21.78 (40.958)
Median	-35.28	-21.07	-52.31	-31.71
Min, Max	-35.3, -35.3	-56.4, 55.5	-52.3, -52.3	-56.4, 55.5
Percent change from Baseline to Cycle 42 Day 1				
n	0	3	1	4
Mean (StdDev)		-30.83 (23.799)	-64.86 (-)	-39.34 (25.828)
Median		-32.18	-64.86	-43.05
Min, Max		-53.9, -6.4	-64.9, -64.9	-64.9, -6.4
Percent change from Baseline to Cycle 48 Day 1				
n	0	0	1	1
Mean (StdDev)			-70.25 (-)	-70.25 (-)
Median			-70.25	-70.25
Min, Max			-70.3, -70.3	-70.3, -70.3

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Overall
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=7)	SM-AHN (N=26)	MCL (N=8)	All AdvSM (N=41)
Baseline				
n	7	26	8	41
Mean (StdDev)	2283.11 (793.529)	2332.67 (547.909)	2345.83 (617.874)	2326.77 (591.032)
Median	2349.73	2233.18	2220.45	2285.21
Min, Max	1019.9, 3603.1	1436.4, 3624.1	1435.8, 3437.5	1019.9, 3624.1
Percent change from Baseline to Cycle 3 Day 1				
n	6	24	7	37
Mean (StdDev)	-12.30 (10.472)	-12.61 (9.673)	-16.82 (12.859)	-13.36 (10.269)
Median	-11.08	-10.03	-19.66	-11.20
Min, Max	-27.2, -0.2	-30.8, 13.1	-28.2, 7.4	-30.8, 13.1
Percent change from Baseline to Cycle 5 Day 1				
n	6	22	8	36
Mean (StdDev)	-7.73 (8.797)	-15.70 (11.756)	-19.34 (14.415)	-15.18 (12.214)
Median	-8.84	-18.53	-26.39	-16.23
Min, Max	-17.2, 2.0	-37.1, 14.4	-34.0, 2.8	-37.1, 14.4
Percent change from Baseline to Cycle 7 Day 1				
n	5	19	6	30
Mean (StdDev)	-7.11 (16.173)	-14.76 (16.062)	-21.49 (13.555)	-14.83 (15.728)
Median	-2.62	-17.87	-28.09	-18.97
Min, Max	-24.6, 14.4	-39.4, 28.0	-34.4, -1.2	-39.4, 28.0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Overall
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=7)	SM-AHN (N=26)	MCL (N=8)	All AdvSM (N=41)
Percent change from Baseline to Cycle 11 Day 1				
n	3	13	5	21
Mean (StdDev)	-22.87 (14.050)	-15.11 (10.710)	-18.67 (19.866)	-17.07 (13.254)
Median	-29.82	-14.82	-14.64	-14.82
Min, Max	-32.1, -6.7	-33.1, 1.1	-45.4, 4.4	-45.4, 4.4
Percent change from Baseline to Cycle 18 Day 1				
n	3	10	3	16
Mean (StdDev)	-17.38 (11.775)	-23.59 (8.357)	-19.75 (15.199)	-21.70 (9.902)
Median	-15.69	-22.33	-17.36	-19.96
Min, Max	-29.9, -6.5	-42.8, -12.8	-36.0, -5.9	-42.8, -5.9
Percent change from Baseline to Cycle 24 Day 1				
n	3	9	2	14
Mean (StdDev)	-14.75 (16.771)	-25.81 (12.149)	-21.94 (21.275)	-22.89 (13.794)
Median	-13.39	-21.63	-21.94	-20.66
Min, Max	-32.2, 1.3	-43.7, -10.7	-37.0, -6.9	-43.7, 1.3
Percent change from Baseline to Cycle 30 Day 1				
n	2	4	2	8
Mean (StdDev)	-26.11 (12.263)	-10.46 (7.409)	-23.70 (13.748)	-17.68 (11.507)
Median	-26.11	-11.24	-23.70	-15.71
Min, Max	-34.8, -17.4	-18.5, -0.9	-33.4, -14.0	-34.8, -0.9

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Overall
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=7)	SM-AHN (N=26)	MCL (N=8)	All AdvSM (N=41)
Percent change from Baseline to Cycle 36 Day 1				
n	2	4	1	7
Mean (StdDev)	-22.97 (12.378)	-14.32 (6.070)	-10.36 (-)	-16.23 (8.203)
Median	-22.97	-15.03	-10.36	-14.22
Min, Max	-31.7, -14.2	-20.6, -6.6	-10.4, -10.4	-31.7, -6.6
Percent change from Baseline to Cycle 42 Day 1				
n	0	3	1	4
Mean (StdDev)		-22.82 (4.674)	-8.42 (-)	-19.22 (8.149)
Median		-23.85	-8.42	-20.78
Min, Max		-26.9, -17.7	-8.4, -8.4	-26.9, -8.4
Percent change from Baseline to Cycle 48 Day 1				
n	1	0	1	2
Mean (StdDev)	-27.20 (-)		-23.82 (-)	-25.51 (2.388)
Median	-27.20		-23.82	-25.51
Min, Max	-27.2, -27.2		-23.8, -23.8	-27.2, -23.8

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <200 mg
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=2)	MCL (N=1)	All AdvSM (N=4)
Baseline				
n	0	2	1	3
Mean (StdDev)		886.08 (673.788)	580.85 (-)	784.34 (507.986)
Median		886.08	580.85	580.85
Min, Max		409.6, 1362.5	580.9, 580.9	409.6, 1362.5
Percent change from Baseline to Cycle 3 Day 1				
n	0	2	1	3
Mean (StdDev)		-32.49 (5.073)	-4.59 (-)	-23.19 (16.503)
Median		-32.49	-4.59	-28.91
Min, Max		-36.1, -28.9	-4.6, -4.6	-36.1, -4.6
Percent change from Baseline to Cycle 5 Day 1				
n	0	2	1	3
Mean (StdDev)		-32.76 (3.702)	1.65 (-)	-21.29 (20.040)
Median		-32.76	1.65	-30.14
Min, Max		-35.4, -30.1	1.7, 1.7	-35.4, 1.7
Percent change from Baseline to Cycle 7 Day 1				
n	0	2	1	3
Mean (StdDev)		-9.84 (33.173)	5.57 (-)	-4.71 (25.089)
Median		-9.84	5.57	5.57
Min, Max		-33.3, 13.6	5.6, 5.6	-33.3, 13.6

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <200 mg
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=2)	MCL (N=1)	All AdvSM (N=4)
Percent change from Baseline to Cycle 11 Day 1				
n	0	2	1	3
Mean (StdDev)		-21.76 (32.791)	-13.81 (-)	-19.11 (23.637)
Median		-21.76	-13.81	-13.81
Min, Max		-44.9, 1.4	-13.8, -13.8	-44.9, 1.4
Percent change from Baseline to Cycle 18 Day 1				
n	0	2	1	3
Mean (StdDev)		-29.36 (28.365)	-42.63 (-)	-33.78 (21.469)
Median		-29.36	-42.63	-42.63
Min, Max		-49.4, -9.3	-42.6, -42.6	-49.4, -9.3
Percent change from Baseline to Cycle 24 Day 1				
n	0	2	1	3
Mean (StdDev)		-33.55 (14.111)	-39.18 (-)	-35.42 (10.495)
Median		-33.55	-39.18	-39.18
Min, Max		-43.5, -23.6	-39.2, -39.2	-43.5, -23.6
Percent change from Baseline to Cycle 30 Day 1				
n	0	2	1	3
Mean (StdDev)		-24.69 (37.348)	-58.96 (-)	-36.11 (33.000)
Median		-24.69	-58.96	-51.09
Min, Max		-51.1, 1.7	-59.0, -59.0	-59.0, 1.7

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <200 mg
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=2)	MCL (N=1)	All AdvSM (N=4)
Percent change from Baseline to Cycle 36 Day 1				
n	0	2	1	3
Mean (StdDev)		-35.22 (29.993)	-52.31 (-)	-40.92 (23.392)
Median		-35.22	-52.31	-52.31
Min, Max		-56.4, -14.0	-52.3, -52.3	-56.4, -14.0
Percent change from Baseline to Cycle 42 Day 1				
n	0	2	1	3
Mean (StdDev)		-30.16 (33.617)	-64.86 (-)	-41.73 (31.088)
Median		-30.16	-64.86	-53.93
Min, Max		-53.9, -6.4	-64.9, -64.9	-64.9, -6.4
Percent change from Baseline to Cycle 48 Day 1				
n	0	0	1	1
Mean (StdDev)			-70.25 (-)	-70.25 (-)
Median			-70.25	-70.25
Min, Max			-70.3, -70.3	-70.3, -70.3

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <200 mg
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=2)	MCL (N=1)	All AdvSM (N=4)
Baseline				
n	1	2	1	4
Mean (StdDev)	2373.51 (-)	2317.88 (193.358)	1435.80 (-)	2111.27 (464.682)
Median	2373.51	2317.88	1435.80	2277.33
Min, Max	2373.5, 2373.5	2181.2, 2454.6	1435.8, 1435.8	1435.8, 2454.6
Percent change from Baseline to Cycle 3 Day 1				
n	1	2	1	4
Mean (StdDev)	-11.20 (-)	-9.43 (0.162)	-7.32 (-)	-9.34 (1.590)
Median	-11.20	-9.43	-7.32	-9.43
Min, Max	-11.2, -11.2	-9.5, -9.3	-7.3, -7.3	-11.2, -7.3
Percent change from Baseline to Cycle 5 Day 1				
n	1	2	1	4
Mean (StdDev)	-17.16 (-)	-15.25 (5.189)	-0.29 (-)	-11.99 (8.401)
Median	-17.16	-15.25	-0.29	-14.37
Min, Max	-17.2, -17.2	-18.9, -11.6	-0.3, -0.3	-18.9, -0.3
Percent change from Baseline to Cycle 7 Day 1				
n	1	2	1	4
Mean (StdDev)	-24.62 (-)	-3.16 (24.699)	-1.16 (-)	-8.02 (18.074)
Median	-24.62	-3.16	-1.16	-10.89
Min, Max	-24.6, -24.6	-20.6, 14.3	-1.2, -1.2	-24.6, 14.3

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <200 mg
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=2)	MCL (N=1)	All AdvSM (N=4)
Percent change from Baseline to Cycle 11 Day 1				
n	1	2	1	4
Mean (StdDev)	-32.09 (-)	-5.39 (3.639)	-6.34 (-)	-12.30 (13.366)
Median	-32.09	-5.39	-6.34	-7.15
Min, Max	-32.1, -32.1	-8.0, -2.8	-6.3, -6.3	-32.1, -2.8
Percent change from Baseline to Cycle 18 Day 1				
n	1	2	1	4
Mean (StdDev)	-29.91 (-)	-17.61 (0.466)	-17.36 (-)	-20.62 (6.197)
Median	-29.91	-17.61	-17.36	-17.65
Min, Max	-29.9, -29.9	-17.9, -17.3	-17.4, -17.4	-29.9, -17.3
Percent change from Baseline to Cycle 24 Day 1				
n	1	2	1	4
Mean (StdDev)	-32.16 (-)	-23.70 (18.406)	-6.90 (-)	-21.61 (15.002)
Median	-32.16	-23.70	-6.90	-21.42
Min, Max	-32.2, -32.2	-36.7, -10.7	-6.9, -6.9	-36.7, -6.9
Percent change from Baseline to Cycle 30 Day 1				
n	1	2	1	4
Mean (StdDev)	-34.78 (-)	-13.92 (6.467)	-13.98 (-)	-19.15 (11.069)
Median	-34.78	-13.92	-13.98	-16.23
Min, Max	-34.8, -34.8	-18.5, -9.3	-14.0, -14.0	-34.8, -9.3

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <200 mg
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=2)	MCL (N=1)	All AdvSM (N=4)
Percent change from Baseline to Cycle 36 Day 1				
n	1	2	1	4
Mean (StdDev)	-31.73 (-)	-16.62 (5.599)	-10.36 (-)	-18.83 (9.645)
Median	-31.73	-16.62	-10.36	-16.62
Min, Max	-31.7, -31.7	-20.6, -12.7	-10.4, -10.4	-31.7, -10.4
Percent change from Baseline to Cycle 42 Day 1				
n	0	2	1	3
Mean (StdDev)		-22.30 (6.488)	-8.42 (-)	-17.67 (9.235)
Median		-22.30	-8.42	-17.71
Min, Max		-26.9, -17.7	-8.4, -8.4	-26.9, -8.4
Percent change from Baseline to Cycle 48 Day 1				
n	1	0	1	2
Mean (StdDev)	-27.20 (-)		-23.82 (-)	-25.51 (2.388)
Median	-27.20		-23.82	-25.51
Min, Max	-27.2, -27.2		-23.8, -23.8	-27.2, -23.8

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <300 mg
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=2)	SM-AHN (N=9)	MCL (N=5)	All AdvSM (N=16)
Baseline				
n	1	9	5	15
Mean (StdDev)	508.66 (-)	899.42 (393.875)	776.61 (195.827)	832.43 (333.305)
Median	508.66	875.83	688.48	810.35
Min, Max	508.7, 508.7	298.5, 1362.5	580.9, 1082.0	298.5, 1362.5
Percent change from Baseline to Cycle 3 Day 1				
n	1	8	4	13
Mean (StdDev)	-12.64 (-)	-35.52 (17.980)	-26.64 (17.472)	-31.03 (17.691)
Median	-12.64	-38.25	-30.54	-36.08
Min, Max	-12.6, -12.6	-56.1, -2.9	-40.9, -4.6	-56.1, -2.9
Percent change from Baseline to Cycle 5 Day 1				
n	1	7	5	13
Mean (StdDev)	-11.68 (-)	-23.91 (24.185)	-30.28 (22.624)	-25.42 (22.135)
Median	-11.68	-30.14	-25.75	-25.75
Min, Max	-11.7, -11.7	-51.1, 11.9	-56.4, 1.7	-56.4, 11.9
Percent change from Baseline to Cycle 7 Day 1				
n	0	7	4	11
Mean (StdDev)		-10.12 (47.580)	-35.61 (33.131)	-19.39 (43.046)
Median		-26.08	-41.07	-26.08
Min, Max		-61.3, 83.4	-65.9, 5.6	-65.9, 83.4

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <300 mg
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=2)	SM-AHN (N=9)	MCL (N=5)	All AdvSM (N=16)
Percent change from Baseline to Cycle 11 Day 1				
n	0	5	3	8
Mean (StdDev)		-35.13 (25.904)	-40.92 (25.703)	-37.30 (24.108)
Median		-31.74	-44.03	-37.89
Min, Max		-70.0, 1.4	-64.9, -13.8	-70.0, 1.4
Percent change from Baseline to Cycle 18 Day 1				
n	0	3	2	5
Mean (StdDev)		-29.63 (20.062)	-55.23 (17.819)	-39.87 (21.843)
Median		-30.18	-55.23	-42.63
Min, Max		-49.4, -9.3	-67.8, -42.6	-67.8, -9.3
Percent change from Baseline to Cycle 24 Day 1				
n	0	3	1	4
Mean (StdDev)		-26.36 (15.953)	-39.18 (-)	-29.57 (14.517)
Median		-23.57	-39.18	-31.37
Min, Max		-43.5, -12.0	-39.2, -39.2	-43.5, -12.0
Percent change from Baseline to Cycle 30 Day 1				
n	0	3	1	4
Mean (StdDev)		-27.35 (26.810)	-58.96 (-)	-35.25 (26.998)
Median		-32.69	-58.96	-41.89
Min, Max		-51.1, 1.7	-59.0, -59.0	-59.0, 1.7

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <300 mg
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=2)	SM-AHN (N=9)	MCL (N=5)	All AdvSM (N=16)
Percent change from Baseline to Cycle 36 Day 1				
n	0	3	1	4
Mean (StdDev)		-32.86 (21.600)	-52.31 (-)	-37.72 (20.141)
Median		-28.13	-52.31	-40.22
Min, Max		-56.4, -14.0	-52.3, -52.3	-56.4, -14.0
Percent change from Baseline to Cycle 42 Day 1				
n	0	3	1	4
Mean (StdDev)		-30.83 (23.799)	-64.86 (-)	-39.34 (25.828)
Median		-32.18	-64.86	-43.05
Min, Max		-53.9, -6.4	-64.9, -64.9	-64.9, -6.4
Percent change from Baseline to Cycle 48 Day 1				
n	0	0	1	1
Mean (StdDev)			-70.25 (-)	-70.25 (-)
Median			-70.25	-70.25
Min, Max			-70.3, -70.3	-70.3, -70.3

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <300 mg
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=2)	SM-AHN (N=9)	MCL (N=5)	All AdvSM (N=16)
Baseline				
n	2	9	5	16
Mean (StdDev)	2988.28 (869.416)	2215.54 (285.564)	2499.23 (758.054)	2400.79 (562.994)
Median	2988.28	2181.15	2566.01	2329.36
Min, Max	2373.5, 3603.1	1764.2, 2731.4	1435.8, 3437.5	1435.8, 3603.1
Percent change from Baseline to Cycle 3 Day 1				
n	2	8	4	14
Mean (StdDev)	-6.93 (6.045)	-7.30 (9.953)	-19.36 (9.053)	-10.69 (10.366)
Median	-6.93	-8.34	-20.94	-9.43
Min, Max	-11.2, -2.7	-21.8, 13.1	-28.2, -7.3	-28.2, 13.1
Percent change from Baseline to Cycle 5 Day 1				
n	2	7	5	14
Mean (StdDev)	-15.58 (2.239)	-8.81 (12.979)	-16.47 (16.353)	-12.51 (13.239)
Median	-15.58	-8.83	-25.57	-12.79
Min, Max	-17.2, -14.0	-26.8, 14.4	-31.4, 2.8	-31.4, 14.4
Percent change from Baseline to Cycle 7 Day 1				
n	1	7	4	12
Mean (StdDev)	-24.62 (-)	-5.91 (20.617)	-18.19 (16.202)	-11.56 (18.849)
Median	-24.62	-8.03	-18.61	-12.95
Min, Max	-24.6, -24.6	-31.0, 28.0	-34.4, -1.2	-34.4, 28.0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <300 mg
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=2)	SM-AHN (N=9)	MCL (N=5)	All AdvSM (N=16)
Percent change from Baseline to Cycle 11 Day 1				
n	1	5	3	9
Mean (StdDev)	-32.09 (-)	-7.83 (9.032)	-22.14 (20.608)	-15.30 (15.317)
Median	-32.09	-6.79	-14.64	-7.96
Min, Max	-32.1, -32.1	-22.7, 1.1	-45.4, -6.3	-45.4, 1.1
Percent change from Baseline to Cycle 18 Day 1				
n	1	3	2	6
Mean (StdDev)	-29.91 (-)	-19.62 (3.492)	-11.63 (8.106)	-18.67 (7.980)
Median	-29.91	-17.94	-11.63	-17.65
Min, Max	-29.9, -29.9	-23.6, -17.3	-17.4, -5.9	-29.9, -5.9
Percent change from Baseline to Cycle 24 Day 1				
n	1	3	1	5
Mean (StdDev)	-32.16 (-)	-22.00 (13.342)	-6.90 (-)	-21.01 (13.061)
Median	-32.16	-18.61	-6.90	-18.61
Min, Max	-32.2, -32.2	-36.7, -10.7	-6.9, -6.9	-36.7, -6.9
Percent change from Baseline to Cycle 30 Day 1				
n	1	3	1	5
Mean (StdDev)	-34.78 (-)	-13.66 (4.595)	-13.98 (-)	-17.94 (9.957)
Median	-34.78	-13.13	-13.98	-13.98
Min, Max	-34.8, -34.8	-18.5, -9.3	-14.0, -14.0	-34.8, -9.3

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: <300 mg
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=2)	SM-AHN (N=9)	MCL (N=5)	All AdvSM (N=16)
Percent change from Baseline to Cycle 36 Day 1				
n	1	3	1	5
Mean (StdDev)	-31.73 (-)	-16.88 (3.984)	-10.36 (-)	-18.55 (8.378)
Median	-31.73	-17.40	-10.36	-17.40
Min, Max	-31.7, -31.7	-20.6, -12.7	-10.4, -10.4	-31.7, -10.4
Percent change from Baseline to Cycle 42 Day 1				
n	0	3	1	4
Mean (StdDev)		-22.82 (4.674)	-8.42 (-)	-19.22 (8.149)
Median		-23.85	-8.42	-20.78
Min, Max		-26.9, -17.7	-8.4, -8.4	-26.9, -8.4
Percent change from Baseline to Cycle 48 Day 1				
n	1	0	1	2
Mean (StdDev)	-27.20 (-)		-23.82 (-)	-25.51 (2.388)
Median	-27.20		-23.82	-25.51
Min, Max	-27.2, -27.2		-23.8, -23.8	-27.2, -23.8

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=7)	MCL (N=4)	All AdvSM (N=12)
Baseline				
n	1	7	4	12
Mean (StdDev)	508.66 (-)	903.23 (362.090)	825.55 (187.519)	844.46 (306.077)
Median	508.66	875.83	768.77	829.70
Min, Max	508.7, 508.7	298.5, 1245.1	682.7, 1082.0	298.5, 1245.1
Percent change from Baseline to Cycle 3 Day 1				
n	1	6	3	10
Mean (StdDev)	-12.64 (-)	-36.53 (21.037)	-33.99 (11.571)	-33.38 (18.171)
Median	-12.64	-42.53	-40.45	-40.44
Min, Max	-12.6, -12.6	-56.1, -2.9	-40.9, -20.6	-56.1, -2.9
Percent change from Baseline to Cycle 5 Day 1				
n	1	5	4	10
Mean (StdDev)	-11.68 (-)	-20.37 (28.621)	-38.26 (16.053)	-26.66 (23.593)
Median	-11.68	-6.96	-36.42	-24.77
Min, Max	-11.7, -11.7	-51.1, 11.9	-56.4, -23.8	-56.4, 11.9
Percent change from Baseline to Cycle 7 Day 1				
n	0	5	3	8
Mean (StdDev)		-10.23 (55.863)	-49.34 (22.713)	-24.90 (48.376)
Median		-26.08	-58.69	-32.83
Min, Max		-61.3, 83.4	-65.9, -23.4	-65.9, 83.4

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=7)	MCL (N=4)	All AdvSM (N=12)
Percent change from Baseline to Cycle 11 Day 1				
n	0	3	2	5
Mean (StdDev)		-44.04 (22.504)	-54.48 (14.780)	-48.22 (18.453)
Median		-31.74	-54.48	-44.03
Min, Max		-70.0, -30.4	-64.9, -44.0	-70.0, -30.4
Percent change from Baseline to Cycle 18 Day 1				
n	0	1	1	2
Mean (StdDev)		-30.18 (-)	-67.83 (-)	-49.00 (26.621)
Median		-30.18	-67.83	-49.00
Min, Max		-30.2, -30.2	-67.8, -67.8	-67.8, -30.2
Percent change from Baseline to Cycle 24 Day 1				
n	0	1	0	1
Mean (StdDev)		-11.99 (-)		-11.99 (-)
Median		-11.99		-11.99
Min, Max		-12.0, -12.0		-12.0, -12.0
Percent change from Baseline to Cycle 30 Day 1				
n	0	1	0	1
Mean (StdDev)		-32.69 (-)		-32.69 (-)
Median		-32.69		-32.69
Min, Max		-32.7, -32.7		-32.7, -32.7

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=7)	MCL (N=4)	All AdvSM (N=12)
Percent change from Baseline to Cycle 36 Day 1				
n	0	1	0	1
Mean (StdDev)		-28.13 (-)		-28.13 (-)
Median		-28.13		-28.13
Min, Max		-28.1, -28.1		-28.1, -28.1
Percent change from Baseline to Cycle 42 Day 1				
n	0	1	0	1
Mean (StdDev)		-32.18 (-)		-32.18 (-)
Median		-32.18		-32.18
Min, Max		-32.2, -32.2		-32.2, -32.2

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=7)	MCL (N=4)	All AdvSM (N=12)
Baseline				
n	1	7	4	12
Mean (StdDev)	3603.05 (-)	2186.30 (313.065)	2765.09 (543.133)	2497.29 (576.794)
Median	3603.05	2067.41	2734.69	2337.74
Min, Max	3603.1, 3603.1	1764.2, 2731.4	2153.5, 3437.5	1764.2, 3603.1
Percent change from Baseline to Cycle 3 Day 1				
n	1	6	3	10
Mean (StdDev)	-2.65 (-)	-6.59 (11.674)	-23.37 (5.134)	-11.23 (12.378)
Median	-2.65	-7.10	-23.87	-10.53
Min, Max	-2.7, -2.7	-21.8, 13.1	-28.2, -18.0	-28.2, 13.1
Percent change from Baseline to Cycle 5 Day 1				
n	1	5	4	10
Mean (StdDev)	-14.00 (-)	-6.23 (14.727)	-20.51 (15.735)	-12.72 (15.149)
Median	-14.00	-7.18	-26.73	-11.41
Min, Max	-14.0, -14.0	-26.8, 14.4	-31.4, 2.8	-31.4, 14.4
Percent change from Baseline to Cycle 7 Day 1				
n	0	5	3	8
Mean (StdDev)		-7.01 (21.904)	-23.87 (14.157)	-13.33 (20.188)
Median		-8.03	-29.44	-12.95
Min, Max		-31.0, 28.0	-34.4, -7.8	-34.4, 28.0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=7)	MCL (N=4)	All AdvSM (N=12)
Percent change from Baseline to Cycle 11 Day 1				
n	0	3	2	5
Mean (StdDev)		-9.46 (12.108)	-30.04 (21.786)	-17.69 (17.863)
Median		-6.79	-30.04	-14.64
Min, Max		-22.7, 1.1	-45.4, -14.6	-45.4, 1.1
Percent change from Baseline to Cycle 18 Day 1				
n	0	1	1	2
Mean (StdDev)		-23.63 (-)	-5.89 (-)	-14.76 (12.545)
Median		-23.63	-5.89	-14.76
Min, Max		-23.6, -23.6	-5.9, -5.9	-23.6, -5.9
Percent change from Baseline to Cycle 24 Day 1				
n	0	1	0	1
Mean (StdDev)		-18.61 (-)		-18.61 (-)
Median		-18.61		-18.61
Min, Max		-18.6, -18.6		-18.6, -18.6
Percent change from Baseline to Cycle 30 Day 1				
n	0	1	0	1
Mean (StdDev)		-13.13 (-)		-13.13 (-)
Median		-13.13		-13.13
Min, Max		-13.1, -13.1		-13.1, -13.1

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=7)	MCL (N=4)	All AdvSM (N=12)
Percent change from Baseline to Cycle 36 Day 1				
n	0	1	0	1
Mean (StdDev)		-17.40 (-)		-17.40 (-)
Median		-17.40		-17.40
Min, Max		-17.4, -17.4		-17.4, -17.4
Percent change from Baseline to Cycle 42 Day 1				
n	0	1	0	1
Mean (StdDev)		-23.85 (-)		-23.85 (-)
Median		-23.85		-23.85
Min, Max		-23.9, -23.9		-23.9, -23.9

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 300 mg
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Baseline				
n	4	12	2	18
Mean (StdDev)	919.82 (677.582)	1181.24 (549.211)	1099.34 (1190.124)	1114.05 (609.591)
Median	638.71	1147.89	1099.34	1092.31
Min, Max	479.2, 1922.7	359.4, 2262.7	257.8, 1940.9	257.8, 2262.7
Percent change from Baseline to Cycle 3 Day 1				
n	4	12	2	18
Mean (StdDev)	-38.38 (5.088)	-47.09 (13.835)	-28.44 (9.542)	-43.08 (13.248)
Median	-40.16	-49.32	-28.44	-43.05
Min, Max	-42.3, -30.9	-75.9, -24.0	-35.2, -21.7	-75.9, -21.7
Percent change from Baseline to Cycle 5 Day 1				
n	3	11	2	16
Mean (StdDev)	-35.72 (11.544)	-50.47 (16.423)	-46.74 (28.450)	-47.23 (16.905)
Median	-36.01	-51.38	-46.74	-49.06
Min, Max	-47.1, -24.0	-82.3, -21.1	-66.9, -26.6	-82.3, -21.1
Percent change from Baseline to Cycle 7 Day 1				
n	3	9	1	13
Mean (StdDev)	-36.72 (25.121)	-57.05 (14.416)	0.32 (-)	-47.94 (23.054)
Median	-41.80	-57.05	0.32	-55.35
Min, Max	-58.9, -9.5	-76.2, -25.7	0.3, 0.3	-76.2, 0.3

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 300 mg
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Percent change from Baseline to Cycle 11 Day 1				
n	3	5	1	9
Mean (StdDev)	-50.39 (29.321)	-60.06 (19.717)	-64.21 (-)	-57.30 (20.927)
Median	-45.65	-67.54	-64.21	-65.00
Min, Max	-81.8, -23.7	-74.4, -25.3	-64.2, -64.2	-81.8, -23.7
Percent change from Baseline to Cycle 18 Day 1				
n	2	5	0	7
Mean (StdDev)	-50.88 (27.564)	-55.07 (28.271)		-53.87 (25.762)
Median	-50.88	-67.22		-67.22
Min, Max	-70.4, -31.4	-81.3, -9.7		-81.3, -9.7
Percent change from Baseline to Cycle 24 Day 1				
n	2	4	0	6
Mean (StdDev)	-44.54 (36.975)	-46.31 (37.265)		-45.72 (33.279)
Median	-44.54	-49.11		-48.59
Min, Max	-70.7, -18.4	-83.0, -4.1		-83.0, -4.1
Percent change from Baseline to Cycle 30 Day 1				
n	1	0	0	1
Mean (StdDev)	-33.85 (-)			-33.85 (-)
Median	-33.85			-33.85
Min, Max	-33.9, -33.9			-33.9, -33.9

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 300 mg
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Percent change from Baseline to Cycle 36 Day 1				
n	1	0	0	1
Mean (StdDev)	-35.28 (-)			-35.28 (-)
Median	-35.28			-35.28
Min, Max	-35.3, -35.3			-35.3, -35.3

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 300 mg
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Baseline				
n	4	13	3	20
Mean (StdDev)	2246.32 (377.128)	2276.97 (657.353)	2090.15 (173.239)	2242.82 (550.463)
Median	2184.95	2112.93	2020.24	2070.22
Min, Max	1885.0, 2730.4	1436.4, 3624.1	1962.8, 2287.4	1436.4, 3624.1
Percent change from Baseline to Cycle 3 Day 1				
n	3	13	3	19
Mean (StdDev)	-19.89 (8.243)	-15.02 (8.078)	-13.43 (18.520)	-15.54 (9.657)
Median	-21.54	-15.30	-19.66	-17.22
Min, Max	-27.2, -10.9	-25.7, -2.9	-28.0, 7.4	-28.0, 7.4
Percent change from Baseline to Cycle 5 Day 1				
n	3	12	3	18
Mean (StdDev)	-5.73 (8.742)	-17.84 (9.710)	-24.13 (11.723)	-16.87 (10.864)
Median	-3.69	-20.34	-27.20	-19.44
Min, Max	-15.3, 1.8	-29.3, -0.2	-34.0, -11.2	-34.0, 1.8
Percent change from Baseline to Cycle 7 Day 1				
n	3	10	2	15
Mean (StdDev)	-2.76 (18.204)	-18.63 (9.341)	-28.09 (0.629)	-16.72 (12.896)
Median	-0.91	-20.37	-28.09	-20.67
Min, Max	-21.8, 14.4	-29.8, -2.1	-28.5, -27.6	-29.8, 14.4

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 300 mg
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Percent change from Baseline to Cycle 11 Day 1				
n	2	6	2	10
Mean (StdDev)	-18.26 (16.348)	-20.93 (10.757)	-13.47 (25.278)	-18.90 (13.205)
Median	-18.26	-22.16	-13.47	-22.16
Min, Max	-29.8, -6.7	-33.1, -4.8	-31.3, 4.4	-33.1, 4.4
Percent change from Baseline to Cycle 18 Day 1				
n	2	6	1	9
Mean (StdDev)	-11.11 (6.466)	-25.99 (10.156)	-36.01 (-)	-23.80 (11.496)
Median	-11.11	-26.38	-36.01	-26.03
Min, Max	-15.7, -6.5	-42.8, -12.8	-36.0, -36.0	-42.8, -6.5
Percent change from Baseline to Cycle 24 Day 1				
n	2	4	1	7
Mean (StdDev)	-6.04 (10.388)	-24.53 (12.304)	-36.99 (-)	-21.02 (14.803)
Median	-6.04	-20.66	-36.99	-19.70
Min, Max	-13.4, 1.3	-42.4, -14.4	-37.0, -37.0	-42.4, 1.3
Percent change from Baseline to Cycle 30 Day 1				
n	1	0	1	2
Mean (StdDev)	-17.44 (-)		-33.42 (-)	-25.43 (11.299)
Median	-17.44		-33.42	-25.43
Min, Max	-17.4, -17.4		-33.4, -33.4	-33.4, -17.4

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 300 mg
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Percent change from Baseline to Cycle 36 Day 1				
n	1	0	0	1
Mean (StdDev)	-14.22 (-)			-14.22 (-)
Median	-14.22			-14.22
Min, Max	-14.2, -14.2			-14.2, -14.2

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=5)	SM-AHN (N=20)	MCL (N=7)	All AdvSM (N=32)
Baseline				
n	5	19	6	30
Mean (StdDev)	837.59 (614.938)	1078.82 (497.009)	916.81 (569.531)	1006.21 (520.975)
Median	540.12	1120.69	768.77	958.12
Min, Max	479.2, 1922.7	298.5, 2262.7	257.8, 1940.9	257.8, 2262.7
Percent change from Baseline to Cycle 3 Day 1				
n	5	18	5	28
Mean (StdDev)	-33.24 (12.328)	-43.57 (16.740)	-31.77 (9.947)	-39.62 (15.588)
Median	-39.55	-47.22	-35.19	-40.83
Min, Max	-42.3, -12.6	-75.9, -2.9	-40.9, -20.6	-75.9, -2.9
Percent change from Baseline to Cycle 5 Day 1				
n	4	16	6	26
Mean (StdDev)	-29.71 (15.273)	-41.06 (24.613)	-41.08 (18.321)	-39.32 (21.819)
Median	-30.02	-50.60	-36.85	-46.65
Min, Max	-47.1, -11.7	-82.3, 11.9	-66.9, -23.8	-82.3, 11.9
Percent change from Baseline to Cycle 7 Day 1				
n	3	14	4	21
Mean (StdDev)	-36.72 (25.121)	-40.33 (40.373)	-36.92 (30.990)	-39.16 (35.630)
Median	-41.80	-54.24	-41.07	-53.12
Min, Max	-58.9, -9.5	-76.2, 83.4	-65.9, 0.3	-76.2, 83.4

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=5)	SM-AHN (N=20)	MCL (N=7)	All AdvSM (N=32)
Percent change from Baseline to Cycle 11 Day 1				
n	3	8	3	14
Mean (StdDev)	-50.39 (29.321)	-54.05 (20.870)	-57.72 (11.864)	-54.05 (19.866)
Median	-45.65	-66.27	-64.21	-64.57
Min, Max	-81.8, -23.7	-74.4, -25.3	-64.9, -44.0	-81.8, -23.7
Percent change from Baseline to Cycle 18 Day 1				
n	2	6	1	9
Mean (StdDev)	-50.88 (27.564)	-50.92 (27.253)	-67.83 (-)	-52.79 (24.309)
Median	-50.88	-56.99	-67.83	-67.22
Min, Max	-70.4, -31.4	-81.3, -9.7	-67.8, -67.8	-81.3, -9.7
Percent change from Baseline to Cycle 24 Day 1				
n	2	5	0	7
Mean (StdDev)	-44.54 (36.975)	-39.44 (35.736)		-40.90 (32.946)
Median	-44.54	-26.50		-26.50
Min, Max	-70.7, -18.4	-83.0, -4.1		-83.0, -4.1
Percent change from Baseline to Cycle 30 Day 1				
n	1	1	0	2
Mean (StdDev)	-33.85 (-)	-32.69 (-)		-33.27 (0.822)
Median	-33.85	-32.69		-33.27
Min, Max	-33.9, -33.9	-32.7, -32.7		-33.9, -32.7

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=5)	SM-AHN (N=20)	MCL (N=7)	All AdvSM (N=32)
Percent change from Baseline to Cycle 36 Day 1				
n	1	1	0	2
Mean (StdDev)	-35.28 (-)	-28.13 (-)		-31.71 (5.054)
Median	-35.28	-28.13		-31.71
Min, Max	-35.3, -35.3	-28.1, -28.1		-35.3, -28.1
Percent change from Baseline to Cycle 42 Day 1				
n	0	1	0	1
Mean (StdDev)		-32.18 (-)		-32.18 (-)
Median		-32.18		-32.18
Min, Max		-32.2, -32.2		-32.2, -32.2

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=5)	SM-AHN (N=20)	MCL (N=7)	All AdvSM (N=32)
Baseline				
n	5	20	7	32
Mean (StdDev)	2517.67 (689.065)	2245.23 (553.021)	2475.83 (536.335)	2338.24 (565.185)
Median	2349.73	2090.17	2287.42	2219.34
Min, Max	1885.0, 3603.1	1436.4, 3624.1	1962.8, 3437.5	1436.4, 3624.1
Percent change from Baseline to Cycle 3 Day 1				
n	4	19	6	29
Mean (StdDev)	-15.58 (10.935)	-12.36 (9.877)	-18.40 (13.319)	-14.05 (10.656)
Median	-16.24	-10.52	-21.76	-15.30
Min, Max	-27.2, -2.7	-25.7, 13.1	-28.2, 7.4	-28.2, 13.1
Percent change from Baseline to Cycle 5 Day 1				
n	4	17	7	28
Mean (StdDev)	-7.79 (8.248)	-14.43 (12.197)	-22.06 (13.165)	-15.39 (12.446)
Median	-8.84	-18.78	-27.20	-17.04
Min, Max	-15.3, 1.8	-29.3, 14.4	-34.0, 2.8	-34.0, 14.4
Percent change from Baseline to Cycle 7 Day 1				
n	3	15	5	23
Mean (StdDev)	-2.76 (18.204)	-14.76 (15.011)	-25.56 (10.279)	-15.54 (15.435)
Median	-0.91	-17.87	-28.54	-20.08
Min, Max	-21.8, 14.4	-31.0, 28.0	-34.4, -7.8	-34.4, 28.0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=5)	SM-AHN (N=20)	MCL (N=7)	All AdvSM (N=32)
Percent change from Baseline to Cycle 11 Day 1				
n	2	9	4	15
Mean (StdDev)	-18.26 (16.348)	-17.11 (11.911)	-21.76 (21.512)	-18.50 (14.270)
Median	-18.26	-18.23	-22.99	-18.23
Min, Max	-29.8, -6.7	-33.1, 1.1	-45.4, 4.4	-45.4, 4.4
Percent change from Baseline to Cycle 18 Day 1				
n	2	7	2	11
Mean (StdDev)	-11.11 (6.466)	-25.66 (9.314)	-20.95 (21.294)	-22.16 (11.611)
Median	-11.11	-26.03	-20.95	-23.63
Min, Max	-15.7, -6.5	-42.8, -12.8	-36.0, -5.9	-42.8, -5.9
Percent change from Baseline to Cycle 24 Day 1				
n	2	5	1	8
Mean (StdDev)	-6.04 (10.388)	-23.34 (10.979)	-36.99 (-)	-20.72 (13.731)
Median	-6.04	-19.70	-36.99	-19.15
Min, Max	-13.4, 1.3	-42.4, -14.4	-37.0, -37.0	-42.4, 1.3
Percent change from Baseline to Cycle 30 Day 1				
n	1	1	1	3
Mean (StdDev)	-17.44 (-)	-13.13 (-)	-33.42 (-)	-21.33 (10.689)
Median	-17.44	-13.13	-33.42	-17.44
Min, Max	-17.4, -17.4	-13.1, -13.1	-33.4, -33.4	-33.4, -13.1

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 200 mg and 300 mg
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=5)	SM-AHN (N=20)	MCL (N=7)	All AdvSM (N=32)
Percent change from Baseline to Cycle 36 Day 1				
n	1	1	0	2
Mean (StdDev)	-14.22 (-)	-17.40 (-)		-15.81 (2.247)
Median	-14.22	-17.40		-15.81
Min, Max	-14.2, -14.2	-17.4, -17.4		-17.4, -14.2
Percent change from Baseline to Cycle 42 Day 1				
n	0	1	0	1
Mean (StdDev)		-23.85 (-)		-23.85 (-)
Median		-23.85		-23.85
Min, Max		-23.9, -23.9		-23.9, -23.9

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 400 mg
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Baseline				
n	1	4	0	5
Mean (StdDev)	163.41 (-)	1058.92 (596.395)		879.82 (653.569)
Median	163.41	1008.52		580.47
Min, Max	163.4, 163.4	521.8, 1696.9		163.4, 1696.9
Percent change from Baseline to Cycle 3 Day 1				
n	1	3	0	4
Mean (StdDev)	-42.13 (-)	-31.50 (17.373)		-34.16 (15.147)
Median	-42.13	-29.16		-35.64
Min, Max	-42.1, -42.1	-49.9, -15.4		-49.9, -15.4
Percent change from Baseline to Cycle 5 Day 1				
n	1	3	0	4
Mean (StdDev)	-40.95 (-)	-28.73 (29.433)		-31.79 (24.797)
Median	-40.95	-13.62		-27.29
Min, Max	-41.0, -41.0	-62.7, -9.9		-62.7, -9.9
Percent change from Baseline to Cycle 7 Day 1				
n	1	2	0	3
Mean (StdDev)	-26.28 (-)	-50.12 (21.253)		-42.17 (20.380)
Median	-26.28	-50.12		-35.09
Min, Max	-26.3, -26.3	-65.1, -35.1		-65.1, -26.3

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 400 mg
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Percent change from Baseline to Cycle 11 Day 1				
n	0	2	0	2
Mean (StdDev)		-14.27 (15.584)		-14.27 (15.584)
Median		-14.27		-14.27
Min, Max		-25.3, -3.2		-25.3, -3.2
Percent change from Baseline to Cycle 18 Day 1				
n	0	1	0	1
Mean (StdDev)		-1.23 (-)		-1.23 (-)
Median		-1.23		-1.23
Min, Max		-1.2, -1.2		-1.2, -1.2
Percent change from Baseline to Cycle 24 Day 1				
n	0	2	0	2
Mean (StdDev)		-34.36 (66.012)		-34.36 (66.012)
Median		-34.36		-34.36
Min, Max		-81.0, 12.3		-81.0, 12.3
Percent change from Baseline to Cycle 30 Day 1				
n	0	1	0	1
Mean (StdDev)		53.13 (-)		53.13 (-)
Median		53.13		53.13
Min, Max		53.1, 53.1		53.1, 53.1

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 400 mg
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Percent change from Baseline to Cycle 36 Day 1				
n	0	1	0	1
Mean (StdDev)		55.50 (-)		55.50 (-)
Median		55.50		55.50
Min, Max		55.5, 55.5		55.5, 55.5

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 400 mg
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Baseline				
n	1	4	0	5
Mean (StdDev)	1019.93 (-)	2777.23 (487.520)		2425.77 (892.121)
Median	1019.93	2791.67		2682.43
Min, Max	1019.9, 1019.9	2176.1, 3349.5		1019.9, 3349.5
Percent change from Baseline to Cycle 3 Day 1				
n	1	3	0	4
Mean (StdDev)	-0.25 (-)	-16.36 (12.890)		-12.33 (13.255)
Median	-0.25	-12.24		-9.14
Min, Max	-0.2, -0.2	-30.8, -6.0		-30.8, -0.2
Percent change from Baseline to Cycle 5 Day 1				
n	1	3	0	4
Mean (StdDev)	1.96 (-)	-23.22 (12.196)		-16.92 (16.052)
Median	1.96	-18.28		-16.27
Min, Max	2.0, 2.0	-37.1, -14.3		-37.1, 2.0
Percent change from Baseline to Cycle 7 Day 1				
n	1	2	0	3
Mean (StdDev)	-2.62 (-)	-26.36 (18.459)		-18.45 (18.927)
Median	-2.62	-26.36		-13.31
Min, Max	-2.6, -2.6	-39.4, -13.3		-39.4, -2.6

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 400 mg
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Percent change from Baseline to Cycle 11 Day 1				
n	0	2	0	2
Mean (StdDev)		-15.86 (1.474)		-15.86 (1.474)
Median		-15.86		-15.86
Min, Max		-16.9, -14.8		-16.9, -14.8
Percent change from Baseline to Cycle 18 Day 1				
n	0	1	0	1
Mean (StdDev)		-21.03 (-)		-21.03 (-)
Median		-21.03		-21.03
Min, Max		-21.0, -21.0		-21.0, -21.0
Percent change from Baseline to Cycle 24 Day 1				
n	0	2	0	2
Mean (StdDev)		-34.11 (13.517)		-34.11 (13.517)
Median		-34.11		-34.11
Min, Max		-43.7, -24.5		-43.7, -24.5
Percent change from Baseline to Cycle 30 Day 1				
n	0	1	0	1
Mean (StdDev)		-0.88 (-)		-0.88 (-)
Median		-0.88		-0.88
Min, Max		-0.9, -0.9		-0.9, -0.9

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101

Starting Dose: 400 mg
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Percent change from Baseline to Cycle 36 Day 1				
n	0	1	0	1
Mean (StdDev)		-6.63 (-)		-6.63 (-)
Median		-6.63		-6.63
Min, Max		-6.6, -6.6		-6.6, -6.6

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2202

Overall
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Baseline				
n	5	28	9	42
Mean (StdDev)	641.10 (467.460)	983.64 (507.650)	1213.12 (645.927)	992.04 (546.109)
Median	651.85	823.26	1166.99	766.96
Min, Max	44.2, 1321.6	449.5, 2600.8	367.4, 2270.0	44.2, 2600.8
Percent change from Baseline to Cycle 3 Day 1				
n	4	19	6	29
Mean (StdDev)	-38.10 (11.136)	-21.20 (30.749)	-25.93 (23.476)	-24.51 (27.455)
Median	-40.54	-27.07	-26.87	-29.25
Min, Max	-47.7, -23.6	-68.1, 51.5	-57.4, 8.3	-68.1, 51.5
Percent change from Baseline to Cycle 7 Day 1				
n	1	13	2	16
Mean (StdDev)	-9.83 (-)	-31.70 (34.373)	-10.09 (16.199)	-27.63 (32.236)
Median	-9.83	-36.11	-10.09	-28.03
Min, Max	-9.8, -9.8	-84.3, 51.0	-21.5, 1.4	-84.3, 51.0
Percent change from Baseline to Cycle 11 Day 1				
n	0	8	1	9
Mean (StdDev)		-41.17 (25.644)	-3.71 (-)	-37.00 (27.042)
Median		-50.59	-3.71	-48.22
Min, Max		-68.1, 15.8	-3.7, -3.7	-68.1, 15.8

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2202

Overall
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Percent change from Baseline to Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		-52.33 (-)	-10.38 (-)	-31.35 (29.662)
Median		-52.33	-10.38	-31.35
Min, Max		-52.3, -52.3	-10.4, -10.4	-52.3, -10.4

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2202

Overall
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Baseline				
n	5	28	9	42
Mean (StdDev)	2019.15 (291.817)	2480.12 (423.795)	3001.19 (680.274)	2536.90 (546.893)
Median	2101.22	2462.19	3141.41	2462.19
Min, Max	1671.6, 2289.8	1707.4, 3311.1	1660.5, 4020.8	1660.5, 4020.8
Percent change from Baseline to Cycle 3 Day 1				
n	4	19	6	29
Mean (StdDev)	-13.33 (5.785)	-14.22 (10.724)	-15.20 (7.233)	-14.30 (9.337)
Median	-11.63	-18.04	-16.21	-16.37
Min, Max	-21.7, -8.4	-27.1, 11.1	-24.5, -6.9	-27.1, 11.1
Percent change from Baseline to Cycle 7 Day 1				
n	1	13	2	16
Mean (StdDev)	6.62 (-)	-21.96 (13.749)	-22.70 (23.769)	-20.27 (15.504)
Median	6.62	-24.95	-22.70	-24.33
Min, Max	6.6, 6.6	-42.0, 9.8	-39.5, -5.9	-42.0, 9.8
Percent change from Baseline to Cycle 11 Day 1				
n	0	8	1	9
Mean (StdDev)		-30.38 (10.623)	-41.71 (-)	-31.64 (10.630)
Median		-28.62	-41.71	-31.17
Min, Max		-43.8, -16.8	-41.7, -41.7	-43.8, -16.8

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2202

Overall
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Percent change from Baseline to Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		-20.93 (-)	-48.86 (-)	-34.90 (19.748)
Median		-20.93	-48.86	-34.90
Min, Max		-20.9, -20.9	-48.9, -48.9	-48.9, -20.9

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2202

Starting Dose: 200 mg
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Baseline				
n	4	27	9	40
Mean (StdDev)	790.33 (378.001)	977.28 (516.182)	1213.12 (645.927)	1011.65 (537.971)
Median	702.10	719.85	1166.99	766.96
Min, Max	435.6, 1321.6	449.5, 2600.8	367.4, 2270.0	367.4, 2600.8
Percent change from Baseline to Cycle 3 Day 1				
n	4	18	6	28
Mean (StdDev)	-38.10 (11.136)	-22.98 (30.612)	-25.93 (23.476)	-25.77 (27.084)
Median	-40.54	-28.16	-26.87	-31.57
Min, Max	-47.7, -23.6	-68.1, 51.5	-57.4, 8.3	-68.1, 51.5
Percent change from Baseline to Cycle 7 Day 1				
n	1	12	2	15
Mean (StdDev)	-9.83 (-)	-35.11 (33.526)	-10.09 (16.199)	-30.09 (31.779)
Median	-9.83	-38.01	-10.09	-28.13
Min, Max	-9.8, -9.8	-84.3, 51.0	-21.5, 1.4	-84.3, 51.0
Percent change from Baseline to Cycle 11 Day 1				
n	0	7	1	8
Mean (StdDev)		-49.30 (12.209)	-3.71 (-)	-43.61 (19.687)
Median		-52.96	-3.71	-50.59
Min, Max		-68.1, -33.3	-3.7, -3.7	-68.1, -3.7

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2202

Starting Dose: 200 mg
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Percent change from Baseline to Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		-52.33 (-)	-10.38 (-)	-31.35 (29.662)
Median		-52.33	-10.38	-31.35
Min, Max		-52.3, -52.3	-10.4, -10.4	-52.3, -10.4

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2202

Starting Dose: 200 mg
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Baseline				
n	4	27	9	40
Mean (StdDev)	1953.70 (291.521)	2449.34 (398.705)	3001.19 (680.274)	2523.95 (545.168)
Median	1926.67	2453.43	3141.41	2462.19
Min, Max	1671.6, 2289.8	1707.4, 3239.5	1660.5, 4020.8	1660.5, 4020.8
Percent change from Baseline to Cycle 3 Day 1				
n	4	18	6	28
Mean (StdDev)	-13.33 (5.785)	-13.66 (10.745)	-15.20 (7.233)	-13.94 (9.304)
Median	-11.63	-17.21	-16.21	-16.21
Min, Max	-21.7, -8.4	-27.1, 11.1	-24.5, -6.9	-27.1, 11.1
Percent change from Baseline to Cycle 7 Day 1				
n	1	12	2	15
Mean (StdDev)	6.62 (-)	-21.35 (14.178)	-22.70 (23.769)	-19.67 (15.855)
Median	6.62	-24.33	-22.70	-23.71
Min, Max	6.6, 6.6	-42.0, 9.8	-39.5, -5.9	-42.0, 9.8
Percent change from Baseline to Cycle 11 Day 1				
n	0	7	1	8
Mean (StdDev)		-30.27 (11.469)	-41.71 (-)	-31.70 (11.363)
Median		-26.07	-41.71	-33.47
Min, Max		-43.8, -16.8	-41.7, -41.7	-43.8, -16.8

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2202

Starting Dose: 200 mg
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Percent change from Baseline to Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		-20.93 (-)	-48.86 (-)	-34.90 (19.748)
Median		-20.93	-48.86	-34.90
Min, Max		-20.9, -20.9	-48.9, -48.9	-48.9, -20.9

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Overall
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=12)	SM-AHN (N=54)	MCL (N=17)	All AdvSM (N=83)
Baseline				
n	11	53	16	80
Mean (StdDev)	686.98 (527.705)	1019.76 (501.348)	1062.49 (606.801)	982.55 (533.849)
Median	540.12	1030.73	815.31	829.70
Min, Max	44.2, 1922.7	298.5, 2600.8	257.8, 2270.0	44.2, 2600.8
Percent change from Baseline to Cycle 3 Day 1				
n	10	42	12	64
Mean (StdDev)	-36.07 (10.920)	-32.06 (25.682)	-26.59 (18.518)	-31.66 (22.677)
Median	-40.16	-39.19	-28.44	-38.66
Min, Max	-47.7, -12.6	-75.9, 51.5	-57.4, 8.3	-75.9, 51.5
Percent change from Baseline to Cycle 5 Day 1				
n	5	21	7	33
Mean (StdDev)	-31.96 (14.151)	-38.51 (23.759)	-34.98 (23.252)	-36.77 (22.035)
Median	-36.01	-46.23	-26.62	-39.35
Min, Max	-47.1, -11.7	-82.3, 11.9	-66.9, 1.7	-82.3, 11.9
Percent change from Baseline to Cycle 7 Day 1				
n	5	31	7	43
Mean (StdDev)	-29.25 (21.306)	-35.37 (36.138)	-23.19 (29.063)	-32.68 (33.444)
Median	-26.28	-39.90	-21.55	-36.11
Min, Max	-58.9, -9.5	-84.3, 83.4	-65.9, 5.6	-84.3, 83.4

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Overall
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=12)	SM-AHN (N=54)	MCL (N=17)	All AdvSM (N=83)
Percent change from Baseline to Cycle 11 Day 1				
n	3	20	5	28
Mean (StdDev)	-50.39 (29.321)	-41.69 (25.643)	-38.14 (28.325)	-41.99 (25.611)
Median	-45.65	-46.58	-44.03	-45.30
Min, Max	-81.8, -23.7	-74.4, 15.8	-64.9, -3.7	-81.8, 15.8
Percent change from Baseline to Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		-52.33 (-)	-10.38 (-)	-31.35 (29.662)
Median		-52.33	-10.38	-31.35
Min, Max		-52.3, -52.3	-10.4, -10.4	-52.3, -10.4
Percent change from Baseline to Cycle 18 Day 1				
n	2	9	2	13
Mean (StdDev)	-50.88 (27.564)	-40.61 (29.495)	-55.23 (17.819)	-44.44 (26.590)
Median	-50.88	-46.75	-55.23	-46.75
Min, Max	-70.4, -31.4	-81.3, -1.2	-67.8, -42.6	-81.3, -1.2
Percent change from Baseline to Cycle 24 Day 1				
n	2	9	1	12
Mean (StdDev)	-44.54 (36.975)	-37.00 (34.880)	-39.18 (-)	-38.44 (31.900)
Median	-44.54	-26.50	-39.18	-32.84
Min, Max	-70.7, -18.4	-83.0, 12.3	-39.2, -39.2	-83.0, 12.3

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Overall
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=12)	SM-AHN (N=54)	MCL (N=17)	All AdvSM (N=83)
Percent change from Baseline to Cycle 30 Day 1				
n	1	4	1	6
Mean (StdDev)	-33.85 (-)	-7.23 (45.809)	-58.96 (-)	-20.29 (41.609)
Median	-33.85	-15.48	-58.96	-33.27
Min, Max	-33.9, -33.9	-51.1, 53.1	-59.0, -59.0	-59.0, 53.1
Percent change from Baseline to Cycle 36 Day 1				
n	1	4	1	6
Mean (StdDev)	-35.28 (-)	-10.77 (47.568)	-52.31 (-)	-21.78 (40.958)
Median	-35.28	-21.07	-52.31	-31.71
Min, Max	-35.3, -35.3	-56.4, 55.5	-52.3, -52.3	-56.4, 55.5
Percent change from Baseline to Cycle 42 Day 1				
n	0	3	1	4
Mean (StdDev)		-30.83 (23.799)	-64.86 (-)	-39.34 (25.828)
Median		-32.18	-64.86	-43.05
Min, Max		-53.9, -6.4	-64.9, -64.9	-64.9, -6.4
Percent change from Baseline to Cycle 48 Day 1				
n	0	0	1	1
Mean (StdDev)			-70.25 (-)	-70.25 (-)
Median			-70.25	-70.25
Min, Max			-70.3, -70.3	-70.3, -70.3

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Overall
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=12)	SM-AHN (N=54)	MCL (N=17)	All AdvSM (N=83)
Baseline				
n	12	54	17	83
Mean (StdDev)	2173.13 (626.823)	2409.13 (488.500)	2692.79 (715.614)	2433.10 (575.428)
Median	2191.09	2406.85	2903.36	2361.64
Min, Max	1019.9, 3603.1	1436.4, 3624.1	1435.8, 4020.8	1019.9, 4020.8
Percent change from Baseline to Cycle 3 Day 1				
n	10	43	13	66
Mean (StdDev)	-12.71 (8.507)	-13.32 (10.059)	-16.07 (10.256)	-13.77 (9.807)
Median	-11.12	-13.70	-19.66	-13.61
Min, Max	-27.2, -0.2	-30.8, 13.1	-28.2, 7.4	-30.8, 13.1
Percent change from Baseline to Cycle 5 Day 1				
n	6	22	8	36
Mean (StdDev)	-7.73 (8.797)	-15.70 (11.756)	-19.34 (14.415)	-15.18 (12.214)
Median	-8.84	-18.53	-26.39	-16.23
Min, Max	-17.2, 2.0	-37.1, 14.4	-34.0, 2.8	-37.1, 14.4
Percent change from Baseline to Cycle 7 Day 1				
n	6	32	8	46
Mean (StdDev)	-4.82 (15.513)	-17.68 (15.359)	-21.79 (14.569)	-16.72 (15.697)
Median	-1.77	-20.35	-28.09	-20.35
Min, Max	-24.6, 14.4	-42.0, 28.0	-39.5, -1.2	-42.0, 28.0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Overall
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=12)	SM-AHN (N=54)	MCL (N=17)	All AdvSM (N=83)
Percent change from Baseline to Cycle 11 Day 1				
n	3	21	6	30
Mean (StdDev)	-22.87 (14.050)	-20.93 (12.886)	-22.51 (20.104)	-21.44 (14.087)
Median	-29.82	-21.01	-22.99	-21.29
Min, Max	-32.1, -6.7	-43.8, 1.1	-45.4, 4.4	-45.4, 4.4
Percent change from Baseline to Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		-20.93 (-)	-48.86 (-)	-34.90 (19.748)
Median		-20.93	-48.86	-34.90
Min, Max		-20.9, -20.9	-48.9, -48.9	-48.9, -20.9
Percent change from Baseline to Cycle 18 Day 1				
n	3	10	3	16
Mean (StdDev)	-17.38 (11.775)	-23.59 (8.357)	-19.75 (15.199)	-21.70 (9.902)
Median	-15.69	-22.33	-17.36	-19.96
Min, Max	-29.9, -6.5	-42.8, -12.8	-36.0, -5.9	-42.8, -5.9
Percent change from Baseline to Cycle 24 Day 1				
n	3	9	2	14
Mean (StdDev)	-14.75 (16.771)	-25.81 (12.149)	-21.94 (21.275)	-22.89 (13.794)
Median	-13.39	-21.63	-21.94	-20.66
Min, Max	-32.2, 1.3	-43.7, -10.7	-37.0, -6.9	-43.7, 1.3

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Overall
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=12)	SM-AHN (N=54)	MCL (N=17)	All AdvSM (N=83)
Percent change from Baseline to Cycle 30 Day 1				
n	2	4	2	8
Mean (StdDev)	-26.11 (12.263)	-10.46 (7.409)	-23.70 (13.748)	-17.68 (11.507)
Median	-26.11	-11.24	-23.70	-15.71
Min, Max	-34.8, -17.4	-18.5, -0.9	-33.4, -14.0	-34.8, -0.9
Percent change from Baseline to Cycle 36 Day 1				
n	2	4	1	7
Mean (StdDev)	-22.97 (12.378)	-14.32 (6.070)	-10.36 (-)	-16.23 (8.203)
Median	-22.97	-15.03	-10.36	-14.22
Min, Max	-31.7, -14.2	-20.6, -6.6	-10.4, -10.4	-31.7, -6.6
Percent change from Baseline to Cycle 42 Day 1				
n	0	3	1	4
Mean (StdDev)		-22.82 (4.674)	-8.42 (-)	-19.22 (8.149)
Median		-23.85	-8.42	-20.78
Min, Max		-26.9, -17.7	-8.4, -8.4	-26.9, -8.4
Percent change from Baseline to Cycle 48 Day 1				
n	1	0	1	2
Mean (StdDev)	-27.20 (-)		-23.82 (-)	-25.51 (2.388)
Median	-27.20		-23.82	-25.51
Min, Max	-27.2, -27.2		-23.8, -23.8	-27.2, -23.8

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=2)	SM-AHN (N=3)	MCL (N=1)	All AdvSM (N=6)
Baseline				
n	1	3	1	5
Mean (StdDev)	44.16 (-)	975.86 (501.173)	580.85 (-)	710.52 (541.851)
Median	44.16	1155.41	580.85	580.85
Min, Max	44.2, 44.2	409.6, 1362.5	580.9, 580.9	44.2, 1362.5
Percent change from Baseline to Cycle 3 Day 1				
n	0	3	1	4
Mean (StdDev)		-18.02 (25.324)	-4.59 (-)	-14.66 (21.740)
Median		-28.91	-4.59	-16.75
Min, Max		-36.1, 10.9	-4.6, -4.6	-36.1, 10.9
Percent change from Baseline to Cycle 5 Day 1				
n	0	2	1	3
Mean (StdDev)		-32.76 (3.702)	1.65 (-)	-21.29 (20.040)
Median		-32.76	1.65	-30.14
Min, Max		-35.4, -30.1	1.7, 1.7	-35.4, 1.7
Percent change from Baseline to Cycle 7 Day 1				
n	0	3	1	4
Mean (StdDev)		-3.49 (25.912)	5.57 (-)	-1.22 (21.637)
Median		9.23	5.57	7.40
Min, Max		-33.3, 13.6	5.6, 5.6	-33.3, 13.6

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=2)	SM-AHN (N=3)	MCL (N=1)	All AdvSM (N=6)
Percent change from Baseline to Cycle 11 Day 1				
n	0	3	1	4
Mean (StdDev)		-9.24 (31.748)	-13.81 (-)	-10.38 (26.022)
Median		1.43	-13.81	-6.19
Min, Max		-44.9, 15.8	-13.8, -13.8	-44.9, 15.8
Percent change from Baseline to Cycle 18 Day 1				
n	0	2	1	3
Mean (StdDev)		-29.36 (28.365)	-42.63 (-)	-33.78 (21.469)
Median		-29.36	-42.63	-42.63
Min, Max		-49.4, -9.3	-42.6, -42.6	-49.4, -9.3
Percent change from Baseline to Cycle 24 Day 1				
n	0	2	1	3
Mean (StdDev)		-33.55 (14.111)	-39.18 (-)	-35.42 (10.495)
Median		-33.55	-39.18	-39.18
Min, Max		-43.5, -23.6	-39.2, -39.2	-43.5, -23.6
Percent change from Baseline to Cycle 30 Day 1				
n	0	2	1	3
Mean (StdDev)		-24.69 (37.348)	-58.96 (-)	-36.11 (33.000)
Median		-24.69	-58.96	-51.09
Min, Max		-51.1, 1.7	-59.0, -59.0	-59.0, 1.7

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=2)	SM-AHN (N=3)	MCL (N=1)	All AdvSM (N=6)
Percent change from Baseline to Cycle 36 Day 1				
n	0	2	1	3
Mean (StdDev)		-35.22 (29.993)	-52.31 (-)	-40.92 (23.392)
Median		-35.22	-52.31	-52.31
Min, Max		-56.4, -14.0	-52.3, -52.3	-56.4, -14.0
Percent change from Baseline to Cycle 42 Day 1				
n	0	2	1	3
Mean (StdDev)		-30.16 (33.617)	-64.86 (-)	-41.73 (31.088)
Median		-30.16	-64.86	-53.93
Min, Max		-53.9, -6.4	-64.9, -64.9	-64.9, -6.4
Percent change from Baseline to Cycle 48 Day 1				
n	0	0	1	1
Mean (StdDev)			-70.25 (-)	-70.25 (-)
Median			-70.25	-70.25
Min, Max			-70.3, -70.3	-70.3, -70.3

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=2)	SM-AHN (N=3)	MCL (N=1)	All AdvSM (N=6)
Baseline				
n	2	3	1	6
Mean (StdDev)	2327.23 (65.450)	2648.96 (589.530)	1435.80 (-)	2339.52 (600.607)
Median	2327.23	2454.60	1435.80	2327.23
Min, Max	2281.0, 2373.5	2181.2, 3311.1	1435.8, 1435.8	1435.8, 3311.1
Percent change from Baseline to Cycle 3 Day 1				
n	1	3	1	5
Mean (StdDev)	-11.20 (-)	-14.38 (8.585)	-7.32 (-)	-12.33 (6.826)
Median	-11.20	-9.54	-7.32	-9.54
Min, Max	-11.2, -11.2	-24.3, -9.3	-7.3, -7.3	-24.3, -7.3
Percent change from Baseline to Cycle 5 Day 1				
n	1	2	1	4
Mean (StdDev)	-17.16 (-)	-15.25 (5.189)	-0.29 (-)	-11.99 (8.401)
Median	-17.16	-15.25	-0.29	-14.37
Min, Max	-17.2, -17.2	-18.9, -11.6	-0.3, -0.3	-18.9, -0.3
Percent change from Baseline to Cycle 7 Day 1				
n	1	3	1	5
Mean (StdDev)	-24.62 (-)	-11.85 (23.063)	-1.16 (-)	-12.27 (18.305)
Median	-24.62	-20.62	-1.16	-20.62
Min, Max	-24.6, -24.6	-29.2, 14.3	-1.2, -1.2	-29.2, 14.3

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=2)	SM-AHN (N=3)	MCL (N=1)	All AdvSM (N=6)
Percent change from Baseline to Cycle 11 Day 1				
n	1	3	1	5
Mean (StdDev)	-32.09 (-)	-13.98 (15.105)	-6.34 (-)	-16.07 (14.325)
Median	-32.09	-7.96	-6.34	-7.96
Min, Max	-32.1, -32.1	-31.2, -2.8	-6.3, -6.3	-32.1, -2.8
Percent change from Baseline to Cycle 18 Day 1				
n	1	2	1	4
Mean (StdDev)	-29.91 (-)	-17.61 (0.466)	-17.36 (-)	-20.62 (6.197)
Median	-29.91	-17.61	-17.36	-17.65
Min, Max	-29.9, -29.9	-17.9, -17.3	-17.4, -17.4	-29.9, -17.3
Percent change from Baseline to Cycle 24 Day 1				
n	1	2	1	4
Mean (StdDev)	-32.16 (-)	-23.70 (18.406)	-6.90 (-)	-21.61 (15.002)
Median	-32.16	-23.70	-6.90	-21.42
Min, Max	-32.2, -32.2	-36.7, -10.7	-6.9, -6.9	-36.7, -6.9
Percent change from Baseline to Cycle 30 Day 1				
n	1	2	1	4
Mean (StdDev)	-34.78 (-)	-13.92 (6.467)	-13.98 (-)	-19.15 (11.069)
Median	-34.78	-13.92	-13.98	-16.23
Min, Max	-34.8, -34.8	-18.5, -9.3	-14.0, -14.0	-34.8, -9.3

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <200 mg
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=2)	SM-AHN (N=3)	MCL (N=1)	All AdvSM (N=6)
Percent change from Baseline to Cycle 36 Day 1				
n	1	2	1	4
Mean (StdDev)	-31.73 (-)	-16.62 (5.599)	-10.36 (-)	-18.83 (9.645)
Median	-31.73	-16.62	-10.36	-16.62
Min, Max	-31.7, -31.7	-20.6, -12.7	-10.4, -10.4	-31.7, -10.4
Percent change from Baseline to Cycle 42 Day 1				
n	0	2	1	3
Mean (StdDev)		-22.30 (6.488)	-8.42 (-)	-17.67 (9.235)
Median		-22.30	-8.42	-17.71
Min, Max		-26.9, -17.7	-8.4, -8.4	-26.9, -8.4
Percent change from Baseline to Cycle 48 Day 1				
n	1	0	1	2
Mean (StdDev)	-27.20 (-)		-23.82 (-)	-25.51 (2.388)
Median	-27.20		-23.82	-25.51
Min, Max	-27.2, -27.2		-23.8, -23.8	-27.2, -23.8

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=7)	SM-AHN (N=37)	MCL (N=14)	All AdvSM (N=58)
Baseline				
n	6	37	14	57
Mean (StdDev)	619.03 (421.590)	963.16 (478.642)	1057.22 (561.839)	950.04 (501.150)
Median	580.26	875.83	815.31	781.57
Min, Max	44.2, 1321.6	298.5, 2600.8	367.4, 2270.0	44.2, 2600.8
Percent change from Baseline to Cycle 3 Day 1				
n	5	27	10	42
Mean (StdDev)	-33.01 (14.921)	-25.44 (28.037)	-26.21 (20.201)	-26.53 (24.814)
Median	-35.23	-29.25	-29.54	-31.57
Min, Max	-47.7, -12.6	-68.1, 51.5	-57.4, 8.3	-68.1, 51.5
Percent change from Baseline to Cycle 5 Day 1				
n	1	7	5	13
Mean (StdDev)	-11.68 (-)	-23.91 (24.185)	-30.28 (22.624)	-25.42 (22.135)
Median	-11.68	-30.14	-25.75	-25.75
Min, Max	-11.7, -11.7	-51.1, 11.9	-56.4, 1.7	-56.4, 11.9
Percent change from Baseline to Cycle 7 Day 1				
n	1	20	6	27
Mean (StdDev)	-9.83 (-)	-24.14 (39.656)	-27.10 (29.743)	-24.27 (36.458)
Median	-9.83	-30.72	-22.49	-27.93
Min, Max	-9.8, -9.8	-84.3, 83.4	-65.9, 5.6	-84.3, 83.4

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=7)	SM-AHN (N=37)	MCL (N=14)	All AdvSM (N=58)
Percent change from Baseline to Cycle 11 Day 1				
n	0	13	4	17
Mean (StdDev)		-38.84 (24.832)	-31.62 (28.046)	-37.14 (24.898)
Median		-44.95	-28.92	-44.03
Min, Max		-70.0, 15.8	-64.9, -3.7	-70.0, 15.8
Percent change from Baseline to Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		-52.33 (-)	-10.38 (-)	-31.35 (29.662)
Median		-52.33	-10.38	-31.35
Min, Max		-52.3, -52.3	-10.4, -10.4	-52.3, -10.4
Percent change from Baseline to Cycle 18 Day 1				
n	0	3	2	5
Mean (StdDev)		-29.63 (20.062)	-55.23 (17.819)	-39.87 (21.843)
Median		-30.18	-55.23	-42.63
Min, Max		-49.4, -9.3	-67.8, -42.6	-67.8, -9.3
Percent change from Baseline to Cycle 24 Day 1				
n	0	3	1	4
Mean (StdDev)		-26.36 (15.953)	-39.18 (-)	-29.57 (14.517)
Median		-23.57	-39.18	-31.37
Min, Max		-43.5, -12.0	-39.2, -39.2	-43.5, -12.0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=7)	SM-AHN (N=37)	MCL (N=14)	All AdvSM (N=58)
Percent change from Baseline to Cycle 30 Day 1				
n	0	3	1	4
Mean (StdDev)		-27.35 (26.810)	-58.96 (-)	-35.25 (26.998)
Median		-32.69	-58.96	-41.89
Min, Max		-51.1, 1.7	-59.0, -59.0	-59.0, 1.7
Percent change from Baseline to Cycle 36 Day 1				
n	0	3	1	4
Mean (StdDev)		-32.86 (21.600)	-52.31 (-)	-37.72 (20.141)
Median		-28.13	-52.31	-40.22
Min, Max		-56.4, -14.0	-52.3, -52.3	-56.4, -14.0
Percent change from Baseline to Cycle 42 Day 1				
n	0	3	1	4
Mean (StdDev)		-30.83 (23.799)	-64.86 (-)	-39.34 (25.828)
Median		-32.18	-64.86	-43.05
Min, Max		-53.9, -6.4	-64.9, -64.9	-64.9, -6.4
Percent change from Baseline to Cycle 48 Day 1				
n	0	0	1	1
Mean (StdDev)			-70.25 (-)	-70.25 (-)
Median			-70.25	-70.25
Min, Max			-70.3, -70.3	-70.3, -70.3

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=7)	SM-AHN (N=37)	MCL (N=14)	All AdvSM (N=58)
Baseline				
n	7	37	14	58
Mean (StdDev)	2296.04 (637.475)	2415.76 (407.513)	2821.92 (723.807)	2499.35 (549.831)
Median	2280.95	2390.27	2919.56	2411.39
Min, Max	1671.6, 3603.1	1707.4, 3311.1	1435.8, 4020.8	1435.8, 4020.8
Percent change from Baseline to Cycle 3 Day 1				
n	6	27	10	43
Mean (StdDev)	-11.20 (6.191)	-12.17 (10.800)	-16.87 (7.809)	-13.12 (9.711)
Median	-11.12	-13.70	-18.84	-13.52
Min, Max	-21.7, -2.7	-27.1, 13.1	-28.2, -6.9	-28.2, 13.1
Percent change from Baseline to Cycle 5 Day 1				
n	2	7	5	14
Mean (StdDev)	-15.58 (2.239)	-8.81 (12.979)	-16.47 (16.353)	-12.51 (13.239)
Median	-15.58	-8.83	-25.57	-12.79
Min, Max	-17.2, -14.0	-26.8, 14.4	-31.4, 2.8	-31.4, 14.4
Percent change from Baseline to Cycle 7 Day 1				
n	2	20	6	28
Mean (StdDev)	-9.00 (22.089)	-16.34 (17.758)	-19.70 (16.611)	-16.54 (17.249)
Median	-9.00	-19.86	-18.61	-19.86
Min, Max	-24.6, 6.6	-42.0, 28.0	-39.5, -1.2	-42.0, 28.0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=7)	SM-AHN (N=37)	MCL (N=14)	All AdvSM (N=58)
Percent change from Baseline to Cycle 11 Day 1				
n	1	13	4	18
Mean (StdDev)	-32.09 (-)	-21.71 (14.946)	-27.03 (19.464)	-23.47 (15.306)
Median	-32.09	-21.57	-28.17	-22.12
Min, Max	-32.1, -32.1	-43.8, 1.1	-45.4, -6.3	-45.4, 1.1
Percent change from Baseline to Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		-20.93 (-)	-48.86 (-)	-34.90 (19.748)
Median		-20.93	-48.86	-34.90
Min, Max		-20.9, -20.9	-48.9, -48.9	-48.9, -20.9
Percent change from Baseline to Cycle 18 Day 1				
n	1	3	2	6
Mean (StdDev)	-29.91 (-)	-19.62 (3.492)	-11.63 (8.106)	-18.67 (7.980)
Median	-29.91	-17.94	-11.63	-17.65
Min, Max	-29.9, -29.9	-23.6, -17.3	-17.4, -5.9	-29.9, -5.9
Percent change from Baseline to Cycle 24 Day 1				
n	1	3	1	5
Mean (StdDev)	-32.16 (-)	-22.00 (13.342)	-6.90 (-)	-21.01 (13.061)
Median	-32.16	-18.61	-6.90	-18.61
Min, Max	-32.2, -32.2	-36.7, -10.7	-6.9, -6.9	-36.7, -6.9

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: <300 mg
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=7)	SM-AHN (N=37)	MCL (N=14)	All AdvSM (N=58)
Percent change from Baseline to Cycle 30 Day 1				
n	1	3	1	5
Mean (StdDev)	-34.78 (-)	-13.66 (4.595)	-13.98 (-)	-17.94 (9.957)
Median	-34.78	-13.13	-13.98	-13.98
Min, Max	-34.8, -34.8	-18.5, -9.3	-14.0, -14.0	-34.8, -9.3
Percent change from Baseline to Cycle 36 Day 1				
n	1	3	1	5
Mean (StdDev)	-31.73 (-)	-16.88 (3.984)	-10.36 (-)	-18.55 (8.378)
Median	-31.73	-17.40	-10.36	-17.40
Min, Max	-31.7, -31.7	-20.6, -12.7	-10.4, -10.4	-31.7, -10.4
Percent change from Baseline to Cycle 42 Day 1				
n	0	3	1	4
Mean (StdDev)		-22.82 (4.674)	-8.42 (-)	-19.22 (8.149)
Median		-23.85	-8.42	-20.78
Min, Max		-26.9, -17.7	-8.4, -8.4	-26.9, -8.4
Percent change from Baseline to Cycle 48 Day 1				
n	1	0	1	2
Mean (StdDev)	-27.20 (-)		-23.82 (-)	-25.51 (2.388)
Median	-27.20		-23.82	-25.51
Min, Max	-27.2, -27.2		-23.8, -23.8	-27.2, -23.8

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=5)	SM-AHN (N=34)	MCL (N=13)	All AdvSM (N=52)
Baseline				
n	5	34	13	52
Mean (StdDev)	734.00 (350.759)	962.03 (484.445)	1093.87 (567.100)	973.07 (496.569)
Median	651.85	843.09	849.05	795.96
Min, Max	435.6, 1321.6	298.5, 2600.8	367.4, 2270.0	298.5, 2600.8
Percent change from Baseline to Cycle 3 Day 1				
n	5	24	9	38
Mean (StdDev)	-33.01 (14.921)	-26.37 (28.719)	-28.62 (19.853)	-27.77 (25.043)
Median	-35.23	-31.57	-38.44	-34.56
Min, Max	-47.7, -12.6	-68.1, 51.5	-57.4, 8.3	-68.1, 51.5
Percent change from Baseline to Cycle 5 Day 1				
n	1	5	4	10
Mean (StdDev)	-11.68 (-)	-20.37 (28.621)	-38.26 (16.053)	-26.66 (23.593)
Median	-11.68	-6.96	-36.42	-24.77
Min, Max	-11.7, -11.7	-51.1, 11.9	-56.4, -23.8	-56.4, 11.9
Percent change from Baseline to Cycle 7 Day 1				
n	1	17	5	23
Mean (StdDev)	-9.83 (-)	-27.79 (41.102)	-33.64 (28.027)	-28.28 (37.332)
Median	-9.83	-36.11	-23.44	-28.13
Min, Max	-9.8, -9.8	-84.3, 83.4	-65.9, 1.4	-84.3, 83.4

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=5)	SM-AHN (N=34)	MCL (N=13)	All AdvSM (N=52)
Percent change from Baseline to Cycle 11 Day 1				
n	0	10	3	13
Mean (StdDev)		-47.73 (14.777)	-37.56 (31.118)	-45.38 (18.575)
Median		-50.59	-44.03	-48.22
Min, Max		-70.0, -30.4	-64.9, -3.7	-70.0, -3.7
Percent change from Baseline to Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		-52.33 (-)	-10.38 (-)	-31.35 (29.662)
Median		-52.33	-10.38	-31.35
Min, Max		-52.3, -52.3	-10.4, -10.4	-52.3, -10.4
Percent change from Baseline to Cycle 18 Day 1				
n	0	1	1	2
Mean (StdDev)		-30.18 (-)	-67.83 (-)	-49.00 (26.621)
Median		-30.18	-67.83	-49.00
Min, Max		-30.2, -30.2	-67.8, -67.8	-67.8, -30.2
Percent change from Baseline to Cycle 24 Day 1				
n	0	1	0	1
Mean (StdDev)		-11.99 (-)		-11.99 (-)
Median		-11.99		-11.99
Min, Max		-12.0, -12.0		-12.0, -12.0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=5)	SM-AHN (N=34)	MCL (N=13)	All AdvSM (N=52)
Percent change from Baseline to Cycle 30 Day 1				
n	0	1	0	1
Mean (StdDev)		-32.69 (-)		-32.69 (-)
Median		-32.69		-32.69
Min, Max		-32.7, -32.7		-32.7, -32.7
Percent change from Baseline to Cycle 36 Day 1				
n	0	1	0	1
Mean (StdDev)		-28.13 (-)		-28.13 (-)
Median		-28.13		-28.13
Min, Max		-28.1, -28.1		-28.1, -28.1
Percent change from Baseline to Cycle 42 Day 1				
n	0	1	0	1
Mean (StdDev)		-32.18 (-)		-32.18 (-)
Median		-32.18		-32.18
Min, Max		-32.2, -32.2		-32.2, -32.2

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=5)	SM-AHN (N=34)	MCL (N=13)	All AdvSM (N=52)
Baseline				
n	5	34	13	52
Mean (StdDev)	2283.57 (779.621)	2395.19 (393.345)	2928.55 (628.592)	2517.79 (546.957)
Median	2101.22	2375.96	2932.82	2442.97
Min, Max	1671.6, 3603.1	1707.4, 3239.5	1660.5, 4020.8	1660.5, 4020.8
Percent change from Baseline to Cycle 3 Day 1				
n	5	24	9	38
Mean (StdDev)	-11.20 (6.921)	-11.89 (11.168)	-17.93 (7.481)	-13.23 (10.095)
Median	-11.04	-14.87	-19.68	-14.87
Min, Max	-21.7, -2.7	-27.1, 13.1	-28.2, -6.9	-28.2, 13.1
Percent change from Baseline to Cycle 5 Day 1				
n	1	5	4	10
Mean (StdDev)	-14.00 (-)	-6.23 (14.727)	-20.51 (15.735)	-12.72 (15.149)
Median	-14.00	-7.18	-26.73	-11.41
Min, Max	-14.0, -14.0	-26.8, 14.4	-31.4, 2.8	-31.4, 14.4
Percent change from Baseline to Cycle 7 Day 1				
n	1	17	5	23
Mean (StdDev)	6.62 (-)	-17.13 (17.422)	-23.40 (15.552)	-17.46 (17.297)
Median	6.62	-19.10	-29.44	-19.10
Min, Max	6.6, 6.6	-42.0, 28.0	-39.5, -5.9	-42.0, 28.0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=5)	SM-AHN (N=34)	MCL (N=13)	All AdvSM (N=52)
Percent change from Baseline to Cycle 11 Day 1				
n	0	10	3	13
Mean (StdDev)		-24.02 (14.876)	-33.93 (16.813)	-26.31 (15.231)
Median		-22.12	-41.71	-22.68
Min, Max		-43.8, 1.1	-45.4, -14.6	-45.4, 1.1
Percent change from Baseline to Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		-20.93 (-)	-48.86 (-)	-34.90 (19.748)
Median		-20.93	-48.86	-34.90
Min, Max		-20.9, -20.9	-48.9, -48.9	-48.9, -20.9
Percent change from Baseline to Cycle 18 Day 1				
n	0	1	1	2
Mean (StdDev)		-23.63 (-)	-5.89 (-)	-14.76 (12.545)
Median		-23.63	-5.89	-14.76
Min, Max		-23.6, -23.6	-5.9, -5.9	-23.6, -5.9
Percent change from Baseline to Cycle 24 Day 1				
n	0	1	0	1
Mean (StdDev)		-18.61 (-)		-18.61 (-)
Median		-18.61		-18.61
Min, Max		-18.6, -18.6		-18.6, -18.6

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=5)	SM-AHN (N=34)	MCL (N=13)	All AdvSM (N=52)
Percent change from Baseline to Cycle 30 Day 1				
n	0	1	0	1
Mean (StdDev)		-13.13 (-)		-13.13 (-)
Median		-13.13		-13.13
Min, Max		-13.1, -13.1		-13.1, -13.1
Percent change from Baseline to Cycle 36 Day 1				
n	0	1	0	1
Mean (StdDev)		-17.40 (-)		-17.40 (-)
Median		-17.40		-17.40
Min, Max		-17.4, -17.4		-17.4, -17.4
Percent change from Baseline to Cycle 42 Day 1				
n	0	1	0	1
Mean (StdDev)		-23.85 (-)		-23.85 (-)
Median		-23.85		-23.85
Min, Max		-23.9, -23.9		-23.9, -23.9

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Baseline				
n	4	12	2	18
Mean (StdDev)	919.82 (677.582)	1181.24 (549.211)	1099.34 (1190.124)	1114.05 (609.591)
Median	638.71	1147.89	1099.34	1092.31
Min, Max	479.2, 1922.7	359.4, 2262.7	257.8, 1940.9	257.8, 2262.7
Percent change from Baseline to Cycle 3 Day 1				
n	4	12	2	18
Mean (StdDev)	-38.38 (5.088)	-47.09 (13.835)	-28.44 (9.542)	-43.08 (13.248)
Median	-40.16	-49.32	-28.44	-43.05
Min, Max	-42.3, -30.9	-75.9, -24.0	-35.2, -21.7	-75.9, -21.7
Percent change from Baseline to Cycle 5 Day 1				
n	3	11	2	16
Mean (StdDev)	-35.72 (11.544)	-50.47 (16.423)	-46.74 (28.450)	-47.23 (16.905)
Median	-36.01	-51.38	-46.74	-49.06
Min, Max	-47.1, -24.0	-82.3, -21.1	-66.9, -26.6	-82.3, -21.1
Percent change from Baseline to Cycle 7 Day 1				
n	3	9	1	13
Mean (StdDev)	-36.72 (25.121)	-57.05 (14.416)	0.32 (-)	-47.94 (23.054)
Median	-41.80	-57.05	0.32	-55.35
Min, Max	-58.9, -9.5	-76.2, -25.7	0.3, 0.3	-76.2, 0.3

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Percent change from Baseline to Cycle 11 Day 1				
n	3	5	1	9
Mean (StdDev)	-50.39 (29.321)	-60.06 (19.717)	-64.21 (-)	-57.30 (20.927)
Median	-45.65	-67.54	-64.21	-65.00
Min, Max	-81.8, -23.7	-74.4, -25.3	-64.2, -64.2	-81.8, -23.7
Percent change from Baseline to Cycle 18 Day 1				
n	2	5	0	7
Mean (StdDev)	-50.88 (27.564)	-55.07 (28.271)		-53.87 (25.762)
Median	-50.88	-67.22		-67.22
Min, Max	-70.4, -31.4	-81.3, -9.7		-81.3, -9.7
Percent change from Baseline to Cycle 24 Day 1				
n	2	4	0	6
Mean (StdDev)	-44.54 (36.975)	-46.31 (37.265)		-45.72 (33.279)
Median	-44.54	-49.11		-48.59
Min, Max	-70.7, -18.4	-83.0, -4.1		-83.0, -4.1
Percent change from Baseline to Cycle 30 Day 1				
n	1	0	0	1
Mean (StdDev)	-33.85 (-)			-33.85 (-)
Median	-33.85			-33.85
Min, Max	-33.9, -33.9			-33.9, -33.9

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Percent change from Baseline to Cycle 36 Day 1				
n	1	0	0	1
Mean (StdDev)	-35.28 (-)			-35.28 (-)
Median	-35.28			-35.28
Min, Max	-35.3, -35.3			-35.3, -35.3

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Baseline				
n	4	13	3	20
Mean (StdDev)	2246.32 (377.128)	2276.97 (657.353)	2090.15 (173.239)	2242.82 (550.463)
Median	2184.95	2112.93	2020.24	2070.22
Min, Max	1885.0, 2730.4	1436.4, 3624.1	1962.8, 2287.4	1436.4, 3624.1
Percent change from Baseline to Cycle 3 Day 1				
n	3	13	3	19
Mean (StdDev)	-19.89 (8.243)	-15.02 (8.078)	-13.43 (18.520)	-15.54 (9.657)
Median	-21.54	-15.30	-19.66	-17.22
Min, Max	-27.2, -10.9	-25.7, -2.9	-28.0, 7.4	-28.0, 7.4
Percent change from Baseline to Cycle 5 Day 1				
n	3	12	3	18
Mean (StdDev)	-5.73 (8.742)	-17.84 (9.710)	-24.13 (11.723)	-16.87 (10.864)
Median	-3.69	-20.34	-27.20	-19.44
Min, Max	-15.3, 1.8	-29.3, -0.2	-34.0, -11.2	-34.0, 1.8
Percent change from Baseline to Cycle 7 Day 1				
n	3	10	2	15
Mean (StdDev)	-2.76 (18.204)	-18.63 (9.341)	-28.09 (0.629)	-16.72 (12.896)
Median	-0.91	-20.37	-28.09	-20.67
Min, Max	-21.8, 14.4	-29.8, -2.1	-28.5, -27.6	-29.8, 14.4

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Percent change from Baseline to Cycle 11 Day 1				
n	2	6	2	10
Mean (StdDev)	-18.26 (16.348)	-20.93 (10.757)	-13.47 (25.278)	-18.90 (13.205)
Median	-18.26	-22.16	-13.47	-22.16
Min, Max	-29.8, -6.7	-33.1, -4.8	-31.3, 4.4	-33.1, 4.4
Percent change from Baseline to Cycle 18 Day 1				
n	2	6	1	9
Mean (StdDev)	-11.11 (6.466)	-25.99 (10.156)	-36.01 (-)	-23.80 (11.496)
Median	-11.11	-26.38	-36.01	-26.03
Min, Max	-15.7, -6.5	-42.8, -12.8	-36.0, -36.0	-42.8, -6.5
Percent change from Baseline to Cycle 24 Day 1				
n	2	4	1	7
Mean (StdDev)	-6.04 (10.388)	-24.53 (12.304)	-36.99 (-)	-21.02 (14.803)
Median	-6.04	-20.66	-36.99	-19.70
Min, Max	-13.4, 1.3	-42.4, -14.4	-37.0, -37.0	-42.4, 1.3
Percent change from Baseline to Cycle 30 Day 1				
n	1	0	1	2
Mean (StdDev)	-17.44 (-)		-33.42 (-)	-25.43 (11.299)
Median	-17.44		-33.42	-25.43
Min, Max	-17.4, -17.4		-33.4, -33.4	-33.4, -17.4

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 300 mg
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=4)	SM-AHN (N=13)	MCL (N=3)	All AdvSM (N=20)
Percent change from Baseline to Cycle 36 Day 1				
n	1	0	0	1
Mean (StdDev)	-14.22 (-)			-14.22 (-)
Median	-14.22			-14.22
Min, Max	-14.2, -14.2			-14.2, -14.2

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=9)	SM-AHN (N=47)	MCL (N=16)	All AdvSM (N=72)
Baseline				
n	9	46	15	70
Mean (StdDev)	816.58 (493.230)	1019.22 (505.279)	1094.60 (613.868)	1009.32 (526.936)
Median	651.85	1024.58	849.05	862.44
Min, Max	435.6, 1922.7	298.5, 2600.8	257.8, 2270.0	257.8, 2600.8
Percent change from Baseline to Cycle 3 Day 1				
n	9	36	11	56
Mean (StdDev)	-35.40 (11.361)	-33.27 (26.463)	-28.59 (18.012)	-32.69 (22.982)
Median	-39.55	-40.37	-35.19	-39.27
Min, Max	-47.7, -12.6	-75.9, 51.5	-57.4, 8.3	-75.9, 51.5
Percent change from Baseline to Cycle 5 Day 1				
n	4	16	6	26
Mean (StdDev)	-29.71 (15.273)	-41.06 (24.613)	-41.08 (18.321)	-39.32 (21.819)
Median	-30.02	-50.60	-36.85	-46.65
Min, Max	-47.1, -11.7	-82.3, 11.9	-66.9, -23.8	-82.3, 11.9
Percent change from Baseline to Cycle 7 Day 1				
n	4	26	6	36
Mean (StdDev)	-30.00 (24.527)	-37.92 (36.731)	-27.98 (28.647)	-35.38 (33.911)
Median	-25.81	-44.96	-22.49	-40.10
Min, Max	-58.9, -9.5	-84.3, 83.4	-65.9, 1.4	-84.3, 83.4

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=9)	SM-AHN (N=47)	MCL (N=16)	All AdvSM (N=72)
Percent change from Baseline to Cycle 11 Day 1				
n	3	15	4	22
Mean (StdDev)	-50.39 (29.321)	-51.84 (16.961)	-44.22 (28.689)	-50.25 (19.999)
Median	-45.65	-53.73	-54.12	-53.34
Min, Max	-81.8, -23.7	-74.4, -25.3	-64.9, -3.7	-81.8, -3.7
Percent change from Baseline to Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		-52.33 (-)	-10.38 (-)	-31.35 (29.662)
Median		-52.33	-10.38	-31.35
Min, Max		-52.3, -52.3	-10.4, -10.4	-52.3, -10.4
Percent change from Baseline to Cycle 18 Day 1				
n	2	6	1	9
Mean (StdDev)	-50.88 (27.564)	-50.92 (27.253)	-67.83 (-)	-52.79 (24.309)
Median	-50.88	-56.99	-67.83	-67.22
Min, Max	-70.4, -31.4	-81.3, -9.7	-67.8, -67.8	-81.3, -9.7
Percent change from Baseline to Cycle 24 Day 1				
n	2	5	0	7
Mean (StdDev)	-44.54 (36.975)	-39.44 (35.736)		-40.90 (32.946)
Median	-44.54	-26.50		-26.50
Min, Max	-70.7, -18.4	-83.0, -4.1		-83.0, -4.1

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=9)	SM-AHN (N=47)	MCL (N=16)	All AdvSM (N=72)
Percent change from Baseline to Cycle 30 Day 1				
n	1	1	0	2
Mean (StdDev)	-33.85 (-)	-32.69 (-)		-33.27 (0.822)
Median	-33.85	-32.69		-33.27
Min, Max	-33.9, -33.9	-32.7, -32.7		-33.9, -32.7
Percent change from Baseline to Cycle 36 Day 1				
n	1	1	0	2
Mean (StdDev)	-35.28 (-)	-28.13 (-)		-31.71 (5.054)
Median	-35.28	-28.13		-31.71
Min, Max	-35.3, -35.3	-28.1, -28.1		-35.3, -28.1
Percent change from Baseline to Cycle 42 Day 1				
n	0	1	0	1
Mean (StdDev)		-32.18 (-)		-32.18 (-)
Median		-32.18		-32.18
Min, Max		-32.2, -32.2		-32.2, -32.2

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=9)	SM-AHN (N=47)	MCL (N=16)	All AdvSM (N=72)
Baseline				
n	9	47	16	72
Mean (StdDev)	2267.02 (598.017)	2362.49 (476.002)	2771.35 (659.035)	2441.41 (557.998)
Median	2101.22	2361.64	2904.83	2355.69
Min, Max	1671.6, 3603.1	1436.4, 3624.1	1660.5, 4020.8	1436.4, 4020.8
Percent change from Baseline to Cycle 3 Day 1				
n	8	37	12	57
Mean (StdDev)	-14.46 (8.188)	-12.99 (10.185)	-16.80 (10.354)	-14.00 (9.925)
Median	-11.63	-15.30	-19.67	-16.05
Min, Max	-27.2, -2.7	-27.1, 13.1	-28.2, 7.4	-28.2, 13.1
Percent change from Baseline to Cycle 5 Day 1				
n	4	17	7	28
Mean (StdDev)	-7.79 (8.248)	-14.43 (12.197)	-22.06 (13.165)	-15.39 (12.446)
Median	-8.84	-18.78	-27.20	-17.04
Min, Max	-15.3, 1.8	-29.3, 14.4	-34.0, 2.8	-34.0, 14.4
Percent change from Baseline to Cycle 7 Day 1				
n	4	27	7	38
Mean (StdDev)	-0.42 (15.586)	-17.69 (14.749)	-24.74 (12.905)	-17.17 (15.523)
Median	2.85	-20.08	-28.54	-20.37
Min, Max	-21.8, 14.4	-42.0, 28.0	-39.5, -5.9	-42.0, 28.0

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=9)	SM-AHN (N=47)	MCL (N=16)	All AdvSM (N=72)
Percent change from Baseline to Cycle 11 Day 1				
n	2	16	5	23
Mean (StdDev)	-18.26 (16.348)	-22.86 (13.181)	-25.75 (20.657)	-23.09 (14.559)
Median	-18.26	-22.12	-31.34	-22.68
Min, Max	-29.8, -6.7	-43.8, 1.1	-45.4, 4.4	-45.4, 4.4
Percent change from Baseline to Cycle 17 Day 1				
n	0	1	1	2
Mean (StdDev)		-20.93 (-)	-48.86 (-)	-34.90 (19.748)
Median		-20.93	-48.86	-34.90
Min, Max		-20.9, -20.9	-48.9, -48.9	-48.9, -20.9
Percent change from Baseline to Cycle 18 Day 1				
n	2	7	2	11
Mean (StdDev)	-11.11 (6.466)	-25.66 (9.314)	-20.95 (21.294)	-22.16 (11.611)
Median	-11.11	-26.03	-20.95	-23.63
Min, Max	-15.7, -6.5	-42.8, -12.8	-36.0, -5.9	-42.8, -5.9
Percent change from Baseline to Cycle 24 Day 1				
n	2	5	1	8
Mean (StdDev)	-6.04 (10.388)	-23.34 (10.979)	-36.99 (-)	-20.72 (13.731)
Median	-6.04	-19.70	-36.99	-19.15
Min, Max	-13.4, 1.3	-42.4, -14.4	-37.0, -37.0	-42.4, 1.3

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg and 300 mg
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=9)	SM-AHN (N=47)	MCL (N=16)	All AdvSM (N=72)
Percent change from Baseline to Cycle 30 Day 1				
n	1	1	1	3
Mean (StdDev)	-17.44 (-)	-13.13 (-)	-33.42 (-)	-21.33 (10.689)
Median	-17.44	-13.13	-33.42	-17.44
Min, Max	-17.4, -17.4	-13.1, -13.1	-33.4, -33.4	-33.4, -13.1
Percent change from Baseline to Cycle 36 Day 1				
n	1	1	0	2
Mean (StdDev)	-14.22 (-)	-17.40 (-)		-15.81 (2.247)
Median	-14.22	-17.40		-15.81
Min, Max	-14.2, -14.2	-17.4, -17.4		-17.4, -14.2
Percent change from Baseline to Cycle 42 Day 1				
n	0	1	0	1
Mean (StdDev)		-23.85 (-)		-23.85 (-)
Median		-23.85		-23.85
Min, Max		-23.9, -23.9		-23.9, -23.9

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Baseline				
n	1	4	0	5
Mean (StdDev)	163.41 (-)	1058.92 (596.395)		879.82 (653.569)
Median	163.41	1008.52		580.47
Min, Max	163.4, 163.4	521.8, 1696.9		163.4, 1696.9
Percent change from Baseline to Cycle 3 Day 1				
n	1	3	0	4
Mean (StdDev)	-42.13 (-)	-31.50 (17.373)		-34.16 (15.147)
Median	-42.13	-29.16		-35.64
Min, Max	-42.1, -42.1	-49.9, -15.4		-49.9, -15.4
Percent change from Baseline to Cycle 5 Day 1				
n	1	3	0	4
Mean (StdDev)	-40.95 (-)	-28.73 (29.433)		-31.79 (24.797)
Median	-40.95	-13.62		-27.29
Min, Max	-41.0, -41.0	-62.7, -9.9		-62.7, -9.9
Percent change from Baseline to Cycle 7 Day 1				
n	1	2	0	3
Mean (StdDev)	-26.28 (-)	-50.12 (21.253)		-42.17 (20.380)
Median	-26.28	-50.12		-35.09
Min, Max	-26.3, -26.3	-65.1, -35.1		-65.1, -26.3

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Percent change from Baseline to Cycle 11 Day 1				
n	0	2	0	2
Mean (StdDev)		-14.27 (15.584)		-14.27 (15.584)
Median		-14.27		-14.27
Min, Max		-25.3, -3.2		-25.3, -3.2
Percent change from Baseline to Cycle 18 Day 1				
n	0	1	0	1
Mean (StdDev)		-1.23 (-)		-1.23 (-)
Median		-1.23		-1.23
Min, Max		-1.2, -1.2		-1.2, -1.2
Percent change from Baseline to Cycle 24 Day 1				
n	0	2	0	2
Mean (StdDev)		-34.36 (66.012)		-34.36 (66.012)
Median		-34.36		-34.36
Min, Max		-81.0, 12.3		-81.0, 12.3
Percent change from Baseline to Cycle 30 Day 1				
n	0	1	0	1
Mean (StdDev)		53.13 (-)		53.13 (-)
Median		53.13		53.13
Min, Max		53.1, 53.1		53.1, 53.1

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg
Organ = Spleen

Volume (mL) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Percent change from Baseline to Cycle 36 Day 1				
n	0	1	0	1
Mean (StdDev)		55.50 (-)		55.50 (-)
Median		55.50		55.50
Min, Max		55.5, 55.5		55.5, 55.5

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Baseline				
n	1	4	0	5
Mean (StdDev)	1019.93 (-)	2777.23 (487.520)		2425.77 (892.121)
Median	1019.93	2791.67		2682.43
Min, Max	1019.9, 1019.9	2176.1, 3349.5		1019.9, 3349.5
Percent change from Baseline to Cycle 3 Day 1				
n	1	3	0	4
Mean (StdDev)	-0.25 (-)	-16.36 (12.890)		-12.33 (13.255)
Median	-0.25	-12.24		-9.14
Min, Max	-0.2, -0.2	-30.8, -6.0		-30.8, -0.2
Percent change from Baseline to Cycle 5 Day 1				
n	1	3	0	4
Mean (StdDev)	1.96 (-)	-23.22 (12.196)		-16.92 (16.052)
Median	1.96	-18.28		-16.27
Min, Max	2.0, 2.0	-37.1, -14.3		-37.1, 2.0
Percent change from Baseline to Cycle 7 Day 1				
n	1	2	0	3
Mean (StdDev)	-2.62 (-)	-26.36 (18.459)		-18.45 (18.927)
Median	-2.62	-26.36		-13.31
Min, Max	-2.6, -2.6	-39.4, -13.3		-39.4, -2.6

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Percent change from Baseline to Cycle 11 Day 1				
n	0	2	0	2
Mean (StdDev)		-15.86 (1.474)		-15.86 (1.474)
Median		-15.86		-15.86
Min, Max		-16.9, -14.8		-16.9, -14.8
Percent change from Baseline to Cycle 18 Day 1				
n	0	1	0	1
Mean (StdDev)		-21.03 (-)		-21.03 (-)
Median		-21.03		-21.03
Min, Max		-21.0, -21.0		-21.0, -21.0
Percent change from Baseline to Cycle 24 Day 1				
n	0	2	0	2
Mean (StdDev)		-34.11 (13.517)		-34.11 (13.517)
Median		-34.11		-34.11
Min, Max		-43.7, -24.5		-43.7, -24.5
Percent change from Baseline to Cycle 30 Day 1				
n	0	1	0	1
Mean (StdDev)		-0.88 (-)		-0.88 (-)
Median		-0.88		-0.88
Min, Max		-0.9, -0.9		-0.9, -0.9

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 35.2.8.2
Summary of Spleen and Liver Volume Percent Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study: BLU-285-2101 and BLU-285-2202

Starting Dose: 400 mg
Organ = Liver

Volume (mL) Percent Change from Baseline	ASM (N=1)	SM-AHN (N=4)	MCL (N=0)	All AdvSM (N=5)
Percent change from Baseline to Cycle 36 Day 1				
n	0	1	0	1
Mean (StdDev)		-6.63 (-)		-6.63 (-)
Median		-6.63		-6.63
Min, Max		-6.6, -6.6		-6.6, -6.6

Notes: Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date. Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-vol-pchg-advsm.sas Date: 19:35/27SEP2021

Table 99.2.8.3.1b
Summary of Spleen Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101 & 200 mg Dose Group

Prior antineoplastic therapy = Yes

Best Response	ASM (N=1) n (%)	SM-AHN (N=7) n (%)	MCL (N=4) n (%)	All AdvSM (N=12) n (%)	ISM/SSM (N=1) n (%)	All Patients (N=13) n (%)
Patients with baseline Spleen Volume assessment	1	7	4	12	1	13
Patients achieved >= 35 % Spleen Volume (mL) reduction from baseline	0	4 (57.1)	4 (100.0)	8 (66.7)	1 (100.0)	9 (69.2)
Patients with baseline Spleen Palpation >=5 cm	1	2	1	4	0	4
Patients achieved >= 35 % Spleen Volume (mL) reduction from baseline	0	2 (100.0)	1 (100.0)	3 (75.0)	0	3 (75.0)
Patients with palpable spleen at baseline	1	3	1	5	0	5
Patients become non-palpable for patients who has palpable spleen at baseline	0	0	1 (100.0)	1 (20.0)	0	1 (20.0)

Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date.
Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/EMA_D120/t99.2.8.3.1b-vol-resp-pant.sas Date: 10:41/04AUG2021

Table 99.2.8.3.1b
Summary of Spleen Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101 & <=200 mg Dose Group

Prior antineoplastic therapy = Yes

Best Response	ASM (N=2) n (%)	SM-AHN (N=9) n (%)	MCL (N=5) n (%)	All AdvSM (N=16) n (%)	ISM/SSM (N=4) n (%)	All Patients (N=20) n (%)
Patients with baseline Spleen Volume assessment	1	9	5	15	4	19
Patients achieved >= 35 % Spleen Volume (mL) reduction from baseline	0	6 (66.7)	5 (100.0)	11 (73.3)	2 (50.0)	13 (68.4)
Patients with baseline Spleen Palpation >=5 cm	1	3	1	5	0	5
Patients achieved >= 35 % Spleen Volume (mL) reduction from baseline	0	3 (100.0)	1 (100.0)	4 (80.0)	0	4 (80.0)
Patients with palpable spleen at baseline	1	4	1	6	0	6
Patients become non-palpable for patients who has palpable spleen at baseline	0	1 (25.0)	1 (100.0)	2 (33.3)	0	2 (33.3)

Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date.
Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/EMA_D120/t99.2.8.3.1b-vol-resp-pant.sas Date: 10:41/04AUG2021

Table 99.2.8.3.1b
Summary of Spleen Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101 & All Dose Groups

Prior antineoplastic therapy = Yes

Best Response	ASM (N=7) n (%)	SM-AHN (N=26) n (%)	MCL (N=8) n (%)	All AdvSM (N=41) n (%)	ISM/SSM (N=9) n (%)	All Patients (N=50) n (%)
Patients with baseline Spleen Volume assessment	6	25	7	38	9	47
Patients achieved >= 35 % Spleen Volume (mL) reduction from baseline	5 (83.3)	20 (80.0)	6 (85.7)	31 (81.6)	6 (66.7)	37 (78.7)
Patients with baseline Spleen Palpation >=5 cm	3	12	2	17	1	18
Patients achieved >= 35 % Spleen Volume (mL) reduction from baseline	2 (66.7)	11 (91.7)	2 (100.0)	15 (88.2)	1 (100.0)	16 (88.9)
Patients with palpable spleen at baseline	4	14	2	20	2	22
Patients become non-palpable for patients who has palpable spleen at baseline	3 (75.0)	9 (64.3)	1 (50.0)	13 (65.0)	2 (100.0)	15 (68.2)

Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date.
Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/EMA_D120/t99.2.8.3.1b-vol-resp-pant.sas Date: 10:41/04AUG2021

Table 99.2.8.3.1b
Summary of Spleen Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101 & 200 mg Dose Group

Prior antineoplastic therapy = No

Best Response	ASM (N=0) n (%)	SM-AHN (N=6) n (%)	MCL (N=2) n (%)	All AdvSM (N=8) n (%)	ISM/SSM (N=0) n (%)	All Patients (N=8) n (%)
Patients with baseline Spleen Volume assessment	0	6	2	8	0	8
Patients achieved >= 35 % Spleen Volume (mL) reduction from baseline	0	4 (66.7)	2 (100.0)	6 (75.0)	0	6 (75.0)
Patients with baseline Spleen Palpation >=5 cm	0	0	2	2	0	2
Patients achieved >= 35 % Spleen Volume (mL) reduction from baseline	0	0	2 (100.0)	2 (100.0)	0	2 (100.0)
Patients with palpable spleen at baseline	0	1	2	3	0	3
Patients become non-palpable for patients who has palpable spleen at baseline	0	1 (100.0)	2 (100.0)	3 (100.0)	0	3 (100.0)

Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date.
Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/EMA_D120/t99.2.8.3.1b-vol-resp-pant.sas Date: 10:41/04AUG2021

Table 99.2.8.3.1b
Summary of Spleen Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101 & <=200 mg Dose Group

Prior antineoplastic therapy = No

Best Response	ASM (N=0) n (%)	SM-AHN (N=11) n (%)	MCL (N=2) n (%)	All AdvSM (N=13) n (%)	ISM/SSM (N=2) n (%)	All Patients (N=15) n (%)
Patients with baseline Spleen Volume assessment	0	11	2	13	2	15
Patients achieved >= 35 % Spleen Volume (mL) reduction from baseline	0	8 (72.7)	2 (100.0)	10 (76.9)	1 (50.0)	11 (73.3)
Patients with baseline Spleen Palpation >=5 cm	0	3	2	5	0	5
Patients achieved >= 35 % Spleen Volume (mL) reduction from baseline	0	2 (66.7)	2 (100.0)	4 (80.0)	0	4 (80.0)
Patients with palpable spleen at baseline	0	6	2	8	0	8
Patients become non-palpable for patients who has palpable spleen at baseline	0	5 (83.3)	2 (100.0)	7 (87.5)	0	7 (87.5)

Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date.
Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/EMA_D120/t99.2.8.3.1b-vol-resp-pant.sas Date: 10:41/04AUG2021

Table 99.2.8.3.1b
Summary of Spleen Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101 & All Dose Groups

Prior antineoplastic therapy = No

Best Response	ASM (N=1) n (%)	SM-AHN (N=22) n (%)	MCL (N=5) n (%)	All AdvSM (N=28) n (%)	ISM/SSM (N=7) n (%)	All Patients (N=35) n (%)
Patients with baseline Spleen Volume assessment	1	22	5	28	7	35
Patients achieved >= 35 % Spleen Volume (mL) reduction from baseline	1 (100.0)	17 (77.3)	5 (100.0)	23 (82.1)	5 (71.4)	28 (80.0)
Patients with baseline Spleen Palpation >=5 cm	1	8	4	13	2	15
Patients achieved >= 35 % Spleen Volume (mL) reduction from baseline	1 (100.0)	6 (75.0)	4 (100.0)	11 (84.6)	2 (100.0)	13 (86.7)
Patients with palpable spleen at baseline	1	15	5	21	5	26
Patients become non-palpable for patients who has palpable spleen at baseline	1 (100.0)	14 (93.3)	5 (100.0)	20 (95.2)	5 (100.0)	25 (96.2)

Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date.
Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/EMA_D120/t99.2.8.3.1b-vol-resp-pant.sas Date: 10:41/04AUG2021

Table 99.2.8.3.1b
Summary of Spleen Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2202 & 200 mg Dose Group

Prior antineoplastic therapy = Yes

Best Response	ASM (N=4) n (%)	SM-AHN (N=27) n (%)	MCL (N=9) n (%)	All AdvSM (N=40) n (%)
Patients with baseline Spleen Volume assessment	4	27	9	40
Patients achieved >= 35 % Spleen Volume (mL) reduction from baseline	3 (75.0)	14 (51.9)	3 (33.3)	20 (50.0)
Patients with baseline Spleen Palpation >=5 cm	1	9	4	14
Patients achieved >= 35 % Spleen Volume (mL) reduction from baseline	1 (100.0)	4 (44.4)	2 (50.0)	7 (50.0)
Patients with palpable spleen at baseline	2	15	4	21
Patients become non-palpable for patients who has palpable spleen at baseline	1 (50.0)	10 (66.7)	1 (25.0)	12 (57.1)

Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date.
Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/EMA_D120/t99.2.8.3.1b-vol-resp-pant.sas Date: 10:41/04AUG2021

Table 99.2.8.3.1b
Summary of Spleen Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2202 & <=200 mg Dose Group

Prior antineoplastic therapy = Yes

Best Response	ASM (N=5) n (%)	SM-AHN (N=28) n (%)	MCL (N=9) n (%)	All AdvSM (N=42) n (%)
Patients with baseline Spleen Volume assessment	5	28	9	42
Patients achieved >= 35 % Spleen Volume (mL) reduction from baseline	3 (60.0)	14 (50.0)	3 (33.3)	20 (47.6)
Patients with baseline Spleen Palpation >=5 cm	1	9	4	14
Patients achieved >= 35 % Spleen Volume (mL) reduction from baseline	1 (100.0)	4 (44.4)	2 (50.0)	7 (50.0)
Patients with palpable spleen at baseline	2	16	4	22
Patients become non-palpable for patients who has palpable spleen at baseline	1 (50.0)	11 (68.8)	1 (25.0)	13 (59.1)

Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date.
Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/EMA_D120/t99.2.8.3.1b-vol-resp-pant.sas Date: 10:41/04AUG2021

Table 99.2.8.3.1b
Summary of Spleen Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2202 & All Dose Groups

Prior antineoplastic therapy = Yes

Best Response	ASM (N=5) n (%)	SM-AHN (N=28) n (%)	MCL (N=9) n (%)	All AdvSM (N=42) n (%)
Patients with baseline Spleen Volume assessment	5	28	9	42
Patients achieved >= 35 % Spleen Volume (mL) reduction from baseline	3 (60.0)	14 (50.0)	3 (33.3)	20 (47.6)
Patients with baseline Spleen Palpation >=5 cm	1	9	4	14
Patients achieved >= 35 % Spleen Volume (mL) reduction from baseline	1 (100.0)	4 (44.4)	2 (50.0)	7 (50.0)
Patients with palpable spleen at baseline	2	16	4	22
Patients become non-palpable for patients who has palpable spleen at baseline	1 (50.0)	11 (68.8)	1 (25.0)	13 (59.1)

Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date.
Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/EMA_D120/t99.2.8.3.1b-vol-resp-pant.sas Date: 10:41/04AUG2021

Table 99.2.8.3.1b
Summary of Spleen Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2202 & 200 mg Dose Group

Prior antineoplastic therapy = No				
Best Response	ASM (N=4) n (%)	SM-AHN (N=15) n (%)	MCL (N=1) n (%)	All AdvSM (N=20) n (%)
Patients with baseline Spleen Volume assessment	4	15	1	20
Patients achieved >= 35 % Spleen Volume (mL) reduction from baseline	2 (50.0)	9 (60.0)	0	11 (55.0)
Patients with baseline Spleen Palpation >=5 cm	1	6	0	7
Patients achieved >= 35 % Spleen Volume (mL) reduction from baseline	1 (100.0)	4 (66.7)	0	5 (71.4)
Patients with palpable spleen at baseline	1	7	0	8
Patients become non-palpable for patients who has palpable spleen at baseline	1 (100.0)	6 (85.7)	0	7 (87.5)

Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date.
Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/EMA_D120/t99.2.8.3.1b-vol-resp-pant.sas Date: 10:41/04AUG2021

Table 99.2.8.3.1b
Summary of Spleen Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2202 & <=200 mg Dose Group

Prior antineoplastic therapy = No				
Best Response	ASM (N=4) n (%)	SM-AHN (N=15) n (%)	MCL (N=1) n (%)	All AdvSM (N=20) n (%)
Patients with baseline Spleen Volume assessment	4	15	1	20
Patients achieved >= 35 % Spleen Volume (mL) reduction from baseline	2 (50.0)	9 (60.0)	0	11 (55.0)
Patients with baseline Spleen Palpation >=5 cm	1	6	0	7
Patients achieved >= 35 % Spleen Volume (mL) reduction from baseline	1 (100.0)	4 (66.7)	0	5 (71.4)
Patients with palpable spleen at baseline	1	7	0	8
Patients become non-palpable for patients who has palpable spleen at baseline	1 (100.0)	6 (85.7)	0	7 (87.5)

Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date.
Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/EMA_D120/t99.2.8.3.1b-vol-resp-pant.sas Date: 10:41/04AUG2021

Table 99.2.8.3.1b
Summary of Spleen Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2202 & All Dose Groups

Prior antineoplastic therapy = No				
Best Response	ASM (N=4) n (%)	SM-AHN (N=15) n (%)	MCL (N=1) n (%)	All AdvSM (N=20) n (%)
Patients with baseline Spleen Volume assessment	4	15	1	20
Patients achieved >= 35 % Spleen Volume (mL) reduction from baseline	2 (50.0)	9 (60.0)	0	11 (55.0)
Patients with baseline Spleen Palpation >=5 cm	1	6	0	7
Patients achieved >= 35 % Spleen Volume (mL) reduction from baseline	1 (100.0)	4 (66.7)	0	5 (71.4)
Patients with palpable spleen at baseline	1	7	0	8
Patients become non-palpable for patients who has palpable spleen at baseline	1 (100.0)	6 (85.7)	0	7 (87.5)

Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date.
Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/EMA_D120/t99.2.8.3.1b-vol-resp-pant.sas Date: 10:41/04AUG2021

Table 99.2.8.3.1b
Summary of Spleen Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101/2202 & 200 mg Dose Group

Prior antineoplastic therapy = Yes

Best Response	ASM (N=5) n (%)	SM-AHN (N=34) n (%)	MCL (N=13) n (%)	All AdvSM (N=52) n (%)	ISM/SSM (N=1) n (%)	All Patients (N=53) n (%)
Patients with baseline Spleen Volume assessment	5	34	13	52	1	53
Patients achieved >= 35 % Spleen Volume (mL) reduction from baseline	3 (60.0)	18 (52.9)	7 (53.8)	28 (53.8)	1 (100.0)	29 (54.7)
Patients with baseline Spleen Palpation >=5 cm	2	11	5	18	0	18
Patients achieved >= 35 % Spleen Volume (mL) reduction from baseline	1 (50.0)	6 (54.5)	3 (60.0)	10 (55.6)	0	10 (55.6)
Patients with palpable spleen at baseline	3	18	5	26	0	26
Patients become non-palpable for patients who has palpable spleen at baseline	1 (33.3)	10 (55.6)	2 (40.0)	13 (50.0)	0	13 (50.0)

Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date.
Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/EMA_D120/t99.2.8.3.1b-vol-resp-pant.sas Date: 10:41/04AUG2021

Table 99.2.8.3.1b
Summary of Spleen Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101/2202 & <=200 mg Dose Group

Prior antineoplastic therapy = Yes

Best Response	ASM (N=7) n (%)	SM-AHN (N=37) n (%)	MCL (N=14) n (%)	All AdvSM (N=58) n (%)	ISM/SSM (N=4) n (%)	All Patients (N=62) n (%)
Patients with baseline Spleen Volume assessment	6	37	14	57	4	61
Patients achieved >= 35 % Spleen Volume (mL) reduction from baseline	3 (50.0)	20 (54.1)	8 (57.1)	31 (54.4)	2 (50.0)	33 (54.1)
Patients with baseline Spleen Palpation >=5 cm	2	12	5	19	0	19
Patients achieved >= 35 % Spleen Volume (mL) reduction from baseline	1 (50.0)	7 (58.3)	3 (60.0)	11 (57.9)	0	11 (57.9)
Patients with palpable spleen at baseline	3	20	5	28	0	28
Patients become non-palpable for patients who has palpable spleen at baseline	1 (33.3)	12 (60.0)	2 (40.0)	15 (53.6)	0	15 (53.6)

Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date.
Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/EMA_D120/t99.2.8.3.1b-vol-resp-pant.sas Date: 10:41/04AUG2021

Table 99.2.8.3.1b
Summary of Spleen Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101/2202 & All Dose Groups

Prior antineoplastic therapy = Yes

Best Response	ASM (N=12) n (%)	SM-AHN (N=54) n (%)	MCL (N=17) n (%)	All AdvSM (N=83) n (%)	ISM/SSM (N=9) n (%)	All Patients (N=92) n (%)
Patients with baseline Spleen Volume assessment	11	53	16	80	9	89
Patients achieved >= 35 % Spleen Volume (mL) reduction from baseline	8 (72.7)	34 (64.2)	9 (56.3)	51 (63.8)	6 (66.7)	57 (64.0)
Patients with baseline Spleen Palpation >=5 cm	4	21	6	31	1	32
Patients achieved >= 35 % Spleen Volume (mL) reduction from baseline	3 (75.0)	15 (71.4)	4 (66.7)	22 (71.0)	1 (100.0)	23 (71.9)
Patients with palpable spleen at baseline	6	30	6	42	2	44
Patients become non-palpable for patients who has palpable spleen at baseline	4 (66.7)	20 (66.7)	2 (33.3)	26 (61.9)	2 (100.0)	28 (63.6)

Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date.
Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/EMA_D120/t99.2.8.3.1b-vol-resp-pant.sas Date: 10:41/04AUG2021

Table 99.2.8.3.1b
Summary of Spleen Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101/2202 & 200 mg Dose Group

Prior antineoplastic therapy = No

Best Response	ASM (N=4) n (%)	SM-AHN (N=21) n (%)	MCL (N=3) n (%)	All AdvSM (N=28) n (%)	ISM/SSM (N=0) n (%)	All Patients (N=28) n (%)
Patients with baseline Spleen Volume assessment	4	21	3	28	0	28
Patients achieved >= 35 % Spleen Volume (mL) reduction from baseline	2 (50.0)	13 (61.9)	2 (66.7)	17 (60.7)	0	17 (60.7)
Patients with baseline Spleen Palpation >=5 cm	1	6	2	9	0	9
Patients achieved >= 35 % Spleen Volume (mL) reduction from baseline	1 (100.0)	4 (66.7)	2 (100.0)	7 (77.8)	0	7 (77.8)
Patients with palpable spleen at baseline	1	8	2	11	0	11
Patients become non-palpable for patients who has palpable spleen at baseline	1 (100.0)	7 (87.5)	2 (100.0)	10 (90.9)	0	10 (90.9)

Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date.
Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/EMA_D120/t99.2.8.3.1b-vol-resp-pant.sas Date: 10:41/04AUG2021

Table 99.2.8.3.1b
Summary of Spleen Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101/2202 & <=200 mg Dose Group

Prior antineoplastic therapy = No

Best Response	ASM (N=4) n (%)	SM-AHN (N=26) n (%)	MCL (N=3) n (%)	All AdvSM (N=33) n (%)	ISM/SSM (N=2) n (%)	All Patients (N=35) n (%)
Patients with baseline Spleen Volume assessment	4	26	3	33	2	35
Patients achieved >= 35 % Spleen Volume (mL) reduction from baseline	2 (50.0)	17 (65.4)	2 (66.7)	21 (63.6)	1 (50.0)	22 (62.9)
Patients with baseline Spleen Palpation >=5 cm	1	9	2	12	0	12
Patients achieved >= 35 % Spleen Volume (mL) reduction from baseline	1 (100.0)	6 (66.7)	2 (100.0)	9 (75.0)	0	9 (75.0)
Patients with palpable spleen at baseline	1	13	2	16	0	16
Patients become non-palpable for patients who has palpable spleen at baseline	1 (100.0)	11 (84.6)	2 (100.0)	14 (87.5)	0	14 (87.5)

Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date.
Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/EMA_D120/t99.2.8.3.1b-vol-resp-pant.sas Date: 10:41/04AUG2021

Table 99.2.8.3.1b
Summary of Spleen Best Response by Prior Anti-Neoplastic Therapy
Safety Population
BLU-285-2101/2202 & All Dose Groups

Prior antineoplastic therapy = No

Best Response	ASM (N=5) n (%)	SM-AHN (N=37) n (%)	MCL (N=6) n (%)	All AdvSM (N=48) n (%)	ISM/SSM (N=7) n (%)	All Patients (N=55) n (%)
Patients with baseline Spleen Volume assessment	5	37	6	48	7	55
Patients achieved >= 35 % Spleen Volume (mL) reduction from baseline	3 (60.0)	26 (70.3)	5 (83.3)	34 (70.8)	5 (71.4)	39 (70.9)
Patients with baseline Spleen Palpation >=5 cm	2	14	4	20	2	22
Patients achieved >= 35 % Spleen Volume (mL) reduction from baseline	2 (100.0)	10 (71.4)	4 (100.0)	16 (80.0)	2 (100.0)	18 (81.8)
Patients with palpable spleen at baseline	2	22	5	29	5	34
Patients become non-palpable for patients who has palpable spleen at baseline	2 (100.0)	20 (90.9)	5 (100.0)	27 (93.1)	5 (100.0)	32 (94.1)

Baseline is defined as the last observation before first dose date of study drug, including pre-dose assessments on the first dose date.
Images by CT or MRI are centrally assessed by independent radiologist.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/EMA_D120/t99.2.8.3.1b-vol-resp-pant.sas Date: 10:41/04AUG2021

Table 35.2.9.1
Summary of AdvSM-SAF Compliance
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

	C1D-7 (N=27)	C1D1 (N=27)	C2D1 (N=27)	C3D1 (N=27)	C4D1 (N=27)	C5D1 (N=27)	C6D1 (N=27)
Treated	27	27	27	26	26	25	24
Q1 Abdominal Pain	20 (74.1)	24 (88.9)	25 (92.6)	22 (84.6)	25 (96.2)	21 (84.0)	20 (83.3)
Q2 Nausea	19 (70.4)	24 (88.9)	25 (92.6)	22 (84.6)	25 (96.2)	21 (84.0)	20 (83.3)
Q3 Spots	20 (74.1)	24 (88.9)	25 (92.6)	22 (84.6)	25 (96.2)	21 (84.0)	20 (83.3)
Q4 Itching	20 (74.1)	24 (88.9)	25 (92.6)	22 (84.6)	25 (96.2)	21 (84.0)	20 (83.3)
Q5 Flushing	19 (70.4)	24 (88.9)	24 (88.9)	22 (84.6)	25 (96.2)	21 (84.0)	20 (83.3)
Q6 Fatigue	20 (74.1)	24 (88.9)	25 (92.6)	22 (84.6)	25 (96.2)	21 (84.0)	20 (83.3)
Q7 Vomitting Count	20 (74.1)	24 (88.9)	25 (92.6)	22 (84.6)	25 (96.2)	21 (84.0)	20 (83.3)
Q8 Vomitting Severity	20 (74.1)	24 (88.9)	25 (92.6)	22 (84.6)	25 (96.2)	21 (84.0)	20 (83.3)
Q9 Diarrhea Count	20 (74.1)	24 (88.9)	25 (92.6)	22 (84.6)	25 (96.2)	21 (84.0)	20 (83.3)
Q10 Diarrhea Severity	20 (74.1)	24 (88.9)	25 (92.6)	22 (84.6)	25 (96.2)	21 (84.0)	20 (83.3)
Skin Domain	19 (70.4)	24 (88.9)	24 (88.9)	22 (84.6)	25 (96.2)	21 (84.0)	20 (83.3)
GI Domain	19 (70.4)	24 (88.9)	25 (92.6)	22 (84.6)	25 (96.2)	21 (84.0)	20 (83.3)
TSS	18 (66.7)	24 (88.9)	24 (88.9)	22 (84.6)	25 (96.2)	21 (84.0)	20 (83.3)

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by Response Assessment Committee adjudication for study 2101 and by Study Steering Committee adjudication for study 2202. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. For study 2101, only a subset of AdvSM subjects are included in this table and number of patients treated on C1D1 is used for C1D-7.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-asm.sas Date: 10:26/29SEP2021

Table 35.2.9.1
Summary of AdvSM-SAF Compliance
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

	C7D1 (N=27)	C8D1 (N=27)	C9D1 (N=27)	C10D1 (N=27)	C11D1 (N=27)	C12D1 (N=27)	C13D1 (N=27)
Treated	24	23	23	19	18	17	17
Q1 Abdominal Pain	17 (70.8)	14 (60.9)	16 (69.6)	14 (73.7)	15 (83.3)	12 (70.6)	10 (58.8)
Q2 Nausea	17 (70.8)	14 (60.9)	16 (69.6)	14 (73.7)	15 (83.3)	12 (70.6)	10 (58.8)
Q3 Spots	17 (70.8)	14 (60.9)	16 (69.6)	14 (73.7)	15 (83.3)	12 (70.6)	10 (58.8)
Q4 Itching	17 (70.8)	14 (60.9)	16 (69.6)	14 (73.7)	15 (83.3)	12 (70.6)	10 (58.8)
Q5 Flushing	17 (70.8)	14 (60.9)	16 (69.6)	14 (73.7)	15 (83.3)	12 (70.6)	10 (58.8)
Q6 Fatigue	17 (70.8)	14 (60.9)	16 (69.6)	14 (73.7)	14 (77.8)	12 (70.6)	10 (58.8)
Q7 Vomitting Count	17 (70.8)	14 (60.9)	16 (69.6)	14 (73.7)	15 (83.3)	12 (70.6)	10 (58.8)
Q8 Vomitting Severity	17 (70.8)	14 (60.9)	16 (69.6)	14 (73.7)	15 (83.3)	12 (70.6)	10 (58.8)
Q9 Diarrhea Count	17 (70.8)	14 (60.9)	16 (69.6)	14 (73.7)	15 (83.3)	12 (70.6)	10 (58.8)
Q10 Diarrhea Severity	17 (70.8)	14 (60.9)	16 (69.6)	14 (73.7)	15 (83.3)	12 (70.6)	10 (58.8)
Skin Domain	17 (70.8)	14 (60.9)	16 (69.6)	14 (73.7)	15 (83.3)	12 (70.6)	10 (58.8)
GI Domain	17 (70.8)	14 (60.9)	16 (69.6)	14 (73.7)	15 (83.3)	12 (70.6)	10 (58.8)
TSS	17 (70.8)	14 (60.9)	16 (69.6)	14 (73.7)	14 (77.8)	12 (70.6)	10 (58.8)

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by Response Assessment Committee adjudication for study 2101 and by Study Steering Committee adjudication for study 2202. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. For study 2101, only a subset of AdvSM subjects are included in this table and number of patients treated on C1D1 is used for C1D-7.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-asm.sas Date: 10:26/29SEP2021

Table 35.2.9.1
Summary of AdvSM-SAF Compliance
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

	C14D1 (N=27)	C15D1 (N=27)	C16D1 (N=27)	C17D1 (N=27)	C18D1 (N=27)	C19D1 (N=27)	C20D1 (N=27)
Treated	16	16	16	16	14	12	12
Q1 Abdominal Pain	9 (56.3)	5 (31.3)	5 (31.3)	5 (31.3)	2 (14.3)	2 (16.7)	1 (8.3)
Q2 Nausea	9 (56.3)	5 (31.3)	5 (31.3)	5 (31.3)	2 (14.3)	2 (16.7)	1 (8.3)
Q3 Spots	9 (56.3)	5 (31.3)	5 (31.3)	5 (31.3)	2 (14.3)	2 (16.7)	1 (8.3)
Q4 Itching	9 (56.3)	5 (31.3)	5 (31.3)	5 (31.3)	2 (14.3)	2 (16.7)	1 (8.3)
Q5 Flushing	9 (56.3)	5 (31.3)	5 (31.3)	5 (31.3)	2 (14.3)	2 (16.7)	1 (8.3)
Q6 Fatigue	9 (56.3)	5 (31.3)	5 (31.3)	5 (31.3)	2 (14.3)	2 (16.7)	1 (8.3)
Q7 Vomitting Count	9 (56.3)	5 (31.3)	5 (31.3)	5 (31.3)	2 (14.3)	2 (16.7)	1 (8.3)
Q8 Vomitting Severity	9 (56.3)	5 (31.3)	5 (31.3)	5 (31.3)	2 (14.3)	2 (16.7)	1 (8.3)
Q9 Diarrhea Count	9 (56.3)	5 (31.3)	5 (31.3)	5 (31.3)	2 (14.3)	2 (16.7)	1 (8.3)
Q10 Diarrhea Severity	9 (56.3)	5 (31.3)	5 (31.3)	5 (31.3)	2 (14.3)	2 (16.7)	1 (8.3)
Skin Domain	9 (56.3)	5 (31.3)	5 (31.3)	5 (31.3)	2 (14.3)	2 (16.7)	1 (8.3)
GI Domain	9 (56.3)	5 (31.3)	5 (31.3)	5 (31.3)	2 (14.3)	2 (16.7)	1 (8.3)
TSS	9 (56.3)	5 (31.3)	5 (31.3)	5 (31.3)	2 (14.3)	2 (16.7)	1 (8.3)

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by Response Assessment Committee adjudication for study 2101 and by Study Steering Committee adjudication for study 2202. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. For study 2101, only a subset of AdvSM subjects are included in this table and number of patients treated on C1D1 is used for C1D-7.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-asm.sas Date: 10:26/29SEP2021

Table 35.2.9.1
Summary of AdvSM-SAF Compliance
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg							
	C1D-7 (N=10)	C1D1 (N=10)	C2D1 (N=10)	C3D1 (N=10)	C4D1 (N=10)	C5D1 (N=10)	C6D1 (N=10)
Treated	10	10	10	9	9	8	8
Q1 Abdominal Pain	9 (90.0)	10 (100)	10 (100)	8 (88.9)	9 (100)	8 (100)	7 (87.5)
Q2 Nausea	8 (80.0)	10 (100)	10 (100)	8 (88.9)	9 (100)	8 (100)	7 (87.5)
Q3 Spots	9 (90.0)	10 (100)	10 (100)	8 (88.9)	9 (100)	8 (100)	7 (87.5)
Q4 Itching	9 (90.0)	10 (100)	10 (100)	8 (88.9)	9 (100)	8 (100)	7 (87.5)
Q5 Flushing	9 (90.0)	10 (100)	10 (100)	8 (88.9)	9 (100)	8 (100)	7 (87.5)
Q6 Fatigue	9 (90.0)	10 (100)	10 (100)	8 (88.9)	9 (100)	8 (100)	7 (87.5)
Q7 Vomitting Count	9 (90.0)	10 (100)	10 (100)	8 (88.9)	9 (100)	8 (100)	7 (87.5)
Q8 Vomitting Severity	9 (90.0)	10 (100)	10 (100)	8 (88.9)	9 (100)	8 (100)	7 (87.5)
Q9 Diarrhea Count	9 (90.0)	10 (100)	10 (100)	8 (88.9)	9 (100)	8 (100)	7 (87.5)
Q10 Diarrhea Severity	9 (90.0)	10 (100)	10 (100)	8 (88.9)	9 (100)	8 (100)	7 (87.5)
Skin Domain	9 (90.0)	10 (100)	10 (100)	8 (88.9)	9 (100)	8 (100)	7 (87.5)
GI Domain	8 (80.0)	10 (100)	10 (100)	8 (88.9)	9 (100)	8 (100)	7 (87.5)
TSS	8 (80.0)	10 (100)	10 (100)	8 (88.9)	9 (100)	8 (100)	7 (87.5)

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by Response Assessment Committee adjudication for study 2101 and by Study Steering Committee adjudication for study 2202. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. For study 2101, only a subset of AdvSM subjects are included in this table and number of patients treated on C1D1 is used for C1D-7.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-asm.sas Date: 10:26/29SEP2021

Table 35.2.9.1
Summary of AdvSM-SAF Compliance
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

	C7D1 (N=10)	C8D1 (N=10)	C9D1 (N=10)	C10D1 (N=10)	C11D1 (N=10)	C12D1 (N=10)	C13D1 (N=10)
Treated	8	7	7	6	5	4	4
Q1 Abdominal Pain	5 (62.5)	4 (57.1)	5 (71.4)	4 (66.7)	4 (80.0)	3 (75.0)	1 (25.0)
Q2 Nausea	5 (62.5)	4 (57.1)	5 (71.4)	4 (66.7)	4 (80.0)	3 (75.0)	1 (25.0)
Q3 Spots	5 (62.5)	4 (57.1)	5 (71.4)	4 (66.7)	4 (80.0)	3 (75.0)	1 (25.0)
Q4 Itching	5 (62.5)	4 (57.1)	5 (71.4)	4 (66.7)	4 (80.0)	3 (75.0)	1 (25.0)
Q5 Flushing	5 (62.5)	4 (57.1)	5 (71.4)	4 (66.7)	4 (80.0)	3 (75.0)	1 (25.0)
Q6 Fatigue	5 (62.5)	4 (57.1)	5 (71.4)	4 (66.7)	4 (80.0)	3 (75.0)	1 (25.0)
Q7 Vomitting Count	5 (62.5)	4 (57.1)	5 (71.4)	4 (66.7)	4 (80.0)	3 (75.0)	1 (25.0)
Q8 Vomitting Severity	5 (62.5)	4 (57.1)	5 (71.4)	4 (66.7)	4 (80.0)	3 (75.0)	1 (25.0)
Q9 Diarrhea Count	5 (62.5)	4 (57.1)	5 (71.4)	4 (66.7)	4 (80.0)	3 (75.0)	1 (25.0)
Q10 Diarrhea Severity	5 (62.5)	4 (57.1)	5 (71.4)	4 (66.7)	4 (80.0)	3 (75.0)	1 (25.0)
Skin Domain	5 (62.5)	4 (57.1)	5 (71.4)	4 (66.7)	4 (80.0)	3 (75.0)	1 (25.0)
GI Domain	5 (62.5)	4 (57.1)	5 (71.4)	4 (66.7)	4 (80.0)	3 (75.0)	1 (25.0)
TSS	5 (62.5)	4 (57.1)	5 (71.4)	4 (66.7)	4 (80.0)	3 (75.0)	1 (25.0)

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by Response Assessment Committee adjudication for study 2101 and by Study Steering Committee adjudication for study 2202. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. For study 2101, only a subset of AdvSM subjects are included in this table and number of patients treated on C1D1 is used for C1D-7.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-asm.sas Date: 10:26/29SEP2021

Table 35.2.9.1
Summary of AdvSM-SAF Compliance
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg	C14D1 (N=10)	C15D1 (N=10)	C16D1 (N=10)	C17D1 (N=10)	C18D1 (N=10)	C19D1 (N=10)	C20D1 (N=10)
Treated	3	3	3	3	2	1	1
Q1 Abdominal Pain	0	0	0	0	0	0	0
Q2 Nausea	0	0	0	0	0	0	0
Q3 Spots	0	0	0	0	0	0	0
Q4 Itching	0	0	0	0	0	0	0
Q5 Flushing	0	0	0	0	0	0	0
Q6 Fatigue	0	0	0	0	0	0	0
Q7 Vomitting Count	0	0	0	0	0	0	0
Q8 Vomitting Severity	0	0	0	0	0	0	0
Q9 Diarrhea Count	0	0	0	0	0	0	0
Q10 Diarrhea Severity	0	0	0	0	0	0	0
Skin Domain	0	0	0	0	0	0	0
GI Domain	0	0	0	0	0	0	0
TSS	0	0	0	0	0	0	0

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by Response Assessment Committee adjudication for study 2101 and by Study Steering Committee adjudication for study 2202. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. For study 2101, only a subset of AdvSM subjects are included in this table and number of patients treated on C1D1 is used for C1D-7.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-asm.sas Date: 10:26/29SEP2021

Table 35.2.9.1
Summary of AdvSM-SAF Compliance
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg							
	C1D-7 (N=10)	C1D1 (N=10)	C2D1 (N=10)	C3D1 (N=10)	C4D1 (N=10)	C5D1 (N=10)	C6D1 (N=10)
Treated	10	10	10	9	9	8	8
Q1 Abdominal Pain	9 (90.0)	10 (100)	10 (100)	8 (88.9)	9 (100)	8 (100)	7 (87.5)
Q2 Nausea	8 (80.0)	10 (100)	10 (100)	8 (88.9)	9 (100)	8 (100)	7 (87.5)
Q3 Spots	9 (90.0)	10 (100)	10 (100)	8 (88.9)	9 (100)	8 (100)	7 (87.5)
Q4 Itching	9 (90.0)	10 (100)	10 (100)	8 (88.9)	9 (100)	8 (100)	7 (87.5)
Q5 Flushing	9 (90.0)	10 (100)	10 (100)	8 (88.9)	9 (100)	8 (100)	7 (87.5)
Q6 Fatigue	9 (90.0)	10 (100)	10 (100)	8 (88.9)	9 (100)	8 (100)	7 (87.5)
Q7 Vomitting Count	9 (90.0)	10 (100)	10 (100)	8 (88.9)	9 (100)	8 (100)	7 (87.5)
Q8 Vomitting Severity	9 (90.0)	10 (100)	10 (100)	8 (88.9)	9 (100)	8 (100)	7 (87.5)
Q9 Diarrhea Count	9 (90.0)	10 (100)	10 (100)	8 (88.9)	9 (100)	8 (100)	7 (87.5)
Q10 Diarrhea Severity	9 (90.0)	10 (100)	10 (100)	8 (88.9)	9 (100)	8 (100)	7 (87.5)
Skin Domain	9 (90.0)	10 (100)	10 (100)	8 (88.9)	9 (100)	8 (100)	7 (87.5)
GI Domain	8 (80.0)	10 (100)	10 (100)	8 (88.9)	9 (100)	8 (100)	7 (87.5)
TSS	8 (80.0)	10 (100)	10 (100)	8 (88.9)	9 (100)	8 (100)	7 (87.5)

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by Response Assessment Committee adjudication for study 2101 and by Study Steering Committee adjudication for study 2202. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. For study 2101, only a subset of AdvSM subjects are included in this table and number of patients treated on C1D1 is used for C1D-7.
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Table 35.2.9.1
Summary of AdvSM-SAF Compliance
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg	C7D1 (N=10)	C8D1 (N=10)	C9D1 (N=10)	C10D1 (N=10)	C11D1 (N=10)	C12D1 (N=10)	C13D1 (N=10)
Treated	8	7	7	6	5	4	4
Q1 Abdominal Pain	5 (62.5)	4 (57.1)	5 (71.4)	4 (66.7)	4 (80.0)	3 (75.0)	1 (25.0)
Q2 Nausea	5 (62.5)	4 (57.1)	5 (71.4)	4 (66.7)	4 (80.0)	3 (75.0)	1 (25.0)
Q3 Spots	5 (62.5)	4 (57.1)	5 (71.4)	4 (66.7)	4 (80.0)	3 (75.0)	1 (25.0)
Q4 Itching	5 (62.5)	4 (57.1)	5 (71.4)	4 (66.7)	4 (80.0)	3 (75.0)	1 (25.0)
Q5 Flushing	5 (62.5)	4 (57.1)	5 (71.4)	4 (66.7)	4 (80.0)	3 (75.0)	1 (25.0)
Q6 Fatigue	5 (62.5)	4 (57.1)	5 (71.4)	4 (66.7)	4 (80.0)	3 (75.0)	1 (25.0)
Q7 Vomitting Count	5 (62.5)	4 (57.1)	5 (71.4)	4 (66.7)	4 (80.0)	3 (75.0)	1 (25.0)
Q8 Vomitting Severity	5 (62.5)	4 (57.1)	5 (71.4)	4 (66.7)	4 (80.0)	3 (75.0)	1 (25.0)
Q9 Diarrhea Count	5 (62.5)	4 (57.1)	5 (71.4)	4 (66.7)	4 (80.0)	3 (75.0)	1 (25.0)
Q10 Diarrhea Severity	5 (62.5)	4 (57.1)	5 (71.4)	4 (66.7)	4 (80.0)	3 (75.0)	1 (25.0)
Skin Domain	5 (62.5)	4 (57.1)	5 (71.4)	4 (66.7)	4 (80.0)	3 (75.0)	1 (25.0)
GI Domain	5 (62.5)	4 (57.1)	5 (71.4)	4 (66.7)	4 (80.0)	3 (75.0)	1 (25.0)
TSS	5 (62.5)	4 (57.1)	5 (71.4)	4 (66.7)	4 (80.0)	3 (75.0)	1 (25.0)

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by Response Assessment Committee adjudication for study 2101 and by Study Steering Committee adjudication for study 2202. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. For study 2101, only a subset of AdvSM subjects are included in this table and number of patients treated on C1D1 is used for C1D-7.
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Table 35.2.9.1
Summary of AdvSM-SAF Compliance
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg							
	C14D1 (N=10)	C15D1 (N=10)	C16D1 (N=10)	C17D1 (N=10)	C18D1 (N=10)	C19D1 (N=10)	C20D1 (N=10)
Treated	3	3	3	3	2	1	1
Q1 Abdominal Pain	0	0	0	0	0	0	0
Q2 Nausea	0	0	0	0	0	0	0
Q3 Spots	0	0	0	0	0	0	0
Q4 Itching	0	0	0	0	0	0	0
Q5 Flushing	0	0	0	0	0	0	0
Q6 Fatigue	0	0	0	0	0	0	0
Q7 Vomitting Count	0	0	0	0	0	0	0
Q8 Vomitting Severity	0	0	0	0	0	0	0
Q9 Diarrhea Count	0	0	0	0	0	0	0
Q10 Diarrhea Severity	0	0	0	0	0	0	0
Skin Domain	0	0	0	0	0	0	0
GI Domain	0	0	0	0	0	0	0
TSS	0	0	0	0	0	0	0

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by Response Assessment Committee adjudication for study 2101 and by Study Steering Committee adjudication for study 2202. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. For study 2101, only a subset of AdvSM subjects are included in this table and number of patients treated on C1D1 is used for C1D-7.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-asm.sas Date: 10:26/29SEP2021

Table 35.2.9.1
Summary of AdvSM-SAF Compliance
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

	C1D1 (N=42)	C2D1 (N=42)	C3D1 (N=42)	C4D1 (N=42)	C5D1 (N=42)	C6D1 (N=42)
Treated	42	40	37	37	32	25
Q1 Abdominal Pain	38 (90.5)	40 (100)	37 (100)	34 (91.9)	31 (96.9)	25 (100)
Q2 Nausea	38 (90.5)	40 (100)	37 (100)	34 (91.9)	31 (96.9)	25 (100)
Q3 Spots	38 (90.5)	40 (100)	37 (100)	34 (91.9)	31 (96.9)	25 (100)
Q4 Itching	38 (90.5)	40 (100)	37 (100)	34 (91.9)	31 (96.9)	25 (100)
Q5 Flushing	38 (90.5)	40 (100)	37 (100)	34 (91.9)	31 (96.9)	25 (100)
Q6 Fatigue	38 (90.5)	40 (100)	37 (100)	34 (91.9)	31 (96.9)	25 (100)
Q7 Vomitting Count	38 (90.5)	40 (100)	37 (100)	34 (91.9)	31 (96.9)	25 (100)
Q8 Vomitting Severity	38 (90.5)	40 (100)	37 (100)	34 (91.9)	31 (96.9)	25 (100)
Q9 Diarrhea Count	38 (90.5)	40 (100)	37 (100)	34 (91.9)	31 (96.9)	25 (100)
Q10 Diarrhea Severity	38 (90.5)	40 (100)	37 (100)	34 (91.9)	31 (96.9)	25 (100)
Skin Domain	38 (90.5)	40 (100)	37 (100)	34 (91.9)	31 (96.9)	25 (100)
GI Domain	38 (90.5)	40 (100)	37 (100)	34 (91.9)	31 (96.9)	25 (100)
TSS	38 (90.5)	40 (100)	37 (100)	34 (91.9)	31 (96.9)	25 (100)

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by Response Assessment Committee adjudication for study 2101 and by Study Steering Committee adjudication for study 2202. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. For study 2101, only a subset of AdvSM subjects are included in this table and number of patients treated on C1D1 is used for C1D-7.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-asm.sas Date: 10:26/29SEP2021

Table 35.2.9.1
Summary of AdvSM-SAF Compliance
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

	C7D1 (N=42)	C8D1 (N=42)	C9D1 (N=42)	C10D1 (N=42)	C11D1 (N=42)	C12D1 (N=42)	C13D1 (N=42)
Treated	22	21	18	13	12	10	6
Q1 Abdominal Pain	21 (95.5)	21 (100)	18 (100)	13 (100)	12 (100)	10 (100)	6 (100)
Q2 Nausea	21 (95.5)	21 (100)	18 (100)	13 (100)	12 (100)	10 (100)	6 (100)
Q3 Spots	21 (95.5)	21 (100)	18 (100)	13 (100)	12 (100)	10 (100)	6 (100)
Q4 Itching	21 (95.5)	21 (100)	18 (100)	13 (100)	12 (100)	10 (100)	6 (100)
Q5 Flushing	21 (95.5)	21 (100)	18 (100)	13 (100)	12 (100)	10 (100)	6 (100)
Q6 Fatigue	21 (95.5)	21 (100)	18 (100)	13 (100)	12 (100)	10 (100)	6 (100)
Q7 Vomitting Count	21 (95.5)	21 (100)	18 (100)	13 (100)	12 (100)	10 (100)	6 (100)
Q8 Vomitting Severity	21 (95.5)	21 (100)	18 (100)	13 (100)	12 (100)	10 (100)	6 (100)
Q9 Diarrhea Count	21 (95.5)	21 (100)	18 (100)	13 (100)	12 (100)	10 (100)	6 (100)
Q10 Diarrhea Severity	21 (95.5)	21 (100)	18 (100)	13 (100)	12 (100)	10 (100)	6 (100)
Skin Domain	21 (95.5)	21 (100)	18 (100)	13 (100)	12 (100)	10 (100)	6 (100)
GI Domain	21 (95.5)	21 (100)	18 (100)	13 (100)	12 (100)	10 (100)	6 (100)
TSS	21 (95.5)	21 (100)	18 (100)	13 (100)	12 (100)	10 (100)	6 (100)

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by Response Assessment Committee adjudication for study 2101 and by Study Steering Committee adjudication for study 2202. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. For study 2101, only a subset of AdvSM subjects are included in this table and number of patients treated on C1D1 is used for C1D-7.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-asm.sas Date: 10:26/29SEP2021

Table 35.2.9.1
Summary of AdvSM-SAF Compliance
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

	C14D1 (N=42)	C15D1 (N=42)	C16D1 (N=42)	C17D1 (N=42)	C18D1 (N=42)
Treated	6	5	5	5	4
Q1 Abdominal Pain	6 (100)	5 (100)	5 (100)	5 (100)	4 (100)
Q2 Nausea	6 (100)	5 (100)	5 (100)	5 (100)	4 (100)
Q3 Spots	6 (100)	5 (100)	5 (100)	5 (100)	4 (100)
Q4 Itching	6 (100)	5 (100)	5 (100)	5 (100)	4 (100)
Q5 Flushing	6 (100)	5 (100)	5 (100)	5 (100)	4 (100)
Q6 Fatigue	6 (100)	5 (100)	5 (100)	5 (100)	4 (100)
Q7 Vomitting Count	6 (100)	5 (100)	5 (100)	5 (100)	4 (100)
Q8 Vomitting Severity	6 (100)	5 (100)	5 (100)	5 (100)	4 (100)
Q9 Diarrhea Count	6 (100)	5 (100)	5 (100)	5 (100)	4 (100)
Q10 Diarrhea Severity	6 (100)	5 (100)	5 (100)	5 (100)	4 (100)
Skin Domain	6 (100)	5 (100)	5 (100)	5 (100)	4 (100)
GI Domain	6 (100)	5 (100)	5 (100)	5 (100)	4 (100)
TSS	6 (100)	5 (100)	5 (100)	5 (100)	4 (100)

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by Response Assessment Committee adjudication for study 2101 and by Study Steering Committee adjudication for study 2202. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. For study 2101, only a subset of AdvSM subjects are included in this table and number of patients treated on C1D1 is used for C1D-7.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-asm.sas Date: 10:26/29SEP2021

Table 35.2.9.1
Summary of AdvSM-SAF Compliance
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg						
	C1D1 (N=40)	C2D1 (N=40)	C3D1 (N=40)	C4D1 (N=40)	C5D1 (N=40)	C6D1 (N=40)
Treated	40	39	36	36	31	24
Q1 Abdominal Pain	36 (90.0)	39 (100)	36 (100)	33 (91.7)	30 (96.8)	24 (100)
Q2 Nausea	36 (90.0)	39 (100)	36 (100)	33 (91.7)	30 (96.8)	24 (100)
Q3 Spots	36 (90.0)	39 (100)	36 (100)	33 (91.7)	30 (96.8)	24 (100)
Q4 Itching	36 (90.0)	39 (100)	36 (100)	33 (91.7)	30 (96.8)	24 (100)
Q5 Flushing	36 (90.0)	39 (100)	36 (100)	33 (91.7)	30 (96.8)	24 (100)
Q6 Fatigue	36 (90.0)	39 (100)	36 (100)	33 (91.7)	30 (96.8)	24 (100)
Q7 Vomitting Count	36 (90.0)	39 (100)	36 (100)	33 (91.7)	30 (96.8)	24 (100)
Q8 Vomitting Severity	36 (90.0)	39 (100)	36 (100)	33 (91.7)	30 (96.8)	24 (100)
Q9 Diarrhea Count	36 (90.0)	39 (100)	36 (100)	33 (91.7)	30 (96.8)	24 (100)
Q10 Diarrhea Severity	36 (90.0)	39 (100)	36 (100)	33 (91.7)	30 (96.8)	24 (100)
Skin Domain	36 (90.0)	39 (100)	36 (100)	33 (91.7)	30 (96.8)	24 (100)
GI Domain	36 (90.0)	39 (100)	36 (100)	33 (91.7)	30 (96.8)	24 (100)
TSS	36 (90.0)	39 (100)	36 (100)	33 (91.7)	30 (96.8)	24 (100)

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by Response Assessment Committee adjudication for study 2101 and by Study Steering Committee adjudication for study 2202. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. For study 2101, only a subset of AdvSM subjects are included in this table and number of patients treated on C1D1 is used for C1D-7.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-asm.sas Date: 10:26/29SEP2021

Table 35.2.9.1
Summary of AdvSM-SAF Compliance
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg							
	C7D1 (N=40)	C8D1 (N=40)	C9D1 (N=40)	C10D1 (N=40)	C11D1 (N=40)	C12D1 (N=40)	C13D1 (N=40)
Treated	21	20	17	12	11	9	5
Q1 Abdominal Pain	20 (95.2)	20 (100)	17 (100)	12 (100)	11 (100)	9 (100)	5 (100)
Q2 Nausea	20 (95.2)	20 (100)	17 (100)	12 (100)	11 (100)	9 (100)	5 (100)
Q3 Spots	20 (95.2)	20 (100)	17 (100)	12 (100)	11 (100)	9 (100)	5 (100)
Q4 Itching	20 (95.2)	20 (100)	17 (100)	12 (100)	11 (100)	9 (100)	5 (100)
Q5 Flushing	20 (95.2)	20 (100)	17 (100)	12 (100)	11 (100)	9 (100)	5 (100)
Q6 Fatigue	20 (95.2)	20 (100)	17 (100)	12 (100)	11 (100)	9 (100)	5 (100)
Q7 Vomitting Count	20 (95.2)	20 (100)	17 (100)	12 (100)	11 (100)	9 (100)	5 (100)
Q8 Vomitting Severity	20 (95.2)	20 (100)	17 (100)	12 (100)	11 (100)	9 (100)	5 (100)
Q9 Diarrhea Count	20 (95.2)	20 (100)	17 (100)	12 (100)	11 (100)	9 (100)	5 (100)
Q10 Diarrhea Severity	20 (95.2)	20 (100)	17 (100)	12 (100)	11 (100)	9 (100)	5 (100)
Skin Domain	20 (95.2)	20 (100)	17 (100)	12 (100)	11 (100)	9 (100)	5 (100)
GI Domain	20 (95.2)	20 (100)	17 (100)	12 (100)	11 (100)	9 (100)	5 (100)
TSS	20 (95.2)	20 (100)	17 (100)	12 (100)	11 (100)	9 (100)	5 (100)

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by Response Assessment Committee adjudication for study 2101 and by Study Steering Committee adjudication for study 2202. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. For study 2101, only a subset of AdvSM subjects are included in this table and number of patients treated on C1D1 is used for C1D-7.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-asm.sas Date: 10:26/29SEP2021

Table 35.2.9.1
Summary of AdvSM-SAF Compliance
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg					
	C14D1 (N=40)	C15D1 (N=40)	C16D1 (N=40)	C17D1 (N=40)	C18D1 (N=40)
Treated	5	5	5	5	4
Q1 Abdominal Pain	5 (100)	5 (100)	5 (100)	5 (100)	4 (100)
Q2 Nausea	5 (100)	5 (100)	5 (100)	5 (100)	4 (100)
Q3 Spots	5 (100)	5 (100)	5 (100)	5 (100)	4 (100)
Q4 Itching	5 (100)	5 (100)	5 (100)	5 (100)	4 (100)
Q5 Flushing	5 (100)	5 (100)	5 (100)	5 (100)	4 (100)
Q6 Fatigue	5 (100)	5 (100)	5 (100)	5 (100)	4 (100)
Q7 Vomitting Count	5 (100)	5 (100)	5 (100)	5 (100)	4 (100)
Q8 Vomitting Severity	5 (100)	5 (100)	5 (100)	5 (100)	4 (100)
Q9 Diarrhea Count	5 (100)	5 (100)	5 (100)	5 (100)	4 (100)
Q10 Diarrhea Severity	5 (100)	5 (100)	5 (100)	5 (100)	4 (100)
Skin Domain	5 (100)	5 (100)	5 (100)	5 (100)	4 (100)
GI Domain	5 (100)	5 (100)	5 (100)	5 (100)	4 (100)
TSS	5 (100)	5 (100)	5 (100)	5 (100)	4 (100)

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by Response Assessment Committee adjudication for study 2101 and by Study Steering Committee adjudication for study 2202. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. For study 2101, only a subset of AdvSM subjects are included in this table and number of patients treated on C1D1 is used for C1D-7.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-asm.sas Date: 10:26/29SEP2021

Table 35.2.9.1
Summary of AdvSM-SAF Compliance
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

	C1D1 (N=69)	C2D1 (N=69)	C3D1 (N=69)	C4D1 (N=69)	C5D1 (N=69)	C6D1 (N=69)
Treated	69	67	63	63	57	49
Q1 Abdominal Pain	62 (89.9)	65 (97.0)	59 (93.7)	59 (93.7)	52 (91.2)	45 (91.8)
Q2 Nausea	62 (89.9)	65 (97.0)	59 (93.7)	59 (93.7)	52 (91.2)	45 (91.8)
Q3 Spots	62 (89.9)	65 (97.0)	59 (93.7)	59 (93.7)	52 (91.2)	45 (91.8)
Q4 Itching	62 (89.9)	65 (97.0)	59 (93.7)	59 (93.7)	52 (91.2)	45 (91.8)
Q5 Flushing	62 (89.9)	64 (95.5)	59 (93.7)	59 (93.7)	52 (91.2)	45 (91.8)
Q6 Fatigue	62 (89.9)	65 (97.0)	59 (93.7)	59 (93.7)	52 (91.2)	45 (91.8)
Q7 Vomitting Count	62 (89.9)	65 (97.0)	59 (93.7)	59 (93.7)	52 (91.2)	45 (91.8)
Q8 Vomitting Severity	62 (89.9)	65 (97.0)	59 (93.7)	59 (93.7)	52 (91.2)	45 (91.8)
Q9 Diarrhea Count	62 (89.9)	65 (97.0)	59 (93.7)	59 (93.7)	52 (91.2)	45 (91.8)
Q10 Diarrhea Severity	62 (89.9)	65 (97.0)	59 (93.7)	59 (93.7)	52 (91.2)	45 (91.8)
Skin Domain	62 (89.9)	64 (95.5)	59 (93.7)	59 (93.7)	52 (91.2)	45 (91.8)
GI Domain	62 (89.9)	65 (97.0)	59 (93.7)	59 (93.7)	52 (91.2)	45 (91.8)
TSS	62 (89.9)	64 (95.5)	59 (93.7)	59 (93.7)	52 (91.2)	45 (91.8)

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by Response Assessment Committee adjudication for study 2101 and by Study Steering Committee adjudication for study 2202. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. For study 2101, only a subset of AdvSM subjects are included in this table and number of patients treated on C1D1 is used for C1D-7.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-asm.sas
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Table 35.2.9.1
Summary of AdvSM-SAF Compliance
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

	C7D1 (N=69)	C8D1 (N=69)	C9D1 (N=69)	C10D1 (N=69)	C11D1 (N=69)	C12D1 (N=69)	C13D1 (N=69)
Treated	46	44	41	32	30	27	23
Q1 Abdominal Pain	38 (82.6)	35 (79.5)	34 (82.9)	27 (84.4)	27 (90.0)	22 (81.5)	16 (69.6)
Q2 Nausea	38 (82.6)	35 (79.5)	34 (82.9)	27 (84.4)	27 (90.0)	22 (81.5)	16 (69.6)
Q3 Spots	38 (82.6)	35 (79.5)	34 (82.9)	27 (84.4)	27 (90.0)	22 (81.5)	16 (69.6)
Q4 Itching	38 (82.6)	35 (79.5)	34 (82.9)	27 (84.4)	27 (90.0)	22 (81.5)	16 (69.6)
Q5 Flushing	38 (82.6)	35 (79.5)	34 (82.9)	27 (84.4)	27 (90.0)	22 (81.5)	16 (69.6)
Q6 Fatigue	38 (82.6)	35 (79.5)	34 (82.9)	27 (84.4)	26 (86.7)	22 (81.5)	16 (69.6)
Q7 Vomitting Count	38 (82.6)	35 (79.5)	34 (82.9)	27 (84.4)	27 (90.0)	22 (81.5)	16 (69.6)
Q8 Vomitting Severity	38 (82.6)	35 (79.5)	34 (82.9)	27 (84.4)	27 (90.0)	22 (81.5)	16 (69.6)
Q9 Diarrhea Count	38 (82.6)	35 (79.5)	34 (82.9)	27 (84.4)	27 (90.0)	22 (81.5)	16 (69.6)
Q10 Diarrhea Severity	38 (82.6)	35 (79.5)	34 (82.9)	27 (84.4)	27 (90.0)	22 (81.5)	16 (69.6)
Skin Domain	38 (82.6)	35 (79.5)	34 (82.9)	27 (84.4)	27 (90.0)	22 (81.5)	16 (69.6)
GI Domain	38 (82.6)	35 (79.5)	34 (82.9)	27 (84.4)	27 (90.0)	22 (81.5)	16 (69.6)
TSS	38 (82.6)	35 (79.5)	34 (82.9)	27 (84.4)	26 (86.7)	22 (81.5)	16 (69.6)

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by Response Assessment Committee adjudication for study 2101 and by Study Steering Committee adjudication for study 2202. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. For study 2101, only a subset of AdvSM subjects are included in this table and number of patients treated on C1D1 is used for C1D-7.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-asm.sas Date: 10:26/29SEP2021

Table 35.2.9.1
Summary of AdvSM-SAF Compliance
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

	C14D1 (N=69)	C15D1 (N=69)	C16D1 (N=69)	C17D1 (N=69)	C18D1 (N=69)	C19D1 (N=69)	C20D1 (N=69)
Treated	22	21	21	21	18	12	12
Q1 Abdominal Pain	15 (68.2)	10 (47.6)	10 (47.6)	10 (47.6)	6 (33.3)	2 (16.7)	1 (8.3)
Q2 Nausea	15 (68.2)	10 (47.6)	10 (47.6)	10 (47.6)	6 (33.3)	2 (16.7)	1 (8.3)
Q3 Spots	15 (68.2)	10 (47.6)	10 (47.6)	10 (47.6)	6 (33.3)	2 (16.7)	1 (8.3)
Q4 Itching	15 (68.2)	10 (47.6)	10 (47.6)	10 (47.6)	6 (33.3)	2 (16.7)	1 (8.3)
Q5 Flushing	15 (68.2)	10 (47.6)	10 (47.6)	10 (47.6)	6 (33.3)	2 (16.7)	1 (8.3)
Q6 Fatigue	15 (68.2)	10 (47.6)	10 (47.6)	10 (47.6)	6 (33.3)	2 (16.7)	1 (8.3)
Q7 Vomitting Count	15 (68.2)	10 (47.6)	10 (47.6)	10 (47.6)	6 (33.3)	2 (16.7)	1 (8.3)
Q8 Vomitting Severity	15 (68.2)	10 (47.6)	10 (47.6)	10 (47.6)	6 (33.3)	2 (16.7)	1 (8.3)
Q9 Diarrhea Count	15 (68.2)	10 (47.6)	10 (47.6)	10 (47.6)	6 (33.3)	2 (16.7)	1 (8.3)
Q10 Diarrhea Severity	15 (68.2)	10 (47.6)	10 (47.6)	10 (47.6)	6 (33.3)	2 (16.7)	1 (8.3)
Skin Domain	15 (68.2)	10 (47.6)	10 (47.6)	10 (47.6)	6 (33.3)	2 (16.7)	1 (8.3)
GI Domain	15 (68.2)	10 (47.6)	10 (47.6)	10 (47.6)	6 (33.3)	2 (16.7)	1 (8.3)
TSS	15 (68.2)	10 (47.6)	10 (47.6)	10 (47.6)	6 (33.3)	2 (16.7)	1 (8.3)

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by Response Assessment Committee adjudication for study 2101 and by Study Steering Committee adjudication for study 2202. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. For study 2101, only a subset of AdvSM subjects are included in this table and number of patients treated on C1D1 is used for C1D-7.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-asm.sas Date: 10:26/29SEP2021

Table 35.2.9.1
Summary of AdvSM-SAF Compliance
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg						
	C1D1 (N=52)	C2D1 (N=52)	C3D1 (N=52)	C4D1 (N=52)	C5D1 (N=52)	C6D1 (N=52)
Treated	52	50	46	46	40	33
Q1 Abdominal Pain	48 (92.3)	50 (100)	45 (97.8)	43 (93.5)	39 (97.5)	32 (97.0)
Q2 Nausea	48 (92.3)	50 (100)	45 (97.8)	43 (93.5)	39 (97.5)	32 (97.0)
Q3 Spots	48 (92.3)	50 (100)	45 (97.8)	43 (93.5)	39 (97.5)	32 (97.0)
Q4 Itching	48 (92.3)	50 (100)	45 (97.8)	43 (93.5)	39 (97.5)	32 (97.0)
Q5 Flushing	48 (92.3)	50 (100)	45 (97.8)	43 (93.5)	39 (97.5)	32 (97.0)
Q6 Fatigue	48 (92.3)	50 (100)	45 (97.8)	43 (93.5)	39 (97.5)	32 (97.0)
Q7 Vomitting Count	48 (92.3)	50 (100)	45 (97.8)	43 (93.5)	39 (97.5)	32 (97.0)
Q8 Vomitting Severity	48 (92.3)	50 (100)	45 (97.8)	43 (93.5)	39 (97.5)	32 (97.0)
Q9 Diarrhea Count	48 (92.3)	50 (100)	45 (97.8)	43 (93.5)	39 (97.5)	32 (97.0)
Q10 Diarrhea Severity	48 (92.3)	50 (100)	45 (97.8)	43 (93.5)	39 (97.5)	32 (97.0)
Skin Domain	48 (92.3)	50 (100)	45 (97.8)	43 (93.5)	39 (97.5)	32 (97.0)
GI Domain	48 (92.3)	50 (100)	45 (97.8)	43 (93.5)	39 (97.5)	32 (97.0)
TSS	48 (92.3)	50 (100)	45 (97.8)	43 (93.5)	39 (97.5)	32 (97.0)

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by Response Assessment Committee adjudication for study 2101 and by Study Steering Committee adjudication for study 2202. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. For study 2101, only a subset of AdvSM subjects are included in this table and number of patients treated on C1D1 is used for C1D-7.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-asm.sas Date: 10:26/29SEP2021

Table 35.2.9.1
Summary of AdvSM-SAF Compliance
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg	C7D1 (N=52)	C8D1 (N=52)	C9D1 (N=52)	C10D1 (N=52)	C11D1 (N=52)	C12D1 (N=52)	C13D1 (N=52)
Treated	30	28	25	19	17	14	10
Q1 Abdominal Pain	26 (86.7)	25 (89.3)	23 (92.0)	17 (89.5)	16 (94.1)	13 (92.9)	7 (70.0)
Q2 Nausea	26 (86.7)	25 (89.3)	23 (92.0)	17 (89.5)	16 (94.1)	13 (92.9)	7 (70.0)
Q3 Spots	26 (86.7)	25 (89.3)	23 (92.0)	17 (89.5)	16 (94.1)	13 (92.9)	7 (70.0)
Q4 Itching	26 (86.7)	25 (89.3)	23 (92.0)	17 (89.5)	16 (94.1)	13 (92.9)	7 (70.0)
Q5 Flushing	26 (86.7)	25 (89.3)	23 (92.0)	17 (89.5)	16 (94.1)	13 (92.9)	7 (70.0)
Q6 Fatigue	26 (86.7)	25 (89.3)	23 (92.0)	17 (89.5)	16 (94.1)	13 (92.9)	7 (70.0)
Q7 Vomitting Count	26 (86.7)	25 (89.3)	23 (92.0)	17 (89.5)	16 (94.1)	13 (92.9)	7 (70.0)
Q8 Vomitting Severity	26 (86.7)	25 (89.3)	23 (92.0)	17 (89.5)	16 (94.1)	13 (92.9)	7 (70.0)
Q9 Diarrhea Count	26 (86.7)	25 (89.3)	23 (92.0)	17 (89.5)	16 (94.1)	13 (92.9)	7 (70.0)
Q10 Diarrhea Severity	26 (86.7)	25 (89.3)	23 (92.0)	17 (89.5)	16 (94.1)	13 (92.9)	7 (70.0)
Skin Domain	26 (86.7)	25 (89.3)	23 (92.0)	17 (89.5)	16 (94.1)	13 (92.9)	7 (70.0)
GI Domain	26 (86.7)	25 (89.3)	23 (92.0)	17 (89.5)	16 (94.1)	13 (92.9)	7 (70.0)
TSS	26 (86.7)	25 (89.3)	23 (92.0)	17 (89.5)	16 (94.1)	13 (92.9)	7 (70.0)

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by Response Assessment Committee adjudication for study 2101 and by Study Steering Committee adjudication for study 2202. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. For study 2101, only a subset of AdvSM subjects are included in this table and number of patients treated on C1D1 is used for C1D-7.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-asm.sas Date: 10:26/29SEP2021

Table 35.2.9.1
Summary of AdvSM-SAF Compliance
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg							
	C14D1 (N=52)	C15D1 (N=52)	C16D1 (N=52)	C17D1 (N=52)	C18D1 (N=52)	C19D1 (N=52)	C20D1 (N=52)
Treated	9	8	8	8	6	1	1
Q1 Abdominal Pain	6 (66.7)	5 (62.5)	5 (62.5)	5 (62.5)	4 (66.7)	0	0
Q2 Nausea	6 (66.7)	5 (62.5)	5 (62.5)	5 (62.5)	4 (66.7)	0	0
Q3 Spots	6 (66.7)	5 (62.5)	5 (62.5)	5 (62.5)	4 (66.7)	0	0
Q4 Itching	6 (66.7)	5 (62.5)	5 (62.5)	5 (62.5)	4 (66.7)	0	0
Q5 Flushing	6 (66.7)	5 (62.5)	5 (62.5)	5 (62.5)	4 (66.7)	0	0
Q6 Fatigue	6 (66.7)	5 (62.5)	5 (62.5)	5 (62.5)	4 (66.7)	0	0
Q7 Vomitting Count	6 (66.7)	5 (62.5)	5 (62.5)	5 (62.5)	4 (66.7)	0	0
Q8 Vomitting Severity	6 (66.7)	5 (62.5)	5 (62.5)	5 (62.5)	4 (66.7)	0	0
Q9 Diarrhea Count	6 (66.7)	5 (62.5)	5 (62.5)	5 (62.5)	4 (66.7)	0	0
Q10 Diarrhea Severity	6 (66.7)	5 (62.5)	5 (62.5)	5 (62.5)	4 (66.7)	0	0
Skin Domain	6 (66.7)	5 (62.5)	5 (62.5)	5 (62.5)	4 (66.7)	0	0
GI Domain	6 (66.7)	5 (62.5)	5 (62.5)	5 (62.5)	4 (66.7)	0	0
TSS	6 (66.7)	5 (62.5)	5 (62.5)	5 (62.5)	4 (66.7)	0	0

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by Response Assessment Committee adjudication for study 2101 and by Study Steering Committee adjudication for study 2202. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. For study 2101, only a subset of AdvSM subjects are included in this table and number of patients treated on C1D1 is used for C1D-7.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-asm.sas Date: 10:26/29SEP2021

Table 35.2.9.1
Summary of AdvSM-SAF Compliance
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg	C1D1 (N=50)	C2D1 (N=50)	C3D1 (N=50)	C4D1 (N=50)	C5D1 (N=50)	C6D1 (N=50)
Treated	50	49	45	45	39	32
Q1 Abdominal Pain	46 (92.0)	49 (100)	44 (97.8)	42 (93.3)	38 (97.4)	31 (96.9)
Q2 Nausea	46 (92.0)	49 (100)	44 (97.8)	42 (93.3)	38 (97.4)	31 (96.9)
Q3 Spots	46 (92.0)	49 (100)	44 (97.8)	42 (93.3)	38 (97.4)	31 (96.9)
Q4 Itching	46 (92.0)	49 (100)	44 (97.8)	42 (93.3)	38 (97.4)	31 (96.9)
Q5 Flushing	46 (92.0)	49 (100)	44 (97.8)	42 (93.3)	38 (97.4)	31 (96.9)
Q6 Fatigue	46 (92.0)	49 (100)	44 (97.8)	42 (93.3)	38 (97.4)	31 (96.9)
Q7 Vomitting Count	46 (92.0)	49 (100)	44 (97.8)	42 (93.3)	38 (97.4)	31 (96.9)
Q8 Vomitting Severity	46 (92.0)	49 (100)	44 (97.8)	42 (93.3)	38 (97.4)	31 (96.9)
Q9 Diarrhea Count	46 (92.0)	49 (100)	44 (97.8)	42 (93.3)	38 (97.4)	31 (96.9)
Q10 Diarrhea Severity	46 (92.0)	49 (100)	44 (97.8)	42 (93.3)	38 (97.4)	31 (96.9)
Skin Domain	46 (92.0)	49 (100)	44 (97.8)	42 (93.3)	38 (97.4)	31 (96.9)
GI Domain	46 (92.0)	49 (100)	44 (97.8)	42 (93.3)	38 (97.4)	31 (96.9)
TSS	46 (92.0)	49 (100)	44 (97.8)	42 (93.3)	38 (97.4)	31 (96.9)

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by Response Assessment Committee adjudication for study 2101 and by Study Steering Committee adjudication for study 2202. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. For study 2101, only a subset of AdvSM subjects are included in this table and number of patients treated on C1D1 is used for C1D-7.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-asm.sas Date: 10:26/29SEP2021

Table 35.2.9.1
Summary of AdvSM-SAF Compliance
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg							
	C7D1 (N=50)	C8D1 (N=50)	C9D1 (N=50)	C10D1 (N=50)	C11D1 (N=50)	C12D1 (N=50)	C13D1 (N=50)
Treated	29	27	24	18	16	13	9
Q1 Abdominal Pain	25 (86.2)	24 (88.9)	22 (91.7)	16 (88.9)	15 (93.8)	12 (92.3)	6 (66.7)
Q2 Nausea	25 (86.2)	24 (88.9)	22 (91.7)	16 (88.9)	15 (93.8)	12 (92.3)	6 (66.7)
Q3 Spots	25 (86.2)	24 (88.9)	22 (91.7)	16 (88.9)	15 (93.8)	12 (92.3)	6 (66.7)
Q4 Itching	25 (86.2)	24 (88.9)	22 (91.7)	16 (88.9)	15 (93.8)	12 (92.3)	6 (66.7)
Q5 Flushing	25 (86.2)	24 (88.9)	22 (91.7)	16 (88.9)	15 (93.8)	12 (92.3)	6 (66.7)
Q6 Fatigue	25 (86.2)	24 (88.9)	22 (91.7)	16 (88.9)	15 (93.8)	12 (92.3)	6 (66.7)
Q7 Vomitting Count	25 (86.2)	24 (88.9)	22 (91.7)	16 (88.9)	15 (93.8)	12 (92.3)	6 (66.7)
Q8 Vomitting Severity	25 (86.2)	24 (88.9)	22 (91.7)	16 (88.9)	15 (93.8)	12 (92.3)	6 (66.7)
Q9 Diarrhea Count	25 (86.2)	24 (88.9)	22 (91.7)	16 (88.9)	15 (93.8)	12 (92.3)	6 (66.7)
Q10 Diarrhea Severity	25 (86.2)	24 (88.9)	22 (91.7)	16 (88.9)	15 (93.8)	12 (92.3)	6 (66.7)
Skin Domain	25 (86.2)	24 (88.9)	22 (91.7)	16 (88.9)	15 (93.8)	12 (92.3)	6 (66.7)
GI Domain	25 (86.2)	24 (88.9)	22 (91.7)	16 (88.9)	15 (93.8)	12 (92.3)	6 (66.7)
TSS	25 (86.2)	24 (88.9)	22 (91.7)	16 (88.9)	15 (93.8)	12 (92.3)	6 (66.7)

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by Response Assessment Committee adjudication for study 2101 and by Study Steering Committee adjudication for study 2202. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. For study 2101, only a subset of AdvSM subjects are included in this table and number of patients treated on C1D1 is used for C1D-7.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-asm.sas Date: 10:26/29SEP2021

Table 35.2.9.1
Summary of AdvSM-SAF Compliance
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg							
	C14D1 (N=50)	C15D1 (N=50)	C16D1 (N=50)	C17D1 (N=50)	C18D1 (N=50)	C19D1 (N=50)	C20D1 (N=50)
Treated	8	8	8	8	6	1	1
Q1 Abdominal Pain	5 (62.5)	5 (62.5)	5 (62.5)	5 (62.5)	4 (66.7)	0	0
Q2 Nausea	5 (62.5)	5 (62.5)	5 (62.5)	5 (62.5)	4 (66.7)	0	0
Q3 Spots	5 (62.5)	5 (62.5)	5 (62.5)	5 (62.5)	4 (66.7)	0	0
Q4 Itching	5 (62.5)	5 (62.5)	5 (62.5)	5 (62.5)	4 (66.7)	0	0
Q5 Flushing	5 (62.5)	5 (62.5)	5 (62.5)	5 (62.5)	4 (66.7)	0	0
Q6 Fatigue	5 (62.5)	5 (62.5)	5 (62.5)	5 (62.5)	4 (66.7)	0	0
Q7 Vomitting Count	5 (62.5)	5 (62.5)	5 (62.5)	5 (62.5)	4 (66.7)	0	0
Q8 Vomitting Severity	5 (62.5)	5 (62.5)	5 (62.5)	5 (62.5)	4 (66.7)	0	0
Q9 Diarrhea Count	5 (62.5)	5 (62.5)	5 (62.5)	5 (62.5)	4 (66.7)	0	0
Q10 Diarrhea Severity	5 (62.5)	5 (62.5)	5 (62.5)	5 (62.5)	4 (66.7)	0	0
Skin Domain	5 (62.5)	5 (62.5)	5 (62.5)	5 (62.5)	4 (66.7)	0	0
GI Domain	5 (62.5)	5 (62.5)	5 (62.5)	5 (62.5)	4 (66.7)	0	0
TSS	5 (62.5)	5 (62.5)	5 (62.5)	5 (62.5)	4 (66.7)	0	0

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by Response Assessment Committee adjudication for study 2101 and by Study Steering Committee adjudication for study 2202. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. For study 2101, only a subset of AdvSM subjects are included in this table and number of patients treated on C1D1 is used for C1D-7.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-asm.sas Date: 10:26/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Scores	TSS (N=27)	Skin Domain (N=27)	GI Domain (N=27)	Q6 Fatigue (N=27)
Baseline (C1D-7 to C1D-1)				
n	23	23	23	23
Mean (StdDev)	21.63 (13.671)	7.38 (5.686)	8.19 (7.140)	6.10 (2.792)
Median	20.00	6.60	8.00	6.86
Min, Max	1.2, 50.2	0.0, 18.0	0.0, 25.2	0.2, 10.0
Cycle 2 Day 1				
n	25	25	25	25
Mean (StdDev)	16.90 (12.267)	6.48 (5.876)	5.12 (5.376)	5.29 (2.688)
Median	14.83	6.14	3.57	5.29
Min, Max	1.9, 49.2	0.0, 23.0	0.0, 22.3	1.3, 10.0
Cycle 3 Day 1				
n	25	25	25	25
Mean (StdDev)	15.73 (10.439)	6.12 (5.366)	4.67 (4.308)	4.99 (2.488)
Median	14.57	5.57	4.00	4.83
Min, Max	0.4, 46.1	0.0, 23.1	0.0, 14.4	0.1, 10.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Scores	Q3 Spots (N=27)	Q4 Itching (N=27)	Q5 Flushing (N=27)
Baseline (C1D-7 to C1D-1)			
n	23	23	23
Mean (StdDev)	2.89 (2.219)	2.25 (2.417)	2.27 (2.651)
Median	3.43	0.83	1.43
Min, Max	0.0, 6.1	0.0, 6.9	0.0, 8.7
Cycle 2 Day 1			
n	25	25	25
Mean (StdDev)	2.52 (2.506)	1.73 (2.293)	2.23 (2.613)
Median	2.29	0.71	1.71
Min, Max	0.0, 8.1	0.0, 7.4	0.0, 8.9
Cycle 3 Day 1			
n	25	25	25
Mean (StdDev)	2.29 (2.113)	1.62 (2.340)	2.21 (2.141)
Median	2.00	0.43	2.00
Min, Max	0.0, 8.0	0.0, 7.6	0.0, 7.6

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Scores	Q1 Abdominal Pain (N=27)	Q2 Nausea (N=27)	Q7 Vomitting Count (N=27)	Q8 Vomitting Severity (N=27)	Q9 Diarrhea Count (N=27)	Q10 Diarrhea Severity (N=27)
Baseline (C1D-7 to C1D-1)						
n	23	23	23	23	23	23
Mean (StdDev)	3.37 (2.988)	2.15 (2.707)	0.69 (2.690)	0.41 (1.278)	8.32 (19.362)	2.25 (2.215)
Median	3.00	0.57	0.00	0.00	1.71	2.57
Min, Max	0.0, 9.0	0.0, 8.0	0.0, 12.9	0.0, 5.8	0.0, 85.7	0.0, 7.6
Cycle 2 Day 1						
n	25	25	25	25	25	25
Mean (StdDev)	1.88 (2.329)	1.61 (2.190)	1.16 (5.712)	0.08 (0.244)	3.42 (11.338)	1.54 (2.329)
Median	1.14	0.86	0.00	0.00	0.50	0.43
Min, Max	0.0, 7.2	0.0, 8.0	0.0, 28.6	0.0, 0.9	0.0, 57.1	0.0, 7.5
Cycle 3 Day 1						
n	25	25	25	25	25	25
Mean (StdDev)	1.81 (2.479)	1.18 (1.557)	0.03 (0.072)	0.06 (0.144)	1.91 (3.347)	1.62 (2.055)
Median	0.80	0.29	0.00	0.00	0.43	0.71
Min, Max	0.0, 7.1	0.0, 6.1	0.0, 0.3	0.0, 0.5	0.0, 14.3	0.0, 6.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas
Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Scores	TSS (N=27)	Skin Domain (N=27)	GI Domain (N=27)	Q6 Fatigue (N=27)
Cycle 4 Day 1				
n	25	25	25	25
Mean (StdDev)	14.91 (9.652)	5.50 (4.458)	4.29 (4.641)	5.12 (2.884)
Median	12.00	5.40	2.29	5.60
Min, Max	1.0, 37.0	0.0, 18.8	0.0, 16.9	0.3, 10.0
Cycle 5 Day 1				
n	24	24	24	24
Mean (StdDev)	14.33 (10.459)	5.19 (5.242)	4.09 (4.797)	5.05 (2.684)
Median	13.14	3.21	2.64	5.46
Min, Max	0.5, 43.5	0.0, 21.6	0.0, 21.5	0.3, 10.0
Cycle 6 Day 1				
n	21	21	21	21
Mean (StdDev)	13.52 (11.105)	5.14 (6.430)	3.60 (4.400)	4.78 (2.749)
Median	11.71	2.43	1.29	4.57
Min, Max	0.1, 41.6	0.0, 23.2	0.0, 17.4	0.1, 9.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Scores	Q3 Spots (N=27)	Q4 Itching (N=27)	Q5 Flushing (N=27)
Cycle 4 Day 1			
n	25	25	25
Mean (StdDev)	2.10 (1.623)	1.45 (1.787)	1.94 (2.199)
Median	2.00	1.00	1.40
Min, Max	0.0, 6.0	0.0, 6.3	0.0, 7.0
Cycle 5 Day 1			
n	24	24	24
Mean (StdDev)	1.93 (1.789)	1.37 (2.023)	1.88 (2.235)
Median	1.86	0.21	1.17
Min, Max	0.0, 6.7	0.0, 6.9	0.0, 8.0
Cycle 6 Day 1			
n	21	21	21
Mean (StdDev)	1.75 (2.003)	1.66 (2.405)	1.74 (2.469)
Median	1.00	0.29	0.33
Min, Max	0.0, 7.4	0.0, 8.0	0.0, 7.8

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Scores	Q1 Abdominal Pain (N=27)	Q2 Nausea (N=27)	Q7 Vomitting Count (N=27)	Q8 Vomitting Severity (N=27)	Q9 Diarrhea Count (N=27)	Q10 Diarrhea Severity (N=27)
Cycle 4 Day 1						
n	25	25	25	25	25	25
Mean (StdDev)	1.31 (1.834)	1.17 (1.550)	0.07 (0.157)	0.20 (0.374)	0.98 (1.667)	1.62 (2.154)
Median	0.67	0.40	0.00	0.00	0.57	0.86
Min, Max	0.0, 7.0	0.0, 5.0	0.0, 0.7	0.0, 1.0	0.0, 8.0	0.0, 7.3
Cycle 5 Day 1						
n	24	24	24	24	24	24
Mean (StdDev)	1.25 (1.834)	1.11 (1.710)	0.04 (0.140)	0.16 (0.451)	1.61 (3.031)	1.57 (2.142)
Median	0.42	0.29	0.00	0.00	0.50	0.57
Min, Max	0.0, 7.3	0.0, 6.3	0.0, 0.7	0.0, 1.7	0.0, 14.3	0.0, 7.8
Cycle 6 Day 1						
n	21	21	21	21	21	21
Mean (StdDev)	1.19 (1.831)	0.80 (1.665)	0.03 (0.131)	0.15 (0.698)	1.55 (3.563)	1.45 (1.993)
Median	0.43	0.00	0.00	0.00	0.33	0.57
Min, Max	0.0, 7.2	0.0, 7.0	0.0, 0.6	0.0, 3.2	0.0, 16.6	0.0, 7.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Scores	TSS (N=27)	Skin Domain (N=27)	GI Domain (N=27)	Q6 Fatigue (N=27)
Cycle 7 Day 1				
n	19	20	20	20
Mean (StdDev)	12.98 (9.636)	5.80 (6.810)	3.45 (3.634)	4.97 (2.681)
Median	11.71	2.36	2.44	4.89
Min, Max	0.1, 36.5	0.0, 23.3	0.0, 13.5	0.0, 9.6
Cycle 8 Day 1				
n	16	16	16	16
Mean (StdDev)	11.21 (8.197)	3.69 (4.375)	2.81 (3.986)	4.71 (2.315)
Median	11.61	1.93	1.15	4.43
Min, Max	0.1, 34.5	0.0, 13.9	0.0, 15.0	0.0, 8.7
Cycle 9 Day 1				
n	18	18	18	18
Mean (StdDev)	12.10 (10.547)	4.59 (5.461)	2.93 (4.544)	4.58 (2.198)
Median	10.02	3.08	0.93	4.86
Min, Max	0.4, 43.6	0.0, 20.8	0.0, 14.8	0.0, 8.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Scores	Q3 Spots (N=27)	Q4 Itching (N=27)	Q5 Flushing (N=27)
Cycle 7 Day 1			
n	20	20	20
Mean (StdDev)	1.87 (2.133)	1.91 (2.548)	2.03 (2.683)
Median	0.86	0.36	0.73
Min, Max	0.0, 6.8	0.0, 7.4	0.0, 9.2
Cycle 8 Day 1			
n	16	16	16
Mean (StdDev)	1.31 (1.443)	1.19 (1.846)	1.20 (1.942)
Median	0.88	0.21	0.45
Min, Max	0.0, 4.9	0.0, 5.7	0.0, 7.0
Cycle 9 Day 1			
n	18	18	18
Mean (StdDev)	1.58 (1.949)	1.38 (1.993)	1.62 (2.230)
Median	1.00	0.23	0.69
Min, Max	0.0, 7.0	0.0, 6.8	0.0, 7.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Scores	Q1 Abdominal Pain (N=27)	Q2 Nausea (N=27)	Q7 Vomitting Count (N=27)	Q8 Vomitting Severity (N=27)	Q9 Diarrhea Count (N=27)	Q10 Diarrhea Severity (N=27)
Cycle 7 Day 1						
n	20	20	20	20	20	20
Mean (StdDev)	1.07 (1.683)	0.91 (1.452)	0.04 (0.106)	0.13 (0.346)	0.71 (1.034)	1.38 (1.881)
Median	0.43	0.36	0.00	0.00	0.07	0.07
Min, Max	0.0, 6.5	0.0, 5.8	0.0, 0.4	0.0, 1.2	0.0, 3.3	0.0, 5.3
Cycle 8 Day 1						
n	16	16	16	16	16	16
Mean (StdDev)	0.57 (0.873)	0.84 (1.357)	1.56 (6.250)	0.08 (0.313)	3.72 (8.023)	1.33 (1.969)
Median	0.08	0.36	0.00	0.00	0.63	0.29
Min, Max	0.0, 2.7	0.0, 5.3	0.0, 25.0	0.0, 1.3	0.0, 30.4	0.0, 7.0
Cycle 9 Day 1						
n	18	18	18	18	18	18
Mean (StdDev)	0.73 (1.693)	0.98 (1.828)	0.06 (0.121)	0.21 (0.457)	0.58 (0.941)	1.01 (1.797)
Median	0.07	0.31	0.00	0.00	0.08	0.25
Min, Max	0.0, 7.0	0.0, 6.4	0.0, 0.4	0.0, 1.4	0.0, 3.1	0.0, 6.9

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Scores	TSS (N=27)	Skin Domain (N=27)	GI Domain (N=27)	Q6 Fatigue (N=27)
Cycle 10 Day 1				
n	16	16	16	16
Mean (StdDev)	13.24 (8.725)	4.34 (4.424)	4.10 (5.741)	4.80 (2.718)
Median	12.42	2.93	0.95	5.00
Min, Max	0.3, 30.3	0.0, 14.8	0.0, 17.0	0.1, 9.4
Cycle 11 Day 1				
n	15	15	15	15
Mean (StdDev)	12.23 (9.256)	4.92 (5.450)	2.23 (3.151)	5.08 (2.578)
Median	13.00	3.57	1.00	5.57
Min, Max	0.7, 35.5	0.0, 16.8	0.0, 11.5	0.0, 9.1
Cycle 12 Day 1				
n	14	14	14	14
Mean (StdDev)	14.82 (13.437)	6.36 (6.576)	3.79 (5.457)	4.67 (2.660)
Median	11.71	3.86	1.61	4.74
Min, Max	0.0, 45.7	0.0, 20.7	0.0, 16.3	0.0, 8.7

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses			
Scores	Q3 Spots (N=27)	Q4 Itching (N=27)	Q5 Flushing (N=27)
Cycle 10 Day 1			
n	16	16	16
Mean (StdDev)	1.43 (1.497)	1.50 (2.083)	1.41 (1.918)
Median	0.76	0.40	0.43
Min, Max	0.0, 5.0	0.0, 6.3	0.0, 6.8
Cycle 11 Day 1			
n	15	15	15
Mean (StdDev)	1.47 (1.653)	1.70 (1.970)	1.74 (2.466)
Median	0.71	0.71	0.43
Min, Max	0.0, 5.8	0.0, 5.3	0.0, 7.8
Cycle 12 Day 1			
n	14	14	14
Mean (StdDev)	1.93 (1.900)	2.34 (2.476)	2.09 (2.831)
Median	1.79	1.27	0.90
Min, Max	0.0, 6.7	0.0, 6.8	0.0, 9.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Scores	Q1 Abdominal Pain (N=27)	Q2 Nausea (N=27)	Q7 Vomitting Count (N=27)	Q8 Vomitting Severity (N=27)	Q9 Diarrhea Count (N=27)	Q10 Diarrhea Severity (N=27)
Cycle 10 Day 1						
n	16	16	16	16	16	16
Mean (StdDev)	1.55 (2.685)	0.96 (1.445)	0.01 (0.036)	0.03 (0.107)	1.25 (1.776)	1.56 (2.135)
Median	0.15	0.17	0.00	0.00	0.55	0.64
Min, Max	0.0, 9.1	0.0, 4.7	0.0, 0.1	0.0, 0.4	0.0, 5.7	0.0, 6.9
Cycle 11 Day 1						
n	15	15	15	15	15	15
Mean (StdDev)	1.16 (2.065)	0.54 (1.172)	0.00 (0.000)	0.00 (0.000)	0.47 (0.652)	0.53 (0.874)
Median	0.29	0.14	0.00	0.00	0.00	0.00
Min, Max	0.0, 7.0	0.0, 4.5	0.0, 0.0	0.0, 0.0	0.0, 2.1	0.0, 2.7
Cycle 12 Day 1						
n	14	14	14	14	14	14
Mean (StdDev)	1.12 (2.125)	1.04 (1.830)	0.10 (0.320)	0.10 (0.320)	0.75 (1.296)	1.45 (2.410)
Median	0.45	0.14	0.00	0.00	0.21	0.47
Min, Max	0.0, 7.7	0.0, 6.2	0.0, 1.2	0.0, 1.2	0.0, 4.3	0.0, 7.3

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Scores	TSS (N=27)	Skin Domain (N=27)	GI Domain (N=27)	Q6 Fatigue (N=27)
Cycle 13 Day 1				
n	10	10	10	10
Mean (StdDev)	13.59 (13.545)	5.58 (6.189)	3.26 (6.056)	4.74 (2.331)
Median	9.76	3.37	0.79	5.17
Min, Max	0.3, 48.8	0.0, 21.0	0.0, 19.8	0.0, 8.0
Cycle 14 Day 1				
n	8	8	9	9
Mean (StdDev)	16.61 (11.933)	7.39 (6.361)	4.84 (6.087)	5.88 (1.616)
Median	15.08	6.96	2.00	5.83
Min, Max	5.0, 43.0	0.9, 20.4	0.0, 15.2	4.0, 7.8
Cycle 15 Day 1				
n	5	5	5	5
Mean (StdDev)	22.41 (12.823)	10.64 (8.012)	5.48 (4.036)	6.36 (1.432)
Median	21.67	8.83	4.86	6.50
Min, Max	5.9, 38.8	1.0, 20.5	0.3, 11.3	4.6, 8.3

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses			
Scores	Q3 Spots (N=27)	Q4 Itching (N=27)	Q5 Flushing (N=27)
Cycle 13 Day 1			
n	10	10	10
Mean (StdDev)	1.90 (2.115)	2.00 (2.423)	1.68 (2.227)
Median	1.36	1.01	1.33
Min, Max	0.0, 7.3	0.0, 6.5	0.0, 7.3
Cycle 14 Day 1			
n	9	9	8
Mean (StdDev)	2.47 (2.066)	2.87 (2.565)	2.20 (2.164)
Median	2.67	3.00	2.21
Min, Max	0.1, 6.8	0.0, 7.0	0.0, 6.6
Cycle 15 Day 1			
n	5	5	5
Mean (StdDev)	3.12 (2.854)	3.60 (3.115)	3.95 (3.546)
Median	3.00	3.75	4.00
Min, Max	0.0, 7.0	0.0, 7.3	0.0, 8.5

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Scores	Q1 Abdominal Pain (N=27)	Q2 Nausea (N=27)	Q7 Vomitting Count (N=27)	Q8 Vomitting Severity (N=27)	Q9 Diarrhea Count (N=27)	Q10 Diarrhea Severity (N=27)
Cycle 13 Day 1						
n	10	10	10	10	10	10
Mean (StdDev)	0.94 (2.324)	1.16 (2.265)	0.16 (0.326)	0.38 (1.022)	0.44 (0.796)	0.79 (1.251)
Median	0.07	0.21	0.00	0.00	0.00	0.00
Min, Max	0.0, 7.5	0.0, 7.3	0.0, 1.0	0.0, 3.3	0.0, 2.2	0.0, 3.2
Cycle 14 Day 1						
n	9	9	9	9	9	9
Mean (StdDev)	1.44 (2.505)	1.84 (2.625)	0.24 (0.574)	0.42 (1.067)	0.71 (0.969)	1.14 (1.592)
Median	0.33	0.50	0.00	0.00	0.33	1.00
Min, Max	0.0, 7.2	0.0, 6.6	0.0, 1.8	0.0, 3.3	0.0, 3.0	0.0, 5.0
Cycle 15 Day 1						
n	5	5	5	5	5	5
Mean (StdDev)	1.93 (2.355)	1.87 (2.154)	0.00 (0.000)	0.00 (0.000)	0.94 (0.901)	1.68 (1.889)
Median	1.00	1.86	0.00	0.00	1.29	1.14
Min, Max	0.3, 6.0	0.0, 5.3	0.0, 0.0	0.0, 0.0	0.0, 2.0	0.0, 4.3

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Scores	TSS (N=27)	Skin Domain (N=27)	GI Domain (N=27)	Q6 Fatigue (N=27)
Cycle 16 Day 1				
n	6	6	6	6
Mean (StdDev)	23.82 (16.520)	10.66 (8.428)	6.90 (6.858)	6.26 (2.367)
Median	21.87	7.92	6.68	6.61
Min, Max	2.9, 49.0	0.4, 22.2	0.0, 18.4	2.3, 8.7
Cycle 17 Day 1				
n	4	4	4	4
Mean (StdDev)	14.99 (8.544)	6.16 (3.974)	2.85 (2.934)	5.93 (2.305)
Median	17.29	7.74	2.61	5.71
Min, Max	3.7, 21.7	0.3, 8.9	0.0, 6.2	3.4, 8.9
Cycle 18 Day 1				
n	4	4	4	4
Mean (StdDev)	17.96 (11.122)	8.08 (6.118)	4.36 (3.769)	5.53 (1.799)
Median	17.60	7.20	4.40	5.99
Min, Max	5.0, 31.7	1.6, 16.3	0.3, 8.3	3.1, 7.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses			
Scores	Q3 Spots (N=27)	Q4 Itching (N=27)	Q5 Flushing (N=27)
Cycle 16 Day 1			
n	6	6	6
Mean (StdDev)	3.07 (2.943)	3.68 (3.038)	3.92 (3.592)
Median	2.75	3.99	3.57
Min, Max	0.0, 8.0	0.0, 7.0	0.0, 8.8
Cycle 17 Day 1			
n	4	4	4
Mean (StdDev)	1.96 (1.141)	2.61 (2.220)	1.59 (1.995)
Median	2.34	2.51	1.10
Min, Max	0.3, 2.9	0.0, 5.4	0.0, 4.1
Cycle 18 Day 1			
n	4	4	4
Mean (StdDev)	2.01 (1.151)	2.02 (1.535)	4.05 (3.760)
Median	1.93	1.90	3.60
Min, Max	0.8, 3.3	0.3, 4.0	0.0, 9.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Scores	Q1 Abdominal Pain (N=27)	Q2 Nausea (N=27)	Q7 Vomitting Count (N=27)	Q8 Vomitting Severity (N=27)	Q9 Diarrhea Count (N=27)	Q10 Diarrhea Severity (N=27)
Cycle 16 Day 1						
n	6	6	6	6	6	6
Mean (StdDev)	1.83 (3.543)	2.27 (3.194)	0.03 (0.082)	0.20 (0.490)	1.45 (1.796)	2.61 (3.305)
Median	0.40	1.33	0.00	0.00	1.00	1.08
Min, Max	0.0, 9.0	0.0, 8.2	0.0, 0.2	0.0, 1.2	0.0, 4.4	0.0, 6.8
Cycle 17 Day 1						
n	4	4	4	4	4	4
Mean (StdDev)	0.61 (0.703)	0.48 (0.829)	0.00 (0.000)	0.00 (0.000)	1.22 (1.297)	1.79 (2.309)
Median	0.57	0.10	0.00	0.00	0.94	1.01
Min, Max	0.0, 1.3	0.0, 1.7	0.0, 0.0	0.0, 0.0	0.0, 3.0	0.0, 5.1
Cycle 18 Day 1						
n	4	4	4	4	4	4
Mean (StdDev)	0.39 (0.427)	0.33 (0.561)	0.00 (0.000)	0.00 (0.000)	1.92 (1.506)	3.63 (3.283)
Median	0.29	0.08	0.00	0.00	2.01	3.68
Min, Max	0.0, 1.0	0.0, 1.2	0.0, 0.0	0.0, 0.0	0.0, 3.7	0.0, 7.2

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Scores	TSS (N=27)	Skin Domain (N=27)	GI Domain (N=27)	Q6 Fatigue (N=27)
Cycle 19 Day 1				
n	3	3	3	3
Mean (StdDev)	30.92 (12.067)	14.84 (5.828)	9.27 (6.280)	6.81 (0.599)
Median	26.83	15.17	6.14	6.50
Min, Max	21.4, 44.5	8.9, 20.5	5.2, 16.5	6.4, 7.5
Cycle 20 Day 1				
n	1	1	1	1
Mean (StdDev)	18.00 (-)	6.83 (-)	4.17 (-)	7.00 (-)
Median	18.00	6.83	4.17	7.00
Min, Max	18.0, 18.0	6.8, 6.8	4.2, 4.2	7.0, 7.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Scores	Q3 Spots (N=27)	Q4 Itching (N=27)	Q5 Flushing (N=27)
Cycle 19 Day 1			
n	3	3	3
Mean (StdDev)	4.03 (2.804)	3.66 (2.462)	7.15 (1.945)
Median	3.67	2.33	7.00
Min, Max	1.4, 7.0	2.1, 6.5	5.3, 9.2
Cycle 20 Day 1			
n	1	1	1
Mean (StdDev)	1.00 (-)	1.33 (-)	4.50 (-)
Median	1.00	1.33	4.50
Min, Max	1.0, 1.0	1.3, 1.3	4.5, 4.5

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Scores	Q1 Abdominal Pain (N=27)	Q2 Nausea (N=27)	Q7 Vomitting Count (N=27)	Q8 Vomitting Severity (N=27)	Q9 Diarrhea Count (N=27)	Q10 Diarrhea Severity (N=27)
Cycle 19 Day 1						
n	3	3	3	3	3	3
Mean (StdDev)	2.84 (4.049)	2.08 (3.608)	0.17 (0.289)	0.42 (0.722)	1.72 (1.277)	3.93 (2.108)
Median	0.86	0.00	0.00	0.00	2.33	5.00
Min, Max	0.2, 7.5	0.0, 6.3	0.0, 0.5	0.0, 1.3	0.3, 2.6	1.5, 5.3
Cycle 20 Day 1						
n	1	1	1	1	1	1
Mean (StdDev)	1.00 (-)	0.00 (-)	0.00 (-)	0.00 (-)	1.50 (-)	3.17 (-)
Median	1.00	0.00	0.00	0.00	1.50	3.17
Min, Max	1.0, 1.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	1.5, 1.5	3.2, 3.2

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg				
Scores	TSS (N=10)	Skin Domain (N=10)	GI Domain (N=10)	Q6 Fatigue (N=10)
Baseline (C1D-7 to C1D-1)				
n	9	9	9	9
Mean (StdDev)	23.41 (10.625)	9.33 (4.627)	8.33 (5.236)	5.76 (2.751)
Median	27.43	10.43	8.60	6.86
Min, Max	1.2, 34.9	0.6, 15.7	0.3, 14.6	0.2, 8.9
Cycle 2 Day 1				
n	9	9	9	9
Mean (StdDev)	14.28 (6.422)	5.54 (3.071)	4.17 (3.257)	4.57 (2.003)
Median	14.43	6.50	4.14	5.00
Min, Max	5.4, 27.5	1.0, 9.9	0.9, 11.5	1.3, 7.2
Cycle 3 Day 1				
n	9	9	9	9
Mean (StdDev)	16.41 (7.053)	6.77 (3.992)	5.08 (3.701)	4.56 (1.684)
Median	14.57	6.43	4.00	4.25
Min, Max	6.8, 29.6	2.0, 13.9	1.0, 11.9	1.9, 7.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg			
Scores	Q3 Spots (N=10)	Q4 Itching (N=10)	Q5 Flushing (N=10)
Baseline (C1D-7 to C1D-1)			
n	9	9	9
Mean (StdDev)	3.38 (2.090)	3.38 (2.489)	2.56 (2.573)
Median	3.86	4.20	1.86
Min, Max	0.2, 6.1	0.3, 6.9	0.0, 6.6
Cycle 2 Day 1			
n	9	9	9
Mean (StdDev)	2.34 (2.452)	1.57 (1.952)	1.64 (1.619)
Median	2.43	1.00	1.71
Min, Max	0.0, 7.0	0.0, 4.7	0.0, 5.0
Cycle 3 Day 1			
n	9	9	9
Mean (StdDev)	2.57 (2.060)	1.82 (2.260)	2.38 (1.988)
Median	2.00	1.50	2.40
Min, Max	0.0, 6.9	0.0, 6.7	0.0, 6.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Scores	Q1 Abdominal Pain (N=10)	Q2 Nausea (N=10)	Q7 Vomitting Count (N=10)	Q8 Vomitting Severity (N=10)	Q9 Diarrhea Count (N=10)	Q10 Diarrhea Severity (N=10)
Baseline (C1D-7 to C1D-1)						
n	9	9	9	9	9	9
Mean (StdDev)	3.71 (2.405)	1.66 (2.413)	0.02 (0.067)	0.04 (0.133)	2.37 (2.213)	2.91 (2.582)
Median	3.43	0.57	0.00	0.00	1.71	3.00
Min, Max	0.3, 7.1	0.0, 7.3	0.0, 0.2	0.0, 0.4	0.0, 5.1	0.0, 7.6
Cycle 2 Day 1						
n	9	9	9	9	9	9
Mean (StdDev)	1.80 (2.198)	1.29 (1.700)	0.00 (0.000)	0.00 (0.000)	1.01 (1.223)	1.07 (1.195)
Median	1.14	1.00	0.00	0.00	0.57	0.71
Min, Max	0.1, 6.2	0.0, 5.3	0.0, 0.0	0.0, 0.0	0.0, 3.4	0.0, 3.4
Cycle 3 Day 1						
n	9	9	9	9	9	9
Mean (StdDev)	2.13 (2.726)	1.00 (0.980)	0.03 (0.083)	0.03 (0.083)	1.46 (1.465)	1.93 (1.777)
Median	0.86	0.50	0.00	0.00	0.57	1.50
Min, Max	0.0, 6.9	0.0, 2.4	0.0, 0.3	0.0, 0.3	0.0, 3.4	0.0, 5.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg				
Scores	TSS (N=10)	Skin Domain (N=10)	GI Domain (N=10)	Q6 Fatigue (N=10)
Cycle 4 Day 1				
n	9	9	9	9
Mean (StdDev)	13.44 (4.778)	5.31 (3.019)	3.69 (3.184)	4.45 (2.581)
Median	13.14	5.86	3.00	3.57
Min, Max	6.0, 20.0	0.9, 9.9	0.0, 8.1	1.5, 8.3
Cycle 5 Day 1				
n	8	8	8	8
Mean (StdDev)	13.25 (3.722)	4.35 (3.341)	4.15 (3.199)	4.76 (2.259)
Median	13.07	3.25	3.64	4.82
Min, Max	7.0, 20.0	0.6, 9.7	0.3, 9.4	1.3, 8.0
Cycle 6 Day 1				
n	6	6	6	6
Mean (StdDev)	10.78 (4.131)	2.95 (3.679)	3.79 (3.549)	4.04 (2.334)
Median	10.86	2.43	2.21	3.12
Min, Max	5.3, 16.7	0.0, 10.0	0.9, 9.0	2.0, 7.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg			
Scores	Q3 Spots (N=10)	Q4 Itching (N=10)	Q5 Flushing (N=10)
Cycle 4 Day 1			
n	9	9	9
Mean (StdDev)	1.89 (1.464)	1.46 (1.484)	1.96 (1.782)
Median	2.00	1.00	1.86
Min, Max	0.0, 4.1	0.0, 4.0	0.0, 5.9
Cycle 5 Day 1			
n	8	8	8
Mean (StdDev)	1.57 (1.571)	1.04 (1.669)	1.74 (1.517)
Median	1.33	0.15	1.83
Min, Max	0.0, 4.0	0.0, 4.0	0.0, 4.0
Cycle 6 Day 1			
n	6	6	6
Mean (StdDev)	0.79 (0.940)	0.94 (1.709)	1.23 (1.427)
Median	0.50	0.14	0.71
Min, Max	0.0, 2.2	0.0, 4.3	0.0, 3.5

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Scores	Q1 Abdominal Pain (N=10)	Q2 Nausea (N=10)	Q7 Vomitting Count (N=10)	Q8 Vomitting Severity (N=10)	Q9 Diarrhea Count (N=10)	Q10 Diarrhea Severity (N=10)
Cycle 4 Day 1						
n	9	9	9	9	9	9
Mean (StdDev)	0.89 (0.964)	1.39 (1.634)	0.12 (0.244)	0.20 (0.406)	0.78 (0.928)	1.21 (1.380)
Median	0.80	0.67	0.00	0.00	0.57	1.00
Min, Max	0.0, 2.6	0.0, 4.4	0.0, 0.7	0.0, 1.0	0.0, 2.9	0.0, 3.6
Cycle 5 Day 1						
n	8	8	8	8	8	8
Mean (StdDev)	0.92 (1.319)	1.54 (1.940)	0.10 (0.235)	0.38 (0.700)	1.07 (1.348)	1.32 (1.573)
Median	0.17	0.98	0.00	0.00	0.50	0.58
Min, Max	0.0, 3.6	0.0, 5.5	0.0, 0.7	0.0, 1.7	0.0, 3.6	0.0, 3.9
Cycle 6 Day 1						
n	6	6	6	6	6	6
Mean (StdDev)	0.69 (1.556)	0.54 (0.780)	0.00 (0.000)	0.00 (0.000)	1.26 (0.934)	2.56 (2.637)
Median	0.00	0.25	0.00	0.00	1.21	1.96
Min, Max	0.0, 3.9	0.0, 2.0	0.0, 0.0	0.0, 0.0	0.0, 2.9	0.0, 7.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg				
Scores	TSS (N=10)	Skin Domain (N=10)	GI Domain (N=10)	Q6 Fatigue (N=10)
Cycle 7 Day 1				
n	6	6	6	6
Mean (StdDev)	11.30 (6.297)	4.00 (4.542)	3.35 (2.325)	3.96 (2.466)
Median	9.69	2.43	3.01	3.41
Min, Max	4.3, 19.6	0.0, 11.0	0.7, 6.7	1.3, 8.0
Cycle 8 Day 1				
n	4	4	4	4
Mean (StdDev)	8.96 (4.701)	1.75 (1.301)	3.64 (3.300)	3.57 (2.235)
Median	9.21	1.93	2.86	3.36
Min, Max	3.9, 13.6	0.0, 3.1	0.7, 8.1	1.3, 6.3
Cycle 9 Day 1				
n	5	5	5	5
Mean (StdDev)	9.14 (4.033)	3.31 (2.864)	2.16 (3.353)	3.66 (2.188)
Median	8.86	3.17	0.71	3.33
Min, Max	4.7, 14.1	0.0, 7.8	0.3, 8.1	0.8, 6.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg			
Scores	Q3 Spots (N=10)	Q4 Itching (N=10)	Q5 Flushing (N=10)
Cycle 7 Day 1			
n	6	6	6
Mean (StdDev)	1.23 (1.386)	1.27 (1.948)	1.50 (1.635)
Median	0.93	0.14	1.36
Min, Max	0.0, 2.8	0.0, 4.6	0.0, 3.6
Cycle 8 Day 1			
n	4	4	4
Mean (StdDev)	0.61 (0.811)	0.18 (0.357)	0.96 (1.473)
Median	0.36	0.00	0.36
Min, Max	0.0, 1.7	0.0, 0.7	0.0, 3.1
Cycle 9 Day 1			
n	5	5	5
Mean (StdDev)	1.14 (1.357)	0.74 (1.299)	1.43 (1.663)
Median	0.71	0.00	0.71
Min, Max	0.0, 3.2	0.0, 3.0	0.0, 3.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Scores	Q1 Abdominal Pain (N=10)	Q2 Nausea (N=10)	Q7 Vomitting Count (N=10)	Q8 Vomitting Severity (N=10)	Q9 Diarrhea Count (N=10)	Q10 Diarrhea Severity (N=10)
Cycle 7 Day 1						
n	6	6	6	6	6	6
Mean (StdDev)	0.42 (0.788)	0.61 (0.664)	0.00 (0.000)	0.00 (0.000)	1.20 (1.017)	2.31 (1.975)
Median	0.07	0.47	0.00	0.00	1.18	2.27
Min, Max	0.0, 2.0	0.0, 1.6	0.0, 0.0	0.0, 0.0	0.0, 2.9	0.0, 5.3
Cycle 8 Day 1						
n	4	4	4	4	4	4
Mean (StdDev)	0.71 (1.082)	1.04 (1.071)	0.00 (0.000)	0.00 (0.000)	1.75 (1.253)	1.89 (1.540)
Median	0.29	0.86	0.00	0.00	1.71	1.86
Min, Max	0.0, 2.3	0.0, 2.4	0.0, 0.0	0.0, 0.0	0.4, 3.1	0.4, 3.4
Cycle 9 Day 1						
n	5	5	5	5	5	5
Mean (StdDev)	0.66 (1.033)	0.50 (0.786)	0.00 (0.000)	0.00 (0.000)	0.83 (1.339)	1.00 (1.622)
Median	0.14	0.14	0.00	0.00	0.17	0.50
Min, Max	0.0, 2.4	0.0, 1.9	0.0, 0.0	0.0, 0.0	0.0, 3.1	0.0, 3.9

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg				
Scores	TSS (N=10)	Skin Domain (N=10)	GI Domain (N=10)	Q6 Fatigue (N=10)
Cycle 10 Day 1				
n	5	5	5	5
Mean (StdDev)	12.56 (8.300)	2.90 (3.245)	5.36 (6.655)	4.30 (3.422)
Median	12.33	2.29	2.17	3.67
Min, Max	3.6, 25.9	0.4, 8.3	0.3, 16.0	0.7, 9.4
Cycle 11 Day 1				
n	4	4	4	4
Mean (StdDev)	9.04 (6.598)	2.57 (4.582)	1.71 (2.416)	4.75 (3.814)
Median	10.14	0.43	0.79	4.93
Min, Max	0.7, 15.1	0.0, 9.4	0.0, 5.3	0.0, 9.1
Cycle 12 Day 1				
n	3	3	3	3
Mean (StdDev)	8.67 (8.505)	4.38 (5.618)	1.24 (1.155)	3.05 (2.700)
Median	9.00	2.43	1.43	4.00
Min, Max	0.0, 17.0	0.0, 10.7	0.0, 2.3	0.0, 5.1

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg			
Scores	Q3 Spots (N=10)	Q4 Itching (N=10)	Q5 Flushing (N=10)
Cycle 10 Day 1			
n	5	5	5
Mean (StdDev)	0.94 (1.105)	0.69 (1.386)	1.26 (1.665)
Median	0.29	0.14	0.14
Min, Max	0.0, 2.3	0.0, 3.2	0.0, 3.2
Cycle 11 Day 1			
n	4	4	4
Mean (StdDev)	0.64 (0.845)	1.00 (1.906)	0.93 (1.857)
Median	0.36	0.07	0.00
Min, Max	0.0, 1.9	0.0, 3.9	0.0, 3.7
Cycle 12 Day 1			
n	3	3	3
Mean (StdDev)	1.62 (1.431)	1.48 (2.314)	1.29 (2.227)
Median	2.14	0.29	0.00
Min, Max	0.0, 2.7	0.0, 4.1	0.0, 3.9

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Scores	Q1 Abdominal Pain (N=10)	Q2 Nausea (N=10)	Q7 Vomitting Count (N=10)	Q8 Vomitting Severity (N=10)	Q9 Diarrhea Count (N=10)	Q10 Diarrhea Severity (N=10)
Cycle 10 Day 1						
n	5	5	5	5	5	5
Mean (StdDev)	2.55 (3.798)	1.41 (2.022)	0.03 (0.064)	0.09 (0.192)	1.77 (1.986)	1.29 (1.348)
Median	1.14	0.17	0.00	0.00	0.71	0.71
Min, Max	0.0, 9.1	0.0, 4.7	0.0, 0.1	0.0, 0.4	0.0, 4.6	0.0, 3.4
Cycle 11 Day 1						
n	4	4	4	4	4	4
Mean (StdDev)	1.46 (2.392)	0.11 (0.137)	0.00 (0.000)	0.00 (0.000)	0.21 (0.429)	0.14 (0.286)
Median	0.43	0.07	0.00	0.00	0.00	0.00
Min, Max	0.0, 5.0	0.0, 0.3	0.0, 0.0	0.0, 0.0	0.0, 0.9	0.0, 0.6
Cycle 12 Day 1						
n	3	3	3	3	3	3
Mean (StdDev)	0.62 (0.577)	0.19 (0.330)	0.00 (0.000)	0.00 (0.000)	0.14 (0.143)	0.43 (0.623)
Median	0.71	0.00	0.00	0.00	0.14	0.14
Min, Max	0.0, 1.1	0.0, 0.6	0.0, 0.0	0.0, 0.0	0.0, 0.3	0.0, 1.1

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg				
Scores	TSS (N=10)	Skin Domain (N=10)	GI Domain (N=10)	Q6 Fatigue (N=10)
Cycle 13 Day 1				
n	1	1	1	1
Mean (StdDev)	7.86 (-)	1.71 (-)	0.86 (-)	5.29 (-)
Median	7.86	1.71	0.86	5.29
Min, Max	7.9, 7.9	1.7, 1.7	0.9, 0.9	5.3, 5.3

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg			
Scores	Q3 Spots (N=10)	Q4 Itching (N=10)	Q5 Flushing (N=10)
Cycle 13 Day 1			
n	1	1	1
Mean (StdDev)	1.71 (-)	0.00 (-)	0.00 (-)
Median	1.71	0.00	0.00
Min, Max	1.7, 1.7	0.0, 0.0	0.0, 0.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Scores	Q1 Abdominal Pain (N=10)	Q2 Nausea (N=10)	Q7 Vomitting Count (N=10)	Q8 Vomitting Severity (N=10)	Q9 Diarrhea Count (N=10)	Q10 Diarrhea Severity (N=10)
Cycle 13 Day 1						
n	1	1	1	1	1	1
Mean (StdDev)	0.14 (-)	0.43 (-)	0.00 (-)	0.00 (-)	0.29 (-)	0.29 (-)
Median	0.14	0.43	0.00	0.00	0.29	0.29
Min, Max	0.1, 0.1	0.4, 0.4	0.0, 0.0	0.0, 0.0	0.3, 0.3	0.3, 0.3

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg				
Scores	TSS (N=10)	Skin Domain (N=10)	GI Domain (N=10)	Q6 Fatigue (N=10)
Baseline (C1D-7 to C1D-1)				
n	9	9	9	9
Mean (StdDev)	23.41 (10.625)	9.33 (4.627)	8.33 (5.236)	5.76 (2.751)
Median	27.43	10.43	8.60	6.86
Min, Max	1.2, 34.9	0.6, 15.7	0.3, 14.6	0.2, 8.9
Cycle 2 Day 1				
n	9	9	9	9
Mean (StdDev)	14.28 (6.422)	5.54 (3.071)	4.17 (3.257)	4.57 (2.003)
Median	14.43	6.50	4.14	5.00
Min, Max	5.4, 27.5	1.0, 9.9	0.9, 11.5	1.3, 7.2
Cycle 3 Day 1				
n	9	9	9	9
Mean (StdDev)	16.41 (7.053)	6.77 (3.992)	5.08 (3.701)	4.56 (1.684)
Median	14.57	6.43	4.00	4.25
Min, Max	6.8, 29.6	2.0, 13.9	1.0, 11.9	1.9, 7.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg			
Scores	Q3 Spots (N=10)	Q4 Itching (N=10)	Q5 Flushing (N=10)
Baseline (C1D-7 to C1D-1)			
n	9	9	9
Mean (StdDev)	3.38 (2.090)	3.38 (2.489)	2.56 (2.573)
Median	3.86	4.20	1.86
Min, Max	0.2, 6.1	0.3, 6.9	0.0, 6.6
Cycle 2 Day 1			
n	9	9	9
Mean (StdDev)	2.34 (2.452)	1.57 (1.952)	1.64 (1.619)
Median	2.43	1.00	1.71
Min, Max	0.0, 7.0	0.0, 4.7	0.0, 5.0
Cycle 3 Day 1			
n	9	9	9
Mean (StdDev)	2.57 (2.060)	1.82 (2.260)	2.38 (1.988)
Median	2.00	1.50	2.40
Min, Max	0.0, 6.9	0.0, 6.7	0.0, 6.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Scores	Q1 Abdominal Pain (N=10)	Q2 Nausea (N=10)	Q7 Vomitting Count (N=10)	Q8 Vomitting Severity (N=10)	Q9 Diarrhea Count (N=10)	Q10 Diarrhea Severity (N=10)
Baseline (C1D-7 to C1D-1)						
n	9	9	9	9	9	9
Mean (StdDev)	3.71 (2.405)	1.66 (2.413)	0.02 (0.067)	0.04 (0.133)	2.37 (2.213)	2.91 (2.582)
Median	3.43	0.57	0.00	0.00	1.71	3.00
Min, Max	0.3, 7.1	0.0, 7.3	0.0, 0.2	0.0, 0.4	0.0, 5.1	0.0, 7.6
Cycle 2 Day 1						
n	9	9	9	9	9	9
Mean (StdDev)	1.80 (2.198)	1.29 (1.700)	0.00 (0.000)	0.00 (0.000)	1.01 (1.223)	1.07 (1.195)
Median	1.14	1.00	0.00	0.00	0.57	0.71
Min, Max	0.1, 6.2	0.0, 5.3	0.0, 0.0	0.0, 0.0	0.0, 3.4	0.0, 3.4
Cycle 3 Day 1						
n	9	9	9	9	9	9
Mean (StdDev)	2.13 (2.726)	1.00 (0.980)	0.03 (0.083)	0.03 (0.083)	1.46 (1.465)	1.93 (1.777)
Median	0.86	0.50	0.00	0.00	0.57	1.50
Min, Max	0.0, 6.9	0.0, 2.4	0.0, 0.3	0.0, 0.3	0.0, 3.4	0.0, 5.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg				
Scores	TSS (N=10)	Skin Domain (N=10)	GI Domain (N=10)	Q6 Fatigue (N=10)
Cycle 4 Day 1				
n	9	9	9	9
Mean (StdDev)	13.44 (4.778)	5.31 (3.019)	3.69 (3.184)	4.45 (2.581)
Median	13.14	5.86	3.00	3.57
Min, Max	6.0, 20.0	0.9, 9.9	0.0, 8.1	1.5, 8.3
Cycle 5 Day 1				
n	8	8	8	8
Mean (StdDev)	13.25 (3.722)	4.35 (3.341)	4.15 (3.199)	4.76 (2.259)
Median	13.07	3.25	3.64	4.82
Min, Max	7.0, 20.0	0.6, 9.7	0.3, 9.4	1.3, 8.0
Cycle 6 Day 1				
n	6	6	6	6
Mean (StdDev)	10.78 (4.131)	2.95 (3.679)	3.79 (3.549)	4.04 (2.334)
Median	10.86	2.43	2.21	3.12
Min, Max	5.3, 16.7	0.0, 10.0	0.9, 9.0	2.0, 7.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg			
Scores	Q3 Spots (N=10)	Q4 Itching (N=10)	Q5 Flushing (N=10)
Cycle 4 Day 1			
n	9	9	9
Mean (StdDev)	1.89 (1.464)	1.46 (1.484)	1.96 (1.782)
Median	2.00	1.00	1.86
Min, Max	0.0, 4.1	0.0, 4.0	0.0, 5.9
Cycle 5 Day 1			
n	8	8	8
Mean (StdDev)	1.57 (1.571)	1.04 (1.669)	1.74 (1.517)
Median	1.33	0.15	1.83
Min, Max	0.0, 4.0	0.0, 4.0	0.0, 4.0
Cycle 6 Day 1			
n	6	6	6
Mean (StdDev)	0.79 (0.940)	0.94 (1.709)	1.23 (1.427)
Median	0.50	0.14	0.71
Min, Max	0.0, 2.2	0.0, 4.3	0.0, 3.5

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Scores	Q1 Abdominal Pain (N=10)	Q2 Nausea (N=10)	Q7 Vomitting Count (N=10)	Q8 Vomitting Severity (N=10)	Q9 Diarrhea Count (N=10)	Q10 Diarrhea Severity (N=10)
Cycle 4 Day 1						
n	9	9	9	9	9	9
Mean (StdDev)	0.89 (0.964)	1.39 (1.634)	0.12 (0.244)	0.20 (0.406)	0.78 (0.928)	1.21 (1.380)
Median	0.80	0.67	0.00	0.00	0.57	1.00
Min, Max	0.0, 2.6	0.0, 4.4	0.0, 0.7	0.0, 1.0	0.0, 2.9	0.0, 3.6
Cycle 5 Day 1						
n	8	8	8	8	8	8
Mean (StdDev)	0.92 (1.319)	1.54 (1.940)	0.10 (0.235)	0.38 (0.700)	1.07 (1.348)	1.32 (1.573)
Median	0.17	0.98	0.00	0.00	0.50	0.58
Min, Max	0.0, 3.6	0.0, 5.5	0.0, 0.7	0.0, 1.7	0.0, 3.6	0.0, 3.9
Cycle 6 Day 1						
n	6	6	6	6	6	6
Mean (StdDev)	0.69 (1.556)	0.54 (0.780)	0.00 (0.000)	0.00 (0.000)	1.26 (0.934)	2.56 (2.637)
Median	0.00	0.25	0.00	0.00	1.21	1.96
Min, Max	0.0, 3.9	0.0, 2.0	0.0, 0.0	0.0, 0.0	0.0, 2.9	0.0, 7.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg				
Scores	TSS (N=10)	Skin Domain (N=10)	GI Domain (N=10)	Q6 Fatigue (N=10)
Cycle 7 Day 1				
n	6	6	6	6
Mean (StdDev)	11.30 (6.297)	4.00 (4.542)	3.35 (2.325)	3.96 (2.466)
Median	9.69	2.43	3.01	3.41
Min, Max	4.3, 19.6	0.0, 11.0	0.7, 6.7	1.3, 8.0
Cycle 8 Day 1				
n	4	4	4	4
Mean (StdDev)	8.96 (4.701)	1.75 (1.301)	3.64 (3.300)	3.57 (2.235)
Median	9.21	1.93	2.86	3.36
Min, Max	3.9, 13.6	0.0, 3.1	0.7, 8.1	1.3, 6.3
Cycle 9 Day 1				
n	5	5	5	5
Mean (StdDev)	9.14 (4.033)	3.31 (2.864)	2.16 (3.353)	3.66 (2.188)
Median	8.86	3.17	0.71	3.33
Min, Max	4.7, 14.1	0.0, 7.8	0.3, 8.1	0.8, 6.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg			
Scores	Q3 Spots (N=10)	Q4 Itching (N=10)	Q5 Flushing (N=10)
Cycle 7 Day 1			
n	6	6	6
Mean (StdDev)	1.23 (1.386)	1.27 (1.948)	1.50 (1.635)
Median	0.93	0.14	1.36
Min, Max	0.0, 2.8	0.0, 4.6	0.0, 3.6
Cycle 8 Day 1			
n	4	4	4
Mean (StdDev)	0.61 (0.811)	0.18 (0.357)	0.96 (1.473)
Median	0.36	0.00	0.36
Min, Max	0.0, 1.7	0.0, 0.7	0.0, 3.1
Cycle 9 Day 1			
n	5	5	5
Mean (StdDev)	1.14 (1.357)	0.74 (1.299)	1.43 (1.663)
Median	0.71	0.00	0.71
Min, Max	0.0, 3.2	0.0, 3.0	0.0, 3.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Scores	Q1 Abdominal Pain (N=10)	Q2 Nausea (N=10)	Q7 Vomitting Count (N=10)	Q8 Vomitting Severity (N=10)	Q9 Diarrhea Count (N=10)	Q10 Diarrhea Severity (N=10)
Cycle 7 Day 1						
n	6	6	6	6	6	6
Mean (StdDev)	0.42 (0.788)	0.61 (0.664)	0.00 (0.000)	0.00 (0.000)	1.20 (1.017)	2.31 (1.975)
Median	0.07	0.47	0.00	0.00	1.18	2.27
Min, Max	0.0, 2.0	0.0, 1.6	0.0, 0.0	0.0, 0.0	0.0, 2.9	0.0, 5.3
Cycle 8 Day 1						
n	4	4	4	4	4	4
Mean (StdDev)	0.71 (1.082)	1.04 (1.071)	0.00 (0.000)	0.00 (0.000)	1.75 (1.253)	1.89 (1.540)
Median	0.29	0.86	0.00	0.00	1.71	1.86
Min, Max	0.0, 2.3	0.0, 2.4	0.0, 0.0	0.0, 0.0	0.4, 3.1	0.4, 3.4
Cycle 9 Day 1						
n	5	5	5	5	5	5
Mean (StdDev)	0.66 (1.033)	0.50 (0.786)	0.00 (0.000)	0.00 (0.000)	0.83 (1.339)	1.00 (1.622)
Median	0.14	0.14	0.00	0.00	0.17	0.50
Min, Max	0.0, 2.4	0.0, 1.9	0.0, 0.0	0.0, 0.0	0.0, 3.1	0.0, 3.9

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg				
Scores	TSS (N=10)	Skin Domain (N=10)	GI Domain (N=10)	Q6 Fatigue (N=10)
Cycle 10 Day 1				
n	5	5	5	5
Mean (StdDev)	12.56 (8.300)	2.90 (3.245)	5.36 (6.655)	4.30 (3.422)
Median	12.33	2.29	2.17	3.67
Min, Max	3.6, 25.9	0.4, 8.3	0.3, 16.0	0.7, 9.4
Cycle 11 Day 1				
n	4	4	4	4
Mean (StdDev)	9.04 (6.598)	2.57 (4.582)	1.71 (2.416)	4.75 (3.814)
Median	10.14	0.43	0.79	4.93
Min, Max	0.7, 15.1	0.0, 9.4	0.0, 5.3	0.0, 9.1
Cycle 12 Day 1				
n	3	3	3	3
Mean (StdDev)	8.67 (8.505)	4.38 (5.618)	1.24 (1.155)	3.05 (2.700)
Median	9.00	2.43	1.43	4.00
Min, Max	0.0, 17.0	0.0, 10.7	0.0, 2.3	0.0, 5.1

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg			
Scores	Q3 Spots (N=10)	Q4 Itching (N=10)	Q5 Flushing (N=10)
Cycle 10 Day 1			
n	5	5	5
Mean (StdDev)	0.94 (1.105)	0.69 (1.386)	1.26 (1.665)
Median	0.29	0.14	0.14
Min, Max	0.0, 2.3	0.0, 3.2	0.0, 3.2
Cycle 11 Day 1			
n	4	4	4
Mean (StdDev)	0.64 (0.845)	1.00 (1.906)	0.93 (1.857)
Median	0.36	0.07	0.00
Min, Max	0.0, 1.9	0.0, 3.9	0.0, 3.7
Cycle 12 Day 1			
n	3	3	3
Mean (StdDev)	1.62 (1.431)	1.48 (2.314)	1.29 (2.227)
Median	2.14	0.29	0.00
Min, Max	0.0, 2.7	0.0, 4.1	0.0, 3.9

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Scores	Q1 Abdominal Pain (N=10)	Q2 Nausea (N=10)	Q7 Vomitting Count (N=10)	Q8 Vomitting Severity (N=10)	Q9 Diarrhea Count (N=10)	Q10 Diarrhea Severity (N=10)
Cycle 10 Day 1						
n	5	5	5	5	5	5
Mean (StdDev)	2.55 (3.798)	1.41 (2.022)	0.03 (0.064)	0.09 (0.192)	1.77 (1.986)	1.29 (1.348)
Median	1.14	0.17	0.00	0.00	0.71	0.71
Min, Max	0.0, 9.1	0.0, 4.7	0.0, 0.1	0.0, 0.4	0.0, 4.6	0.0, 3.4
Cycle 11 Day 1						
n	4	4	4	4	4	4
Mean (StdDev)	1.46 (2.392)	0.11 (0.137)	0.00 (0.000)	0.00 (0.000)	0.21 (0.429)	0.14 (0.286)
Median	0.43	0.07	0.00	0.00	0.00	0.00
Min, Max	0.0, 5.0	0.0, 0.3	0.0, 0.0	0.0, 0.0	0.0, 0.9	0.0, 0.6
Cycle 12 Day 1						
n	3	3	3	3	3	3
Mean (StdDev)	0.62 (0.577)	0.19 (0.330)	0.00 (0.000)	0.00 (0.000)	0.14 (0.143)	0.43 (0.623)
Median	0.71	0.00	0.00	0.00	0.14	0.14
Min, Max	0.0, 1.1	0.0, 0.6	0.0, 0.0	0.0, 0.0	0.0, 0.3	0.0, 1.1

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg				
Scores	TSS (N=10)	Skin Domain (N=10)	GI Domain (N=10)	Q6 Fatigue (N=10)
Cycle 13 Day 1				
n	1	1	1	1
Mean (StdDev)	7.86 (-)	1.71 (-)	0.86 (-)	5.29 (-)
Median	7.86	1.71	0.86	5.29
Min, Max	7.9, 7.9	1.7, 1.7	0.9, 0.9	5.3, 5.3

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg			
Scores	Q3 Spots (N=10)	Q4 Itching (N=10)	Q5 Flushing (N=10)
Cycle 13 Day 1			
n	1	1	1
Mean (StdDev)	1.71 (-)	0.00 (-)	0.00 (-)
Median	1.71	0.00	0.00
Min, Max	1.7, 1.7	0.0, 0.0	0.0, 0.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Scores	Q1 Abdominal Pain (N=10)	Q2 Nausea (N=10)	Q7 Vomitting Count (N=10)	Q8 Vomitting Severity (N=10)	Q9 Diarrhea Count (N=10)	Q10 Diarrhea Severity (N=10)
Cycle 13 Day 1						
n	1	1	1	1	1	1
Mean (StdDev)	0.14 (-)	0.43 (-)	0.00 (-)	0.00 (-)	0.29 (-)	0.29 (-)
Median	0.14	0.43	0.00	0.00	0.29	0.29
Min, Max	0.1, 0.1	0.4, 0.4	0.0, 0.0	0.0, 0.0	0.3, 0.3	0.3, 0.3

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Scores	TSS (N=42)	Skin Domain (N=42)	GI Domain (N=42)	Q6 Fatigue (N=42)
Baseline (C1D-7 to C1D-1)				
n	38	38	38	38
Mean (StdDev)	19.26 (13.287)	7.67 (7.666)	6.08 (5.789)	5.51 (3.035)
Median	18.18	6.43	5.14	6.29
Min, Max	0.0, 53.7	0.0, 28.6	0.0, 21.7	0.0, 10.0
Cycle 2 Day 1				
n	41	41	41	41
Mean (StdDev)	12.04 (9.518)	4.36 (5.016)	3.29 (3.961)	4.39 (3.146)
Median	10.71	2.00	1.71	4.86
Min, Max	0.0, 38.7	0.0, 15.9	0.0, 17.6	0.0, 9.1
Cycle 3 Day 1				
n	39	39	39	39
Mean (StdDev)	11.98 (8.531)	4.66 (4.439)	2.84 (3.498)	4.49 (2.923)
Median	11.14	3.00	2.00	4.86
Min, Max	0.0, 35.6	0.0, 15.4	0.0, 16.9	0.0, 9.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Scores	Q3 Spots (N=42)	Q4 Itching (N=42)	Q5 Flushing (N=42)
Baseline (C1D-7 to C1D-1)			
n	38	38	38
Mean (StdDev)	2.66 (2.945)	2.65 (2.966)	2.36 (2.581)
Median	1.93	1.00	1.43
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 8.6
Cycle 2 Day 1			
n	41	41	41
Mean (StdDev)	1.96 (2.256)	1.21 (1.663)	1.19 (1.683)
Median	1.00	0.17	0.14
Min, Max	0.0, 7.3	0.0, 6.4	0.0, 5.9
Cycle 3 Day 1			
n	39	39	39
Mean (StdDev)	1.97 (2.033)	1.48 (1.825)	1.21 (1.633)
Median	1.43	0.43	0.43
Min, Max	0.0, 7.7	0.0, 6.3	0.0, 6.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Scores	Q1 Abdominal Pain (N=42)	Q2 Nausea (N=42)	Q7 Vomitting Count (N=42)	Q8 Vomitting Severity (N=42)	Q9 Diarrhea Count (N=42)	Q10 Diarrhea Severity (N=42)
Baseline (C1D-7 to C1D-1)						
n	38	38	38	38	38	38
Mean (StdDev)	2.70 (2.869)	1.69 (2.217)	0.07 (0.188)	0.14 (0.397)	1.06 (1.719)	1.54 (1.989)
Median	1.79	0.76	0.00	0.00	0.36	0.77
Min, Max	0.0, 10.0	0.0, 7.3	0.0, 1.0	0.0, 1.7	0.0, 7.1	0.0, 7.1
Cycle 2 Day 1						
n	41	41	41	41	41	41
Mean (StdDev)	1.53 (1.934)	0.72 (1.318)	0.06 (0.235)	0.13 (0.694)	0.69 (1.282)	0.90 (1.341)
Median	0.80	0.14	0.00	0.00	0.14	0.40
Min, Max	0.0, 7.0	0.0, 5.9	0.0, 1.4	0.0, 4.4	0.0, 6.1	0.0, 5.0
Cycle 3 Day 1						
n	39	39	39	39	39	39
Mean (StdDev)	1.27 (1.739)	0.71 (1.279)	0.07 (0.259)	0.21 (0.783)	0.42 (0.740)	0.66 (1.032)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 6.3	0.0, 5.1	0.0, 1.6	0.0, 4.7	0.0, 3.1	0.0, 3.7

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Scores	TSS (N=42)	Skin Domain (N=42)	GI Domain (N=42)	Q6 Fatigue (N=42)
Cycle 4 Day 1				
n	37	37	37	37
Mean (StdDev)	12.51 (9.724)	4.87 (4.794)	3.17 (4.728)	4.47 (2.791)
Median	11.71	3.00	1.29	4.86
Min, Max	0.7, 45.6	0.0, 17.3	0.0, 21.7	0.0, 9.4
Cycle 5 Day 1				
n	34	34	34	34
Mean (StdDev)	11.86 (9.546)	4.47 (4.300)	3.19 (4.567)	4.19 (2.837)
Median	9.43	2.86	1.37	4.25
Min, Max	0.1, 41.7	0.0, 14.2	0.0, 21.5	0.0, 9.4
Cycle 6 Day 1				
n	30	30	30	30
Mean (StdDev)	11.40 (8.666)	4.48 (4.157)	2.55 (3.997)	4.38 (2.994)
Median	10.46	3.57	0.71	4.43
Min, Max	0.0, 33.6	0.0, 14.0	0.0, 13.7	0.0, 9.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses			
Scores	Q3 Spots (N=42)	Q4 Itching (N=42)	Q5 Flushing (N=42)
Cycle 4 Day 1			
n	37	37	37
Mean (StdDev)	1.97 (2.128)	1.47 (1.914)	1.44 (1.847)
Median	1.00	0.29	0.43
Min, Max	0.0, 7.3	0.0, 7.6	0.0, 6.7
Cycle 5 Day 1			
n	34	34	34
Mean (StdDev)	1.88 (1.975)	1.22 (1.532)	1.37 (1.764)
Median	1.07	0.17	0.52
Min, Max	0.0, 7.0	0.0, 4.3	0.0, 5.8
Cycle 6 Day 1			
n	30	30	30
Mean (StdDev)	1.98 (2.174)	1.31 (1.583)	1.18 (1.737)
Median	1.57	0.39	0.14
Min, Max	0.0, 7.0	0.0, 4.4	0.0, 5.6

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Scores	Q1 Abdominal Pain (N=42)	Q2 Nausea (N=42)	Q7 Vomitting Count (N=42)	Q8 Vomitting Severity (N=42)	Q9 Diarrhea Count (N=42)	Q10 Diarrhea Severity (N=42)
Cycle 4 Day 1						
n	37	37	37	37	37	37
Mean (StdDev)	1.25 (2.014)	0.81 (1.559)	0.13 (0.536)	0.28 (1.108)	0.51 (0.831)	0.84 (1.341)
Median	0.14	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 8.2	0.0, 6.3	0.0, 3.1	0.0, 6.3	0.0, 3.4	0.0, 5.6
Cycle 5 Day 1						
n	34	34	34	34	34	34
Mean (StdDev)	1.31 (1.915)	0.68 (1.305)	0.13 (0.601)	0.23 (0.927)	0.63 (1.033)	0.97 (1.748)
Median	0.08	0.00	0.00	0.00	0.07	0.00
Min, Max	0.0, 6.7	0.0, 5.0	0.0, 3.5	0.0, 5.3	0.0, 4.0	0.0, 6.7
Cycle 6 Day 1						
n	30	30	30	30	30	30
Mean (StdDev)	1.28 (2.029)	0.58 (1.214)	0.10 (0.400)	0.20 (0.702)	0.33 (0.689)	0.50 (1.232)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 7.7	0.0, 4.7	0.0, 2.1	0.0, 3.6	0.0, 3.4	0.0, 6.6

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Scores	TSS (N=42)	Skin Domain (N=42)	GI Domain (N=42)	Q6 Fatigue (N=42)
Cycle 7 Day 1				
n	27	27	27	27
Mean (StdDev)	10.27 (7.565)	3.96 (3.783)	2.11 (2.989)	4.20 (3.046)
Median	11.14	3.14	0.14	4.00
Min, Max	0.0, 27.6	0.0, 10.9	0.0, 8.7	0.0, 9.4
Cycle 8 Day 1				
n	27	27	27	27
Mean (StdDev)	10.73 (7.266)	4.30 (3.571)	2.22 (2.828)	4.21 (2.971)
Median	11.14	5.00	0.33	4.00
Min, Max	0.0, 27.6	0.0, 10.9	0.0, 8.7	0.0, 9.4
Cycle 9 Day 1				
n	24	24	24	24
Mean (StdDev)	10.12 (7.283)	4.07 (3.731)	2.04 (2.641)	4.01 (3.003)
Median	9.65	2.93	0.57	4.00
Min, Max	0.4, 27.6	0.0, 10.9	0.0, 7.7	0.0, 9.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses			
Scores	Q3 Spots (N=42)	Q4 Itching (N=42)	Q5 Flushing (N=42)
Cycle 7 Day 1			
n	27	27	27
Mean (StdDev)	1.78 (1.986)	1.18 (1.511)	1.00 (1.428)
Median	1.00	0.00	0.14
Min, Max	0.0, 7.0	0.0, 4.9	0.0, 5.0
Cycle 8 Day 1			
n	27	27	27
Mean (StdDev)	1.87 (1.904)	1.35 (1.470)	1.08 (1.474)
Median	1.71	1.00	0.00
Min, Max	0.0, 6.9	0.0, 3.9	0.0, 5.0
Cycle 9 Day 1			
n	24	24	24
Mean (StdDev)	1.95 (2.006)	1.18 (1.521)	0.93 (1.459)
Median	1.57	0.25	0.07
Min, Max	0.0, 6.7	0.0, 4.3	0.0, 5.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Scores	Q1 Abdominal Pain (N=42)	Q2 Nausea (N=42)	Q7 Vomitting Count (N=42)	Q8 Vomitting Severity (N=42)	Q9 Diarrhea Count (N=42)	Q10 Diarrhea Severity (N=42)
Cycle 7 Day 1						
n	27	27	27	27	27	27
Mean (StdDev)	1.13 (1.871)	0.43 (1.048)	0.02 (0.046)	0.03 (0.089)	0.25 (0.487)	0.52 (1.112)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 6.9	0.0, 4.7	0.0, 0.1	0.0, 0.4	0.0, 1.9	0.0, 4.9
Cycle 8 Day 1						
n	27	27	27	27	27	27
Mean (StdDev)	1.08 (1.729)	0.54 (1.108)	0.03 (0.076)	0.05 (0.152)	0.35 (0.616)	0.55 (0.873)
Median	0.00	0.00	0.00	0.00	0.14	0.14
Min, Max	0.0, 6.3	0.0, 4.7	0.0, 0.3	0.0, 0.7	0.0, 2.8	0.0, 3.5
Cycle 9 Day 1						
n	24	24	24	24	24	24
Mean (StdDev)	0.99 (1.591)	0.48 (1.052)	0.04 (0.099)	0.07 (0.163)	0.35 (0.666)	0.50 (1.022)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 5.4	0.0, 4.7	0.0, 0.4	0.0, 0.6	0.0, 2.3	0.0, 4.3

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Scores	TSS (N=42)	Skin Domain (N=42)	GI Domain (N=42)	Q6 Fatigue (N=42)
Cycle 10 Day 1				
n	21	21	21	21
Mean (StdDev)	10.97 (7.325)	4.22 (3.791)	2.16 (2.815)	4.60 (2.969)
Median	11.00	3.14	0.71	4.00
Min, Max	0.0, 27.6	0.0, 10.9	0.0, 8.7	0.0, 9.4
Cycle 11 Day 1				
n	20	20	20	20
Mean (StdDev)	11.11 (7.516)	4.14 (3.742)	2.42 (3.017)	4.55 (2.969)
Median	10.82	3.79	0.43	4.43
Min, Max	0.0, 27.6	0.0, 10.9	0.0, 8.7	0.0, 9.4
Cycle 12 Day 1				
n	18	18	18	18
Mean (StdDev)	10.88 (7.083)	3.93 (3.531)	2.13 (3.045)	4.82 (2.888)
Median	10.57	3.50	0.21	4.91
Min, Max	0.0, 27.6	0.0, 10.9	0.0, 8.7	0.0, 9.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses			
Scores	Q3 Spots (N=42)	Q4 Itching (N=42)	Q5 Flushing (N=42)
Cycle 10 Day 1			
n	21	21	21
Mean (StdDev)	2.02 (1.972)	1.24 (1.558)	0.96 (1.503)
Median	2.00	0.00	0.00
Min, Max	0.0, 6.0	0.0, 4.0	0.0, 4.7
Cycle 11 Day 1			
n	20	20	20
Mean (StdDev)	2.09 (1.958)	1.13 (1.500)	0.92 (1.438)
Median	2.21	0.07	0.00
Min, Max	0.0, 6.0	0.0, 4.0	0.0, 4.0
Cycle 12 Day 1			
n	18	18	18
Mean (StdDev)	2.12 (1.956)	1.03 (1.428)	0.78 (1.325)
Median	2.36	0.00	0.00
Min, Max	0.0, 6.0	0.0, 3.9	0.0, 3.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Scores	Q1 Abdominal Pain (N=42)	Q2 Nausea (N=42)	Q7 Vomitting Count (N=42)	Q8 Vomitting Severity (N=42)	Q9 Diarrhea Count (N=42)	Q10 Diarrhea Severity (N=42)
Cycle 10 Day 1						
n	21	21	21	21	21	21
Mean (StdDev)	1.14 (1.679)	0.59 (1.156)	0.09 (0.280)	0.18 (0.544)	0.15 (0.241)	0.24 (0.450)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 5.4	0.0, 4.7	0.0, 1.3	0.0, 2.4	0.0, 0.7	0.0, 1.4
Cycle 11 Day 1						
n	20	20	20	20	20	20
Mean (StdDev)	1.20 (1.701)	0.56 (1.188)	0.09 (0.287)	0.18 (0.546)	0.32 (0.650)	0.47 (0.911)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 5.4	0.0, 4.7	0.0, 1.3	0.0, 2.4	0.0, 2.7	0.0, 3.2
Cycle 12 Day 1						
n	18	18	18	18	18	18
Mean (StdDev)	1.21 (1.792)	0.58 (1.240)	0.10 (0.302)	0.17 (0.573)	0.11 (0.222)	0.17 (0.358)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 5.4	0.0, 4.7	0.0, 1.3	0.0, 2.4	0.0, 0.7	0.0, 1.3

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Scores	TSS (N=42)	Skin Domain (N=42)	GI Domain (N=42)	Q6 Fatigue (N=42)
Cycle 13 Day 1				
n	14	14	14	14
Mean (StdDev)	11.38 (7.640)	4.28 (3.745)	2.32 (3.327)	4.79 (2.919)
Median	10.61	4.57	0.14	4.36
Min, Max	0.0, 27.6	0.0, 10.9	0.0, 8.7	0.0, 9.4
Cycle 14 Day 1				
n	14	14	14	14
Mean (StdDev)	11.49 (7.641)	4.25 (3.709)	2.48 (3.279)	4.76 (2.879)
Median	11.04	4.36	0.14	4.50
Min, Max	0.0, 27.6	0.0, 10.9	0.0, 8.7	0.0, 9.4
Cycle 15 Day 1				
n	13	13	13	13
Mean (StdDev)	11.17 (7.968)	4.28 (3.788)	2.36 (3.398)	4.52 (3.037)
Median	9.00	4.29	0.14	3.57
Min, Max	0.0, 27.6	0.0, 10.9	0.0, 8.7	0.0, 9.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Scores	Q3 Spots (N=42)	Q4 Itching (N=42)	Q5 Flushing (N=42)
Cycle 13 Day 1			
n	14	14	14
Mean (StdDev)	2.18 (1.916)	1.08 (1.394)	1.02 (1.455)
Median	3.15	0.25	0.00
Min, Max	0.0, 5.5	0.0, 3.9	0.0, 3.4
Cycle 14 Day 1			
n	14	14	14
Mean (StdDev)	2.13 (1.866)	1.01 (1.368)	1.12 (1.385)
Median	2.86	0.25	0.20
Min, Max	0.0, 5.5	0.0, 3.9	0.0, 3.4
Cycle 15 Day 1			
n	13	13	13
Mean (StdDev)	2.10 (1.885)	1.08 (1.450)	1.10 (1.428)
Median	3.00	0.00	0.25
Min, Max	0.0, 5.5	0.0, 3.9	0.0, 3.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Scores	Q1 Abdominal Pain (N=42)	Q2 Nausea (N=42)	Q7 Vomitting Count (N=42)	Q8 Vomitting Severity (N=42)	Q9 Diarrhea Count (N=42)	Q10 Diarrhea Severity (N=42)
Cycle 13 Day 1						
n	14	14	14	14	14	14
Mean (StdDev)	1.28 (1.928)	0.65 (1.346)	0.12 (0.340)	0.22 (0.646)	0.10 (0.234)	0.16 (0.396)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 5.4	0.0, 4.7	0.0, 1.3	0.0, 2.4	0.0, 0.7	0.0, 1.3
Cycle 14 Day 1						
n	14	14	14	14	14	14
Mean (StdDev)	1.35 (1.893)	0.65 (1.346)	0.12 (0.340)	0.22 (0.646)	0.13 (0.247)	0.26 (0.492)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 5.4	0.0, 4.7	0.0, 1.3	0.0, 2.4	0.0, 0.7	0.0, 1.3
Cycle 15 Day 1						
n	13	13	13	13	13	13
Mean (StdDev)	1.27 (1.946)	0.65 (1.405)	0.13 (0.352)	0.24 (0.668)	0.12 (0.239)	0.20 (0.406)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 5.4	0.0, 4.7	0.0, 1.3	0.0, 2.4	0.0, 0.7	0.0, 1.3

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Scores	TSS (N=42)	Skin Domain (N=42)	GI Domain (N=42)	Q6 Fatigue (N=42)
Cycle 16 Day 1				
n	13	13	13	13
Mean (StdDev)	10.87 (8.169)	3.96 (3.799)	2.32 (3.419)	4.59 (3.026)
Median	9.00	3.14	0.14	3.71
Min, Max	0.0, 27.6	0.0, 10.9	0.0, 8.7	0.0, 9.4
Cycle 17 Day 1				
n	13	13	13	13
Mean (StdDev)	10.74 (8.304)	4.00 (3.777)	2.27 (3.435)	4.47 (3.125)
Median	9.00	3.14	0.14	3.57
Min, Max	0.0, 27.6	0.0, 10.9	0.0, 8.7	0.0, 9.4
Cycle 18 Day 1				
n	12	12	12	12
Mean (StdDev)	11.47 (8.251)	4.38 (3.723)	2.39 (3.560)	4.70 (3.143)
Median	10.33	3.65	0.07	4.29
Min, Max	0.0, 27.6	0.0, 10.9	0.0, 8.7	0.0, 9.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses			
Scores	Q3 Spots (N=42)	Q4 Itching (N=42)	Q5 Flushing (N=42)
Cycle 16 Day 1			
n	13	13	13
Mean (StdDev)	1.95 (1.888)	1.01 (1.424)	1.01 (1.366)
Median	2.00	0.00	0.00
Min, Max	0.0, 5.5	0.0, 3.9	0.0, 3.4
Cycle 17 Day 1			
n	13	13	13
Mean (StdDev)	1.95 (1.888)	1.05 (1.433)	1.00 (1.357)
Median	2.00	0.00	0.00
Min, Max	0.0, 5.5	0.0, 3.9	0.0, 3.4
Cycle 18 Day 1			
n	12	12	12
Mean (StdDev)	2.10 (1.883)	1.20 (1.473)	1.08 (1.382)
Median	2.57	0.33	0.13
Min, Max	0.0, 5.5	0.0, 3.9	0.0, 3.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Scores	Q1 Abdominal Pain (N=42)	Q2 Nausea (N=42)	Q7 Vomitting Count (N=42)	Q8 Vomitting Severity (N=42)	Q9 Diarrhea Count (N=42)	Q10 Diarrhea Severity (N=42)
Cycle 16 Day 1						
n	13	13	13	13	13	13
Mean (StdDev)	1.25 (1.942)	0.65 (1.405)	0.15 (0.352)	0.24 (0.668)	0.11 (0.242)	0.18 (0.409)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 5.4	0.0, 4.7	0.0, 1.3	0.0, 2.4	0.0, 0.7	0.0, 1.3
Cycle 17 Day 1						
n	13	13	13	13	13	13
Mean (StdDev)	1.21 (1.944)	0.65 (1.405)	0.13 (0.352)	0.24 (0.668)	0.11 (0.242)	0.18 (0.409)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 5.4	0.0, 4.7	0.0, 1.3	0.0, 2.4	0.0, 0.7	0.0, 1.3
Cycle 18 Day 1						
n	12	12	12	12	12	12
Mean (StdDev)	1.24 (2.028)	0.70 (1.454)	0.14 (0.365)	0.26 (0.694)	0.12 (0.250)	0.19 (0.423)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 5.4	0.0, 4.7	0.0, 1.3	0.0, 2.4	0.0, 0.7	0.0, 1.3

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas
Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Scores	TSS (N=40)	Skin Domain (N=40)	GI Domain (N=40)	Q6 Fatigue (N=40)
Baseline (C1D-7 to C1D-1)				
n	36	36	36	36
Mean (StdDev)	19.09 (13.591)	7.53 (7.857)	6.18 (5.847)	5.38 (3.066)
Median	18.13	5.07	5.14	6.21
Min, Max	0.0, 53.7	0.0, 28.6	0.0, 21.7	0.0, 10.0
Cycle 2 Day 1				
n	40	40	40	40
Mean (StdDev)	12.00 (9.634)	4.33 (5.077)	3.34 (3.996)	4.32 (3.151)
Median	10.50	1.86	1.79	4.71
Min, Max	0.0, 38.7	0.0, 15.9	0.0, 17.6	0.0, 9.1
Cycle 3 Day 1				
n	38	38	38	38
Mean (StdDev)	11.81 (8.575)	4.49 (4.373)	2.91 (3.513)	4.41 (2.918)
Median	11.14	3.00	2.00	4.79
Min, Max	0.0, 35.6	0.0, 15.4	0.0, 16.9	0.0, 9.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg			
Scores	Q3 Spots (N=40)	Q4 Itching (N=40)	Q5 Flushing (N=40)
Baseline (C1D-7 to C1D-1)			
n	36	36	36
Mean (StdDev)	2.59 (3.013)	2.52 (2.985)	2.42 (2.623)
Median	1.71	1.00	1.43
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 8.6
Cycle 2 Day 1			
n	40	40	40
Mean (StdDev)	1.95 (2.285)	1.20 (1.684)	1.18 (1.701)
Median	1.00	0.15	0.07
Min, Max	0.0, 7.3	0.0, 6.4	0.0, 5.9
Cycle 3 Day 1			
n	38	38	38
Mean (StdDev)	1.95 (2.058)	1.35 (1.667)	1.19 (1.647)
Median	1.43	0.43	0.36
Min, Max	0.0, 7.7	0.0, 5.6	0.0, 6.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Scores	Q1 Abdominal Pain (N=40)	Q2 Nausea (N=40)	Q7 Vomitting Count (N=40)	Q8 Vomitting Severity (N=40)	Q9 Diarrhea Count (N=40)	Q10 Diarrhea Severity (N=40)
Baseline (C1D-7 to C1D-1)						
n	36	36	36	36	36	36
Mean (StdDev)	2.71 (2.893)	1.76 (2.257)	0.07 (0.192)	0.15 (0.407)	1.10 (1.757)	1.55 (2.017)
Median	1.79	0.76	0.00	0.00	0.36	0.77
Min, Max	0.0, 10.0	0.0, 7.3	0.0, 1.0	0.0, 1.7	0.0, 7.1	0.0, 7.1
Cycle 2 Day 1						
n	40	40	40	40	40	40
Mean (StdDev)	1.56 (1.949)	0.74 (1.332)	0.06 (0.238)	0.14 (0.702)	0.70 (1.297)	0.91 (1.357)
Median	0.83	0.07	0.00	0.00	0.07	0.20
Min, Max	0.0, 7.0	0.0, 5.9	0.0, 1.4	0.0, 4.4	0.0, 6.1	0.0, 5.0
Cycle 3 Day 1						
n	38	38	38	38	38	38
Mean (StdDev)	1.30 (1.750)	0.73 (1.290)	0.07 (0.262)	0.21 (0.793)	0.43 (0.747)	0.67 (1.040)
Median	0.29	0.00	0.00	0.00	0.07	0.07
Min, Max	0.0, 6.3	0.0, 5.1	0.0, 1.6	0.0, 4.7	0.0, 3.1	0.0, 3.7

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg				
Scores	TSS (N=40)	Skin Domain (N=40)	GI Domain (N=40)	Q6 Fatigue (N=40)
Cycle 4 Day 1				
n	36	36	36	36
Mean (StdDev)	12.53 (9.862)	4.86 (4.862)	3.21 (4.790)	4.46 (2.829)
Median	11.50	3.00	1.21	4.79
Min, Max	0.7, 45.6	0.0, 17.3	0.0, 21.7	0.0, 9.4
Cycle 5 Day 1				
n	33	33	33	33
Mean (StdDev)	11.74 (9.669)	4.36 (4.315)	3.19 (4.638)	4.19 (2.881)
Median	9.14	2.71	1.17	4.33
Min, Max	0.1, 41.7	0.0, 14.2	0.0, 21.5	0.0, 9.4
Cycle 6 Day 1				
n	29	29	29	29
Mean (StdDev)	11.33 (8.809)	4.37 (4.185)	2.61 (4.055)	4.35 (3.045)
Median	9.43	3.14	0.57	4.00
Min, Max	0.0, 33.6	0.0, 14.0	0.0, 13.7	0.0, 9.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg			
Scores	Q3 Spots (N=40)	Q4 Itching (N=40)	Q5 Flushing (N=40)
Cycle 4 Day 1			
n	36	36	36
Mean (StdDev)	1.96 (2.158)	1.46 (1.940)	1.44 (1.872)
Median	1.00	0.29	0.36
Min, Max	0.0, 7.3	0.0, 7.6	0.0, 6.7
Cycle 5 Day 1			
n	33	33	33
Mean (StdDev)	1.83 (1.988)	1.17 (1.529)	1.35 (1.788)
Median	1.00	0.17	0.33
Min, Max	0.0, 7.0	0.0, 4.3	0.0, 5.8
Cycle 6 Day 1			
n	29	29	29
Mean (StdDev)	1.95 (2.203)	1.21 (1.517)	1.21 (1.763)
Median	1.43	0.29	0.14
Min, Max	0.0, 7.0	0.0, 4.4	0.0, 5.6

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Scores	Q1 Abdominal Pain (N=40)	Q2 Nausea (N=40)	Q7 Vomitting Count (N=40)	Q8 Vomitting Severity (N=40)	Q9 Diarrhea Count (N=40)	Q10 Diarrhea Severity (N=40)
Cycle 4 Day 1						
n	36	36	36	36	36	36
Mean (StdDev)	1.28 (2.032)	0.82 (1.579)	0.13 (0.543)	0.29 (1.123)	0.50 (0.842)	0.82 (1.357)
Median	0.21	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 8.2	0.0, 6.3	0.0, 3.1	0.0, 6.3	0.0, 3.4	0.0, 5.6
Cycle 5 Day 1						
n	33	33	33	33	33	33
Mean (StdDev)	1.30 (1.942)	0.67 (1.325)	0.14 (0.610)	0.24 (0.941)	0.62 (1.049)	0.98 (1.775)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 6.7	0.0, 5.0	0.0, 3.5	0.0, 5.3	0.0, 4.0	0.0, 6.7
Cycle 6 Day 1						
n	29	29	29	29	29	29
Mean (StdDev)	1.32 (2.050)	0.60 (1.230)	0.11 (0.407)	0.20 (0.714)	0.32 (0.697)	0.49 (1.252)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 7.7	0.0, 4.7	0.0, 2.1	0.0, 3.6	0.0, 3.4	0.0, 6.6

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg				
Scores	TSS (N=40)	Skin Domain (N=40)	GI Domain (N=40)	Q6 Fatigue (N=40)
Cycle 7 Day 1				
n	26	26	26	26
Mean (StdDev)	10.05 (7.630)	3.71 (3.636)	2.14 (3.043)	4.20 (3.107)
Median	10.71	2.86	0.14	3.93
Min, Max	0.0, 27.6	0.0, 10.9	0.0, 8.7	0.0, 9.4
Cycle 8 Day 1				
n	26	26	26	26
Mean (StdDev)	10.69 (7.406)	4.21 (3.612)	2.26 (2.878)	4.22 (3.030)
Median	10.93	4.07	0.31	4.00
Min, Max	0.0, 27.6	0.0, 10.9	0.0, 8.7	0.0, 9.4
Cycle 9 Day 1				
n	23	23	23	23
Mean (StdDev)	10.06 (7.441)	3.97 (3.780)	2.13 (2.663)	3.97 (3.063)
Median	9.14	2.71	0.57	4.00
Min, Max	0.4, 27.6	0.0, 10.9	0.0, 7.7	0.0, 9.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg			
Scores	Q3 Spots (N=40)	Q4 Itching (N=40)	Q5 Flushing (N=40)
Cycle 7 Day 1			
n	26	26	26
Mean (StdDev)	1.71 (1.992)	1.04 (1.346)	0.97 (1.445)
Median	1.00	0.00	0.07
Min, Max	0.0, 7.0	0.0, 3.9	0.0, 5.0
Cycle 8 Day 1			
n	26	26	26
Mean (StdDev)	1.87 (1.942)	1.25 (1.410)	1.10 (1.501)
Median	1.57	0.75	0.00
Min, Max	0.0, 6.9	0.0, 3.9	0.0, 5.0
Cycle 9 Day 1			
n	23	23	23
Mean (StdDev)	1.94 (2.050)	1.06 (1.429)	0.97 (1.482)
Median	1.14	0.00	0.00
Min, Max	0.0, 6.7	0.0, 4.3	0.0, 5.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Scores	Q1 Abdominal Pain (N=40)	Q2 Nausea (N=40)	Q7 Vomitting Count (N=40)	Q8 Vomitting Severity (N=40)	Q9 Diarrhea Count (N=40)	Q10 Diarrhea Severity (N=40)
Cycle 7 Day 1						
n	26	26	26	26	26	26
Mean (StdDev)	1.15 (1.905)	0.43 (1.069)	0.02 (0.047)	0.03 (0.091)	0.25 (0.497)	0.53 (1.133)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 6.9	0.0, 4.7	0.0, 0.1	0.0, 0.4	0.0, 1.9	0.0, 4.9
Cycle 8 Day 1						
n	26	26	26	26	26	26
Mean (StdDev)	1.12 (1.750)	0.53 (1.128)	0.03 (0.077)	0.05 (0.154)	0.35 (0.627)	0.56 (0.890)
Median	0.00	0.00	0.00	0.00	0.14	0.14
Min, Max	0.0, 6.3	0.0, 4.7	0.0, 0.3	0.0, 0.7	0.0, 2.8	0.0, 3.5
Cycle 9 Day 1						
n	23	23	23	23	23	23
Mean (StdDev)	1.03 (1.613)	0.50 (1.070)	0.04 (0.100)	0.07 (0.166)	0.37 (0.677)	0.52 (1.040)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 5.4	0.0, 4.7	0.0, 0.4	0.0, 0.6	0.0, 2.3	0.0, 4.3

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg				
Scores	TSS (N=40)	Skin Domain (N=40)	GI Domain (N=40)	Q6 Fatigue (N=40)
Cycle 10 Day 1				
n	20	20	20	20
Mean (StdDev)	10.97 (7.516)	4.15 (3.876)	2.19 (2.885)	4.63 (3.041)
Median	10.82	2.74	0.43	4.07
Min, Max	0.0, 27.6	0.0, 10.9	0.0, 8.7	0.0, 9.4
Cycle 11 Day 1				
n	19	19	19	19
Mean (StdDev)	11.16 (7.718)	4.13 (3.844)	2.45 (3.097)	4.58 (3.045)
Median	11.50	3.14	0.43	4.71
Min, Max	0.0, 27.6	0.0, 10.9	0.0, 8.7	0.0, 9.4
Cycle 12 Day 1				
n	17	17	17	17
Mean (StdDev)	11.01 (7.277)	3.93 (3.639)	2.17 (3.134)	4.91 (2.950)
Median	11.14	3.14	0.14	5.25
Min, Max	0.0, 27.6	0.0, 10.9	0.0, 8.7	0.0, 9.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg			
Scores	Q3 Spots (N=40)	Q4 Itching (N=40)	Q5 Flushing (N=40)
Cycle 10 Day 1			
n	20	20	20
Mean (StdDev)	2.02 (2.023)	1.12 (1.501)	1.01 (1.525)
Median	2.00	0.00	0.00
Min, Max	0.0, 6.0	0.0, 4.0	0.0, 4.7
Cycle 11 Day 1			
n	19	19	19
Mean (StdDev)	2.09 (2.011)	1.06 (1.509)	0.97 (1.461)
Median	2.43	0.00	0.00
Min, Max	0.0, 6.0	0.0, 4.0	0.0, 4.0
Cycle 12 Day 1			
n	17	17	17
Mean (StdDev)	2.12 (2.016)	0.98 (1.456)	0.83 (1.351)
Median	2.71	0.00	0.00
Min, Max	0.0, 6.0	0.0, 3.9	0.0, 3.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Scores	Q1 Abdominal Pain (N=40)	Q2 Nausea (N=40)	Q7 Vomitting Count (N=40)	Q8 Vomitting Severity (N=40)	Q9 Diarrhea Count (N=40)	Q10 Diarrhea Severity (N=40)
Cycle 10 Day 1						
n	20	20	20	20	20	20
Mean (StdDev)	1.17 (1.717)	0.60 (1.184)	0.09 (0.287)	0.19 (0.557)	0.14 (0.238)	0.22 (0.448)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 5.4	0.0, 4.7	0.0, 1.3	0.0, 2.4	0.0, 0.7	0.0, 1.4
Cycle 11 Day 1						
n	19	19	19	19	19	19
Mean (StdDev)	1.23 (1.741)	0.58 (1.219)	0.10 (0.294)	0.19 (0.560)	0.31 (0.665)	0.44 (0.927)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 5.4	0.0, 4.7	0.0, 1.3	0.0, 2.4	0.0, 2.7	0.0, 3.2
Cycle 12 Day 1						
n	17	17	17	17	17	17
Mean (StdDev)	1.23 (1.845)	0.60 (1.276)	0.10 (0.310)	0.18 (0.589)	0.11 (0.229)	0.16 (0.367)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 5.4	0.0, 4.7	0.0, 1.3	0.0, 2.4	0.0, 0.7	0.0, 1.3

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg				
Scores	TSS (N=40)	Skin Domain (N=40)	GI Domain (N=40)	Q6 Fatigue (N=40)
Cycle 13 Day 1				
n	13	13	13	13
Mean (StdDev)	11.51 (7.936)	4.15 (3.864)	2.47 (3.409)	4.89 (3.011)
Median	11.50	3.14	0.14	5.14
Min, Max	0.0, 27.6	0.0, 10.9	0.0, 8.7	0.0, 9.4
Cycle 14 Day 1				
n	13	13	13	13
Mean (StdDev)	11.32 (7.925)	4.10 (3.813)	2.41 (3.401)	4.82 (2.988)
Median	10.57	3.14	0.14	5.00
Min, Max	0.0, 27.6	0.0, 10.9	0.0, 8.7	0.0, 9.4
Cycle 15 Day 1				
n	13	13	13	13
Mean (StdDev)	11.17 (7.968)	4.28 (3.788)	2.36 (3.398)	4.52 (3.037)
Median	9.00	4.29	0.14	3.57
Min, Max	0.0, 27.6	0.0, 10.9	0.0, 8.7	0.0, 9.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg			
Scores	Q3 Spots (N=40)	Q4 Itching (N=40)	Q5 Flushing (N=40)
Cycle 13 Day 1			
n	13	13	13
Mean (StdDev)	2.04 (1.918)	1.01 (1.424)	1.10 (1.483)
Median	3.14	0.00	0.00
Min, Max	0.0, 5.5	0.0, 3.9	0.0, 3.4
Cycle 14 Day 1			
n	13	13	13
Mean (StdDev)	2.01 (1.884)	1.01 (1.424)	1.09 (1.436)
Median	2.57	0.00	0.14
Min, Max	0.0, 5.5	0.0, 3.9	0.0, 3.4
Cycle 15 Day 1			
n	13	13	13
Mean (StdDev)	2.10 (1.885)	1.08 (1.450)	1.10 (1.428)
Median	3.00	0.00	0.25
Min, Max	0.0, 5.5	0.0, 3.9	0.0, 3.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Scores	Q1 Abdominal Pain (N=40)	Q2 Nausea (N=40)	Q7 Vomitting Count (N=40)	Q8 Vomitting Severity (N=40)	Q9 Diarrhea Count (N=40)	Q10 Diarrhea Severity (N=40)
Cycle 13 Day 1						
n	13	13	13	13	13	13
Mean (StdDev)	1.35 (1.984)	0.70 (1.387)	0.13 (0.352)	0.24 (0.668)	0.11 (0.242)	0.18 (0.409)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 5.4	0.0, 4.7	0.0, 1.3	0.0, 2.4	0.0, 0.7	0.0, 1.3
Cycle 14 Day 1						
n	13	13	13	13	13	13
Mean (StdDev)	1.33 (1.969)	0.66 (1.400)	0.13 (0.352)	0.24 (0.668)	0.11 (0.242)	0.18 (0.409)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 5.4	0.0, 4.7	0.0, 1.3	0.0, 2.4	0.0, 0.7	0.0, 1.3
Cycle 15 Day 1						
n	13	13	13	13	13	13
Mean (StdDev)	1.27 (1.946)	0.65 (1.405)	0.13 (0.352)	0.24 (0.668)	0.12 (0.239)	0.20 (0.406)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 5.4	0.0, 4.7	0.0, 1.3	0.0, 2.4	0.0, 0.7	0.0, 1.3

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg				
Scores	TSS (N=40)	Skin Domain (N=40)	GI Domain (N=40)	Q6 Fatigue (N=40)
Cycle 16 Day 1				
n	13	13	13	13
Mean (StdDev)	10.87 (8.169)	3.96 (3.799)	2.32 (3.419)	4.59 (3.026)
Median	9.00	3.14	0.14	3.71
Min, Max	0.0, 27.6	0.0, 10.9	0.0, 8.7	0.0, 9.4
Cycle 17 Day 1				
n	13	13	13	13
Mean (StdDev)	10.74 (8.304)	4.00 (3.777)	2.27 (3.435)	4.47 (3.125)
Median	9.00	3.14	0.14	3.57
Min, Max	0.0, 27.6	0.0, 10.9	0.0, 8.7	0.0, 9.4
Cycle 18 Day 1				
n	12	12	12	12
Mean (StdDev)	11.47 (8.251)	4.38 (3.723)	2.39 (3.560)	4.70 (3.143)
Median	10.33	3.65	0.07	4.29
Min, Max	0.0, 27.6	0.0, 10.9	0.0, 8.7	0.0, 9.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg			
Scores	Q3 Spots (N=40)	Q4 Itching (N=40)	Q5 Flushing (N=40)
Cycle 16 Day 1			
n	13	13	13
Mean (StdDev)	1.95 (1.888)	1.01 (1.424)	1.01 (1.366)
Median	2.00	0.00	0.00
Min, Max	0.0, 5.5	0.0, 3.9	0.0, 3.4
Cycle 17 Day 1			
n	13	13	13
Mean (StdDev)	1.95 (1.888)	1.05 (1.433)	1.00 (1.357)
Median	2.00	0.00	0.00
Min, Max	0.0, 5.5	0.0, 3.9	0.0, 3.4
Cycle 18 Day 1			
n	12	12	12
Mean (StdDev)	2.10 (1.883)	1.20 (1.473)	1.08 (1.382)
Median	2.57	0.33	0.13
Min, Max	0.0, 5.5	0.0, 3.9	0.0, 3.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Scores	Q1 Abdominal Pain (N=40)	Q2 Nausea (N=40)	Q7 Vomitting Count (N=40)	Q8 Vomitting Severity (N=40)	Q9 Diarrhea Count (N=40)	Q10 Diarrhea Severity (N=40)
Cycle 16 Day 1						
n	13	13	13	13	13	13
Mean (StdDev)	1.25 (1.942)	0.65 (1.405)	0.15 (0.352)	0.24 (0.668)	0.11 (0.242)	0.18 (0.409)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 5.4	0.0, 4.7	0.0, 1.3	0.0, 2.4	0.0, 0.7	0.0, 1.3
Cycle 17 Day 1						
n	13	13	13	13	13	13
Mean (StdDev)	1.21 (1.944)	0.65 (1.405)	0.13 (0.352)	0.24 (0.668)	0.11 (0.242)	0.18 (0.409)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 5.4	0.0, 4.7	0.0, 1.3	0.0, 2.4	0.0, 0.7	0.0, 1.3
Cycle 18 Day 1						
n	12	12	12	12	12	12
Mean (StdDev)	1.24 (2.028)	0.70 (1.454)	0.14 (0.365)	0.26 (0.694)	0.12 (0.250)	0.19 (0.423)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 5.4	0.0, 4.7	0.0, 1.3	0.0, 2.4	0.0, 0.7	0.0, 1.3

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Scores	TSS (N=69)	Skin Domain (N=69)	GI Domain (N=69)	Q6 Fatigue (N=69)
Baseline (C1D-7 to C1D-1)				
n	61	61	61	61
Mean (StdDev)	20.16 (13.369)	7.56 (6.936)	6.88 (6.358)	5.73 (2.936)
Median	18.86	6.60	5.86	6.29
Min, Max	0.0, 53.7	0.0, 28.6	0.0, 25.2	0.0, 10.0
Cycle 2 Day 1				
n	66	66	66	66
Mean (StdDev)	13.88 (10.815)	5.16 (5.414)	3.98 (4.596)	4.73 (2.992)
Median	12.29	3.57	2.36	5.17
Min, Max	0.0, 49.2	0.0, 23.0	0.0, 22.3	0.0, 10.0
Cycle 3 Day 1				
n	64	64	64	64
Mean (StdDev)	13.45 (9.424)	5.23 (4.834)	3.55 (3.906)	4.69 (2.752)
Median	11.71	3.69	2.36	4.85
Min, Max	0.0, 46.1	0.0, 23.1	0.0, 16.9	0.0, 10.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Scores	Q3 Spots (N=69)	Q4 Itching (N=69)	Q5 Flushing (N=69)
Baseline (C1D-7 to C1D-1)			
n	61	61	61
Mean (StdDev)	2.75 (2.677)	2.50 (2.758)	2.33 (2.586)
Median	2.57	1.00	1.43
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 8.7
Cycle 2 Day 1			
n	66	66	66
Mean (StdDev)	2.17 (2.351)	1.41 (1.925)	1.58 (2.126)
Median	1.36	0.31	0.14
Min, Max	0.0, 8.1	0.0, 7.4	0.0, 8.9
Cycle 3 Day 1			
n	64	64	64
Mean (StdDev)	2.10 (2.054)	1.53 (2.025)	1.60 (1.896)
Median	1.66	0.43	0.69
Min, Max	0.0, 8.0	0.0, 7.6	0.0, 7.6

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Scores	Q1 Abdominal Pain (N=69)	Q2 Nausea (N=69)	Q7 Vomitting Count (N=69)	Q8 Vomitting Severity (N=69)	Q9 Diarrhea Count (N=69)	Q10 Diarrhea Severity (N=69)
Baseline (C1D-7 to C1D-1)						
n	61	61	61	61	61	61
Mean (StdDev)	2.95 (2.908)	1.86 (2.402)	0.30 (1.664)	0.24 (0.844)	3.80 (12.323)	1.81 (2.088)
Median	2.43	0.67	0.00	0.00	0.50	0.86
Min, Max	0.0, 10.0	0.0, 8.0	0.0, 12.9	0.0, 5.8	0.0, 85.7	0.0, 7.6
Cycle 2 Day 1						
n	66	66	66	66	66	66
Mean (StdDev)	1.67 (2.082)	1.06 (1.740)	0.47 (3.517)	0.12 (0.565)	1.72 (7.089)	1.14 (1.791)
Median	1.00	0.27	0.00	0.00	0.21	0.41
Min, Max	0.0, 7.2	0.0, 8.0	0.0, 28.6	0.0, 4.4	0.0, 57.1	0.0, 7.5
Cycle 3 Day 1						
n	64	64	64	64	64	64
Mean (StdDev)	1.48 (2.059)	0.89 (1.401)	0.06 (0.207)	0.15 (0.619)	1.00 (2.266)	1.03 (1.573)
Median	0.50	0.14	0.00	0.00	0.14	0.36
Min, Max	0.0, 7.1	0.0, 6.1	0.0, 1.6	0.0, 4.7	0.0, 14.3	0.0, 6.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Scores	TSS (N=69)	Skin Domain (N=69)	GI Domain (N=69)	Q6 Fatigue (N=69)
Cycle 4 Day 1				
n	62	62	62	62
Mean (StdDev)	13.48 (9.688)	5.12 (4.635)	3.62 (4.687)	4.73 (2.824)
Median	12.00	3.57	1.79	4.93
Min, Max	0.7, 45.6	0.0, 18.8	0.0, 21.7	0.0, 10.0
Cycle 5 Day 1				
n	58	58	58	58
Mean (StdDev)	12.88 (9.920)	4.77 (4.682)	3.57 (4.643)	4.55 (2.783)
Median	11.86	2.93	2.14	4.77
Min, Max	0.1, 43.5	0.0, 21.6	0.0, 21.5	0.0, 10.0
Cycle 6 Day 1				
n	51	51	51	51
Mean (StdDev)	12.27 (9.695)	4.75 (5.164)	2.98 (4.157)	4.54 (2.875)
Median	11.50	2.43	1.29	4.57
Min, Max	0.0, 41.6	0.0, 23.2	0.0, 17.4	0.0, 9.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Scores	Q3 Spots (N=69)	Q4 Itching (N=69)	Q5 Flushing (N=69)
Cycle 4 Day 1			
n	62	62	62
Mean (StdDev)	2.02 (1.927)	1.46 (1.849)	1.64 (1.994)
Median	1.79	0.58	0.71
Min, Max	0.0, 7.3	0.0, 7.6	0.0, 7.0
Cycle 5 Day 1			
n	58	58	58
Mean (StdDev)	1.90 (1.884)	1.29 (1.737)	1.58 (1.971)
Median	1.21	0.17	0.69
Min, Max	0.0, 7.0	0.0, 6.9	0.0, 8.0
Cycle 6 Day 1			
n	51	51	51
Mean (StdDev)	1.89 (2.088)	1.46 (1.949)	1.41 (2.065)
Median	1.00	0.29	0.25
Min, Max	0.0, 7.4	0.0, 8.0	0.0, 7.8

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Scores	Q1 Abdominal Pain (N=69)	Q2 Nausea (N=69)	Q7 Vomitting Count (N=69)	Q8 Vomitting Severity (N=69)	Q9 Diarrhea Count (N=69)	Q10 Diarrhea Severity (N=69)
Cycle 4 Day 1						
n	62	62	62	62	62	62
Mean (StdDev)	1.27 (1.928)	0.95 (1.552)	0.11 (0.425)	0.25 (0.884)	0.70 (1.247)	1.15 (1.742)
Median	0.21	0.00	0.00	0.00	0.24	0.31
Min, Max	0.0, 8.2	0.0, 6.3	0.0, 3.1	0.0, 6.3	0.0, 8.0	0.0, 7.3
Cycle 5 Day 1						
n	58	58	58	58	58	58
Mean (StdDev)	1.29 (1.866)	0.86 (1.487)	0.09 (0.468)	0.20 (0.762)	1.03 (2.137)	1.22 (1.926)
Median	0.21	0.00	0.00	0.00	0.29	0.15
Min, Max	0.0, 7.3	0.0, 6.3	0.0, 3.5	0.0, 5.3	0.0, 14.3	0.0, 7.8
Cycle 6 Day 1						
n	51	51	51	51	51	51
Mean (StdDev)	1.24 (1.931)	0.67 (1.406)	0.07 (0.318)	0.18 (0.694)	0.83 (2.392)	0.89 (1.641)
Median	0.14	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 7.7	0.0, 7.0	0.0, 2.1	0.0, 3.6	0.0, 16.6	0.0, 7.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Scores	TSS (N=69)	Skin Domain (N=69)	GI Domain (N=69)	Q6 Fatigue (N=69)
Cycle 7 Day 1				
n	46	47	47	47
Mean (StdDev)	11.39 (8.487)	4.74 (5.300)	2.68 (3.309)	4.53 (2.892)
Median	11.29	2.57	1.29	4.29
Min, Max	0.0, 36.5	0.0, 23.3	0.0, 13.5	0.0, 9.6
Cycle 8 Day 1				
n	43	43	43	43
Mean (StdDev)	10.91 (7.532)	4.08 (3.849)	2.44 (3.272)	4.40 (2.728)
Median	11.50	2.67	1.14	4.29
Min, Max	0.0, 34.5	0.0, 13.9	0.0, 15.0	0.0, 9.4
Cycle 9 Day 1				
n	42	42	42	42
Mean (StdDev)	10.97 (8.767)	4.29 (4.499)	2.42 (3.560)	4.25 (2.672)
Median	9.68	3.07	0.76	4.50
Min, Max	0.4, 43.6	0.0, 20.8	0.0, 14.8	0.0, 9.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Scores	Q3 Spots (N=69)	Q4 Itching (N=69)	Q5 Flushing (N=69)
Cycle 7 Day 1			
n	47	47	47
Mean (StdDev)	1.82 (2.027)	1.49 (2.026)	1.44 (2.095)
Median	1.00	0.29	0.25
Min, Max	0.0, 7.0	0.0, 7.4	0.0, 9.2
Cycle 8 Day 1			
n	43	43	43
Mean (StdDev)	1.66 (1.750)	1.29 (1.600)	1.13 (1.642)
Median	1.00	0.50	0.25
Min, Max	0.0, 6.9	0.0, 5.7	0.0, 7.0
Cycle 9 Day 1			
n	42	42	42
Mean (StdDev)	1.80 (1.966)	1.27 (1.719)	1.23 (1.837)
Median	1.07	0.23	0.17
Min, Max	0.0, 7.0	0.0, 6.8	0.0, 7.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Scores	Q1 Abdominal Pain (N=69)	Q2 Nausea (N=69)	Q7 Vomitting Count (N=69)	Q8 Vomitting Severity (N=69)	Q9 Diarrhea Count (N=69)	Q10 Diarrhea Severity (N=69)
Cycle 7 Day 1						
n	47	47	47	47	47	47
Mean (StdDev)	1.11 (1.775)	0.64 (1.245)	0.03 (0.077)	0.07 (0.238)	0.45 (0.792)	0.89 (1.531)
Median	0.29	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 6.9	0.0, 5.8	0.0, 0.4	0.0, 1.2	0.0, 3.3	0.0, 5.3
Cycle 8 Day 1						
n	43	43	43	43	43	43
Mean (StdDev)	0.89 (1.478)	0.65 (1.199)	0.60 (3.810)	0.06 (0.222)	1.60 (5.093)	0.84 (1.414)
Median	0.00	0.00	0.00	0.00	0.14	0.14
Min, Max	0.0, 6.3	0.0, 5.3	0.0, 25.0	0.0, 1.3	0.0, 30.4	0.0, 7.0
Cycle 9 Day 1						
n	42	42	42	42	42	42
Mean (StdDev)	0.88 (1.620)	0.69 (1.438)	0.05 (0.108)	0.13 (0.326)	0.45 (0.794)	0.72 (1.411)
Median	0.00	0.07	0.00	0.00	0.00	0.00
Min, Max	0.0, 7.0	0.0, 6.4	0.0, 0.4	0.0, 1.4	0.0, 3.1	0.0, 6.9

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Scores	TSS (N=69)	Skin Domain (N=69)	GI Domain (N=69)	Q6 Fatigue (N=69)
Cycle 10 Day 1				
n	37	37	37	37
Mean (StdDev)	11.95 (7.927)	4.27 (4.018)	3.00 (4.369)	4.68 (2.826)
Median	11.86	3.00	0.71	4.14
Min, Max	0.0, 30.3	0.0, 14.8	0.0, 17.0	0.0, 9.4
Cycle 11 Day 1				
n	35	35	35	35
Mean (StdDev)	11.59 (8.195)	4.47 (4.495)	2.34 (3.030)	4.77 (2.781)
Median	11.50	3.57	1.00	5.00
Min, Max	0.0, 35.5	0.0, 16.8	0.0, 11.5	0.0, 9.4
Cycle 12 Day 1				
n	32	32	32	32
Mean (StdDev)	12.60 (10.352)	4.99 (5.145)	2.85 (4.275)	4.76 (2.747)
Median	10.79	3.50	0.57	4.86
Min, Max	0.0, 45.7	0.0, 20.7	0.0, 16.3	0.0, 9.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Scores	Q3 Spots (N=69)	Q4 Itching (N=69)	Q5 Flushing (N=69)
Cycle 10 Day 1			
n	37	37	37
Mean (StdDev)	1.76 (1.784)	1.35 (1.781)	1.16 (1.685)
Median	1.00	0.14	0.14
Min, Max	0.0, 6.0	0.0, 6.3	0.0, 6.8
Cycle 11 Day 1			
n	35	35	35
Mean (StdDev)	1.82 (1.834)	1.38 (1.714)	1.27 (1.957)
Median	1.14	0.50	0.00
Min, Max	0.0, 6.0	0.0, 5.3	0.0, 7.8
Cycle 12 Day 1			
n	32	32	32
Mean (StdDev)	2.03 (1.903)	1.60 (2.032)	1.36 (2.181)
Median	2.07	0.75	0.00
Min, Max	0.0, 6.7	0.0, 6.8	0.0, 9.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Scores	Q1 Abdominal Pain (N=69)	Q2 Nausea (N=69)	Q7 Vomitting Count (N=69)	Q8 Vomitting Severity (N=69)	Q9 Diarrhea Count (N=69)	Q10 Diarrhea Severity (N=69)
Cycle 10 Day 1						
n	37	37	37	37	37	37
Mean (StdDev)	1.32 (2.147)	0.75 (1.284)	0.05 (0.214)	0.12 (0.419)	0.62 (1.285)	0.81 (1.564)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 9.1	0.0, 4.7	0.0, 1.3	0.0, 2.4	0.0, 5.7	0.0, 6.9
Cycle 11 Day 1						
n	35	35	35	35	35	35
Mean (StdDev)	1.18 (1.837)	0.55 (1.164)	0.05 (0.219)	0.10 (0.418)	0.38 (0.645)	0.50 (0.883)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 7.0	0.0, 4.7	0.0, 1.3	0.0, 2.4	0.0, 2.7	0.0, 3.2
Cycle 12 Day 1						
n	32	32	32	32	32	32
Mean (StdDev)	1.17 (1.912)	0.78 (1.517)	0.10 (0.305)	0.14 (0.474)	0.39 (0.914)	0.73 (1.710)
Median	0.14	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 7.7	0.0, 6.2	0.0, 1.3	0.0, 2.4	0.0, 4.3	0.0, 7.3

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Scores	TSS (N=69)	Skin Domain (N=69)	GI Domain (N=69)	Q6 Fatigue (N=69)
Cycle 13 Day 1				
n	24	24	24	24
Mean (StdDev)	12.30 (10.297)	4.82 (4.831)	2.71 (4.564)	4.77 (2.635)
Median	10.19	3.65	0.29	5.15
Min, Max	0.0, 48.8	0.0, 21.0	0.0, 19.8	0.0, 9.4
Cycle 14 Day 1				
n	22	22	23	23
Mean (StdDev)	13.35 (9.484)	5.39 (4.938)	3.41 (4.606)	5.20 (2.482)
Median	12.64	5.54	1.83	5.14
Min, Max	0.0, 43.0	0.0, 20.4	0.0, 15.2	0.0, 9.4
Cycle 15 Day 1				
n	18	18	18	18
Mean (StdDev)	14.29 (10.505)	6.05 (5.815)	3.23 (3.748)	5.03 (2.776)
Median	12.11	5.93	1.00	4.91
Min, Max	0.0, 38.8	0.0, 20.5	0.0, 11.3	0.0, 9.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Scores	Q3 Spots (N=69)	Q4 Itching (N=69)	Q5 Flushing (N=69)
Cycle 13 Day 1			
n	24	24	24
Mean (StdDev)	2.06 (1.961)	1.46 (1.901)	1.29 (1.802)
Median	1.86	0.68	0.13
Min, Max	0.0, 7.3	0.0, 6.5	0.0, 7.3
Cycle 14 Day 1			
n	23	23	22
Mean (StdDev)	2.26 (1.908)	1.73 (2.089)	1.51 (1.741)
Median	2.67	1.00	1.07
Min, Max	0.0, 6.8	0.0, 7.0	0.0, 6.6
Cycle 15 Day 1			
n	18	18	18
Mean (StdDev)	2.39 (2.155)	1.78 (2.262)	1.89 (2.476)
Median	3.00	0.75	0.64
Min, Max	0.0, 7.0	0.0, 7.3	0.0, 8.5

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Scores	Q1 Abdominal Pain (N=69)	Q2 Nausea (N=69)	Q7 Vomitting Count (N=69)	Q8 Vomitting Severity (N=69)	Q9 Diarrhea Count (N=69)	Q10 Diarrhea Severity (N=69)
Cycle 13 Day 1						
n	24	24	24	24	24	24
Mean (StdDev)	1.13 (2.060)	0.86 (1.760)	0.14 (0.328)	0.29 (0.806)	0.24 (0.555)	0.42 (0.894)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 7.5	0.0, 7.3	0.0, 1.3	0.0, 3.3	0.0, 2.2	0.0, 3.2
Cycle 14 Day 1						
n	23	23	23	23	23	23
Mean (StdDev)	1.38 (2.098)	1.12 (1.981)	0.17 (0.438)	0.30 (0.819)	0.36 (0.679)	0.60 (1.123)
Median	0.17	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 7.2	0.0, 6.6	0.0, 1.8	0.0, 3.3	0.0, 3.0	0.0, 5.0
Cycle 15 Day 1						
n	18	18	18	18	18	18
Mean (StdDev)	1.46 (2.017)	0.99 (1.674)	0.10 (0.302)	0.17 (0.573)	0.35 (0.612)	0.61 (1.193)
Median	0.39	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 6.0	0.0, 5.3	0.0, 1.3	0.0, 2.4	0.0, 2.0	0.0, 4.3

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Scores	TSS (N=69)	Skin Domain (N=69)	GI Domain (N=69)	Q6 Fatigue (N=69)
Cycle 16 Day 1				
n	19	19	19	19
Mean (StdDev)	14.96 (12.591)	6.08 (6.291)	3.77 (5.064)	5.12 (2.881)
Median	11.83	6.00	0.14	5.00
Min, Max	0.0, 49.0	0.0, 22.2	0.0, 18.4	0.0, 9.4
Cycle 17 Day 1				
n	17	17	17	17
Mean (StdDev)	11.74 (8.298)	4.51 (3.815)	2.41 (3.245)	4.81 (2.955)
Median	11.50	4.00	0.14	5.00
Min, Max	0.0, 27.6	0.0, 10.9	0.0, 8.7	0.0, 9.4
Cycle 18 Day 1				
n	16	16	16	16
Mean (StdDev)	13.10 (9.116)	5.30 (4.515)	2.88 (3.593)	4.91 (2.833)
Median	12.11	5.21	0.21	5.07
Min, Max	0.0, 31.7	0.0, 16.3	0.0, 8.7	0.0, 9.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Scores	Q3 Spots (N=69)	Q4 Itching (N=69)	Q5 Flushing (N=69)
Cycle 16 Day 1			
n	19	19	19
Mean (StdDev)	2.30 (2.251)	1.85 (2.355)	1.93 (2.600)
Median	2.33	0.86	0.43
Min, Max	0.0, 8.0	0.0, 7.0	0.0, 8.8
Cycle 17 Day 1			
n	17	17	17
Mean (StdDev)	1.95 (1.708)	1.42 (1.712)	1.14 (1.481)
Median	2.29	0.50	0.00
Min, Max	0.0, 5.5	0.0, 5.4	0.0, 4.1
Cycle 18 Day 1			
n	16	16	16
Mean (StdDev)	2.08 (1.693)	1.40 (1.483)	1.82 (2.447)
Median	2.29	1.08	0.84
Min, Max	0.0, 5.5	0.0, 4.0	0.0, 9.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Scores	Q1 Abdominal Pain (N=69)	Q2 Nausea (N=69)	Q7 Vomitting Count (N=69)	Q8 Vomitting Severity (N=69)	Q9 Diarrhea Count (N=69)	Q10 Diarrhea Severity (N=69)
Cycle 16 Day 1						
n	19	19	19	19	19	19
Mean (StdDev)	1.43 (2.465)	1.16 (2.179)	0.12 (0.296)	0.23 (0.604)	0.53 (1.158)	0.94 (2.119)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 9.0	0.0, 8.2	0.0, 1.3	0.0, 2.4	0.0, 4.4	0.0, 6.8
Cycle 17 Day 1						
n	17	17	17	17	17	17
Mean (StdDev)	1.07 (1.731)	0.61 (1.271)	0.10 (0.310)	0.18 (0.589)	0.37 (0.772)	0.56 (1.275)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 5.4	0.0, 4.7	0.0, 1.3	0.0, 2.4	0.0, 3.0	0.0, 5.1
Cycle 18 Day 1						
n	16	16	16	16	16	16
Mean (StdDev)	1.03 (1.787)	0.61 (1.281)	0.11 (0.319)	0.20 (0.606)	0.57 (1.072)	1.05 (2.157)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 5.4	0.0, 4.7	0.0, 1.3	0.0, 2.4	0.0, 3.7	0.0, 7.2

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Scores	TSS (N=69)	Skin Domain (N=69)	GI Domain (N=69)	Q6 Fatigue (N=69)
Cycle 19 Day 1				
n	3	3	3	3
Mean (StdDev)	30.92 (12.067)	14.84 (5.828)	9.27 (6.280)	6.81 (0.599)
Median	26.83	15.17	6.14	6.50
Min, Max	21.4, 44.5	8.9, 20.5	5.2, 16.5	6.4, 7.5
Cycle 20 Day 1				
n	1	1	1	1
Mean (StdDev)	18.00 (-)	6.83 (-)	4.17 (-)	7.00 (-)
Median	18.00	6.83	4.17	7.00
Min, Max	18.0, 18.0	6.8, 6.8	4.2, 4.2	7.0, 7.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Scores	Q3 Spots (N=69)	Q4 Itching (N=69)	Q5 Flushing (N=69)
Cycle 19 Day 1			
n	3	3	3
Mean (StdDev)	4.03 (2.804)	3.66 (2.462)	7.15 (1.945)
Median	3.67	2.33	7.00
Min, Max	1.4, 7.0	2.1, 6.5	5.3, 9.2
Cycle 20 Day 1			
n	1	1	1
Mean (StdDev)	1.00 (-)	1.33 (-)	4.50 (-)
Median	1.00	1.33	4.50
Min, Max	1.0, 1.0	1.3, 1.3	4.5, 4.5

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Scores	Q1 Abdominal Pain (N=69)	Q2 Nausea (N=69)	Q7 Vomitting Count (N=69)	Q8 Vomitting Severity (N=69)	Q9 Diarrhea Count (N=69)	Q10 Diarrhea Severity (N=69)
Cycle 19 Day 1						
n	3	3	3	3	3	3
Mean (StdDev)	2.84 (4.049)	2.08 (3.608)	0.17 (0.289)	0.42 (0.722)	1.72 (1.277)	3.93 (2.108)
Median	0.86	0.00	0.00	0.00	2.33	5.00
Min, Max	0.2, 7.5	0.0, 6.3	0.0, 0.5	0.0, 1.3	0.3, 2.6	1.5, 5.3
Cycle 20 Day 1						
n	1	1	1	1	1	1
Mean (StdDev)	1.00 (-)	0.00 (-)	0.00 (-)	0.00 (-)	1.50 (-)	3.17 (-)
Median	1.00	0.00	0.00	0.00	1.50	3.17
Min, Max	1.0, 1.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	1.5, 1.5	3.2, 3.2

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg				
Scores	TSS (N=52)	Skin Domain (N=52)	GI Domain (N=52)	Q6 Fatigue (N=52)
Baseline (C1D-7 to C1D-1)				
n	47	47	47	47
Mean (StdDev)	20.06 (12.820)	7.99 (7.171)	6.51 (5.703)	5.56 (2.955)
Median	19.29	7.00	5.86	6.29
Min, Max	0.0, 53.7	0.0, 28.6	0.0, 21.7	0.0, 10.0
Cycle 2 Day 1				
n	50	50	50	50
Mean (StdDev)	12.44 (9.024)	4.57 (4.721)	3.45 (3.828)	4.43 (2.956)
Median	11.89	3.07	1.86	4.93
Min, Max	0.0, 38.7	0.0, 15.9	0.0, 17.6	0.0, 9.1
Cycle 3 Day 1				
n	48	48	48	48
Mean (StdDev)	12.81 (8.388)	5.05 (4.397)	3.26 (3.607)	4.50 (2.719)
Median	11.71	3.62	2.36	4.71
Min, Max	0.0, 35.6	0.0, 15.4	0.0, 16.9	0.0, 9.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg			
Scores	Q3 Spots (N=52)	Q4 Itching (N=52)	Q5 Flushing (N=52)
Baseline (C1D-7 to C1D-1)			
n	47	47	47
Mean (StdDev)	2.80 (2.796)	2.79 (2.870)	2.40 (2.553)
Median	2.57	1.57	1.86
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 8.6
Cycle 2 Day 1			
n	50	50	50
Mean (StdDev)	2.02 (2.272)	1.27 (1.703)	1.27 (1.664)
Median	1.00	0.18	0.14
Min, Max	0.0, 7.3	0.0, 6.4	0.0, 5.9
Cycle 3 Day 1			
n	48	48	48
Mean (StdDev)	2.08 (2.030)	1.54 (1.892)	1.43 (1.743)
Median	1.57	0.64	0.43
Min, Max	0.0, 7.7	0.0, 6.7	0.0, 6.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Scores	Q1 Abdominal Pain (N=52)	Q2 Nausea (N=52)	Q7 Vomitting Count (N=52)	Q8 Vomitting Severity (N=52)	Q9 Diarrhea Count (N=52)	Q10 Diarrhea Severity (N=52)
Baseline (C1D-7 to C1D-1)						
n	47	47	47	47	47	47
Mean (StdDev)	2.89 (2.791)	1.69 (2.229)	0.06 (0.172)	0.13 (0.363)	1.31 (1.871)	1.81 (2.153)
Median	2.43	0.67	0.00	0.00	0.43	0.86
Min, Max	0.0, 10.0	0.0, 7.3	0.0, 1.0	0.0, 1.7	0.0, 7.1	0.0, 7.6
Cycle 2 Day 1						
n	50	50	50	50	50	50
Mean (StdDev)	1.58 (1.963)	0.83 (1.392)	0.05 (0.214)	0.11 (0.629)	0.75 (1.266)	0.93 (1.306)
Median	0.83	0.14	0.00	0.00	0.21	0.46
Min, Max	0.0, 7.0	0.0, 5.9	0.0, 1.4	0.0, 4.4	0.0, 6.1	0.0, 5.0
Cycle 3 Day 1						
n	48	48	48	48	48	48
Mean (StdDev)	1.43 (1.956)	0.77 (1.224)	0.06 (0.236)	0.17 (0.708)	0.62 (0.988)	0.89 (1.284)
Median	0.50	0.00	0.00	0.00	0.14	0.36
Min, Max	0.0, 6.9	0.0, 5.1	0.0, 1.6	0.0, 4.7	0.0, 3.4	0.0, 5.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg				
Scores	TSS (N=52)	Skin Domain (N=52)	GI Domain (N=52)	Q6 Fatigue (N=52)
Cycle 4 Day 1				
n	46	46	46	46
Mean (StdDev)	12.70 (8.936)	4.96 (4.476)	3.27 (4.441)	4.46 (2.723)
Median	11.86	3.50	1.64	4.71
Min, Max	0.7, 45.6	0.0, 17.3	0.0, 21.7	0.0, 9.4
Cycle 5 Day 1				
n	42	42	42	42
Mean (StdDev)	12.12 (8.719)	4.45 (4.097)	3.38 (4.322)	4.30 (2.720)
Median	11.50	2.86	2.21	4.25
Min, Max	0.1, 41.7	0.0, 14.2	0.0, 21.5	0.0, 9.4
Cycle 6 Day 1				
n	36	36	36	36
Mean (StdDev)	11.30 (8.045)	4.23 (4.073)	2.75 (3.906)	4.32 (2.868)
Median	10.75	2.64	1.14	3.93
Min, Max	0.0, 33.6	0.0, 14.0	0.0, 13.7	0.0, 9.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg			
Scores	Q3 Spots (N=52)	Q4 Itching (N=52)	Q5 Flushing (N=52)
Cycle 4 Day 1			
n	46	46	46
Mean (StdDev)	1.95 (2.001)	1.47 (1.823)	1.54 (1.827)
Median	1.21	0.58	0.71
Min, Max	0.0, 7.3	0.0, 7.6	0.0, 6.7
Cycle 5 Day 1			
n	42	42	42
Mean (StdDev)	1.82 (1.891)	1.19 (1.540)	1.44 (1.709)
Median	1.07	0.17	0.79
Min, Max	0.0, 7.0	0.0, 4.3	0.0, 5.8
Cycle 6 Day 1			
n	36	36	36
Mean (StdDev)	1.78 (2.060)	1.25 (1.586)	1.19 (1.670)
Median	1.21	0.29	0.20
Min, Max	0.0, 7.0	0.0, 4.4	0.0, 5.6

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Scores	Q1 Abdominal Pain (N=52)	Q2 Nausea (N=52)	Q7 Vomitting Count (N=52)	Q8 Vomitting Severity (N=52)	Q9 Diarrhea Count (N=52)	Q10 Diarrhea Severity (N=52)
Cycle 4 Day 1						
n	46	46	46	46	46	46
Mean (StdDev)	1.18 (1.853)	0.92 (1.572)	0.13 (0.490)	0.27 (1.006)	0.56 (0.847)	0.91 (1.342)
Median	0.21	0.00	0.00	0.00	0.07	0.07
Min, Max	0.0, 8.2	0.0, 6.3	0.0, 3.1	0.0, 6.3	0.0, 3.4	0.0, 5.6
Cycle 5 Day 1						
n	42	42	42	42	42	42
Mean (StdDev)	1.24 (1.809)	0.84 (1.459)	0.13 (0.548)	0.26 (0.883)	0.71 (1.096)	1.04 (1.703)
Median	0.08	0.00	0.00	0.00	0.14	0.07
Min, Max	0.0, 6.7	0.0, 5.5	0.0, 3.5	0.0, 5.3	0.0, 4.0	0.0, 6.7
Cycle 6 Day 1						
n	36	36	36	36	36	36
Mean (StdDev)	1.18 (1.951)	0.57 (1.143)	0.09 (0.367)	0.16 (0.644)	0.48 (0.801)	0.84 (1.690)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 7.7	0.0, 4.7	0.0, 2.1	0.0, 3.6	0.0, 3.4	0.0, 7.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg				
Scores	TSS (N=52)	Skin Domain (N=52)	GI Domain (N=52)	Q6 Fatigue (N=52)
Cycle 7 Day 1				
n	33	33	33	33
Mean (StdDev)	10.46 (7.270)	3.96 (3.854)	2.34 (2.887)	4.16 (2.915)
Median	11.14	2.57	0.71	4.00
Min, Max	0.0, 27.6	0.0, 11.0	0.0, 8.7	0.0, 9.4
Cycle 8 Day 1				
n	31	31	31	31
Mean (StdDev)	10.50 (6.952)	3.97 (3.461)	2.41 (2.873)	4.13 (2.863)
Median	11.14	3.14	1.29	4.00
Min, Max	0.0, 27.6	0.0, 10.9	0.0, 8.7	0.0, 9.4
Cycle 9 Day 1				
n	29	29	29	29
Mean (StdDev)	9.95 (6.785)	3.94 (3.563)	2.06 (2.709)	3.95 (2.847)
Median	9.14	3.14	0.57	4.00
Min, Max	0.4, 27.6	0.0, 10.9	0.0, 8.1	0.0, 9.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg			
Scores	Q3 Spots (N=52)	Q4 Itching (N=52)	Q5 Flushing (N=52)
Cycle 7 Day 1			
n	33	33	33
Mean (StdDev)	1.68 (1.884)	1.19 (1.565)	1.09 (1.454)
Median	1.00	0.00	0.14
Min, Max	0.0, 7.0	0.0, 4.9	0.0, 5.0
Cycle 8 Day 1			
n	31	31	31
Mean (StdDev)	1.71 (1.842)	1.20 (1.430)	1.07 (1.449)
Median	1.43	0.50	0.14
Min, Max	0.0, 6.9	0.0, 3.9	0.0, 5.0
Cycle 9 Day 1			
n	29	29	29
Mean (StdDev)	1.81 (1.915)	1.11 (1.473)	1.02 (1.476)
Median	1.14	0.00	0.14
Min, Max	0.0, 6.7	0.0, 4.3	0.0, 5.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Scores	Q1 Abdominal Pain (N=52)	Q2 Nausea (N=52)	Q7 Vomitting Count (N=52)	Q8 Vomitting Severity (N=52)	Q9 Diarrhea Count (N=52)	Q10 Diarrhea Severity (N=52)
Cycle 7 Day 1						
n	33	33	33	33	33	33
Mean (StdDev)	1.00 (1.738)	0.46 (0.983)	0.01 (0.042)	0.02 (0.081)	0.43 (0.701)	0.85 (1.451)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 6.9	0.0, 4.7	0.0, 0.1	0.0, 0.4	0.0, 2.9	0.0, 5.3
Cycle 8 Day 1						
n	31	31	31	31	31	31
Mean (StdDev)	1.03 (1.651)	0.60 (1.099)	0.02 (0.072)	0.04 (0.142)	0.53 (0.844)	0.73 (1.051)
Median	0.00	0.00	0.00	0.00	0.14	0.29
Min, Max	0.0, 6.3	0.0, 4.7	0.0, 0.3	0.0, 0.7	0.0, 3.1	0.0, 3.5
Cycle 9 Day 1						
n	29	29	29	29	29	29
Mean (StdDev)	0.93 (1.500)	0.48 (0.999)	0.03 (0.091)	0.06 (0.150)	0.43 (0.809)	0.59 (1.128)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 5.4	0.0, 4.7	0.0, 0.4	0.0, 0.6	0.0, 3.1	0.0, 4.3

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas
Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Scores	TSS (N=52)	Skin Domain (N=52)	GI Domain (N=52)	Q6 Fatigue (N=52)
Cycle 10 Day 1				
n	26	26	26	26
Mean (StdDev)	11.28 (7.373)	3.96 (3.669)	2.77 (3.883)	4.54 (2.990)
Median	11.25	2.67	0.86	4.00
Min, Max	0.0, 27.6	0.0, 10.9	0.0, 16.0	0.0, 9.4
Cycle 11 Day 1				
n	24	24	24	24
Mean (StdDev)	10.76 (7.277)	3.88 (3.829)	2.30 (2.890)	4.58 (3.030)
Median	10.82	2.57	0.50	4.43
Min, Max	0.0, 27.6	0.0, 10.9	0.0, 8.7	0.0, 9.4
Cycle 12 Day 1				
n	21	21	21	21
Mean (StdDev)	10.56 (7.107)	3.99 (3.712)	2.00 (2.849)	4.57 (2.867)
Median	10.00	3.14	0.29	4.57
Min, Max	0.0, 27.6	0.0, 10.9	0.0, 8.7	0.0, 9.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg			
Scores	Q3 Spots (N=52)	Q4 Itching (N=52)	Q5 Flushing (N=52)
Cycle 10 Day 1			
n	26	26	26
Mean (StdDev)	1.81 (1.869)	1.13 (1.516)	1.02 (1.505)
Median	1.50	0.07	0.00
Min, Max	0.0, 6.0	0.0, 4.0	0.0, 4.7
Cycle 11 Day 1			
n	24	24	24
Mean (StdDev)	1.85 (1.888)	1.11 (1.528)	0.92 (1.469)
Median	1.43	0.07	0.00
Min, Max	0.0, 6.0	0.0, 4.0	0.0, 4.0
Cycle 12 Day 1			
n	21	21	21
Mean (StdDev)	2.04 (1.868)	1.09 (1.515)	0.86 (1.421)
Median	2.14	0.00	0.00
Min, Max	0.0, 6.0	0.0, 4.1	0.0, 3.9

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Scores	Q1 Abdominal Pain (N=52)	Q2 Nausea (N=52)	Q7 Vomitting Count (N=52)	Q8 Vomitting Severity (N=52)	Q9 Diarrhea Count (N=52)	Q10 Diarrhea Severity (N=52)
Cycle 10 Day 1						
n	26	26	26	26	26	26
Mean (StdDev)	1.41 (2.209)	0.74 (1.354)	0.08 (0.253)	0.16 (0.494)	0.46 (1.050)	0.45 (0.792)
Median	0.08	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 9.1	0.0, 4.7	0.0, 1.3	0.0, 2.4	0.0, 4.6	0.0, 3.4
Cycle 11 Day 1						
n	24	24	24	24	24	24
Mean (StdDev)	1.25 (1.773)	0.49 (1.095)	0.08 (0.263)	0.15 (0.501)	0.30 (0.612)	0.42 (0.844)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 5.4	0.0, 4.7	0.0, 1.3	0.0, 2.4	0.0, 2.7	0.0, 3.2
Cycle 12 Day 1						
n	21	21	21	21	21	21
Mean (StdDev)	1.12 (1.676)	0.52 (1.156)	0.08 (0.281)	0.15 (0.532)	0.12 (0.210)	0.20 (0.395)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 5.4	0.0, 4.7	0.0, 1.3	0.0, 2.4	0.0, 0.7	0.0, 1.3

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Scores	TSS (N=52)	Skin Domain (N=52)	GI Domain (N=52)	Q6 Fatigue (N=52)
Cycle 13 Day 1				
n	15	15	15	15
Mean (StdDev)	11.15 (7.418)	4.11 (3.669)	2.22 (3.228)	4.82 (2.816)
Median	9.71	3.14	0.14	5.14
Min, Max	0.0, 27.6	0.0, 10.9	0.0, 8.7	0.0, 9.4
Cycle 14 Day 1				
n	14	14	14	14
Mean (StdDev)	11.49 (7.641)	4.25 (3.709)	2.48 (3.279)	4.76 (2.879)
Median	11.04	4.36	0.14	4.50
Min, Max	0.0, 27.6	0.0, 10.9	0.0, 8.7	0.0, 9.4
Cycle 15 Day 1				
n	13	13	13	13
Mean (StdDev)	11.17 (7.968)	4.28 (3.788)	2.36 (3.398)	4.52 (3.037)
Median	9.00	4.29	0.14	3.57
Min, Max	0.0, 27.6	0.0, 10.9	0.0, 8.7	0.0, 9.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Scores	Q3 Spots (N=52)	Q4 Itching (N=52)	Q5 Flushing (N=52)
Cycle 13 Day 1			
n	15	15	15
Mean (StdDev)	2.15 (1.850)	1.00 (1.371)	0.95 (1.427)
Median	3.14	0.00	0.00
Min, Max	0.0, 5.5	0.0, 3.9	0.0, 3.4
Cycle 14 Day 1			
n	14	14	14
Mean (StdDev)	2.13 (1.866)	1.01 (1.368)	1.12 (1.385)
Median	2.86	0.25	0.20
Min, Max	0.0, 5.5	0.0, 3.9	0.0, 3.4
Cycle 15 Day 1			
n	13	13	13
Mean (StdDev)	2.10 (1.885)	1.08 (1.450)	1.10 (1.428)
Median	3.00	0.00	0.25
Min, Max	0.0, 5.5	0.0, 3.9	0.0, 3.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Scores	Q1 Abdominal Pain (N=52)	Q2 Nausea (N=52)	Q7 Vomitting Count (N=52)	Q8 Vomitting Severity (N=52)	Q9 Diarrhea Count (N=52)	Q10 Diarrhea Severity (N=52)
Cycle 13 Day 1						
n	15	15	15	15	15	15
Mean (StdDev)	1.20 (1.880)	0.64 (1.298)	0.11 (0.329)	0.21 (0.625)	0.11 (0.230)	0.17 (0.383)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 5.4	0.0, 4.7	0.0, 1.3	0.0, 2.4	0.0, 0.7	0.0, 1.3
Cycle 14 Day 1						
n	14	14	14	14	14	14
Mean (StdDev)	1.35 (1.893)	0.65 (1.346)	0.12 (0.340)	0.22 (0.646)	0.13 (0.247)	0.26 (0.492)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 5.4	0.0, 4.7	0.0, 1.3	0.0, 2.4	0.0, 0.7	0.0, 1.3
Cycle 15 Day 1						
n	13	13	13	13	13	13
Mean (StdDev)	1.27 (1.946)	0.65 (1.405)	0.13 (0.352)	0.24 (0.668)	0.12 (0.239)	0.20 (0.406)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 5.4	0.0, 4.7	0.0, 1.3	0.0, 2.4	0.0, 0.7	0.0, 1.3

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg				
Scores	TSS (N=52)	Skin Domain (N=52)	GI Domain (N=52)	Q6 Fatigue (N=52)
Cycle 16 Day 1				
n	13	13	13	13
Mean (StdDev)	10.87 (8.169)	3.96 (3.799)	2.32 (3.419)	4.59 (3.026)
Median	9.00	3.14	0.14	3.71
Min, Max	0.0, 27.6	0.0, 10.9	0.0, 8.7	0.0, 9.4
Cycle 17 Day 1				
n	13	13	13	13
Mean (StdDev)	10.74 (8.304)	4.00 (3.777)	2.27 (3.435)	4.47 (3.125)
Median	9.00	3.14	0.14	3.57
Min, Max	0.0, 27.6	0.0, 10.9	0.0, 8.7	0.0, 9.4
Cycle 18 Day 1				
n	12	12	12	12
Mean (StdDev)	11.47 (8.251)	4.38 (3.723)	2.39 (3.560)	4.70 (3.143)
Median	10.33	3.65	0.07	4.29
Min, Max	0.0, 27.6	0.0, 10.9	0.0, 8.7	0.0, 9.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg			
Scores	Q3 Spots (N=52)	Q4 Itching (N=52)	Q5 Flushing (N=52)
Cycle 16 Day 1			
n	13	13	13
Mean (StdDev)	1.95 (1.888)	1.01 (1.424)	1.01 (1.366)
Median	2.00	0.00	0.00
Min, Max	0.0, 5.5	0.0, 3.9	0.0, 3.4
Cycle 17 Day 1			
n	13	13	13
Mean (StdDev)	1.95 (1.888)	1.05 (1.433)	1.00 (1.357)
Median	2.00	0.00	0.00
Min, Max	0.0, 5.5	0.0, 3.9	0.0, 3.4
Cycle 18 Day 1			
n	12	12	12
Mean (StdDev)	2.10 (1.883)	1.20 (1.473)	1.08 (1.382)
Median	2.57	0.33	0.13
Min, Max	0.0, 5.5	0.0, 3.9	0.0, 3.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Scores	Q1 Abdominal Pain (N=52)	Q2 Nausea (N=52)	Q7 Vomitting Count (N=52)	Q8 Vomitting Severity (N=52)	Q9 Diarrhea Count (N=52)	Q10 Diarrhea Severity (N=52)
Cycle 16 Day 1						
n	13	13	13	13	13	13
Mean (StdDev)	1.25 (1.942)	0.65 (1.405)	0.15 (0.352)	0.24 (0.668)	0.11 (0.242)	0.18 (0.409)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 5.4	0.0, 4.7	0.0, 1.3	0.0, 2.4	0.0, 0.7	0.0, 1.3
Cycle 17 Day 1						
n	13	13	13	13	13	13
Mean (StdDev)	1.21 (1.944)	0.65 (1.405)	0.13 (0.352)	0.24 (0.668)	0.11 (0.242)	0.18 (0.409)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 5.4	0.0, 4.7	0.0, 1.3	0.0, 2.4	0.0, 0.7	0.0, 1.3
Cycle 18 Day 1						
n	12	12	12	12	12	12
Mean (StdDev)	1.24 (2.028)	0.70 (1.454)	0.14 (0.365)	0.26 (0.694)	0.12 (0.250)	0.19 (0.423)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 5.4	0.0, 4.7	0.0, 1.3	0.0, 2.4	0.0, 0.7	0.0, 1.3

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Scores	TSS (N=50)	Skin Domain (N=50)	GI Domain (N=50)	Q6 Fatigue (N=50)
Baseline (C1D-7 to C1D-1)				
n	45	45	45	45
Mean (StdDev)	19.96 (13.058)	7.89 (7.316)	6.61 (5.738)	5.46 (2.979)
Median	19.29	6.86	5.86	6.29
Min, Max	0.0, 53.7	0.0, 28.6	0.0, 21.7	0.0, 10.0
Cycle 2 Day 1				
n	49	49	49	49
Mean (StdDev)	12.42 (9.115)	4.55 (4.769)	3.50 (3.853)	4.37 (2.957)
Median	11.50	3.00	1.86	4.86
Min, Max	0.0, 38.7	0.0, 15.9	0.0, 17.6	0.0, 9.1
Cycle 3 Day 1				
n	47	47	47	47
Mean (StdDev)	12.69 (8.435)	4.93 (4.355)	3.33 (3.613)	4.44 (2.710)
Median	11.67	3.57	2.43	4.71
Min, Max	0.0, 35.6	0.0, 15.4	0.0, 16.9	0.0, 9.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg			
Scores	Q3 Spots (N=50)	Q4 Itching (N=50)	Q5 Flushing (N=50)
Baseline (C1D-7 to C1D-1)			
n	45	45	45
Mean (StdDev)	2.75 (2.849)	2.69 (2.887)	2.45 (2.584)
Median	2.00	1.00	1.86
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 8.6
Cycle 2 Day 1			
n	49	49	49
Mean (StdDev)	2.02 (2.295)	1.27 (1.720)	1.26 (1.679)
Median	1.00	0.17	0.14
Min, Max	0.0, 7.3	0.0, 6.4	0.0, 5.9
Cycle 3 Day 1			
n	47	47	47
Mean (StdDev)	2.07 (2.051)	1.44 (1.777)	1.42 (1.759)
Median	1.57	0.43	0.43
Min, Max	0.0, 7.7	0.0, 6.7	0.0, 6.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
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Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Scores	Q1 Abdominal Pain (N=50)	Q2 Nausea (N=50)	Q7 Vomitting Count (N=50)	Q8 Vomitting Severity (N=50)	Q9 Diarrhea Count (N=50)	Q10 Diarrhea Severity (N=50)
Baseline (C1D-7 to C1D-1)						
n	45	45	45	45	45	45
Mean (StdDev)	2.91 (2.806)	1.74 (2.261)	0.06 (0.175)	0.13 (0.370)	1.35 (1.901)	1.82 (2.179)
Median	2.43	0.67	0.00	0.00	0.43	0.86
Min, Max	0.0, 10.0	0.0, 7.3	0.0, 1.0	0.0, 1.7	0.0, 7.1	0.0, 7.6
Cycle 2 Day 1						
n	49	49	49	49	49	49
Mean (StdDev)	1.61 (1.975)	0.84 (1.403)	0.05 (0.216)	0.11 (0.635)	0.76 (1.277)	0.94 (1.319)
Median	0.86	0.14	0.00	0.00	0.14	0.43
Min, Max	0.0, 7.0	0.0, 5.9	0.0, 1.4	0.0, 4.4	0.0, 6.1	0.0, 5.0
Cycle 3 Day 1						
n	47	47	47	47	47	47
Mean (StdDev)	1.46 (1.966)	0.78 (1.232)	0.06 (0.238)	0.18 (0.716)	0.63 (0.995)	0.91 (1.291)
Median	0.57	0.00	0.00	0.00	0.14	0.43
Min, Max	0.0, 6.9	0.0, 5.1	0.0, 1.6	0.0, 4.7	0.0, 3.4	0.0, 5.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Scores	TSS (N=50)	Skin Domain (N=50)	GI Domain (N=50)	Q6 Fatigue (N=50)
Cycle 4 Day 1				
n	45	45	45	45
Mean (StdDev)	12.71 (9.036)	4.95 (4.527)	3.31 (4.486)	4.46 (2.753)
Median	11.71	3.14	1.57	4.57
Min, Max	0.7, 45.6	0.0, 17.3	0.0, 21.7	0.0, 9.4
Cycle 5 Day 1				
n	41	41	41	41
Mean (StdDev)	12.03 (8.809)	4.35 (4.105)	3.38 (4.376)	4.30 (2.754)
Median	11.33	2.71	2.00	4.33
Min, Max	0.1, 41.7	0.0, 14.2	0.0, 21.5	0.0, 9.4
Cycle 6 Day 1				
n	35	35	35	35
Mean (StdDev)	11.23 (8.153)	4.13 (4.087)	2.81 (3.949)	4.30 (2.907)
Median	10.00	2.43	1.29	3.86
Min, Max	0.0, 33.6	0.0, 14.0	0.0, 13.7	0.0, 9.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg			
Scores	Q3 Spots (N=50)	Q4 Itching (N=50)	Q5 Flushing (N=50)
Cycle 4 Day 1			
n	45	45	45
Mean (StdDev)	1.94 (2.023)	1.46 (1.843)	1.55 (1.846)
Median	1.00	0.50	0.43
Min, Max	0.0, 7.3	0.0, 7.6	0.0, 6.7
Cycle 5 Day 1			
n	41	41	41
Mean (StdDev)	1.78 (1.899)	1.15 (1.536)	1.43 (1.728)
Median	1.00	0.17	0.71
Min, Max	0.0, 7.0	0.0, 4.3	0.0, 5.8
Cycle 6 Day 1			
n	35	35	35
Mean (StdDev)	1.75 (2.080)	1.17 (1.528)	1.21 (1.691)
Median	1.00	0.29	0.14
Min, Max	0.0, 7.0	0.0, 4.4	0.0, 5.6

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Scores	Q1 Abdominal Pain (N=50)	Q2 Nausea (N=50)	Q7 Vomitting Count (N=50)	Q8 Vomitting Severity (N=50)	Q9 Diarrhea Count (N=50)	Q10 Diarrhea Severity (N=50)
Cycle 4 Day 1						
n	45	45	45	45	45	45
Mean (StdDev)	1.20 (1.865)	0.93 (1.588)	0.13 (0.496)	0.27 (1.017)	0.56 (0.856)	0.90 (1.355)
Median	0.29	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 8.2	0.0, 6.3	0.0, 3.1	0.0, 6.3	0.0, 3.4	0.0, 5.6
Cycle 5 Day 1						
n	41	41	41	41	41	41
Mean (StdDev)	1.22 (1.829)	0.84 (1.477)	0.13 (0.554)	0.26 (0.893)	0.71 (1.109)	1.05 (1.723)
Median	0.00	0.00	0.00	0.00	0.14	0.00
Min, Max	0.0, 6.7	0.0, 5.5	0.0, 3.5	0.0, 5.3	0.0, 4.0	0.0, 6.7
Cycle 6 Day 1						
n	35	35	35	35	35	35
Mean (StdDev)	1.21 (1.968)	0.59 (1.156)	0.09 (0.372)	0.17 (0.652)	0.48 (0.811)	0.84 (1.715)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 7.7	0.0, 4.7	0.0, 2.1	0.0, 3.6	0.0, 3.4	0.0, 7.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas
Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Scores	TSS (N=50)	Skin Domain (N=50)	GI Domain (N=50)	Q6 Fatigue (N=50)
Cycle 7 Day 1				
n	32	32	32	32
Mean (StdDev)	10.29 (7.321)	3.77 (3.742)	2.37 (2.927)	4.15 (2.962)
Median	10.71	2.57	0.64	3.93
Min, Max	0.0, 27.6	0.0, 11.0	0.0, 8.7	0.0, 9.4
Cycle 8 Day 1				
n	30	30	30	30
Mean (StdDev)	10.46 (7.066)	3.89 (3.485)	2.44 (2.915)	4.13 (2.912)
Median	10.93	2.90	1.07	4.00
Min, Max	0.0, 27.6	0.0, 10.9	0.0, 8.7	0.0, 9.4
Cycle 9 Day 1				
n	28	28	28	28
Mean (StdDev)	9.90 (6.904)	3.85 (3.595)	2.13 (2.729)	3.91 (2.892)
Median	9.00	2.93	0.62	3.79
Min, Max	0.4, 27.6	0.0, 10.9	0.0, 8.1	0.0, 9.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg			
Scores	Q3 Spots (N=50)	Q4 Itching (N=50)	Q5 Flushing (N=50)
Cycle 7 Day 1			
n	32	32	32
Mean (StdDev)	1.62 (1.883)	1.08 (1.443)	1.07 (1.470)
Median	1.00	0.00	0.14
Min, Max	0.0, 7.0	0.0, 4.6	0.0, 5.0
Cycle 8 Day 1			
n	30	30	30
Mean (StdDev)	1.70 (1.873)	1.11 (1.365)	1.08 (1.473)
Median	1.21	0.25	0.07
Min, Max	0.0, 6.9	0.0, 3.9	0.0, 5.0
Cycle 9 Day 1			
n	28	28	28
Mean (StdDev)	1.80 (1.948)	1.00 (1.389)	1.05 (1.494)
Median	1.07	0.00	0.07
Min, Max	0.0, 6.7	0.0, 4.3	0.0, 5.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Scores	Q1 Abdominal Pain (N=50)	Q2 Nausea (N=50)	Q7 Vomitting Count (N=50)	Q8 Vomitting Severity (N=50)	Q9 Diarrhea Count (N=50)	Q10 Diarrhea Severity (N=50)
Cycle 7 Day 1						
n	32	32	32	32	32	32
Mean (StdDev)	1.02 (1.764)	0.47 (0.999)	0.01 (0.042)	0.02 (0.082)	0.43 (0.712)	0.86 (1.472)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 6.9	0.0, 4.7	0.0, 0.1	0.0, 0.4	0.0, 2.9	0.0, 5.3
Cycle 8 Day 1						
n	30	30	30	30	30	30
Mean (StdDev)	1.06 (1.668)	0.60 (1.117)	0.03 (0.073)	0.05 (0.144)	0.53 (0.859)	0.74 (1.068)
Median	0.00	0.00	0.00	0.00	0.14	0.21
Min, Max	0.0, 6.3	0.0, 4.7	0.0, 0.3	0.0, 0.7	0.0, 3.1	0.0, 3.5
Cycle 9 Day 1						
n	28	28	28	28	28	28
Mean (StdDev)	0.96 (1.516)	0.50 (1.012)	0.04 (0.092)	0.06 (0.153)	0.45 (0.819)	0.61 (1.143)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 5.4	0.0, 4.7	0.0, 0.4	0.0, 0.6	0.0, 3.1	0.0, 4.3

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg				
Scores	TSS (N=50)	Skin Domain (N=50)	GI Domain (N=50)	Q6 Fatigue (N=50)
Cycle 10 Day 1				
n	25	25	25	25
Mean (StdDev)	11.29 (7.525)	3.90 (3.730)	2.82 (3.956)	4.57 (3.048)
Median	11.50	2.33	0.71	4.00
Min, Max	0.0, 27.6	0.0, 10.9	0.0, 16.0	0.0, 9.4
Cycle 11 Day 1				
n	23	23	23	23
Mean (StdDev)	10.79 (7.440)	3.86 (3.913)	2.32 (2.954)	4.61 (3.094)
Median	11.50	2.00	0.43	4.71
Min, Max	0.0, 27.6	0.0, 10.9	0.0, 8.7	0.0, 9.4
Cycle 12 Day 1				
n	20	20	20	20
Mean (StdDev)	10.66 (7.276)	4.00 (3.808)	2.03 (2.920)	4.63 (2.926)
Median	10.57	2.79	0.21	4.86
Min, Max	0.0, 27.6	0.0, 10.9	0.0, 8.7	0.0, 9.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg			
Scores	Q3 Spots (N=50)	Q4 Itching (N=50)	Q5 Flushing (N=50)
Cycle 10 Day 1			
n	25	25	25
Mean (StdDev)	1.80 (1.907)	1.03 (1.461)	1.06 (1.521)
Median	1.00	0.00	0.00
Min, Max	0.0, 6.0	0.0, 4.0	0.0, 4.7
Cycle 11 Day 1			
n	23	23	23
Mean (StdDev)	1.84 (1.930)	1.05 (1.536)	0.96 (1.489)
Median	1.00	0.00	0.00
Min, Max	0.0, 6.0	0.0, 4.0	0.0, 4.0
Cycle 12 Day 1			
n	20	20	20
Mean (StdDev)	2.05 (1.917)	1.05 (1.544)	0.90 (1.444)
Median	2.43	0.00	0.00
Min, Max	0.0, 6.0	0.0, 4.1	0.0, 3.9

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Scores	Q1 Abdominal Pain (N=50)	Q2 Nausea (N=50)	Q7 Vomitting Count (N=50)	Q8 Vomitting Severity (N=50)	Q9 Diarrhea Count (N=50)	Q10 Diarrhea Severity (N=50)
Cycle 10 Day 1						
n	25	25	25	25	25	25
Mean (StdDev)	1.45 (2.248)	0.76 (1.378)	0.08 (0.258)	0.17 (0.503)	0.46 (1.072)	0.43 (0.807)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 9.1	0.0, 4.7	0.0, 1.3	0.0, 2.4	0.0, 4.6	0.0, 3.4
Cycle 11 Day 1						
n	23	23	23	23	23	23
Mean (StdDev)	1.27 (1.807)	0.50 (1.119)	0.08 (0.268)	0.16 (0.511)	0.29 (0.623)	0.39 (0.853)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 5.4	0.0, 4.7	0.0, 1.3	0.0, 2.4	0.0, 2.7	0.0, 3.2
Cycle 12 Day 1						
n	20	20	20	20	20	20
Mean (StdDev)	1.14 (1.718)	0.54 (1.185)	0.09 (0.287)	0.16 (0.544)	0.11 (0.215)	0.20 (0.405)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 5.4	0.0, 4.7	0.0, 1.3	0.0, 2.4	0.0, 0.7	0.0, 1.3

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas
Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg				
Scores	TSS (N=50)	Skin Domain (N=50)	GI Domain (N=50)	Q6 Fatigue (N=50)
Cycle 13 Day 1				
n	14	14	14	14
Mean (StdDev)	11.25 (7.687)	3.97 (3.769)	2.36 (3.304)	4.92 (2.895)
Median	10.25	2.57	0.14	5.20
Min, Max	0.0, 27.6	0.0, 10.9	0.0, 8.7	0.0, 9.4
Cycle 14 Day 1				
n	13	13	13	13
Mean (StdDev)	11.32 (7.925)	4.10 (3.813)	2.41 (3.401)	4.82 (2.988)
Median	10.57	3.14	0.14	5.00
Min, Max	0.0, 27.6	0.0, 10.9	0.0, 8.7	0.0, 9.4
Cycle 15 Day 1				
n	13	13	13	13
Mean (StdDev)	11.17 (7.968)	4.28 (3.788)	2.36 (3.398)	4.52 (3.037)
Median	9.00	4.29	0.14	3.57
Min, Max	0.0, 27.6	0.0, 10.9	0.0, 8.7	0.0, 9.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg			
Scores	Q3 Spots (N=50)	Q4 Itching (N=50)	Q5 Flushing (N=50)
Cycle 13 Day 1			
n	14	14	14
Mean (StdDev)	2.02 (1.845)	0.93 (1.394)	1.02 (1.455)
Median	2.43	0.00	0.00
Min, Max	0.0, 5.5	0.0, 3.9	0.0, 3.4
Cycle 14 Day 1			
n	13	13	13
Mean (StdDev)	2.01 (1.884)	1.01 (1.424)	1.09 (1.436)
Median	2.57	0.00	0.14
Min, Max	0.0, 5.5	0.0, 3.9	0.0, 3.4
Cycle 15 Day 1			
n	13	13	13
Mean (StdDev)	2.10 (1.885)	1.08 (1.450)	1.10 (1.428)
Median	3.00	0.00	0.25
Min, Max	0.0, 5.5	0.0, 3.9	0.0, 3.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Scores	Q1 Abdominal Pain (N=50)	Q2 Nausea (N=50)	Q7 Vomitting Count (N=50)	Q8 Vomitting Severity (N=50)	Q9 Diarrhea Count (N=50)	Q10 Diarrhea Severity (N=50)
Cycle 13 Day 1						
n	14	14	14	14	14	14
Mean (StdDev)	1.27 (1.934)	0.68 (1.334)	0.12 (0.340)	0.22 (0.646)	0.12 (0.237)	0.18 (0.394)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 5.4	0.0, 4.7	0.0, 1.3	0.0, 2.4	0.0, 0.7	0.0, 1.3
Cycle 14 Day 1						
n	13	13	13	13	13	13
Mean (StdDev)	1.33 (1.969)	0.66 (1.400)	0.13 (0.352)	0.24 (0.668)	0.11 (0.242)	0.18 (0.409)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 5.4	0.0, 4.7	0.0, 1.3	0.0, 2.4	0.0, 0.7	0.0, 1.3
Cycle 15 Day 1						
n	13	13	13	13	13	13
Mean (StdDev)	1.27 (1.946)	0.65 (1.405)	0.13 (0.352)	0.24 (0.668)	0.12 (0.239)	0.20 (0.406)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 5.4	0.0, 4.7	0.0, 1.3	0.0, 2.4	0.0, 0.7	0.0, 1.3

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg				
Scores	TSS (N=50)	Skin Domain (N=50)	GI Domain (N=50)	Q6 Fatigue (N=50)
Cycle 16 Day 1				
n	13	13	13	13
Mean (StdDev)	10.87 (8.169)	3.96 (3.799)	2.32 (3.419)	4.59 (3.026)
Median	9.00	3.14	0.14	3.71
Min, Max	0.0, 27.6	0.0, 10.9	0.0, 8.7	0.0, 9.4
Cycle 17 Day 1				
n	13	13	13	13
Mean (StdDev)	10.74 (8.304)	4.00 (3.777)	2.27 (3.435)	4.47 (3.125)
Median	9.00	3.14	0.14	3.57
Min, Max	0.0, 27.6	0.0, 10.9	0.0, 8.7	0.0, 9.4
Cycle 18 Day 1				
n	12	12	12	12
Mean (StdDev)	11.47 (8.251)	4.38 (3.723)	2.39 (3.560)	4.70 (3.143)
Median	10.33	3.65	0.07	4.29
Min, Max	0.0, 27.6	0.0, 10.9	0.0, 8.7	0.0, 9.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg			
Scores	Q3 Spots (N=50)	Q4 Itching (N=50)	Q5 Flushing (N=50)
Cycle 16 Day 1			
n	13	13	13
Mean (StdDev)	1.95 (1.888)	1.01 (1.424)	1.01 (1.366)
Median	2.00	0.00	0.00
Min, Max	0.0, 5.5	0.0, 3.9	0.0, 3.4
Cycle 17 Day 1			
n	13	13	13
Mean (StdDev)	1.95 (1.888)	1.05 (1.433)	1.00 (1.357)
Median	2.00	0.00	0.00
Min, Max	0.0, 5.5	0.0, 3.9	0.0, 3.4
Cycle 18 Day 1			
n	12	12	12
Mean (StdDev)	2.10 (1.883)	1.20 (1.473)	1.08 (1.382)
Median	2.57	0.33	0.13
Min, Max	0.0, 5.5	0.0, 3.9	0.0, 3.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas Date: 15:00/29SEP2021

Table 35.2.9.2
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Scores	Q1 Abdominal Pain (N=50)	Q2 Nausea (N=50)	Q7 Vomitting Count (N=50)	Q8 Vomitting Severity (N=50)	Q9 Diarrhea Count (N=50)	Q10 Diarrhea Severity (N=50)
Cycle 16 Day 1						
n	13	13	13	13	13	13
Mean (StdDev)	1.25 (1.942)	0.65 (1.405)	0.15 (0.352)	0.24 (0.668)	0.11 (0.242)	0.18 (0.409)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 5.4	0.0, 4.7	0.0, 1.3	0.0, 2.4	0.0, 0.7	0.0, 1.3
Cycle 17 Day 1						
n	13	13	13	13	13	13
Mean (StdDev)	1.21 (1.944)	0.65 (1.405)	0.13 (0.352)	0.24 (0.668)	0.11 (0.242)	0.18 (0.409)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 5.4	0.0, 4.7	0.0, 1.3	0.0, 2.4	0.0, 0.7	0.0, 1.3
Cycle 18 Day 1						
n	12	12	12	12	12	12
Mean (StdDev)	1.24 (2.028)	0.70 (1.454)	0.14 (0.365)	0.26 (0.694)	0.12 (0.250)	0.19 (0.423)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 5.4	0.0, 4.7	0.0, 1.3	0.0, 2.4	0.0, 0.7	0.0, 1.3

Source: Listing 16.3.11
Abbreviations: C=Cycle, D=Day, GI=Gastrointestinal, Q=Question, SAF= symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. For example, Baseline score is determined by the 7-day average from C1D-7 to C1D-1; score on C3D1 is determined by the 7-day average from C2D22 to C2D28, so on so forth. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp.sas
Date: 15:00/29SEP2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Scores	TSS (N=27)	Skin Domain (N=27)	GI Domain (N=27)	Q6 Fatigue (N=27)
Baseline (C1D-7 to C1D-1)				
n	23	23	23	23
Mean (StdDev)	21.63 (13.671)	7.38 (5.686)	8.19 (7.140)	6.10 (2.792)
Median	20.00	6.60	8.00	6.86
Min, Max	1.2, 50.2	0.0, 18.0	0.0, 25.2	0.2, 10.0
Change from Baseline to Cycle 2 Day 1				
n	22	22	22	22
Mean (StdDev)	-6.67 (10.673)	-1.56 (6.282)	-4.05 (6.046)	-1.12 (1.426)
Median	-3.29	-1.58	-2.64	-0.71
Min, Max	-33.9, 11.3	-14.4, 12.9	-22.0, 5.1	-4.0, 1.0
Change from Baseline to Cycle 3 Day 1				
n	22	22	22	22
Mean (StdDev)	-7.22 (11.206)	-1.54 (6.436)	-4.28 (6.447)	-1.39 (1.911)
95% CIs of Mean	(-12.19 - -2.25)	(-4.39 - 1.32)	(-7.14 - -1.43)	(-2.24 - -0.55)
p-value [1]	0.0065**	0.2751	0.0052**	0.0026**
Median	-2.64	-1.21	-3.50	-1.39
Min, Max	-41.9, 8.9	-13.0, 10.4	-24.5, 4.4	-5.3, 1.2

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Scores	Q3 Spots (N=27)	Q4 Itching (N=27)	Q5 Flushing (N=27)
Baseline (C1D-7 to C1D-1)			
n	23	23	23
Mean (StdDev)	2.89 (2.219)	2.25 (2.417)	2.27 (2.651)
Median	3.43	0.83	1.43
Min, Max	0.0, 6.1	0.0, 6.9	0.0, 8.7
Change from Baseline to Cycle 2 Day 1			
n	22	22	22
Mean (StdDev)	-0.48 (2.285)	-0.76 (2.694)	-0.35 (2.932)
Median	-0.29	-0.21	-0.14
Min, Max	-4.4, 6.3	-6.9, 7.1	-4.4, 6.4
Change from Baseline to Cycle 3 Day 1			
n	22	22	22
Mean (StdDev)	-0.66 (2.041)	-0.68 (2.839)	-0.23 (3.246)
95% CIs of Mean	(-1.56 - 0.25)	(-1.94 - 0.58)	(-1.67 - 1.21)
p-value [1]	0.1467	0.2754	0.7419
Median	-0.29	0.00	-0.14
Min, Max	-3.9, 4.5	-6.9, 6.6	-6.2, 5.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Scores	Q1 Abdominal Pain (N=27)	Q2 Nausea (N=27)	Q7 Vomitting Count (N=27)	Q8 Vomitting Severity (N=27)	Q9 Diarrhea Count (N=27)	Q10 Diarrhea Severity (N=27)
Baseline (C1D-7 to C1D-1)						
n	23	23	23	23	23	23
Mean (StdDev)	3.37 (2.988)	2.15 (2.707)	0.69 (2.690)	0.41 (1.278)	8.32 (19.362)	2.25 (2.215)
Median	3.00	0.57	0.00	0.00	1.71	2.57
Min, Max	0.0, 9.0	0.0, 8.0	0.0, 12.9	0.0, 5.8	0.0, 85.7	0.0, 7.6
Change from Baseline to Cycle 2 Day 1						
n	22	22	22	22	22	22
Mean (StdDev)	-1.75 (2.091)	-0.76 (2.370)	0.58 (3.412)	-0.37 (1.334)	-5.21 (22.701)	-1.15 (2.252)
Median	-1.21	-0.21	0.00	0.00	-0.14	-0.29
Min, Max	-6.1, 1.6	-6.6, 3.9	-2.2, 15.7	-5.8, 0.9	-85.7, 42.9	-6.9, 2.1
Change from Baseline to Cycle 3 Day 1						
n	22	22	22	22	22	22
Mean (StdDev)	-1.81 (2.215)	-1.21 (2.152)	-0.69 (2.752)	-0.37 (1.292)	-6.82 (19.134)	-0.87 (2.270)
95% CIs of Mean	(-2.79 - -0.83)	(-2.16 - -0.25)	(-1.91 - 0.53)	(-0.95 - 0.20)	(-15.30 - 1.67)	(-1.88 - 0.14)
p-value [1]	<0.001***	0.0156*	0.2511	0.1904	0.1096	0.0868
Median	-1.23	-0.33	0.00	0.00	-0.64	-0.18
Min, Max	-6.5, 1.0	-7.7, 1.7	-12.9, 0.2	-5.7, 0.5	-85.7, 5.0	-6.3, 2.9

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Scores	TSS (N=27)	Skin Domain (N=27)	GI Domain (N=27)	Q6 Fatigue (N=27)
Change from Baseline to Cycle 4 Day 1				
n	22	22	22	22
Mean (StdDev)	-6.97 (11.674)	-1.65 (5.886)	-4.42 (6.909)	-0.93 (1.893)
Median	-4.36	-0.02	-3.40	-0.65
Min, Max	-38.4, 16.6	-14.0, 7.5	-21.8, 10.0	-6.0, 2.3
Change from Baseline to Cycle 5 Day 1				
n	21	21	21	21
Mean (StdDev)	-9.24 (11.252)	-2.52 (6.439)	-5.36 (6.130)	-1.39 (2.065)
Median	-5.21	-1.57	-4.67	-1.86
Min, Max	-37.7, 8.0	-13.4, 8.0	-20.7, 2.6	-6.4, 2.9
Change from Baseline to Cycle 6 Day 1				
n	18	18	18	18
Mean (StdDev)	-10.09 (14.742)	-2.52 (7.868)	-6.01 (8.136)	-1.61 (2.299)
Median	-6.53	-1.50	-3.64	-1.79
Min, Max	-45.3, 12.7	-15.5, 9.6	-25.0, 5.0	-5.7, 3.6

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Scores	Q3 Spots (N=27)	Q4 Itching (N=27)	Q5 Flushing (N=27)
Change from Baseline to Cycle 4 Day 1			
n	22	22	22
Mean (StdDev)	-0.68 (2.097)	-0.61 (2.606)	-0.39 (3.459)
Median	0.00	0.00	0.00
Min, Max	-4.2, 3.0	-6.9, 5.0	-7.3, 6.9
Change from Baseline to Cycle 5 Day 1			
n	21	21	21
Mean (StdDev)	-1.13 (2.266)	-0.84 (2.652)	-0.59 (3.432)
Median	-1.13	-0.12	-0.29
Min, Max	-6.0, 3.0	-6.9, 4.7	-6.2, 5.6
Change from Baseline to Cycle 6 Day 1			
n	18	18	18
Mean (StdDev)	-1.44 (2.720)	-0.41 (2.829)	-0.72 (3.963)
Median	-1.60	-0.07	-0.41
Min, Max	-6.0, 3.0	-6.9, 5.0	-8.3, 6.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Scores	Q1 Abdominal Pain (N=27)	Q2 Nausea (N=27)	Q7 Vomitting Count (N=27)	Q8 Vomitting Severity (N=27)	Q9 Diarrhea Count (N=27)	Q10 Diarrhea Severity (N=27)
Change from Baseline to Cycle 4 Day 1						
n	22	22	22	22	22	22
Mean (StdDev)	-2.03 (2.605)	-1.19 (2.609)	-0.65 (2.735)	-0.20 (1.210)	-7.72 (19.978)	-0.98 (2.328)
Median	-1.21	-0.29	0.00	0.00	-1.06	0.00
Min, Max	-7.8, 2.9	-7.6, 3.2	-12.7, 0.7	-4.8, 1.0	-85.7, 4.3	-6.4, 3.3
Change from Baseline to Cycle 5 Day 1						
n	21	21	21	21	21	21
Mean (StdDev)	-2.28 (2.244)	-1.40 (2.462)	-0.72 (2.819)	-0.34 (1.199)	-7.54 (19.349)	-1.33 (2.273)
Median	-2.29	-0.29	0.00	0.00	-1.00	-0.43
Min, Max	-6.0, 0.1	-6.9, 1.7	-12.9, 0.5	-5.0, 0.9	-85.7, 2.6	-6.6, 3.0
Change from Baseline to Cycle 6 Day 1						
n	18	18	18	18	18	18
Mean (StdDev)	-2.35 (2.809)	-1.84 (3.213)	-0.16 (0.512)	-0.50 (1.438)	-7.93 (22.581)	-1.33 (2.424)
Median	-2.36	-0.29	0.00	0.00	-1.19	-0.46
Min, Max	-7.0, 1.5	-8.0, 3.2	-2.2, 0.0	-5.8, 0.0	-85.7, 16.6	-6.7, 2.1

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Scores	TSS (N=27)	Skin Domain (N=27)	GI Domain (N=27)	Q6 Fatigue (N=27)
Change from Baseline to Cycle 7 Day 1				
n	16	17	17	17
Mean (StdDev)	-10.09 (15.897)	-2.01 (8.491)	-6.43 (7.736)	-1.56 (2.723)
95% CIs of Mean	(-18.56 - -1.62)	(-6.37 - 2.36)	(-10.41 - -2.45)	(-2.96 - -0.16)
p-value [1]	0.0227*	0.3441	0.0035**	0.0308*
Median	-8.21	-0.86	-4.86	-1.43
Min, Max	-40.8, 15.7	-15.6, 10.1	-22.6, 5.9	-6.4, 4.3
Change from Baseline to Cycle 8 Day 1				
n	15	15	15	15
Mean (StdDev)	-11.22 (16.440)	-3.80 (7.873)	-5.68 (8.560)	-1.81 (2.908)
Median	-7.86	-3.50	-6.14	-1.57
Min, Max	-42.5, 19.1	-15.1, 9.9	-24.0, 10.9	-6.4, 4.0
Change from Baseline to Cycle 9 Day 1				
n	16	16	16	16
Mean (StdDev)	-11.70 (15.043)	-3.81 (7.091)	-6.03 (7.869)	-1.93 (2.856)
Median	-8.57	-3.13	-6.07	-1.46
Min, Max	-41.0, 18.0	-15.6, 7.0	-22.2, 9.6	-6.9, 2.9

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Scores	Q3 Spots (N=27)	Q4 Itching (N=27)	Q5 Flushing (N=27)
Change from Baseline to Cycle 7 Day 1			
n	17	17	17
Mean (StdDev)	-1.28 (2.834)	-0.25 (3.040)	-0.52 (4.154)
95% CIs of Mean	(-2.74 - 0.18)	(-1.81 - 1.32)	(-2.66 - 1.62)
p-value [1]	0.0809	0.7425	0.6122
Median	-1.00	-0.14	-0.40
Min, Max	-6.0, 3.0	-6.9, 5.9	-8.1, 7.4
Change from Baseline to Cycle 8 Day 1			
n	15	15	15
Mean (StdDev)	-1.77 (2.748)	-0.66 (3.098)	-1.42 (3.646)
Median	-1.79	-0.29	-1.29
Min, Max	-6.0, 2.9	-6.9, 5.4	-7.8, 6.9
Change from Baseline to Cycle 9 Day 1			
n	16	16	16
Mean (StdDev)	-1.64 (2.377)	-0.79 (2.680)	-1.43 (3.536)
Median	-1.45	-0.21	-0.71
Min, Max	-6.0, 3.0	-6.9, 4.5	-8.5, 6.1

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Scores	Q1 Abdominal Pain (N=27)	Q2 Nausea (N=27)	Q7 Vomitting Count (N=27)	Q8 Vomitting Severity (N=27)	Q9 Diarrhea Count (N=27)	Q10 Diarrhea Severity (N=27)
Change from Baseline to Cycle 7 Day 1						
n	17	17	17	17	17	17
Mean (StdDev)	-2.64 (2.390)	-1.80 (3.147)	-0.12 (0.445)	-0.37 (1.272)	-9.56 (22.330)	-1.56 (2.599)
95% CIs of Mean	(-3.87 - -1.42)	(-3.42 - -0.18)	(-0.35 - 0.11)	(-1.03 - 0.28)	(-21.04 - 1.92)	(-2.90 - -0.23)
p-value [1]	<0.001***	0.0315*	0.2721	0.2436	0.0967	0.0247*
Median	-2.43	-0.29	0.00	0.00	-1.71	-1.00
Min, Max	-5.9, 0.9	-7.4, 3.5	-1.8, 0.3	-4.6, 1.0	-85.7, 1.6	-6.9, 3.3
Change from Baseline to Cycle 8 Day 1						
n	15	15	15	15	15	15
Mean (StdDev)	-2.57 (2.686)	-1.59 (3.547)	1.50 (6.524)	-0.36 (1.558)	-7.34 (22.559)	-1.16 (2.602)
Median	-2.71	-0.29	0.00	0.00	-0.29	-0.86
Min, Max	-6.1, 1.4	-7.8, 5.3	-2.2, 25.0	-5.8, 1.3	-85.4, 13.2	-6.9, 3.0
Change from Baseline to Cycle 9 Day 1						
n	16	16	16	16	16	16
Mean (StdDev)	-2.78 (2.633)	-1.67 (3.415)	-0.10 (0.455)	-0.27 (1.325)	-9.86 (23.057)	-1.32 (2.430)
Median	-2.43	-0.29	0.00	0.00	-1.33	-0.43
Min, Max	-6.7, 0.3	-7.3, 5.1	-1.8, 0.3	-5.0, 1.3	-85.7, 1.0	-6.9, 2.9

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Scores	TSS (N=27)	Skin Domain (N=27)	GI Domain (N=27)	Q6 Fatigue (N=27)
Change from Baseline to Cycle 10 Day 1				
n	15	15	15	15
Mean (StdDev)	-9.82 (15.219)	-3.59 (7.608)	-4.80 (9.384)	-1.51 (2.839)
Median	-5.43	-3.57	-5.95	-1.07
Min, Max	-40.3, 14.8	-15.1, 8.2	-25.0, 15.6	-7.3, 3.2
Change from Baseline to Cycle 11 Day 1				
n	13	13	13	13
Mean (StdDev)	-11.61 (15.967)	-3.40 (8.063)	-6.95 (7.858)	-1.28 (3.353)
95% CIs of Mean	(-21.26 - -1.96)	(-8.27 - 1.48)	(-11.70 - -2.20)	(-3.31 - 0.74)
p-value [1]	0.0223*	0.1546	0.0078**	0.1931
Median	-5.14	-3.64	-6.29	-1.14
Min, Max	-37.2, 10.4	-16.4, 7.6	-23.7, 4.9	-7.7, 3.7
Change from Baseline to Cycle 12 Day 1				
n	12	12	12	12
Mean (StdDev)	-10.37 (18.775)	-2.00 (9.026)	-6.69 (8.207)	-1.70 (3.433)
Median	-7.14	-1.50	-6.98	-1.36
Min, Max	-40.0, 25.3	-15.3, 11.9	-22.2, 10.4	-7.7, 3.5

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Scores	Q3 Spots (N=27)	Q4 Itching (N=27)	Q5 Flushing (N=27)
Change from Baseline to Cycle 10 Day 1			
n	15	15	15
Mean (StdDev)	-1.70 (2.533)	-0.48 (2.958)	-1.46 (3.708)
Median	-1.79	-0.14	-1.43
Min, Max	-5.9, 3.0	-6.9, 4.5	-8.5, 6.6
Change from Baseline to Cycle 11 Day 1			
n	13	13	13
Mean (StdDev)	-1.84 (2.816)	-0.34 (2.645)	-1.22 (4.078)
95% CIs of Mean	(-3.54 - -0.14)	(-1.94 - 1.26)	(-3.69 - 1.24)
p-value [1]	0.0366*	0.6542	0.3008
Median	-2.00	-0.29	-0.43
Min, Max	-6.0, 3.0	-4.7, 5.0	-7.0, 7.7
Change from Baseline to Cycle 12 Day 1			
n	12	12	12
Mean (StdDev)	-1.45 (3.094)	0.43 (2.802)	-0.97 (4.536)
Median	-1.61	-0.07	-0.41
Min, Max	-6.1, 3.8	-4.3, 5.7	-7.9, 8.9

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Scores	Q1 Abdominal Pain (N=27)	Q2 Nausea (N=27)	Q7 Vomitting Count (N=27)	Q8 Vomitting Severity (N=27)	Q9 Diarrhea Count (N=27)	Q10 Diarrhea Severity (N=27)
Change from Baseline to Cycle 10 Day 1						
n	15	15	15	15	15	15
Mean (StdDev)	-1.81 (3.958)	-1.50 (3.512)	-0.15 (0.561)	-0.42 (1.511)	-9.94 (23.246)	-1.08 (2.703)
Median	-1.86	-0.40	0.00	0.00	-1.71	-0.86
Min, Max	-6.7, 8.9	-7.8, 4.6	-2.2, 0.1	-5.8, 0.4	-85.4, 4.6	-7.0, 3.5
Change from Baseline to Cycle 11 Day 1						
n	13	13	13	13	13	13
Mean (StdDev)	-2.26 (3.234)	-2.26 (3.213)	-0.19 (0.597)	-0.51 (1.606)	-8.82 (23.525)	-1.92 (2.348)
95% CIs of Mean	(-4.21 - -0.31)	(-4.20 - -0.32)	(-0.55 - 0.17)	(-1.49 - 0.46)	(-23.04 - 5.39)	(-3.34 - -0.50)
p-value [1]	0.0269*	0.0262*	0.2766	0.2704	0.2012	0.0122*
Median	-2.50	-0.57	0.00	0.00	-1.62	-1.33
Min, Max	-6.1, 4.7	-7.9, 1.7	-2.2, 0.0	-5.8, 0.0	-85.7, 1.3	-7.0, 1.0
Change from Baseline to Cycle 12 Day 1						
n	12	12	12	12	12	12
Mean (StdDev)	-2.62 (2.994)	-2.03 (3.414)	-0.09 (0.287)	-0.44 (1.331)	-9.50 (24.444)	-1.60 (2.758)
Median	-2.36	-0.43	0.00	0.00	-0.86	-1.43
Min, Max	-6.7, 3.6	-7.2, 3.5	-1.0, 0.2	-4.6, 0.2	-85.7, 1.0	-7.6, 3.3

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Scores	TSS (N=27)	Skin Domain (N=27)	GI Domain (N=27)	Q6 Fatigue (N=27)
Change from Baseline to Cycle 13 Day 1				
n	8	8	8	8
Mean (StdDev)	-9.98 (12.589)	-1.86 (6.852)	-6.29 (4.909)	-1.88 (3.291)
Median	-6.29	-1.57	-6.14	-2.06
Min, Max	-29.0, 7.5	-15.4, 8.0	-13.7, 0.0	-7.7, 3.3
Change from Baseline to Cycle 14 Day 1				
n	6	6	7	7
Mean (StdDev)	-7.52 (11.695)	-0.82 (8.084)	-3.45 (7.357)	-0.35 (3.252)
Median	-6.50	-0.57	-7.00	-0.76
Min, Max	-25.3, 8.2	-14.4, 9.5	-9.2, 10.9	-6.0, 3.3
Change from Baseline to Cycle 15 Day 1				
n	3	3	3	3
Mean (StdDev)	2.87 (11.653)	5.11 (7.244)	-3.33 (5.369)	1.12 (1.093)
Median	1.67	8.03	-6.14	1.71
Min, Max	-8.1, 15.1	-3.1, 10.4	-6.7, 2.9	-0.1, 1.8

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Scores	Q3 Spots (N=27)	Q4 Itching (N=27)	Q5 Flushing (N=27)
Change from Baseline to Cycle 13 Day 1			
n	8	8	8
Mean (StdDev)	-1.04 (2.638)	0.05 (2.888)	-0.86 (2.529)
Median	-0.71	-0.14	-0.41
Min, Max	-4.7, 3.0	-4.4, 5.5	-6.3, 1.8
Change from Baseline to Cycle 14 Day 1			
n	7	7	6
Mean (StdDev)	-0.55 (2.647)	0.68 (3.285)	-0.93 (2.988)
Median	-1.29	0.00	-1.13
Min, Max	-4.7, 3.7	-4.1, 6.4	-5.6, 2.9
Change from Baseline to Cycle 15 Day 1			
n	3	3	3
Mean (StdDev)	0.35 (2.342)	2.73 (2.930)	2.13 (5.426)
Median	-0.54	2.61	-0.40
Min, Max	-1.4, 3.0	-0.1, 5.7	-1.6, 8.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Scores	Q1 Abdominal Pain (N=27)	Q2 Nausea (N=27)	Q7 Vomitting Count (N=27)	Q8 Vomitting Severity (N=27)	Q9 Diarrhea Count (N=27)	Q10 Diarrhea Severity (N=27)
Change from Baseline to Cycle 13 Day 1						
n	8	8	8	8	8	8
Mean (StdDev)	-2.76 (2.247)	-2.45 (2.964)	0.04 (0.185)	-0.04 (0.293)	-13.34 (29.803)	-1.04 (2.112)
Median	-2.64	-1.49	0.00	0.00	-1.29	-0.71
Min, Max	-6.1, 0.0	-7.3, 0.0	-0.1, 0.4	-0.4, 0.5	-85.7, 2.2	-4.0, 2.7
Change from Baseline to Cycle 14 Day 1						
n	7	7	7	7	7	7
Mean (StdDev)	-2.09 (3.431)	-0.92 (3.763)	0.27 (0.665)	0.42 (1.264)	-2.60 (5.983)	-0.87 (1.380)
Median	-2.57	-0.86	0.00	0.00	-0.14	-0.29
Min, Max	-6.0, 3.9	-6.0, 6.0	-0.1, 1.8	-0.4, 3.3	-16.0, 1.2	-2.6, 1.0
Change from Baseline to Cycle 15 Day 1						
n	3	3	3	3	3	3
Mean (StdDev)	-2.21 (2.361)	-0.61 (2.548)	-0.05 (0.082)	-0.14 (0.247)	-0.19 (1.902)	-0.39 (1.939)
Median	-2.71	-1.43	0.00	0.00	0.29	0.25
Min, Max	-4.3, 0.4	-2.6, 2.3	-0.1, 0.0	-0.4, 0.0	-2.3, 1.4	-2.6, 1.1

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Scores	TSS (N=27)	Skin Domain (N=27)	GI Domain (N=27)	Q6 Fatigue (N=27)
Change from Baseline to Cycle 16 Day 1				
n	4	4	4	4
Mean (StdDev)	4.52 (12.796)	5.06 (7.158)	-1.75 (5.589)	1.15 (1.660)
Median	4.58	5.52	-2.75	1.01
Min, Max	-11.1, 20.1	-3.7, 12.9	-6.9, 5.4	-0.6, 3.2
Change from Baseline to Cycle 17 Day 1				
n	3	3	3	3
Mean (StdDev)	-0.52 (8.911)	2.28 (5.728)	-4.26 (4.385)	1.39 (1.541)
Median	1.57	3.20	-6.57	0.57
Min, Max	-10.3, 7.2	-3.9, 7.5	-7.0, 0.8	0.4, 3.2
Change from Baseline to Cycle 18 Day 1				
n	3	3	3	3
Mean (StdDev)	5.42 (12.999)	3.59 (6.167)	-0.13 (5.796)	1.96 (1.538)
Median	9.02	3.57	2.14	2.29
Min, Max	-9.0, 16.2	-2.6, 9.8	-6.7, 4.2	0.3, 3.3

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Scores	Q3 Spots (N=27)	Q4 Itching (N=27)	Q5 Flushing (N=27)
Change from Baseline to Cycle 16 Day 1			
n	4	4	4
Mean (StdDev)	0.32 (2.032)	2.96 (2.808)	1.83 (4.726)
Median	-0.23	3.21	0.43
Min, Max	-1.4, 3.2	-0.1, 5.5	-2.1, 8.6
Change from Baseline to Cycle 17 Day 1			
n	3	3	3
Mean (StdDev)	0.70 (2.017)	2.26 (2.677)	-0.65 (1.815)
Median	0.40	1.77	-0.40
Min, Max	-1.1, 2.9	-0.1, 5.1	-2.6, 1.0
Change from Baseline to Cycle 18 Day 1			
n	3	3	3
Mean (StdDev)	-0.51 (1.301)	1.44 (1.362)	2.66 (5.775)
Median	-0.14	1.31	1.69
Min, Max	-2.0, 0.6	0.1, 2.9	-2.6, 8.9

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Scores	Q1 Abdominal Pain (N=27)	Q2 Nausea (N=27)	Q7 Vomitting Count (N=27)	Q8 Vomitting Severity (N=27)	Q9 Diarrhea Count (N=27)	Q10 Diarrhea Severity (N=27)
Change from Baseline to Cycle 16 Day 1						
n	4	4	4	4	4	4
Mean (StdDev)	-2.12 (2.596)	-0.13 (2.074)	-0.04 (0.071)	-0.11 (0.214)	0.06 (1.779)	0.59 (2.415)
Median	-1.50	-0.71	0.00	0.00	0.27	1.08
Min, Max	-5.5, 0.0	-1.8, 2.8	-0.1, 0.0	-0.4, 0.0	-2.3, 2.0	-2.6, 2.8
Change from Baseline to Cycle 17 Day 1						
n	3	3	3	3	3	3
Mean (StdDev)	-2.62 (2.451)	-1.34 (1.495)	-0.05 (0.082)	-0.14 (0.247)	-0.13 (1.895)	-0.18 (2.111)
Median	-3.00	-1.43	0.00	0.00	0.60	0.60
Min, Max	-4.9, 0.0	-2.8, 0.2	-0.1, 0.0	-0.4, 0.0	-2.3, 1.3	-2.6, 1.4
Change from Baseline to Cycle 18 Day 1						
n	3	3	3	3	3	3
Mean (StdDev)	-0.86 (1.623)	-0.09 (1.300)	0.00 (0.000)	0.00 (0.000)	0.01 (2.107)	0.82 (3.007)
Median	-0.14	0.00	0.00	0.00	0.45	1.86
Min, Max	-2.7, 0.3	-1.4, 1.2	0.0, 0.0	0.0, 0.0	-2.3, 1.9	-2.6, 3.2

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses				
Scores	TSS (N=27)	Skin Domain (N=27)	GI Domain (N=27)	Q6 Fatigue (N=27)
Change from Baseline to Cycle 19 Day 1				
n	1	1	1	1
Mean (StdDev)	11.40 (-)	8.60 (-)	1.02 (-)	1.79 (-)
Median	11.40	8.60	1.02	1.79
Min, Max	11.4, 11.4	8.6, 8.6	1.0, 1.0	1.8, 1.8

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Scores	Q3 Spots (N=27)	Q4 Itching (N=27)	Q5 Flushing (N=27)
Change from Baseline to Cycle 19 Day 1			
n	1	1	1
Mean (StdDev)	-1.62 (-)	1.19 (-)	9.02 (-)
Median	-1.62	1.19	9.02
Min, Max	-1.6, -1.6	1.2, 1.2	9.0, 9.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Scores	Q1 Abdominal Pain (N=27)	Q2 Nausea (N=27)	Q7 Vomitting Count (N=27)	Q8 Vomitting Severity (N=27)	Q9 Diarrhea Count (N=27)	Q10 Diarrhea Severity (N=27)
Change from Baseline to Cycle 19 Day 1						
n	1	1	1	1	1	1
Mean (StdDev)	0.02 (-)	0.00 (-)	0.00 (-)	0.00 (-)	0.62 (-)	1.00 (-)
Median	0.02	0.00	0.00	0.00	0.62	1.00
Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.6, 0.6	1.0, 1.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Scores	TSS (N=10)	Skin Domain (N=10)	GI Domain (N=10)	Q6 Fatigue (N=10)
Baseline (C1D-7 to C1D-1)				
n	9	9	9	9
Mean (StdDev)	23.41 (10.625)	9.33 (4.627)	8.33 (5.236)	5.76 (2.751)
Median	27.43	10.43	8.60	6.86
Min, Max	1.2, 34.9	0.6, 15.7	0.3, 14.6	0.2, 8.9
Change from Baseline to Cycle 2 Day 1				
n	8	8	8	8
Mean (StdDev)	-10.80 (10.439)	-4.30 (5.904)	-4.78 (5.507)	-1.72 (1.644)
Median	-13.30	-4.14	-4.80	-1.17
Min, Max	-23.4, 3.7	-14.4, 4.9	-12.4, 2.9	-4.0, 0.3
Change from Baseline to Cycle 3 Day 1				
n	8	8	8	8
Mean (StdDev)	-8.58 (9.092)	-3.06 (6.279)	-3.86 (5.891)	-1.68 (1.913)
95% CIs of Mean	(-16.18 - -0.98)	(-8.31 - 2.19)	(-8.78 - 1.07)	(-3.28 - -0.08)
p-value [1]	0.0320*	0.2110	0.1066	0.0420*
Median	-6.57	-3.79	-2.59	-2.86
Min, Max	-20.0, 3.8	-13.0, 4.1	-11.7, 3.6	-3.6, 0.9

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg			
Scores	Q3 Spots (N=10)	Q4 Itching (N=10)	Q5 Flushing (N=10)
Baseline (C1D-7 to C1D-1)			
n	9	9	9
Mean (StdDev)	3.38 (2.090)	3.38 (2.489)	2.56 (2.573)
Median	3.86	4.20	1.86
Min, Max	0.2, 6.1	0.3, 6.9	0.0, 6.6
Change from Baseline to Cycle 2 Day 1			
n	8	8	8
Mean (StdDev)	-1.14 (2.128)	-2.12 (2.755)	-1.04 (2.635)
Median	-0.76	-1.74	-0.21
Min, Max	-4.4, 1.4	-6.9, 2.1	-4.4, 2.7
Change from Baseline to Cycle 3 Day 1			
n	8	8	8
Mean (StdDev)	-1.14 (1.708)	-1.71 (2.943)	-0.21 (3.813)
95% CIs of Mean	(-2.56 - 0.29)	(-4.17 - 0.75)	(-3.39 - 2.98)
p-value [1]	0.1018	0.1438	0.8822
Median	-0.63	-1.07	0.34
Min, Max	-3.9, 0.9	-6.9, 1.4	-6.2, 4.1

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Scores	Q1 Abdominal Pain (N=10)	Q2 Nausea (N=10)	Q7 Vomitting Count (N=10)	Q8 Vomitting Severity (N=10)	Q9 Diarrhea Count (N=10)	Q10 Diarrhea Severity (N=10)
Baseline (C1D-7 to C1D-1)						
n	9	9	9	9	9	9
Mean (StdDev)	3.71 (2.405)	1.66 (2.413)	0.02 (0.067)	0.04 (0.133)	2.37 (2.213)	2.91 (2.582)
Median	3.43	0.57	0.00	0.00	1.71	3.00
Min, Max	0.3, 7.1	0.0, 7.3	0.0, 0.2	0.0, 0.4	0.0, 5.1	0.0, 7.6
Change from Baseline to Cycle 2 Day 1						
n	8	8	8	8	8	8
Mean (StdDev)	-2.12 (1.960)	-0.45 (2.692)	-0.03 (0.071)	-0.05 (0.141)	-1.61 (2.637)	-2.15 (2.784)
Median	-1.36	-0.21	0.00	0.00	-1.21	-1.37
Min, Max	-5.2, -0.1	-5.6, 3.9	-0.2, 0.0	-0.4, 0.0	-4.6, 2.2	-6.9, 0.7
Change from Baseline to Cycle 3 Day 1						
n	8	8	8	8	8	8
Mean (StdDev)	-1.74 (2.342)	-0.80 (1.907)	0.01 (0.018)	-0.02 (0.053)	-1.08 (2.563)	-1.29 (2.936)
95% CIs of Mean	(-3.69 - 0.22)	(-2.40 - 0.79)	(-0.01 - 0.02)	(-0.06 - 0.03)	(-3.23 - 1.06)	(-3.74 - 1.16)
p-value [1]	0.0742	0.2722	0.3506	0.3506	0.2703	0.2539
Median	-1.40	-0.33	0.00	0.00	-1.07	-0.60
Min, Max	-5.0, 1.0	-4.9, 1.4	0.0, 0.1	-0.2, 0.0	-4.6, 2.6	-6.3, 2.9

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg				
Scores	TSS (N=10)	Skin Domain (N=10)	GI Domain (N=10)	Q6 Fatigue (N=10)
Change from Baseline to Cycle 4 Day 1				
n	8	8	8	8
Mean (StdDev)	-9.25 (9.869)	-3.33 (5.434)	-4.86 (5.266)	-1.06 (2.387)
Median	-11.27	-2.64	-5.54	-0.26
Min, Max	-25.6, 4.8	-12.7, 3.4	-12.6, 2.7	-6.0, 1.3
Change from Baseline to Cycle 5 Day 1				
n	7	7	7	7
Mean (StdDev)	-12.76 (10.673)	-5.73 (6.155)	-5.52 (5.792)	-1.51 (2.552)
Median	-15.43	-6.86	-6.00	-1.70
Min, Max	-27.9, 2.9	-13.4, 4.7	-12.7, 2.6	-6.4, 1.1
Change from Baseline to Cycle 6 Day 1				
n	5	5	5	5
Mean (StdDev)	-14.04 (12.854)	-6.43 (7.048)	-5.54 (7.223)	-2.07 (2.466)
Median	-14.86	-6.71	-3.29	-2.43
Min, Max	-29.6, 2.4	-13.3, 5.0	-13.6, 1.0	-5.7, 0.7

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Scores	Q3 Spots (N=10)	Q4 Itching (N=10)	Q5 Flushing (N=10)
Change from Baseline to Cycle 4 Day 1			
n	8	8	8
Mean (StdDev)	-1.27 (2.297)	-1.37 (3.194)	-0.68 (3.085)
Median	-0.85	0.07	0.00
Min, Max	-4.0, 1.3	-6.9, 2.4	-5.6, 3.6
Change from Baseline to Cycle 5 Day 1			
n	7	7	7
Mean (StdDev)	-2.22 (2.613)	-2.21 (3.013)	-1.30 (3.117)
Median	-2.14	-0.86	-0.29
Min, Max	-6.0, 1.1	-6.9, 1.4	-6.0, 2.1
Change from Baseline to Cycle 6 Day 1			
n	5	5	5
Mean (StdDev)	-3.14 (2.832)	-1.85 (3.325)	-1.44 (2.956)
Median	-4.43	-0.43	-1.00
Min, Max	-6.0, 1.2	-6.9, 1.8	-6.0, 2.1

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Scores	Q1 Abdominal Pain (N=10)	Q2 Nausea (N=10)	Q7 Vomitting Count (N=10)	Q8 Vomitting Severity (N=10)	Q9 Diarrhea Count (N=10)	Q10 Diarrhea Severity (N=10)
Change from Baseline to Cycle 4 Day 1						
n	8	8	8	8	8	8
Mean (StdDev)	-2.29 (2.275)	-0.43 (1.787)	0.11 (0.236)	0.18 (0.338)	-1.86 (1.826)	-2.32 (2.313)
Median	-2.00	-0.21	0.00	0.00	-1.71	-2.16
Min, Max	-5.9, 0.8	-4.3, 1.7	0.0, 0.7	0.0, 0.8	-4.1, 0.5	-6.4, 0.3
Change from Baseline to Cycle 5 Day 1						
n	7	7	7	7	7	7
Mean (StdDev)	-2.65 (2.250)	-0.41 (2.072)	0.07 (0.176)	0.13 (0.353)	-1.90 (2.508)	-2.59 (3.115)
Median	-2.71	-0.29	0.00	0.00	-1.71	-3.00
Min, Max	-5.9, 0.1	-4.4, 1.7	0.0, 0.5	0.0, 0.9	-4.6, 2.6	-6.6, 3.0
Change from Baseline to Cycle 6 Day 1						
n	5	5	5	5	5	5
Mean (StdDev)	-2.23 (2.474)	-1.07 (3.182)	0.00 (0.000)	0.00 (0.000)	-1.98 (2.306)	-2.24 (3.236)
Median	-2.71	-0.14	0.00	0.00	-1.71	-1.14
Min, Max	-5.9, 0.4	-6.6, 1.7	0.0, 0.0	0.0, 0.0	-4.6, 1.1	-6.7, 1.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg				
Scores	TSS (N=10)	Skin Domain (N=10)	GI Domain (N=10)	Q6 Fatigue (N=10)
Change from Baseline to Cycle 7 Day 1				
n	5	5	5	5
Mean (StdDev)	-12.94 (15.425)	-5.17 (7.826)	-5.65 (7.247)	-2.12 (3.118)
95% CIs of Mean	(-32.10 - 6.21)	(-14.89 - 4.55)	(-14.65 - 3.35)	(-5.99 - 1.75)
p-value [1]	0.1339	0.2136	0.1561	0.2030
Median	-16.71	-6.71	-3.69	-2.29
Min, Max	-30.6, 3.7	-13.1, 6.0	-13.3, 3.0	-6.4, 1.4
Change from Baseline to Cycle 8 Day 1				
n	4	4	4	4
Mean (StdDev)	-18.68 (11.340)	-9.46 (3.040)	-5.54 (8.651)	-3.68 (2.217)
Median	-19.43	-9.29	-6.36	-3.43
Min, Max	-31.0, -4.9	-12.6, -6.7	-13.0, 3.6	-6.4, -1.4
Change from Baseline to Cycle 9 Day 1				
n	5	5	5	5
Mean (StdDev)	-15.83 (11.457)	-6.66 (5.805)	-6.44 (6.764)	-2.74 (2.739)
Median	-14.29	-6.86	-5.29	-2.14
Min, Max	-30.2, -2.1	-12.3, 2.8	-13.9, 0.1	-6.9, 0.3

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg			
Scores	Q3 Spots (N=10)	Q4 Itching (N=10)	Q5 Flushing (N=10)
Change from Baseline to Cycle 7 Day 1			
n	5	5	5
Mean (StdDev)	-2.61 (3.284)	-1.45 (3.295)	-1.11 (3.323)
95% CIs of Mean	(-6.69 - 1.47)	(-5.54 - 2.64)	(-5.23 - 3.02)
p-value [1]	0.1500	0.3805	0.4971
Median	-4.29	-0.43	-0.29
Min, Max	-6.0, 1.8	-6.9, 2.0	-6.4, 2.2
Change from Baseline to Cycle 8 Day 1			
n	4	4	4
Mean (StdDev)	-4.25 (1.588)	-2.89 (3.000)	-2.32 (2.778)
Median	-4.43	-2.14	-1.29
Min, Max	-6.0, -2.1	-6.9, -0.4	-6.4, -0.3
Change from Baseline to Cycle 9 Day 1			
n	5	5	5
Mean (StdDev)	-2.94 (2.572)	-2.23 (2.993)	-1.49 (3.042)
Median	-2.98	-0.71	-1.00
Min, Max	-6.0, 0.8	-6.9, 0.4	-6.6, 1.6

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Scores	Q1 Abdominal Pain (N=10)	Q2 Nausea (N=10)	Q7 Vomitting Count (N=10)	Q8 Vomitting Severity (N=10)	Q9 Diarrhea Count (N=10)	Q10 Diarrhea Severity (N=10)
Change from Baseline to Cycle 7 Day 1						
n	5	5	5	5	5	5
Mean (StdDev)	-2.55 (2.090)	-0.98 (2.945)	0.00 (0.000)	0.00 (0.000)	-2.06 (2.506)	-2.12 (3.794)
95% CIs of Mean	(-5.14 - 0.05)	(-4.64 - 2.67)	(0.00 - 0.00)	(0.00 - 0.00)	(-5.17 - 1.05)	(-6.83 - 2.59)
p-value [1]	0.0526	0.4970	<0.001***	<0.001***	0.1395	0.2796
Median	-2.31	0.00	0.00	0.00	-1.71	-1.60
Min, Max	-5.9, -0.3	-6.1, 1.3	0.0, 0.0	0.0, 0.0	-4.6, 1.6	-6.9, 3.3
Change from Baseline to Cycle 8 Day 1						
n	4	4	4	4	4	4
Mean (StdDev)	-2.43 (2.652)	-0.96 (3.514)	0.00 (0.000)	0.00 (0.000)	-1.82 (3.109)	-2.14 (4.214)
Median	-2.07	0.00	0.00	0.00	-2.79	-2.36
Min, Max	-5.9, 0.3	-6.0, 2.1	0.0, 0.0	0.0, 0.0	-4.1, 2.4	-6.9, 3.0
Change from Baseline to Cycle 9 Day 1						
n	5	5	5	5	5	5
Mean (StdDev)	-2.40 (2.186)	-1.21 (3.474)	0.00 (0.000)	0.00 (0.000)	-2.37 (1.987)	-2.82 (2.855)
Median	-2.29	-0.07	0.00	0.00	-1.55	-2.50
Min, Max	-5.9, -0.1	-7.3, 1.6	0.0, 0.0	0.0, 0.0	-4.6, 0.0	-6.9, 0.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg				
Scores	TSS (N=10)	Skin Domain (N=10)	GI Domain (N=10)	Q6 Fatigue (N=10)
Change from Baseline to Cycle 10 Day 1				
n	5	5	5	5
Mean (StdDev)	-12.41 (15.899)	-7.08 (6.316)	-3.24 (11.747)	-2.10 (3.452)
Median	-15.71	-8.57	-5.95	-2.71
Min, Max	-31.3, 8.7	-12.7, 3.3	-13.1, 15.6	-7.0, 1.7
Change from Baseline to Cycle 11 Day 1				
n	4	4	4	4
Mean (StdDev)	-15.07 (16.372)	-5.96 (7.474)	-7.04 (8.603)	-2.07 (4.258)
95% CIs of Mean	(-41.12 - 10.98)	(-17.86 - 5.93)	(-20.72 - 6.65)	(-8.85 - 4.70)
p-value [1]	0.1629	0.2087	0.2004	0.4023
Median	-12.64	-7.50	-9.71	-1.00
Min, Max	-34.1, -0.9	-13.3, 4.4	-13.6, 4.9	-7.7, 1.4
Change from Baseline to Cycle 12 Day 1				
n	3	3	3	3
Mean (StdDev)	-17.76 (19.013)	-4.00 (9.575)	-10.29 (5.451)	-3.48 (4.362)
Median	-21.14	-4.29	-13.14	-3.71
Min, Max	-34.9, 2.7	-13.4, 5.7	-13.7, -4.0	-7.7, 1.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg			
Scores	Q3 Spots (N=10)	Q4 Itching (N=10)	Q5 Flushing (N=10)
Change from Baseline to Cycle 10 Day 1			
n	5	5	5
Mean (StdDev)	-3.14 (2.599)	-2.28 (3.127)	-1.65 (3.085)
Median	-3.86	-0.71	-1.43
Min, Max	-5.9, 1.0	-6.9, 0.6	-6.6, 1.7
Change from Baseline to Cycle 11 Day 1			
n	4	4	4
Mean (StdDev)	-3.36 (3.310)	-1.00 (2.274)	-1.61 (3.724)
95% CIs of Mean	(-8.62 - 1.91)	(-4.62 - 2.62)	(-7.53 - 4.32)
p-value [1]	0.1356	0.4438	0.4516
Median	-4.14	-0.57	-1.07
Min, Max	-6.0, 0.9	-4.1, 1.3	-6.6, 2.3
Change from Baseline to Cycle 12 Day 1			
n	3	3	3
Mean (StdDev)	-2.76 (4.041)	0.24 (1.190)	-1.48 (4.617)
Median	-3.86	-0.14	-0.29
Min, Max	-6.1, 1.7	-0.7, 1.6	-6.6, 2.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Scores	Q1 Abdominal Pain (N=10)	Q2 Nausea (N=10)	Q7 Vomitting Count (N=10)	Q8 Vomitting Severity (N=10)	Q9 Diarrhea Count (N=10)	Q10 Diarrhea Severity (N=10)
Change from Baseline to Cycle 10 Day 1						
n	5	5	5	5	5	5
Mean (StdDev)	-0.51 (5.539)	-0.30 (4.310)	0.03 (0.064)	0.09 (0.192)	-1.43 (3.621)	-2.54 (3.244)
Median	-1.86	-0.29	0.00	0.00	-1.71	-3.00
Min, Max	-5.9, 8.9	-7.1, 4.6	0.0, 0.1	0.0, 0.4	-4.4, 4.6	-7.0, 1.7
Change from Baseline to Cycle 11 Day 1						
n	4	4	4	4	4	4
Mean (StdDev)	-1.50 (4.453)	-1.96 (3.465)	0.00 (0.000)	0.00 (0.000)	-2.64 (2.181)	-3.57 (2.907)
95% CIs of Mean	(-8.59 - 5.59)	(-7.48 - 3.55)	(0.00 - 0.00)	(0.00 - 0.00)	(-6.11 - 0.83)	(-8.20 - 1.05)
p-value [1]	0.5488	0.3393	<0.001***	<0.001***	0.0938	0.0911
Median	-2.43	-0.43	0.00	0.00	-3.00	-3.64
Min, Max	-5.9, 4.7	-7.1, 0.1	0.0, 0.0	0.0, 0.0	-4.6, 0.0	-7.0, 0.0
Change from Baseline to Cycle 12 Day 1						
n	3	3	3	3	3	3
Mean (StdDev)	-3.24 (2.296)	-2.52 (3.632)	0.00 (0.000)	0.00 (0.000)	-3.67 (1.971)	-4.52 (2.876)
Median	-2.29	-0.57	0.00	0.00	-4.43	-4.14
Min, Max	-5.9, -1.6	-6.7, -0.3	0.0, 0.0	0.0, 0.0	-5.1, -1.4	-7.6, -1.9

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg				
Scores	TSS (N=10)	Skin Domain (N=10)	GI Domain (N=10)	Q6 Fatigue (N=10)
Change from Baseline to Cycle 13 Day 1				
n	1	1	1	1
Mean (StdDev)	-22.29 (-)	-5.00 (-)	-13.71 (-)	-3.57 (-)
Median	-22.29	-5.00	-13.71	-3.57
Min, Max	-22.3, -22.3	-5.0, -5.0	-13.7, -13.7	-3.6, -3.6

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg			
Scores	Q3 Spots (N=10)	Q4 Itching (N=10)	Q5 Flushing (N=10)
Change from Baseline to Cycle 13 Day 1			
n	1	1	1
Mean (StdDev)	-4.29 (-)	-0.43 (-)	-0.29 (-)
Median	-4.29	-0.43	-0.29
Min, Max	-4.3, -4.3	-0.4, -0.4	-0.3, -0.3

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Scores	Q1 Abdominal Pain (N=10)	Q2 Nausea (N=10)	Q7 Vomitting Count (N=10)	Q8 Vomitting Severity (N=10)	Q9 Diarrhea Count (N=10)	Q10 Diarrhea Severity (N=10)
Change from Baseline to Cycle 13 Day 1						
n	1	1	1	1	1	1
Mean (StdDev)	-2.86 (-)	-6.86 (-)	0.00 (-)	0.00 (-)	-4.29 (-)	-4.00 (-)
Median	-2.86	-6.86	0.00	0.00	-4.29	-4.00
Min, Max	-2.9, -2.9	-6.9, -6.9	0.0, 0.0	0.0, 0.0	-4.3, -4.3	-4.0, -4.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg				
Scores	TSS (N=10)	Skin Domain (N=10)	GI Domain (N=10)	Q6 Fatigue (N=10)
Baseline (C1D-7 to C1D-1)				
n	9	9	9	9
Mean (StdDev)	23.41 (10.625)	9.33 (4.627)	8.33 (5.236)	5.76 (2.751)
Median	27.43	10.43	8.60	6.86
Min, Max	1.2, 34.9	0.6, 15.7	0.3, 14.6	0.2, 8.9
Change from Baseline to Cycle 2 Day 1				
n	8	8	8	8
Mean (StdDev)	-10.80 (10.439)	-4.30 (5.904)	-4.78 (5.507)	-1.72 (1.644)
Median	-13.30	-4.14	-4.80	-1.17
Min, Max	-23.4, 3.7	-14.4, 4.9	-12.4, 2.9	-4.0, 0.3
Change from Baseline to Cycle 3 Day 1				
n	8	8	8	8
Mean (StdDev)	-8.58 (9.092)	-3.06 (6.279)	-3.86 (5.891)	-1.68 (1.913)
95% CIs of Mean	(-16.18 - -0.98)	(-8.31 - 2.19)	(-8.78 - 1.07)	(-3.28 - -0.08)
p-value [1]	0.0320*	0.2110	0.1066	0.0420*
Median	-6.57	-3.79	-2.59	-2.86
Min, Max	-20.0, 3.8	-13.0, 4.1	-11.7, 3.6	-3.6, 0.9

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg			
Scores	Q3 Spots (N=10)	Q4 Itching (N=10)	Q5 Flushing (N=10)
Baseline (C1D-7 to C1D-1)			
n	9	9	9
Mean (StdDev)	3.38 (2.090)	3.38 (2.489)	2.56 (2.573)
Median	3.86	4.20	1.86
Min, Max	0.2, 6.1	0.3, 6.9	0.0, 6.6
Change from Baseline to Cycle 2 Day 1			
n	8	8	8
Mean (StdDev)	-1.14 (2.128)	-2.12 (2.755)	-1.04 (2.635)
Median	-0.76	-1.74	-0.21
Min, Max	-4.4, 1.4	-6.9, 2.1	-4.4, 2.7
Change from Baseline to Cycle 3 Day 1			
n	8	8	8
Mean (StdDev)	-1.14 (1.708)	-1.71 (2.943)	-0.21 (3.813)
95% CIs of Mean	(-2.56 - 0.29)	(-4.17 - 0.75)	(-3.39 - 2.98)
p-value [1]	0.1018	0.1438	0.8822
Median	-0.63	-1.07	0.34
Min, Max	-3.9, 0.9	-6.9, 1.4	-6.2, 4.1

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Scores	Q1 Abdominal Pain (N=10)	Q2 Nausea (N=10)	Q7 Vomitting Count (N=10)	Q8 Vomitting Severity (N=10)	Q9 Diarrhea Count (N=10)	Q10 Diarrhea Severity (N=10)
Baseline (C1D-7 to C1D-1)						
n	9	9	9	9	9	9
Mean (StdDev)	3.71 (2.405)	1.66 (2.413)	0.02 (0.067)	0.04 (0.133)	2.37 (2.213)	2.91 (2.582)
Median	3.43	0.57	0.00	0.00	1.71	3.00
Min, Max	0.3, 7.1	0.0, 7.3	0.0, 0.2	0.0, 0.4	0.0, 5.1	0.0, 7.6
Change from Baseline to Cycle 2 Day 1						
n	8	8	8	8	8	8
Mean (StdDev)	-2.12 (1.960)	-0.45 (2.692)	-0.03 (0.071)	-0.05 (0.141)	-1.61 (2.637)	-2.15 (2.784)
Median	-1.36	-0.21	0.00	0.00	-1.21	-1.37
Min, Max	-5.2, -0.1	-5.6, 3.9	-0.2, 0.0	-0.4, 0.0	-4.6, 2.2	-6.9, 0.7
Change from Baseline to Cycle 3 Day 1						
n	8	8	8	8	8	8
Mean (StdDev)	-1.74 (2.342)	-0.80 (1.907)	0.01 (0.018)	-0.02 (0.053)	-1.08 (2.563)	-1.29 (2.936)
95% CIs of Mean	(-3.69 - 0.22)	(-2.40 - 0.79)	(-0.01 - 0.02)	(-0.06 - 0.03)	(-3.23 - 1.06)	(-3.74 - 1.16)
p-value [1]	0.0742	0.2722	0.3506	0.3506	0.2703	0.2539
Median	-1.40	-0.33	0.00	0.00	-1.07	-0.60
Min, Max	-5.0, 1.0	-4.9, 1.4	0.0, 0.1	-0.2, 0.0	-4.6, 2.6	-6.3, 2.9

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg				
Scores	TSS (N=10)	Skin Domain (N=10)	GI Domain (N=10)	Q6 Fatigue (N=10)
Change from Baseline to Cycle 4 Day 1				
n	8	8	8	8
Mean (StdDev)	-9.25 (9.869)	-3.33 (5.434)	-4.86 (5.266)	-1.06 (2.387)
Median	-11.27	-2.64	-5.54	-0.26
Min, Max	-25.6, 4.8	-12.7, 3.4	-12.6, 2.7	-6.0, 1.3
Change from Baseline to Cycle 5 Day 1				
n	7	7	7	7
Mean (StdDev)	-12.76 (10.673)	-5.73 (6.155)	-5.52 (5.792)	-1.51 (2.552)
Median	-15.43	-6.86	-6.00	-1.70
Min, Max	-27.9, 2.9	-13.4, 4.7	-12.7, 2.6	-6.4, 1.1
Change from Baseline to Cycle 6 Day 1				
n	5	5	5	5
Mean (StdDev)	-14.04 (12.854)	-6.43 (7.048)	-5.54 (7.223)	-2.07 (2.466)
Median	-14.86	-6.71	-3.29	-2.43
Min, Max	-29.6, 2.4	-13.3, 5.0	-13.6, 1.0	-5.7, 0.7

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg			
Scores	Q3 Spots (N=10)	Q4 Itching (N=10)	Q5 Flushing (N=10)
Change from Baseline to Cycle 4 Day 1			
n	8	8	8
Mean (StdDev)	-1.27 (2.297)	-1.37 (3.194)	-0.68 (3.085)
Median	-0.85	0.07	0.00
Min, Max	-4.0, 1.3	-6.9, 2.4	-5.6, 3.6
Change from Baseline to Cycle 5 Day 1			
n	7	7	7
Mean (StdDev)	-2.22 (2.613)	-2.21 (3.013)	-1.30 (3.117)
Median	-2.14	-0.86	-0.29
Min, Max	-6.0, 1.1	-6.9, 1.4	-6.0, 2.1
Change from Baseline to Cycle 6 Day 1			
n	5	5	5
Mean (StdDev)	-3.14 (2.832)	-1.85 (3.325)	-1.44 (2.956)
Median	-4.43	-0.43	-1.00
Min, Max	-6.0, 1.2	-6.9, 1.8	-6.0, 2.1

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Scores	Q1 Abdominal Pain (N=10)	Q2 Nausea (N=10)	Q7 Vomitting Count (N=10)	Q8 Vomitting Severity (N=10)	Q9 Diarrhea Count (N=10)	Q10 Diarrhea Severity (N=10)
Change from Baseline to Cycle 4 Day 1						
n	8	8	8	8	8	8
Mean (StdDev)	-2.29 (2.275)	-0.43 (1.787)	0.11 (0.236)	0.18 (0.338)	-1.86 (1.826)	-2.32 (2.313)
Median	-2.00	-0.21	0.00	0.00	-1.71	-2.16
Min, Max	-5.9, 0.8	-4.3, 1.7	0.0, 0.7	0.0, 0.8	-4.1, 0.5	-6.4, 0.3
Change from Baseline to Cycle 5 Day 1						
n	7	7	7	7	7	7
Mean (StdDev)	-2.65 (2.250)	-0.41 (2.072)	0.07 (0.176)	0.13 (0.353)	-1.90 (2.508)	-2.59 (3.115)
Median	-2.71	-0.29	0.00	0.00	-1.71	-3.00
Min, Max	-5.9, 0.1	-4.4, 1.7	0.0, 0.5	0.0, 0.9	-4.6, 2.6	-6.6, 3.0
Change from Baseline to Cycle 6 Day 1						
n	5	5	5	5	5	5
Mean (StdDev)	-2.23 (2.474)	-1.07 (3.182)	0.00 (0.000)	0.00 (0.000)	-1.98 (2.306)	-2.24 (3.236)
Median	-2.71	-0.14	0.00	0.00	-1.71	-1.14
Min, Max	-5.9, 0.4	-6.6, 1.7	0.0, 0.0	0.0, 0.0	-4.6, 1.1	-6.7, 1.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg				
Scores	TSS (N=10)	Skin Domain (N=10)	GI Domain (N=10)	Q6 Fatigue (N=10)
Change from Baseline to Cycle 7 Day 1				
n	5	5	5	5
Mean (StdDev)	-12.94 (15.425)	-5.17 (7.826)	-5.65 (7.247)	-2.12 (3.118)
95% CIs of Mean	(-32.10 - 6.21)	(-14.89 - 4.55)	(-14.65 - 3.35)	(-5.99 - 1.75)
p-value [1]	0.1339	0.2136	0.1561	0.2030
Median	-16.71	-6.71	-3.69	-2.29
Min, Max	-30.6, 3.7	-13.1, 6.0	-13.3, 3.0	-6.4, 1.4
Change from Baseline to Cycle 8 Day 1				
n	4	4	4	4
Mean (StdDev)	-18.68 (11.340)	-9.46 (3.040)	-5.54 (8.651)	-3.68 (2.217)
Median	-19.43	-9.29	-6.36	-3.43
Min, Max	-31.0, -4.9	-12.6, -6.7	-13.0, 3.6	-6.4, -1.4
Change from Baseline to Cycle 9 Day 1				
n	5	5	5	5
Mean (StdDev)	-15.83 (11.457)	-6.66 (5.805)	-6.44 (6.764)	-2.74 (2.739)
Median	-14.29	-6.86	-5.29	-2.14
Min, Max	-30.2, -2.1	-12.3, 2.8	-13.9, 0.1	-6.9, 0.3

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg			
Scores	Q3 Spots (N=10)	Q4 Itching (N=10)	Q5 Flushing (N=10)
Change from Baseline to Cycle 7 Day 1			
n	5	5	5
Mean (StdDev)	-2.61 (3.284)	-1.45 (3.295)	-1.11 (3.323)
95% CIs of Mean	(-6.69 - 1.47)	(-5.54 - 2.64)	(-5.23 - 3.02)
p-value [1]	0.1500	0.3805	0.4971
Median	-4.29	-0.43	-0.29
Min, Max	-6.0, 1.8	-6.9, 2.0	-6.4, 2.2
Change from Baseline to Cycle 8 Day 1			
n	4	4	4
Mean (StdDev)	-4.25 (1.588)	-2.89 (3.000)	-2.32 (2.778)
Median	-4.43	-2.14	-1.29
Min, Max	-6.0, -2.1	-6.9, -0.4	-6.4, -0.3
Change from Baseline to Cycle 9 Day 1			
n	5	5	5
Mean (StdDev)	-2.94 (2.572)	-2.23 (2.993)	-1.49 (3.042)
Median	-2.98	-0.71	-1.00
Min, Max	-6.0, 0.8	-6.9, 0.4	-6.6, 1.6

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas
Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Scores	Q1 Abdominal Pain (N=10)	Q2 Nausea (N=10)	Q7 Vomitting Count (N=10)	Q8 Vomitting Severity (N=10)	Q9 Diarrhea Count (N=10)	Q10 Diarrhea Severity (N=10)
Change from Baseline to Cycle 7 Day 1						
n	5	5	5	5	5	5
Mean (StdDev)	-2.55 (2.090)	-0.98 (2.945)	0.00 (0.000)	0.00 (0.000)	-2.06 (2.506)	-2.12 (3.794)
95% CIs of Mean	(-5.14 - 0.05)	(-4.64 - 2.67)	(0.00 - 0.00)	(0.00 - 0.00)	(-5.17 - 1.05)	(-6.83 - 2.59)
p-value [1]	0.0526	0.4970	<0.001***	<0.001***	0.1395	0.2796
Median	-2.31	0.00	0.00	0.00	-1.71	-1.60
Min, Max	-5.9, -0.3	-6.1, 1.3	0.0, 0.0	0.0, 0.0	-4.6, 1.6	-6.9, 3.3
Change from Baseline to Cycle 8 Day 1						
n	4	4	4	4	4	4
Mean (StdDev)	-2.43 (2.652)	-0.96 (3.514)	0.00 (0.000)	0.00 (0.000)	-1.82 (3.109)	-2.14 (4.214)
Median	-2.07	0.00	0.00	0.00	-2.79	-2.36
Min, Max	-5.9, 0.3	-6.0, 2.1	0.0, 0.0	0.0, 0.0	-4.1, 2.4	-6.9, 3.0
Change from Baseline to Cycle 9 Day 1						
n	5	5	5	5	5	5
Mean (StdDev)	-2.40 (2.186)	-1.21 (3.474)	0.00 (0.000)	0.00 (0.000)	-2.37 (1.987)	-2.82 (2.855)
Median	-2.29	-0.07	0.00	0.00	-1.55	-2.50
Min, Max	-5.9, -0.1	-7.3, 1.6	0.0, 0.0	0.0, 0.0	-4.6, 0.0	-6.9, 0.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg				
Scores	TSS (N=10)	Skin Domain (N=10)	GI Domain (N=10)	Q6 Fatigue (N=10)
Change from Baseline to Cycle 10 Day 1				
n	5	5	5	5
Mean (StdDev)	-12.41 (15.899)	-7.08 (6.316)	-3.24 (11.747)	-2.10 (3.452)
Median	-15.71	-8.57	-5.95	-2.71
Min, Max	-31.3, 8.7	-12.7, 3.3	-13.1, 15.6	-7.0, 1.7
Change from Baseline to Cycle 11 Day 1				
n	4	4	4	4
Mean (StdDev)	-15.07 (16.372)	-5.96 (7.474)	-7.04 (8.603)	-2.07 (4.258)
95% CIs of Mean	(-41.12 - 10.98)	(-17.86 - 5.93)	(-20.72 - 6.65)	(-8.85 - 4.70)
p-value [1]	0.1629	0.2087	0.2004	0.4023
Median	-12.64	-7.50	-9.71	-1.00
Min, Max	-34.1, -0.9	-13.3, 4.4	-13.6, 4.9	-7.7, 1.4
Change from Baseline to Cycle 12 Day 1				
n	3	3	3	3
Mean (StdDev)	-17.76 (19.013)	-4.00 (9.575)	-10.29 (5.451)	-3.48 (4.362)
Median	-21.14	-4.29	-13.14	-3.71
Min, Max	-34.9, 2.7	-13.4, 5.7	-13.7, -4.0	-7.7, 1.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg			
Scores	Q3 Spots (N=10)	Q4 Itching (N=10)	Q5 Flushing (N=10)
Change from Baseline to Cycle 10 Day 1			
n	5	5	5
Mean (StdDev)	-3.14 (2.599)	-2.28 (3.127)	-1.65 (3.085)
Median	-3.86	-0.71	-1.43
Min, Max	-5.9, 1.0	-6.9, 0.6	-6.6, 1.7
Change from Baseline to Cycle 11 Day 1			
n	4	4	4
Mean (StdDev)	-3.36 (3.310)	-1.00 (2.274)	-1.61 (3.724)
95% CIs of Mean	(-8.62 - 1.91)	(-4.62 - 2.62)	(-7.53 - 4.32)
p-value [1]	0.1356	0.4438	0.4516
Median	-4.14	-0.57	-1.07
Min, Max	-6.0, 0.9	-4.1, 1.3	-6.6, 2.3
Change from Baseline to Cycle 12 Day 1			
n	3	3	3
Mean (StdDev)	-2.76 (4.041)	0.24 (1.190)	-1.48 (4.617)
Median	-3.86	-0.14	-0.29
Min, Max	-6.1, 1.7	-0.7, 1.6	-6.6, 2.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Scores	Q1 Abdominal Pain (N=10)	Q2 Nausea (N=10)	Q7 Vomitting Count (N=10)	Q8 Vomitting Severity (N=10)	Q9 Diarrhea Count (N=10)	Q10 Diarrhea Severity (N=10)
Change from Baseline to Cycle 10 Day 1						
n	5	5	5	5	5	5
Mean (StdDev)	-0.51 (5.539)	-0.30 (4.310)	0.03 (0.064)	0.09 (0.192)	-1.43 (3.621)	-2.54 (3.244)
Median	-1.86	-0.29	0.00	0.00	-1.71	-3.00
Min, Max	-5.9, 8.9	-7.1, 4.6	0.0, 0.1	0.0, 0.4	-4.4, 4.6	-7.0, 1.7
Change from Baseline to Cycle 11 Day 1						
n	4	4	4	4	4	4
Mean (StdDev)	-1.50 (4.453)	-1.96 (3.465)	0.00 (0.000)	0.00 (0.000)	-2.64 (2.181)	-3.57 (2.907)
95% CIs of Mean	(-8.59 - 5.59)	(-7.48 - 3.55)	(0.00 - 0.00)	(0.00 - 0.00)	(-6.11 - 0.83)	(-8.20 - 1.05)
p-value [1]	0.5488	0.3393	<0.001***	<0.001***	0.0938	0.0911
Median	-2.43	-0.43	0.00	0.00	-3.00	-3.64
Min, Max	-5.9, 4.7	-7.1, 0.1	0.0, 0.0	0.0, 0.0	-4.6, 0.0	-7.0, 0.0
Change from Baseline to Cycle 12 Day 1						
n	3	3	3	3	3	3
Mean (StdDev)	-3.24 (2.296)	-2.52 (3.632)	0.00 (0.000)	0.00 (0.000)	-3.67 (1.971)	-4.52 (2.876)
Median	-2.29	-0.57	0.00	0.00	-4.43	-4.14
Min, Max	-5.9, -1.6	-6.7, -0.3	0.0, 0.0	0.0, 0.0	-5.1, -1.4	-7.6, -1.9

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg				
Scores	TSS (N=10)	Skin Domain (N=10)	GI Domain (N=10)	Q6 Fatigue (N=10)
Change from Baseline to Cycle 13 Day 1				
n	1	1	1	1
Mean (StdDev)	-22.29 (-)	-5.00 (-)	-13.71 (-)	-3.57 (-)
Median	-22.29	-5.00	-13.71	-3.57
Min, Max	-22.3, -22.3	-5.0, -5.0	-13.7, -13.7	-3.6, -3.6

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg			
Scores	Q3 Spots (N=10)	Q4 Itching (N=10)	Q5 Flushing (N=10)
Change from Baseline to Cycle 13 Day 1			
n	1	1	1
Mean (StdDev)	-4.29 (-)	-0.43 (-)	-0.29 (-)
Median	-4.29	-0.43	-0.29
Min, Max	-4.3, -4.3	-0.4, -0.4	-0.3, -0.3

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Scores	Q1 Abdominal Pain (N=10)	Q2 Nausea (N=10)	Q7 Vomitting Count (N=10)	Q8 Vomitting Severity (N=10)	Q9 Diarrhea Count (N=10)	Q10 Diarrhea Severity (N=10)
Change from Baseline to Cycle 13 Day 1						
n	1	1	1	1	1	1
Mean (StdDev)	-2.86 (-)	-6.86 (-)	0.00 (-)	0.00 (-)	-4.29 (-)	-4.00 (-)
Median	-2.86	-6.86	0.00	0.00	-4.29	-4.00
Min, Max	-2.9, -2.9	-6.9, -6.9	0.0, 0.0	0.0, 0.0	-4.3, -4.3	-4.0, -4.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Scores	TSS (N=42)	Skin Domain (N=42)	GI Domain (N=42)	Q6 Fatigue (N=42)
Baseline (C1D-7 to C1D-1)				
n	38	38	38	38
Mean (StdDev)	19.26 (13.287)	7.67 (7.666)	6.08 (5.789)	5.51 (3.035)
Median	18.18	6.43	5.14	6.29
Min, Max	0.0, 53.7	0.0, 28.6	0.0, 21.7	0.0, 10.0
Change from Baseline to Cycle 2 Day 1				
n	37	37	37	37
Mean (StdDev)	-6.61 (9.053)	-3.21 (4.854)	-2.71 (4.977)	-0.69 (1.884)
Median	-5.13	-1.71	-1.71	-0.43
Min, Max	-30.1, 10.7	-23.1, 2.0	-16.9, 6.4	-8.3, 2.3
Change from Baseline to Cycle 3 Day 1				
n	35	35	35	35
Mean (StdDev)	-7.63 (10.713)	-3.27 (6.058)	-3.58 (4.806)	-0.78 (2.476)
95% CIs of Mean	(-11.31 - -3.95)	(-5.35 - -1.19)	(-5.23 - -1.93)	(-1.63 - 0.07)
p-value [1]	<0.001***	0.0030**	<0.001***	0.0723
Median	-6.86	-2.43	-2.86	-0.71
Min, Max	-32.9, 21.7	-21.6, 10.0	-13.0, 5.3	-7.6, 6.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Scores	Q3 Spots (N=42)	Q4 Itching (N=42)	Q5 Flushing (N=42)
Baseline (C1D-7 to C1D-1)			
n	38	38	38
Mean (StdDev)	2.66 (2.945)	2.65 (2.966)	2.36 (2.581)
Median	1.93	1.00	1.43
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 8.6
Change from Baseline to Cycle 2 Day 1			
n	37	37	37
Mean (StdDev)	-0.70 (1.354)	-1.32 (2.247)	-1.19 (2.068)
Median	0.00	-0.29	-0.57
Min, Max	-5.3, 1.6	-10.0, 1.0	-7.9, 1.7
Change from Baseline to Cycle 3 Day 1			
n	35	35	35
Mean (StdDev)	-0.78 (2.170)	-1.19 (2.845)	-1.30 (2.280)
95% CIs of Mean	(-1.53 - -0.04)	(-2.17 - -0.21)	(-2.08 - -0.51)
p-value [1]	0.0399*	0.0185*	0.0019**
Median	-0.43	-0.43	-0.57
Min, Max	-6.4, 5.0	-10.0, 4.6	-7.0, 4.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Scores	Q1 Abdominal Pain (N=42)	Q2 Nausea (N=42)	Q7 Vomitting Count (N=42)	Q8 Vomitting Severity (N=42)	Q9 Diarrhea Count (N=42)	Q10 Diarrhea Severity (N=42)
Baseline (C1D-7 to C1D-1)						
n	38	38	38	38	38	38
Mean (StdDev)	2.70 (2.869)	1.69 (2.217)	0.07 (0.188)	0.14 (0.397)	1.06 (1.719)	1.54 (1.989)
Median	1.79	0.76	0.00	0.00	0.36	0.77
Min, Max	0.0, 10.0	0.0, 7.3	0.0, 1.0	0.0, 1.7	0.0, 7.1	0.0, 7.1
Change from Baseline to Cycle 2 Day 1						
n	37	37	37	37	37	37
Mean (StdDev)	-1.14 (2.660)	-0.97 (1.614)	-0.01 (0.209)	-0.01 (0.536)	-0.33 (1.951)	-0.59 (1.966)
Median	-0.43	-0.57	0.00	0.00	0.00	0.00
Min, Max	-8.3, 5.6	-5.1, 1.4	-0.5, 1.0	-1.4, 2.7	-5.4, 6.1	-6.6, 2.9
Change from Baseline to Cycle 3 Day 1						
n	35	35	35	35	35	35
Mean (StdDev)	-1.58 (2.807)	-1.10 (1.818)	0.00 (0.259)	0.06 (0.654)	-0.69 (1.580)	-0.96 (1.635)
95% CIs of Mean	(-2.54 - -0.61)	(-1.73 - -0.48)	(-0.09 - 0.09)	(-0.16 - 0.28)	(-1.24 - -0.15)	(-1.52 - -0.40)
p-value [1]	0.0021**	0.0010**	0.9311	0.5891	0.0137*	0.0014**
Median	-0.86	-0.67	0.00	0.00	-0.21	-0.57
Min, Max	-10.0, 5.3	-6.9, 1.7	-0.7, 1.1	-1.4, 3.0	-5.4, 1.9	-4.7, 1.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Scores	TSS (N=42)	Skin Domain (N=42)	GI Domain (N=42)	Q6 Fatigue (N=42)
Change from Baseline to Cycle 4 Day 1				
n	33	33	33	33
Mean (StdDev)	-7.70 (11.904)	-3.26 (6.697)	-3.58 (5.307)	-0.86 (2.627)
Median	-8.05	-1.82	-2.86	-0.57
Min, Max	-34.9, 21.6	-19.7, 13.4	-18.5, 6.9	-9.0, 4.1
Change from Baseline to Cycle 5 Day 1				
n	30	30	30	30
Mean (StdDev)	-9.25 (10.273)	-4.36 (5.897)	-3.40 (4.821)	-1.49 (2.764)
Median	-9.79	-2.57	-2.57	-1.01
Min, Max	-30.9, 12.4	-19.0, 2.7	-13.7, 6.6	-9.0, 5.3
Change from Baseline to Cycle 6 Day 1				
n	26	26	26	26
Mean (StdDev)	-7.88 (10.535)	-3.02 (6.009)	-3.89 (4.466)	-0.98 (3.137)
Median	-6.99	-1.86	-2.17	-0.43
Min, Max	-30.6, 12.6	-18.9, 7.6	-14.0, 3.4	-9.0, 7.9

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Scores	Q3 Spots (N=42)	Q4 Itching (N=42)	Q5 Flushing (N=42)
Change from Baseline to Cycle 4 Day 1			
n	33	33	33
Mean (StdDev)	-0.83 (2.185)	-1.23 (3.085)	-1.20 (2.586)
Median	-0.14	-0.29	-0.71
Min, Max	-6.4, 3.6	-10.0, 7.6	-7.3, 3.0
Change from Baseline to Cycle 5 Day 1			
n	30	30	30
Mean (StdDev)	-1.09 (2.212)	-1.70 (2.847)	-1.57 (2.070)
Median	-0.42	-0.52	-1.08
Min, Max	-6.4, 3.6	-10.0, 2.0	-7.0, 2.1
Change from Baseline to Cycle 6 Day 1			
n	26	26	26
Mean (StdDev)	-0.54 (2.371)	-1.14 (2.792)	-1.34 (2.209)
Median	-0.14	-0.21	-0.57
Min, Max	-5.0, 6.9	-10.0, 2.0	-7.3, 1.6

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Scores	Q1 Abdominal Pain (N=42)	Q2 Nausea (N=42)	Q7 Vomitting Count (N=42)	Q8 Vomitting Severity (N=42)	Q9 Diarrhea Count (N=42)	Q10 Diarrhea Severity (N=42)
Change from Baseline to Cycle 4 Day 1						
n	33	33	33	33	33	33
Mean (StdDev)	-1.76 (2.841)	-1.11 (1.978)	0.07 (0.537)	0.14 (0.985)	-0.66 (1.655)	-0.85 (1.765)
Median	-0.83	-0.57	0.00	0.00	-0.29	-0.71
Min, Max	-9.6, 4.0	-7.3, 2.0	-0.9, 2.7	-1.4, 4.6	-5.4, 2.1	-5.2, 2.9
Change from Baseline to Cycle 5 Day 1						
n	30	30	30	30	30	30
Mean (StdDev)	-1.58 (2.614)	-1.25 (1.894)	0.06 (0.603)	0.06 (0.786)	-0.58 (1.699)	-0.63 (2.012)
Median	-0.86	-0.43	0.00	0.00	-0.21	-0.52
Min, Max	-10.0, 5.0	-6.6, 1.1	-0.9, 3.1	-1.4, 3.6	-5.0, 3.4	-4.3, 4.8
Change from Baseline to Cycle 6 Day 1						
n	26	26	26	26	26	26
Mean (StdDev)	-1.51 (2.790)	-1.42 (1.825)	0.03 (0.413)	0.03 (0.595)	-0.74 (1.410)	-0.99 (1.452)
Median	-0.85	-0.76	0.00	0.00	-0.36	-0.71
Min, Max	-10.0, 3.4	-6.1, 0.6	-0.9, 1.7	-1.4, 1.9	-5.4, 1.4	-4.7, 1.1

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Scores	TSS (N=42)	Skin Domain (N=42)	GI Domain (N=42)	Q6 Fatigue (N=42)
Change from Baseline to Cycle 7 Day 1				
n	23	23	23	23
Mean (StdDev)	-9.24 (10.252)	-3.65 (5.873)	-4.08 (4.699)	-1.51 (2.713)
95% CIs of Mean	(-13.67 - -4.80)	(-6.19 - -1.11)	(-6.11 - -2.04)	(-2.69 - -0.34)
p-value [1]	<0.001***	0.0070**	<0.001***	0.0138*
Median	-7.83	-2.43	-2.33	-0.86
Min, Max	-31.4, 7.0	-18.6, 2.7	-14.4, 4.1	-9.0, 2.4
Change from Baseline to Cycle 8 Day 1				
n	24	24	24	24
Mean (StdDev)	-9.68 (10.304)	-3.69 (5.816)	-4.37 (4.817)	-1.62 (2.767)
Median	-8.20	-1.93	-2.74	-1.36
Min, Max	-34.6, 7.0	-18.6, 3.0	-17.3, 4.1	-9.0, 2.4
Change from Baseline to Cycle 9 Day 1				
n	21	21	21	21
Mean (StdDev)	-10.12 (10.711)	-3.77 (6.239)	-4.52 (5.058)	-1.84 (2.806)
Median	-8.43	-1.57	-3.71	-1.86
Min, Max	-32.6, 7.0	-18.6, 3.6	-15.3, 4.1	-9.0, 2.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Scores	Q3 Spots (N=42)	Q4 Itching (N=42)	Q5 Flushing (N=42)
Change from Baseline to Cycle 7 Day 1			
n	23	23	23
Mean (StdDev)	-0.90 (1.938)	-1.24 (2.908)	-1.51 (2.176)
95% CIs of Mean	(-1.74 - -0.06)	(-2.49 - 0.02)	(-2.45 - -0.57)
p-value [1]	0.0367*	0.0538	0.0030**
Median	-0.43	-0.14	-0.71
Min, Max	-5.0, 2.9	-10.0, 2.0	-7.3, 1.4
Change from Baseline to Cycle 8 Day 1			
n	24	24	24
Mean (StdDev)	-0.95 (1.950)	-1.19 (2.884)	-1.54 (2.076)
Median	-0.21	-0.21	-0.93
Min, Max	-5.0, 2.9	-10.0, 2.0	-7.3, 1.1
Change from Baseline to Cycle 9 Day 1			
n	21	21	21
Mean (StdDev)	-0.85 (2.092)	-1.19 (3.074)	-1.73 (2.218)
Median	0.00	0.00	-0.71
Min, Max	-5.0, 2.9	-10.0, 2.0	-7.3, 1.2

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Scores	Q1 Abdominal Pain (N=42)	Q2 Nausea (N=42)	Q7 Vomitting Count (N=42)	Q8 Vomitting Severity (N=42)	Q9 Diarrhea Count (N=42)	Q10 Diarrhea Severity (N=42)
Change from Baseline to Cycle 7 Day 1						
n	23	23	23	23	23	23
Mean (StdDev)	-1.49 (3.008)	-1.51 (2.053)	-0.07 (0.203)	-0.12 (0.344)	-0.88 (1.284)	-0.96 (1.207)
95% CIs of Mean	(-2.79 - -0.19)	(-2.40 - -0.62)	(-0.16 - 0.02)	(-0.27 - 0.03)	(-1.43 - -0.32)	(-1.48 - -0.43)
p-value [1]	0.0264*	0.0019**	0.1081	0.1072	0.0034**	<0.001***
Median	-0.43	-0.71	0.00	0.00	-0.43	-0.71
Min, Max	-10.0, 5.4	-7.3, 0.7	-0.9, 0.1	-1.4, 0.1	-3.9, 0.1	-3.9, 0.9
Change from Baseline to Cycle 8 Day 1						
n	24	24	24	24	24	24
Mean (StdDev)	-1.77 (3.004)	-1.55 (2.112)	-0.07 (0.198)	-0.16 (0.386)	-0.75 (1.682)	-0.90 (1.690)
Median	-0.77	-0.62	0.00	0.00	-0.33	-0.71
Min, Max	-10.0, 5.4	-7.3, 1.1	-0.9, 0.1	-1.4, 0.1	-4.9, 2.7	-4.6, 2.9
Change from Baseline to Cycle 9 Day 1						
n	21	21	21	21	21	21
Mean (StdDev)	-1.73 (3.149)	-1.65 (2.109)	-0.04 (0.240)	-0.07 (0.406)	-0.78 (1.832)	-1.06 (1.685)
Median	-0.83	-1.00	0.00	0.00	-0.50	-0.83
Min, Max	-10.0, 5.4	-7.3, 0.4	-0.9, 0.4	-1.4, 0.6	-5.4, 2.3	-4.7, 1.9

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Scores	TSS (N=42)	Skin Domain (N=42)	GI Domain (N=42)	Q6 Fatigue (N=42)
Change from Baseline to Cycle 10 Day 1				
n	19	19	19	19
Mean (StdDev)	-9.59 (11.657)	-3.36 (6.329)	-4.64 (5.505)	-1.59 (2.798)
Median	-7.83	-1.29	-3.14	-0.43
Min, Max	-35.4, 7.0	-19.9, 3.4	-19.0, 4.1	-9.0, 2.4
Change from Baseline to Cycle 11 Day 1				
n	18	18	18	18
Mean (StdDev)	-9.28 (12.182)	-3.72 (6.777)	-4.07 (5.271)	-1.49 (2.766)
95% CIs of Mean	(-15.34 - -3.23)	(-7.09 - -0.35)	(-6.69 - -1.45)	(-2.87 - -0.11)
p-value [1]	0.0049**	0.0324*	0.0044**	0.0354*
Median	-5.99	-1.43	-3.14	-0.34
Min, Max	-35.4, 7.0	-20.6, 3.4	-17.4, 4.1	-9.0, 2.4
Change from Baseline to Cycle 12 Day 1				
n	16	16	16	16
Mean (StdDev)	-9.10 (13.299)	-3.25 (7.224)	-4.84 (6.021)	-1.01 (2.207)
Median	-4.14	-0.93	-3.57	-0.13
Min, Max	-39.7, 7.0	-22.4, 3.4	-21.7, 4.1	-4.7, 2.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Scores	Q3 Spots (N=42)	Q4 Itching (N=42)	Q5 Flushing (N=42)
Change from Baseline to Cycle 10 Day 1			
n	19	19	19
Mean (StdDev)	-0.75 (2.147)	-1.05 (3.187)	-1.56 (2.057)
Median	0.00	-0.14	-0.57
Min, Max	-6.0, 2.9	-10.0, 2.3	-7.0, 0.4
Change from Baseline to Cycle 11 Day 1			
n	18	18	18
Mean (StdDev)	-0.82 (2.191)	-1.29 (3.165)	-1.61 (2.370)
95% CIs of Mean	(-1.91 - 0.27)	(-2.86 - 0.28)	(-2.79 - -0.43)
p-value [1]	0.1301	0.1020	0.0103*
Median	-0.21	-0.21	-0.57
Min, Max	-6.0, 2.9	-10.0, 2.0	-7.3, 0.4
Change from Baseline to Cycle 12 Day 1			
n	16	16	16
Mean (StdDev)	-0.59 (2.235)	-1.30 (3.292)	-1.36 (2.162)
Median	0.00	-0.21	-0.57
Min, Max	-7.0, 2.9	-10.0, 2.0	-7.3, 0.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Scores	Q1 Abdominal Pain (N=42)	Q2 Nausea (N=42)	Q7 Vomitting Count (N=42)	Q8 Vomitting Severity (N=42)	Q9 Diarrhea Count (N=42)	Q10 Diarrhea Severity (N=42)
Change from Baseline to Cycle 10 Day 1						
n	19	19	19	19	19	19
Mean (StdDev)	-1.74 (3.298)	-1.59 (2.201)	0.01 (0.382)	0.04 (0.717)	-1.00 (1.738)	-1.34 (1.681)
Median	-0.83	-0.71	0.00	0.00	-0.43	-0.86
Min, Max	-10.0, 5.4	-7.3, 0.9	-0.9, 1.3	-1.4, 2.4	-5.4, 0.3	-5.6, 0.1
Change from Baseline to Cycle 11 Day 1						
n	18	18	18	18	18	18
Mean (StdDev)	-1.57 (3.296)	-1.49 (2.195)	0.03 (0.378)	0.10 (0.629)	-0.83 (1.866)	-1.11 (1.673)
95% CIs of Mean	(-3.21 - 0.07)	(-2.58 - -0.40)	(-0.16 - 0.22)	(-0.21 - 0.42)	(-1.76 - 0.09)	(-1.95 - -0.28)
p-value [1]	0.0588	0.0104*	0.7261	0.4959	0.0754	0.0117*
Median	-0.63	-0.69	0.00	0.00	-0.36	-0.85
Min, Max	-10.0, 5.4	-7.3, 0.7	-0.9, 1.3	-0.9, 2.4	-5.4, 2.4	-4.7, 1.9
Change from Baseline to Cycle 12 Day 1						
n	16	16	16	16	16	16
Mean (StdDev)	-1.76 (3.598)	-1.51 (2.226)	0.03 (0.401)	0.09 (0.664)	-1.21 (1.895)	-1.66 (1.996)
Median	-0.63	-0.69	0.00	0.00	-0.54	-0.92
Min, Max	-10.0, 5.4	-7.3, 0.0	-0.9, 1.3	-0.9, 2.4	-5.4, 0.1	-7.0, 0.1

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Scores	TSS (N=42)	Skin Domain (N=42)	GI Domain (N=42)	Q6 Fatigue (N=42)
Change from Baseline to Cycle 13 Day 1				
n	13	13	13	13
Mean (StdDev)	-6.37 (10.815)	-2.10 (6.563)	-3.12 (3.735)	-1.15 (2.308)
Median	-2.43	0.00	-3.14	-0.43
Min, Max	-35.7, 7.0	-22.1, 3.4	-10.0, 4.1	-4.6, 2.4
Change from Baseline to Cycle 14 Day 1				
n	13	13	13	13
Mean (StdDev)	-6.24 (11.086)	-2.13 (6.805)	-2.94 (3.491)	-1.17 (2.337)
Median	-1.86	0.00	-3.14	-0.43
Min, Max	-38.0, 7.0	-23.0, 3.4	-10.0, 4.1	-5.0, 2.4
Change from Baseline to Cycle 15 Day 1				
n	12	12	12	12
Mean (StdDev)	-5.81 (11.918)	-1.75 (7.084)	-2.80 (3.623)	-1.26 (2.804)
Median	-2.00	0.00	-2.74	-0.34
Min, Max	-39.6, 7.0	-22.6, 4.0	-10.0, 4.1	-7.0, 2.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Scores	Q3 Spots (N=42)	Q4 Itching (N=42)	Q5 Flushing (N=42)
Change from Baseline to Cycle 13 Day 1			
n	13	13	13
Mean (StdDev)	-0.25 (2.335)	-0.86 (2.955)	-1.00 (1.600)
Median	0.00	-0.14	-0.29
Min, Max	-6.8, 2.9	-10.0, 2.0	-5.2, 0.4
Change from Baseline to Cycle 14 Day 1			
n	13	13	13
Mean (StdDev)	-0.30 (2.477)	-0.94 (3.000)	-0.89 (1.612)
Median	0.00	-0.14	-0.14
Min, Max	-7.4, 2.9	-10.0, 2.0	-5.6, 0.4
Change from Baseline to Cycle 15 Day 1			
n	12	12	12
Mean (StdDev)	-0.20 (2.542)	-0.68 (3.131)	-0.87 (1.689)
Median	0.00	-0.07	0.00
Min, Max	-7.0, 2.9	-10.0, 2.0	-5.6, 0.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Scores	Q1 Abdominal Pain (N=42)	Q2 Nausea (N=42)	Q7 Vomitting Count (N=42)	Q8 Vomitting Severity (N=42)	Q9 Diarrhea Count (N=42)	Q10 Diarrhea Severity (N=42)
Change from Baseline to Cycle 13 Day 1						
n	13	13	13	13	13	13
Mean (StdDev)	-1.00 (3.433)	-0.85 (1.280)	0.04 (0.446)	0.13 (0.732)	-1.05 (1.670)	-1.39 (1.556)
Median	-0.29	-0.67	0.00	0.00	-0.50	-0.86
Min, Max	-10.0, 5.4	-4.1, 0.6	-0.9, 1.3	-0.9, 2.4	-5.4, 0.1	-4.7, 0.1
Change from Baseline to Cycle 14 Day 1						
n	13	13	13	13	13	13
Mean (StdDev)	-0.93 (3.334)	-0.85 (1.242)	0.04 (0.446)	0.13 (0.732)	-1.01 (1.679)	-1.29 (1.499)
Median	-0.29	-0.43	0.00	0.00	-0.43	-0.86
Min, Max	-10.0, 5.4	-4.1, 0.0	-0.9, 1.3	-0.9, 2.4	-5.4, 0.1	-4.7, 0.1
Change from Baseline to Cycle 15 Day 1						
n	12	12	12	12	12	12
Mean (StdDev)	-0.80 (3.398)	-0.90 (1.289)	0.05 (0.465)	0.14 (0.763)	-1.05 (1.748)	-1.25 (1.573)
Median	-0.36	-0.33	0.00	0.00	-0.39	-0.77
Min, Max	-10.0, 5.4	-4.1, 0.0	-0.9, 1.3	-0.9, 2.4	-5.4, 0.1	-4.7, 0.1

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Scores	TSS (N=42)	Skin Domain (N=42)	GI Domain (N=42)	Q6 Fatigue (N=42)
Change from Baseline to Cycle 16 Day 1				
n	12	12	12	12
Mean (StdDev)	-6.13 (11.950)	-2.09 (7.449)	-2.85 (3.636)	-1.19 (2.678)
Median	-2.00	0.00	-2.74	-0.13
Min, Max	-39.7, 7.0	-24.4, 3.4	-10.0, 4.1	-5.3, 2.4
Change from Baseline to Cycle 17 Day 1				
n	12	12	12	12
Mean (StdDev)	-6.27 (12.009)	-2.06 (7.516)	-2.90 (3.680)	-1.32 (2.768)
Median	-2.00	0.00	-2.74	-0.34
Min, Max	-39.6, 7.0	-24.6, 3.4	-10.0, 4.1	-5.7, 2.4
Change from Baseline to Cycle 18 Day 1				
n	11	11	11	11
Mean (StdDev)	-5.45 (12.241)	-1.93 (7.855)	-2.59 (3.694)	-0.93 (2.537)
Median	-1.00	0.00	-2.33	-0.25
Min, Max	-39.4, 7.0	-24.4, 3.4	-10.0, 4.1	-5.1, 2.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Scores	Q3 Spots (N=42)	Q4 Itching (N=42)	Q5 Flushing (N=42)
Change from Baseline to Cycle 16 Day 1			
n	12	12	12
Mean (StdDev)	-0.36 (2.730)	-0.77 (3.066)	-0.96 (1.899)
Median	0.00	-0.07	-0.14
Min, Max	-8.0, 2.9	-10.0, 2.0	-6.4, 0.4
Change from Baseline to Cycle 17 Day 1			
n	12	12	12
Mean (StdDev)	-0.36 (2.730)	-0.72 (3.100)	-0.97 (1.936)
Median	0.00	-0.07	-0.14
Min, Max	-8.0, 2.9	-10.0, 2.0	-6.6, 0.4
Change from Baseline to Cycle 18 Day 1			
n	11	11	11
Mean (StdDev)	-0.41 (2.854)	-0.63 (3.247)	-0.89 (2.010)
Median	0.00	0.00	0.00
Min, Max	-8.0, 2.9	-9.8, 2.1	-6.6, 0.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Scores	Q1 Abdominal Pain (N=42)	Q2 Nausea (N=42)	Q7 Vomitting Count (N=42)	Q8 Vomitting Severity (N=42)	Q9 Diarrhea Count (N=42)	Q10 Diarrhea Severity (N=42)
Change from Baseline to Cycle 16 Day 1						
n	12	12	12	12	12	12
Mean (StdDev)	-0.82 (3.399)	-0.90 (1.289)	0.07 (0.470)	0.14 (0.763)	-1.07 (1.743)	-1.27 (1.564)
Median	-0.36	-0.33	0.00	0.00	-0.46	-0.85
Min, Max	-10.0, 5.4	-4.1, 0.0	-0.9, 1.3	-0.9, 2.4	-5.4, 0.1	-4.7, 0.1
Change from Baseline to Cycle 17 Day 1						
n	12	12	12	12	12	12
Mean (StdDev)	-0.87 (3.405)	-0.90 (1.289)	0.05 (0.465)	0.14 (0.763)	-1.07 (1.743)	-1.27 (1.564)
Median	-0.36	-0.33	0.00	0.00	-0.46	-0.85
Min, Max	-10.0, 5.4	-4.1, 0.0	-0.9, 1.3	-0.9, 2.4	-5.4, 0.1	-4.7, 0.1
Change from Baseline to Cycle 18 Day 1						
n	11	11	11	11	11	11
Mean (StdDev)	-0.80 (3.564)	-0.98 (1.319)	0.05 (0.488)	0.16 (0.799)	-0.67 (1.124)	-0.96 (1.182)
Median	-0.29	-0.67	0.00	0.00	-0.43	-0.83
Min, Max	-10.0, 5.4	-4.1, 0.0	-0.9, 1.3	-0.9, 2.4	-3.9, 0.1	-3.9, 0.1

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg				
Scores	TSS (N=40)	Skin Domain (N=40)	GI Domain (N=40)	Q6 Fatigue (N=40)
Baseline (C1D-7 to C1D-1)				
n	36	36	36	36
Mean (StdDev)	19.09 (13.591)	7.53 (7.857)	6.18 (5.847)	5.38 (3.066)
Median	18.13	5.07	5.14	6.21
Min, Max	0.0, 53.7	0.0, 28.6	0.0, 21.7	0.0, 10.0
Change from Baseline to Cycle 2 Day 1				
n	36	36	36	36
Mean (StdDev)	-6.42 (9.109)	-3.16 (4.911)	-2.57 (4.981)	-0.69 (1.911)
Median	-5.07	-1.56	-1.50	-0.36
Min, Max	-30.1, 10.7	-23.1, 2.0	-16.9, 6.4	-8.3, 2.3
Change from Baseline to Cycle 3 Day 1				
n	34	34	34	34
Mean (StdDev)	-7.60 (10.872)	-3.38 (6.115)	-3.43 (4.797)	-0.79 (2.512)
95% CIs of Mean	(-11.39 - -3.81)	(-5.51 - -1.25)	(-5.11 - -1.76)	(-1.66 - 0.09)
p-value [1]	<0.001***	0.0029**	<0.001***	0.0770
Median	-6.56	-2.50	-2.71	-0.71
Min, Max	-32.9, 21.7	-21.6, 10.0	-13.0, 5.3	-7.6, 6.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg			
Scores	Q3 Spots (N=40)	Q4 Itching (N=40)	Q5 Flushing (N=40)
Baseline (C1D-7 to C1D-1)			
n	36	36	36
Mean (StdDev)	2.59 (3.013)	2.52 (2.985)	2.42 (2.623)
Median	1.71	1.00	1.43
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 8.6
Change from Baseline to Cycle 2 Day 1			
n	36	36	36
Mean (StdDev)	-0.66 (1.358)	-1.29 (2.269)	-1.21 (2.096)
Median	0.00	-0.29	-0.50
Min, Max	-5.3, 1.6	-10.0, 1.0	-7.9, 1.7
Change from Baseline to Cycle 3 Day 1			
n	34	34	34
Mean (StdDev)	-0.76 (2.199)	-1.29 (2.822)	-1.32 (2.310)
95% CIs of Mean	(-1.53 - 0.00)	(-2.28 - -0.31)	(-2.13 - -0.52)
p-value [1]	0.0507	0.0117*	0.0021**
Median	-0.36	-0.50	-0.64
Min, Max	-6.4, 5.0	-10.0, 4.6	-7.0, 4.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas
Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Scores	Q1 Abdominal Pain (N=40)	Q2 Nausea (N=40)	Q7 Vomitting Count (N=40)	Q8 Vomitting Severity (N=40)	Q9 Diarrhea Count (N=40)	Q10 Diarrhea Severity (N=40)
Baseline (C1D-7 to C1D-1)						
n	36	36	36	36	36	36
Mean (StdDev)	2.71 (2.893)	1.76 (2.257)	0.07 (0.192)	0.15 (0.407)	1.10 (1.757)	1.55 (2.017)
Median	1.79	0.76	0.00	0.00	0.36	0.77
Min, Max	0.0, 10.0	0.0, 7.3	0.0, 1.0	0.0, 1.7	0.0, 7.1	0.0, 7.1
Change from Baseline to Cycle 2 Day 1						
n	36	36	36	36	36	36
Mean (StdDev)	-1.05 (2.636)	-0.97 (1.637)	-0.01 (0.212)	-0.01 (0.544)	-0.32 (1.978)	-0.55 (1.977)
Median	-0.36	-0.50	0.00	0.00	0.00	0.00
Min, Max	-8.3, 5.6	-5.1, 1.4	-0.5, 1.0	-1.4, 2.7	-5.4, 6.1	-6.6, 2.9
Change from Baseline to Cycle 3 Day 1						
n	34	34	34	34	34	34
Mean (StdDev)	-1.48 (2.791)	-1.11 (1.845)	0.00 (0.262)	0.06 (0.664)	-0.69 (1.604)	-0.91 (1.628)
95% CIs of Mean	(-2.45 - -0.51)	(-1.75 - -0.46)	(-0.09 - 0.10)	(-0.17 - 0.29)	(-1.25 - -0.13)	(-1.48 - -0.34)
p-value [1]	0.0040**	0.0014**	0.9311	0.5893	0.0170*	0.0026**
Median	-0.85	-0.62	0.00	0.00	-0.21	-0.56
Min, Max	-10.0, 5.3	-6.9, 1.7	-0.7, 1.1	-1.4, 3.0	-5.4, 1.9	-4.7, 1.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg				
Scores	TSS (N=40)	Skin Domain (N=40)	GI Domain (N=40)	Q6 Fatigue (N=40)
Change from Baseline to Cycle 4 Day 1				
n	32	32	32	32
Mean (StdDev)	-7.47 (12.017)	-3.20 (6.793)	-3.48 (5.361)	-0.79 (2.636)
Median	-7.74	-1.70	-2.60	-0.45
Min, Max	-34.9, 21.6	-19.7, 13.4	-18.5, 6.9	-9.0, 4.1
Change from Baseline to Cycle 5 Day 1				
n	29	29	29	29
Mean (StdDev)	-9.17 (10.446)	-4.43 (5.990)	-3.34 (4.893)	-1.41 (2.777)
Median	-8.86	-2.71	-2.00	-0.86
Min, Max	-30.9, 12.4	-19.0, 2.7	-13.7, 6.6	-9.0, 5.3
Change from Baseline to Cycle 6 Day 1				
n	25	25	25	25
Mean (StdDev)	-7.66 (10.686)	-3.02 (6.133)	-3.73 (4.486)	-0.90 (3.174)
Median	-6.14	-1.57	-2.00	-0.29
Min, Max	-30.6, 12.6	-18.9, 7.6	-14.0, 3.4	-9.0, 7.9

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg			
Scores	Q3 Spots (N=40)	Q4 Itching (N=40)	Q5 Flushing (N=40)
Change from Baseline to Cycle 4 Day 1			
n	32	32	32
Mean (StdDev)	-0.80 (2.214)	-1.20 (3.129)	-1.19 (2.627)
Median	-0.14	-0.29	-0.64
Min, Max	-6.4, 3.6	-10.0, 7.6	-7.3, 3.0
Change from Baseline to Cycle 5 Day 1			
n	29	29	29
Mean (StdDev)	-1.10 (2.250)	-1.72 (2.895)	-1.60 (2.098)
Median	-0.40	-0.38	-1.45
Min, Max	-6.4, 3.6	-10.0, 2.0	-7.0, 2.1
Change from Baseline to Cycle 6 Day 1			
n	25	25	25
Mean (StdDev)	-0.52 (2.418)	-1.19 (2.837)	-1.31 (2.250)
Median	-0.14	-0.29	-0.57
Min, Max	-5.0, 6.9	-10.0, 2.0	-7.3, 1.6

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Scores	Q1 Abdominal Pain (N=40)	Q2 Nausea (N=40)	Q7 Vomitting Count (N=40)	Q8 Vomitting Severity (N=40)	Q9 Diarrhea Count (N=40)	Q10 Diarrhea Severity (N=40)
Change from Baseline to Cycle 4 Day 1						
n	32	32	32	32	32	32
Mean (StdDev)	-1.66 (2.833)	-1.13 (2.007)	0.08 (0.545)	0.15 (1.000)	-0.68 (1.678)	-0.84 (1.790)
Median	-0.63	-0.43	0.00	0.00	-0.32	-0.68
Min, Max	-9.6, 4.0	-7.3, 2.0	-0.9, 2.7	-1.4, 4.6	-5.4, 2.1	-5.2, 2.9
Change from Baseline to Cycle 5 Day 1						
n	29	29	29	29	29	29
Mean (StdDev)	-1.53 (2.647)	-1.29 (1.916)	0.06 (0.614)	0.06 (0.799)	-0.59 (1.727)	-0.58 (2.027)
Median	-0.71	-0.43	0.00	0.00	-0.29	-0.33
Min, Max	-10.0, 5.0	-6.6, 1.1	-0.9, 3.1	-1.4, 3.6	-5.0, 3.4	-4.3, 4.8
Change from Baseline to Cycle 6 Day 1						
n	25	25	25	25	25	25
Mean (StdDev)	-1.38 (2.764)	-1.43 (1.861)	0.03 (0.422)	0.03 (0.607)	-0.77 (1.433)	-0.95 (1.469)
Median	-0.83	-0.67	0.00	0.00	-0.43	-0.71
Min, Max	-10.0, 3.4	-6.1, 0.6	-0.9, 1.7	-1.4, 1.9	-5.4, 1.4	-4.7, 1.1

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg				
Scores	TSS (N=40)	Skin Domain (N=40)	GI Domain (N=40)	Q6 Fatigue (N=40)
Change from Baseline to Cycle 7 Day 1				
n	22	22	22	22
Mean (StdDev)	-9.14 (10.482)	-3.80 (5.965)	-3.93 (4.755)	-1.41 (2.733)
95% CIs of Mean	(-13.79 - -4.49)	(-6.44 - -1.15)	(-6.04 - -1.82)	(-2.63 - -0.20)
p-value [1]	<0.001***	0.0070**	<0.001***	0.0243*
Median	-6.85	-2.43	-2.17	-0.55
Min, Max	-31.4, 7.0	-18.6, 2.7	-14.4, 4.1	-9.0, 2.4
Change from Baseline to Cycle 8 Day 1				
n	23	23	23	23
Mean (StdDev)	-9.43 (10.464)	-3.67 (5.947)	-4.24 (4.884)	-1.52 (2.782)
Median	-7.83	-1.57	-2.33	-1.00
Min, Max	-34.6, 7.0	-18.6, 3.0	-17.3, 4.1	-9.0, 2.4
Change from Baseline to Cycle 9 Day 1				
n	20	20	20	20
Mean (StdDev)	-9.84 (10.909)	-3.75 (6.400)	-4.32 (5.100)	-1.78 (2.866)
Median	-8.13	-1.43	-3.43	-1.79
Min, Max	-32.6, 7.0	-18.6, 3.6	-15.3, 4.1	-9.0, 2.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg			
Scores	Q3 Spots (N=40)	Q4 Itching (N=40)	Q5 Flushing (N=40)
Change from Baseline to Cycle 7 Day 1			
n	22	22	22
Mean (StdDev)	-0.92 (1.981)	-1.33 (2.939)	-1.55 (2.221)
95% CIs of Mean	(-1.80 - -0.04)	(-2.63 - -0.03)	(-2.53 - -0.56)
p-value [1]	0.0409*	0.0458*	0.0037**
Median	-0.36	-0.21	-0.64
Min, Max	-5.0, 2.9	-10.0, 2.0	-7.3, 1.4
Change from Baseline to Cycle 8 Day 1			
n	23	23	23
Mean (StdDev)	-0.90 (1.981)	-1.24 (2.940)	-1.53 (2.121)
Median	0.00	-0.29	-0.71
Min, Max	-5.0, 2.9	-10.0, 2.0	-7.3, 1.1
Change from Baseline to Cycle 9 Day 1			
n	20	20	20
Mean (StdDev)	-0.80 (2.136)	-1.25 (3.141)	-1.69 (2.269)
Median	0.00	-0.07	-0.64
Min, Max	-5.0, 2.9	-10.0, 2.0	-7.3, 1.2

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Scores	Q1 Abdominal Pain (N=40)	Q2 Nausea (N=40)	Q7 Vomitting Count (N=40)	Q8 Vomitting Severity (N=40)	Q9 Diarrhea Count (N=40)	Q10 Diarrhea Severity (N=40)
Change from Baseline to Cycle 7 Day 1						
n	22	22	22	22	22	22
Mean (StdDev)	-1.37 (3.018)	-1.54 (2.094)	-0.07 (0.207)	-0.13 (0.351)	-0.90 (1.312)	-0.89 (1.194)
95% CIs of Mean	(-2.71 - -0.03)	(-2.47 - -0.61)	(-0.17 - 0.02)	(-0.28 - 0.03)	(-1.48 - -0.31)	(-1.42 - -0.36)
p-value [1]	0.0454*	0.0024**	0.1081	0.1072	0.0043**	0.0021**
Median	-0.36	-0.76	0.00	0.00	-0.43	-0.71
Min, Max	-10.0, 5.4	-7.3, 0.7	-0.9, 0.1	-1.4, 0.1	-3.9, 0.1	-3.9, 0.9
Change from Baseline to Cycle 8 Day 1						
n	23	23	23	23	23	23
Mean (StdDev)	-1.64 (3.000)	-1.61 (2.138)	-0.07 (0.202)	-0.17 (0.393)	-0.76 (1.718)	-0.83 (1.698)
Median	-0.71	-0.67	0.00	0.00	-0.29	-0.71
Min, Max	-10.0, 5.4	-7.3, 1.1	-0.9, 0.1	-1.4, 0.1	-4.9, 2.7	-4.6, 2.9
Change from Baseline to Cycle 9 Day 1						
n	20	20	20	20	20	20
Mean (StdDev)	-1.58 (3.149)	-1.68 (2.159)	-0.04 (0.246)	-0.08 (0.416)	-0.78 (1.879)	-0.98 (1.680)
Median	-0.63	-1.07	0.00	0.00	-0.39	-0.77
Min, Max	-10.0, 5.4	-7.3, 0.4	-0.9, 0.4	-1.4, 0.6	-5.4, 2.3	-4.7, 1.9

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg				
Scores	TSS (N=40)	Skin Domain (N=40)	GI Domain (N=40)	Q6 Fatigue (N=40)
Change from Baseline to Cycle 10 Day 1				
n	18	18	18	18
Mean (StdDev)	-9.22 (11.881)	-3.27 (6.499)	-4.50 (5.633)	-1.45 (2.808)
Median	-5.99	-0.76	-3.14	-0.34
Min, Max	-35.4, 7.0	-19.9, 3.4	-19.0, 4.1	-9.0, 2.4
Change from Baseline to Cycle 11 Day 1				
n	17	17	17	17
Mean (StdDev)	-8.83 (12.397)	-3.58 (6.957)	-3.92 (5.390)	-1.33 (2.768)
95% CIs of Mean	(-15.20 - -2.45)	(-7.15 - -0.00)	(-6.69 - -1.14)	(-2.76 - 0.09)
p-value [1]	0.0097**	0.0499*	0.0086**	0.0643
Median	-4.14	-1.29	-3.14	-0.25
Min, Max	-35.4, 7.0	-20.6, 3.4	-17.4, 4.1	-9.0, 2.4
Change from Baseline to Cycle 12 Day 1				
n	15	15	15	15
Mean (StdDev)	-8.47 (13.513)	-3.02 (7.415)	-4.69 (6.199)	-0.76 (2.043)
Median	-4.14	-0.57	-3.14	0.00
Min, Max	-39.7, 7.0	-22.4, 3.4	-21.7, 4.1	-4.0, 2.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg			
Scores	Q3 Spots (N=40)	Q4 Itching (N=40)	Q5 Flushing (N=40)
Change from Baseline to Cycle 10 Day 1			
n	18	18	18
Mean (StdDev)	-0.68 (2.187)	-1.08 (3.276)	-1.51 (2.101)
Median	0.00	-0.07	-0.57
Min, Max	-6.0, 2.9	-10.0, 2.3	-7.0, 0.4
Change from Baseline to Cycle 11 Day 1			
n	17	17	17
Mean (StdDev)	-0.75 (2.238)	-1.27 (3.262)	-1.55 (2.429)
95% CIs of Mean	(-1.90 - 0.40)	(-2.95 - 0.40)	(-2.80 - -0.30)
p-value [1]	0.1849	0.1271	0.0180*
Median	0.00	-0.14	-0.57
Min, Max	-6.0, 2.9	-10.0, 2.0	-7.3, 0.4
Change from Baseline to Cycle 12 Day 1			
n	15	15	15
Mean (StdDev)	-0.50 (2.281)	-1.24 (3.400)	-1.27 (2.212)
Median	0.00	-0.14	-0.57
Min, Max	-7.0, 2.9	-10.0, 2.0	-7.3, 0.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Scores	Q1 Abdominal Pain (N=40)	Q2 Nausea (N=40)	Q7 Vomitting Count (N=40)	Q8 Vomitting Severity (N=40)	Q9 Diarrhea Count (N=40)	Q10 Diarrhea Severity (N=40)
Change from Baseline to Cycle 10 Day 1						
n	18	18	18	18	18	18
Mean (StdDev)	-1.60 (3.336)	-1.64 (2.254)	0.01 (0.393)	0.04 (0.738)	-1.04 (1.781)	-1.30 (1.720)
Median	-0.63	-0.76	0.00	0.00	-0.46	-0.85
Min, Max	-10.0, 5.4	-7.3, 0.9	-0.9, 1.3	-1.4, 2.4	-5.4, 0.3	-5.6, 0.1
Change from Baseline to Cycle 11 Day 1						
n	17	17	17	17	17	17
Mean (StdDev)	-1.42 (3.328)	-1.54 (2.253)	0.03 (0.390)	0.11 (0.648)	-0.87 (1.917)	-1.07 (1.716)
95% CIs of Mean	(-3.13 - 0.29)	(-2.69 - -0.38)	(-0.17 - 0.23)	(-0.22 - 0.44)	(-1.85 - 0.12)	(-1.96 - -0.19)
p-value [1]	0.0982	0.0126*	0.7268	0.4969	0.0802	0.0202*
Median	-0.43	-0.67	0.00	0.00	-0.43	-0.83
Min, Max	-10.0, 5.4	-7.3, 0.7	-0.9, 1.3	-0.9, 2.4	-5.4, 2.4	-4.7, 1.9
Change from Baseline to Cycle 12 Day 1						
n	15	15	15	15	15	15
Mean (StdDev)	-1.62 (3.675)	-1.57 (2.294)	0.03 (0.415)	0.10 (0.687)	-1.24 (1.956)	-1.60 (2.053)
Median	-0.43	-0.67	0.00	0.00	-0.50	-0.83
Min, Max	-10.0, 5.4	-7.3, 0.0	-0.9, 1.3	-0.9, 2.4	-5.4, 0.1	-7.0, 0.1

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg				
Scores	TSS (N=40)	Skin Domain (N=40)	GI Domain (N=40)	Q6 Fatigue (N=40)
Change from Baseline to Cycle 13 Day 1				
n	12	12	12	12
Mean (StdDev)	-5.44 (10.743)	-1.90 (6.810)	-2.68 (3.544)	-0.86 (2.158)
Median	-1.71	0.00	-2.74	-0.34
Min, Max	-35.7, 7.0	-22.1, 3.4	-10.0, 4.1	-4.4, 2.4
Change from Baseline to Cycle 14 Day 1				
n	12	12	12	12
Mean (StdDev)	-5.64 (11.354)	-1.95 (7.075)	-2.75 (3.578)	-0.94 (2.274)
Median	-1.43	0.00	-2.74	-0.34
Min, Max	-38.0, 7.0	-23.0, 3.4	-10.0, 4.1	-5.0, 2.4
Change from Baseline to Cycle 15 Day 1				
n	12	12	12	12
Mean (StdDev)	-5.81 (11.918)	-1.75 (7.084)	-2.80 (3.623)	-1.26 (2.804)
Median	-2.00	0.00	-2.74	-0.34
Min, Max	-39.6, 7.0	-22.6, 4.0	-10.0, 4.1	-7.0, 2.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg			
Scores	Q3 Spots (N=40)	Q4 Itching (N=40)	Q5 Flushing (N=40)
Change from Baseline to Cycle 13 Day 1			
n	12	12	12
Mean (StdDev)	-0.27 (2.438)	-0.77 (3.066)	-0.86 (1.594)
Median	0.00	-0.07	-0.14
Min, Max	-6.8, 2.9	-10.0, 2.0	-5.2, 0.4
Change from Baseline to Cycle 14 Day 1			
n	12	12	12
Mean (StdDev)	-0.30 (2.587)	-0.77 (3.066)	-0.88 (1.683)
Median	0.00	-0.07	-0.07
Min, Max	-7.4, 2.9	-10.0, 2.0	-5.6, 0.4
Change from Baseline to Cycle 15 Day 1			
n	12	12	12
Mean (StdDev)	-0.20 (2.542)	-0.68 (3.131)	-0.87 (1.689)
Median	0.00	-0.07	0.00
Min, Max	-7.0, 2.9	-10.0, 2.0	-5.6, 0.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Scores	Q1 Abdominal Pain (N=40)	Q2 Nausea (N=40)	Q7 Vomitting Count (N=40)	Q8 Vomitting Severity (N=40)	Q9 Diarrhea Count (N=40)	Q10 Diarrhea Severity (N=40)
Change from Baseline to Cycle 13 Day 1						
n	12	12	12	12	12	12
Mean (StdDev)	-0.71 (3.413)	-0.84 (1.336)	0.05 (0.465)	0.14 (0.763)	-1.07 (1.743)	-1.27 (1.564)
Median	-0.14	-0.33	0.00	0.00	-0.46	-0.85
Min, Max	-10.0, 5.4	-4.1, 0.6	-0.9, 1.3	-0.9, 2.4	-5.4, 0.1	-4.7, 0.1
Change from Baseline to Cycle 14 Day 1						
n	12	12	12	12	12	12
Mean (StdDev)	-0.74 (3.406)	-0.89 (1.290)	0.05 (0.465)	0.14 (0.763)	-1.07 (1.743)	-1.27 (1.564)
Median	-0.14	-0.33	0.00	0.00	-0.46	-0.85
Min, Max	-10.0, 5.4	-4.1, 0.0	-0.9, 1.3	-0.9, 2.4	-5.4, 0.1	-4.7, 0.1
Change from Baseline to Cycle 15 Day 1						
n	12	12	12	12	12	12
Mean (StdDev)	-0.80 (3.398)	-0.90 (1.289)	0.05 (0.465)	0.14 (0.763)	-1.05 (1.748)	-1.25 (1.573)
Median	-0.36	-0.33	0.00	0.00	-0.39	-0.77
Min, Max	-10.0, 5.4	-4.1, 0.0	-0.9, 1.3	-0.9, 2.4	-5.4, 0.1	-4.7, 0.1

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg				
Scores	TSS (N=40)	Skin Domain (N=40)	GI Domain (N=40)	Q6 Fatigue (N=40)
Change from Baseline to Cycle 16 Day 1				
n	12	12	12	12
Mean (StdDev)	-6.13 (11.950)	-2.09 (7.449)	-2.85 (3.636)	-1.19 (2.678)
Median	-2.00	0.00	-2.74	-0.13
Min, Max	-39.7, 7.0	-24.4, 3.4	-10.0, 4.1	-5.3, 2.4
Change from Baseline to Cycle 17 Day 1				
n	12	12	12	12
Mean (StdDev)	-6.27 (12.009)	-2.06 (7.516)	-2.90 (3.680)	-1.32 (2.768)
Median	-2.00	0.00	-2.74	-0.34
Min, Max	-39.6, 7.0	-24.6, 3.4	-10.0, 4.1	-5.7, 2.4
Change from Baseline to Cycle 18 Day 1				
n	11	11	11	11
Mean (StdDev)	-5.45 (12.241)	-1.93 (7.855)	-2.59 (3.694)	-0.93 (2.537)
Median	-1.00	0.00	-2.33	-0.25
Min, Max	-39.4, 7.0	-24.4, 3.4	-10.0, 4.1	-5.1, 2.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg			
Scores	Q3 Spots (N=40)	Q4 Itching (N=40)	Q5 Flushing (N=40)
Change from Baseline to Cycle 16 Day 1			
n	12	12	12
Mean (StdDev)	-0.36 (2.730)	-0.77 (3.066)	-0.96 (1.899)
Median	0.00	-0.07	-0.14
Min, Max	-8.0, 2.9	-10.0, 2.0	-6.4, 0.4
Change from Baseline to Cycle 17 Day 1			
n	12	12	12
Mean (StdDev)	-0.36 (2.730)	-0.72 (3.100)	-0.97 (1.936)
Median	0.00	-0.07	-0.14
Min, Max	-8.0, 2.9	-10.0, 2.0	-6.6, 0.4
Change from Baseline to Cycle 18 Day 1			
n	11	11	11
Mean (StdDev)	-0.41 (2.854)	-0.63 (3.247)	-0.89 (2.010)
Median	0.00	0.00	0.00
Min, Max	-8.0, 2.9	-9.8, 2.1	-6.6, 0.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Scores	Q1 Abdominal Pain (N=40)	Q2 Nausea (N=40)	Q7 Vomitting Count (N=40)	Q8 Vomitting Severity (N=40)	Q9 Diarrhea Count (N=40)	Q10 Diarrhea Severity (N=40)
Change from Baseline to Cycle 16 Day 1						
n	12	12	12	12	12	12
Mean (StdDev)	-0.82 (3.399)	-0.90 (1.289)	0.07 (0.470)	0.14 (0.763)	-1.07 (1.743)	-1.27 (1.564)
Median	-0.36	-0.33	0.00	0.00	-0.46	-0.85
Min, Max	-10.0, 5.4	-4.1, 0.0	-0.9, 1.3	-0.9, 2.4	-5.4, 0.1	-4.7, 0.1
Change from Baseline to Cycle 17 Day 1						
n	12	12	12	12	12	12
Mean (StdDev)	-0.87 (3.405)	-0.90 (1.289)	0.05 (0.465)	0.14 (0.763)	-1.07 (1.743)	-1.27 (1.564)
Median	-0.36	-0.33	0.00	0.00	-0.46	-0.85
Min, Max	-10.0, 5.4	-4.1, 0.0	-0.9, 1.3	-0.9, 2.4	-5.4, 0.1	-4.7, 0.1
Change from Baseline to Cycle 18 Day 1						
n	11	11	11	11	11	11
Mean (StdDev)	-0.80 (3.564)	-0.98 (1.319)	0.05 (0.488)	0.16 (0.799)	-0.67 (1.124)	-0.96 (1.182)
Median	-0.29	-0.67	0.00	0.00	-0.43	-0.83
Min, Max	-10.0, 5.4	-4.1, 0.0	-0.9, 1.3	-0.9, 2.4	-3.9, 0.1	-3.9, 0.1

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Scores	TSS (N=69)	Skin Domain (N=69)	GI Domain (N=69)	Q6 Fatigue (N=69)
Baseline (C1D-7 to C1D-1)				
n	61	61	61	61
Mean (StdDev)	20.16 (13.369)	7.56 (6.936)	6.88 (6.358)	5.73 (2.936)
Median	18.86	6.60	5.86	6.29
Min, Max	0.0, 53.7	0.0, 28.6	0.0, 25.2	0.0, 10.0
Change from Baseline to Cycle 2 Day 1				
n	59	59	59	59
Mean (StdDev)	-6.63 (9.598)	-2.59 (5.437)	-3.21 (5.389)	-0.85 (1.728)
Median	-4.86	-1.60	-1.86	-0.57
Min, Max	-33.9, 11.3	-23.1, 12.9	-22.0, 6.4	-8.3, 2.3
Change from Baseline to Cycle 3 Day 1				
n	57	57	57	57
Mean (StdDev)	-7.47 (10.808)	-2.60 (6.208)	-3.85 (5.452)	-1.01 (2.277)
95% CIs of Mean	(-10.34 - -4.60)	(-4.25 - -0.95)	(-5.30 - -2.41)	(-1.62 - -0.41)
p-value [1]	<0.001***	0.0025**	<0.001***	0.0014**
Median	-5.76	-1.57	-2.86	-0.71
Min, Max	-41.9, 21.7	-21.6, 10.4	-24.5, 5.3	-7.6, 6.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Scores	Q3 Spots (N=69)	Q4 Itching (N=69)	Q5 Flushing (N=69)
Baseline (C1D-7 to C1D-1)			
n	61	61	61
Mean (StdDev)	2.75 (2.677)	2.50 (2.758)	2.33 (2.586)
Median	2.57	1.00	1.43
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 8.7
Change from Baseline to Cycle 2 Day 1			
n	59	59	59
Mean (StdDev)	-0.62 (1.743)	-1.11 (2.416)	-0.88 (2.436)
Median	-0.14	-0.29	-0.29
Min, Max	-5.3, 6.3	-10.0, 7.1	-7.9, 6.4
Change from Baseline to Cycle 3 Day 1			
n	57	57	57
Mean (StdDev)	-0.73 (2.103)	-0.99 (2.829)	-0.89 (2.717)
95% CIs of Mean	(-1.29 - -0.18)	(-1.74 - -0.24)	(-1.61 - -0.17)
p-value [1]	0.0108*	0.0105*	0.0169*
Median	-0.29	-0.14	-0.43
Min, Max	-6.4, 5.0	-10.0, 6.6	-7.0, 5.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Scores	Q1 Abdominal Pain (N=69)	Q2 Nausea (N=69)	Q7 Vomitting Count (N=69)	Q8 Vomitting Severity (N=69)	Q9 Diarrhea Count (N=69)	Q10 Diarrhea Severity (N=69)
Baseline (C1D-7 to C1D-1)						
n	61	61	61	61	61	61
Mean (StdDev)	2.95 (2.908)	1.86 (2.402)	0.30 (1.664)	0.24 (0.844)	3.80 (12.323)	1.81 (2.088)
Median	2.43	0.67	0.00	0.00	0.50	0.86
Min, Max	0.0, 10.0	0.0, 8.0	0.0, 12.9	0.0, 5.8	0.0, 85.7	0.0, 7.6
Change from Baseline to Cycle 2 Day 1						
n	59	59	59	59	59	59
Mean (StdDev)	-1.37 (2.463)	-0.89 (1.914)	0.21 (2.079)	-0.14 (0.924)	-2.15 (13.951)	-0.80 (2.076)
Median	-0.71	-0.29	0.00	0.00	-0.10	-0.20
Min, Max	-8.3, 5.6	-6.6, 3.9	-2.2, 15.7	-5.8, 2.7	-85.7, 42.9	-6.9, 2.9
Change from Baseline to Cycle 3 Day 1						
n	57	57	57	57	57	57
Mean (StdDev)	-1.67 (2.576)	-1.14 (1.935)	-0.26 (1.732)	-0.11 (0.965)	-3.06 (12.159)	-0.93 (1.886)
95% CIs of Mean	(-2.35 - -0.98)	(-1.66 - -0.63)	(-0.72 - 0.19)	(-0.36 - 0.15)	(-6.28 - 0.17)	(-1.43 - -0.43)
p-value [1]	<0.001***	<0.001***	0.2529	0.4067	0.0628	<0.001***
Median	-0.86	-0.57	0.00	0.00	-0.29	-0.43
Min, Max	-10.0, 5.3	-7.7, 1.7	-12.9, 1.1	-5.7, 3.0	-85.7, 5.0	-6.3, 2.9

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Scores	TSS (N=69)	Skin Domain (N=69)	GI Domain (N=69)	Q6 Fatigue (N=69)
Change from Baseline to Cycle 4 Day 1				
n	55	55	55	55
Mean (StdDev)	-7.41 (11.709)	-2.62 (6.378)	-3.92 (5.952)	-0.89 (2.342)
Median	-7.43	-1.29	-2.86	-0.57
Min, Max	-38.4, 21.6	-19.7, 13.4	-21.8, 10.0	-9.0, 4.1
Change from Baseline to Cycle 5 Day 1				
n	51	51	51	51
Mean (StdDev)	-9.25 (10.576)	-3.60 (6.131)	-4.21 (5.428)	-1.45 (2.478)
Median	-8.00	-2.40	-3.40	-1.43
Min, Max	-37.7, 12.4	-19.0, 8.0	-20.7, 6.6	-9.0, 5.3
Change from Baseline to Cycle 6 Day 1				
n	44	44	44	44
Mean (StdDev)	-8.79 (12.314)	-2.81 (6.748)	-4.76 (6.235)	-1.24 (2.812)
Median	-6.81	-1.64	-2.74	-1.07
Min, Max	-45.3, 12.7	-18.9, 9.6	-25.0, 5.0	-9.0, 7.9

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Scores	Q3 Spots (N=69)	Q4 Itching (N=69)	Q5 Flushing (N=69)
Change from Baseline to Cycle 4 Day 1			
n	55	55	55
Mean (StdDev)	-0.77 (2.132)	-0.98 (2.894)	-0.88 (2.963)
Median	-0.14	-0.14	-0.43
Min, Max	-6.4, 3.6	-10.0, 7.6	-7.3, 6.9
Change from Baseline to Cycle 5 Day 1			
n	51	51	51
Mean (StdDev)	-1.11 (2.212)	-1.35 (2.775)	-1.17 (2.726)
Median	-0.67	-0.29	-0.57
Min, Max	-6.4, 3.6	-10.0, 4.7	-7.0, 5.6
Change from Baseline to Cycle 6 Day 1			
n	44	44	44
Mean (StdDev)	-0.91 (2.528)	-0.84 (2.798)	-1.08 (3.023)
Median	-0.50	-0.14	-0.50
Min, Max	-6.0, 6.9	-10.0, 5.0	-8.3, 6.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Scores	Q1 Abdominal Pain (N=69)	Q2 Nausea (N=69)	Q7 Vomitting Count (N=69)	Q8 Vomitting Severity (N=69)	Q9 Diarrhea Count (N=69)	Q10 Diarrhea Severity (N=69)
Change from Baseline to Cycle 4 Day 1						
n	55	55	55	55	55	55
Mean (StdDev)	-1.87 (2.728)	-1.14 (2.229)	-0.21 (1.791)	0.00 (1.083)	-3.48 (13.001)	-0.90 (1.989)
Median	-1.14	-0.29	0.00	0.00	-0.36	-0.64
Min, Max	-9.6, 4.0	-7.6, 3.2	-12.7, 2.7	-4.8, 4.6	-85.7, 4.3	-6.4, 3.3
Change from Baseline to Cycle 5 Day 1						
n	51	51	51	51	51	51
Mean (StdDev)	-1.87 (2.469)	-1.31 (2.123)	-0.26 (1.882)	-0.10 (0.987)	-3.45 (12.783)	-0.92 (2.129)
Median	-1.00	-0.33	0.00	0.00	-0.43	-0.43
Min, Max	-10.0, 5.0	-6.9, 1.7	-12.9, 3.1	-5.0, 3.6	-85.7, 3.4	-6.6, 4.8
Change from Baseline to Cycle 6 Day 1						
n	44	44	44	44	44	44
Mean (StdDev)	-1.85 (2.796)	-1.59 (2.463)	-0.05 (0.460)	-0.19 (1.044)	-3.68 (14.681)	-1.13 (1.892)
Median	-0.93	-0.55	0.00	0.00	-0.46	-0.64
Min, Max	-10.0, 3.4	-8.0, 3.2	-2.2, 1.7	-5.8, 1.9	-85.7, 16.6	-6.7, 2.1

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Scores	TSS (N=69)	Skin Domain (N=69)	GI Domain (N=69)	Q6 Fatigue (N=69)
Change from Baseline to Cycle 7 Day 1				
n	39	40	40	40
Mean (StdDev)	-9.59 (12.680)	-2.95 (7.050)	-5.08 (6.196)	-1.54 (2.682)
95% CIs of Mean	(-13.70 - -5.48)	(-5.20 - -0.69)	(-7.06 - -3.09)	(-2.39 - -0.68)
p-value [1]	<0.001***	0.0117*	<0.001***	<0.001***
Median	-7.83	-1.79	-3.41	-1.14
Min, Max	-40.8, 15.7	-18.6, 10.1	-22.6, 5.9	-9.0, 4.3
Change from Baseline to Cycle 8 Day 1				
n	39	39	39	39
Mean (StdDev)	-10.27 (12.823)	-3.73 (6.582)	-4.87 (6.439)	-1.69 (2.786)
Median	-7.86	-2.86	-3.14	-1.57
Min, Max	-42.5, 19.1	-18.6, 9.9	-24.0, 10.9	-9.0, 4.0
Change from Baseline to Cycle 9 Day 1				
n	37	37	37	37
Mean (StdDev)	-10.81 (12.596)	-3.79 (6.525)	-5.17 (6.371)	-1.88 (2.789)
Median	-8.43	-2.83	-3.86	-1.71
Min, Max	-41.0, 18.0	-18.6, 7.0	-22.2, 9.6	-9.0, 2.9

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Scores	Q3 Spots (N=69)	Q4 Itching (N=69)	Q5 Flushing (N=69)
Change from Baseline to Cycle 7 Day 1			
n	40	40	40
Mean (StdDev)	-1.06 (2.334)	-0.82 (2.968)	-1.09 (3.162)
95% CIs of Mean	(-1.81 - -0.31)	(-1.76 - 0.13)	(-2.10 - -0.08)
p-value [1]	0.0065**	0.0903	0.0353*
Median	-0.43	-0.14	-0.57
Min, Max	-6.0, 3.0	-10.0, 5.9	-8.1, 7.4
Change from Baseline to Cycle 8 Day 1			
n	39	39	39
Mean (StdDev)	-1.27 (2.291)	-0.99 (2.939)	-1.50 (2.740)
Median	-0.71	-0.29	-1.14
Min, Max	-6.0, 2.9	-10.0, 5.4	-7.8, 6.9
Change from Baseline to Cycle 9 Day 1			
n	37	37	37
Mean (StdDev)	-1.19 (2.223)	-1.02 (2.878)	-1.60 (2.822)
Median	-0.43	-0.14	-0.71
Min, Max	-6.0, 3.0	-10.0, 4.5	-8.5, 6.1

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Scores	Q1 Abdominal Pain (N=69)	Q2 Nausea (N=69)	Q7 Vomitting Count (N=69)	Q8 Vomitting Severity (N=69)	Q9 Diarrhea Count (N=69)	Q10 Diarrhea Severity (N=69)
Change from Baseline to Cycle 7 Day 1						
n	40	40	40	40	40	40
Mean (StdDev)	-1.98 (2.789)	-1.63 (2.542)	-0.09 (0.324)	-0.23 (0.864)	-4.57 (14.979)	-1.21 (1.920)
95% CIs of Mean	(-2.87 - -1.09)	(-2.44 - -0.82)	(-0.20 - 0.01)	(-0.50 - 0.05)	(-9.36 - 0.22)	(-1.83 - -0.60)
p-value [1]	<0.001***	<0.001***	0.0777	0.1031	0.0611	<0.001***
Median	-1.29	-0.69	0.00	0.00	-0.46	-0.77
Min, Max	-10.0, 5.4	-7.4, 3.5	-1.8, 0.3	-4.6, 1.0	-85.7, 1.6	-6.9, 3.3
Change from Baseline to Cycle 8 Day 1						
n	39	39	39	39	39	39
Mean (StdDev)	-2.08 (2.877)	-1.56 (2.708)	0.53 (4.038)	-0.24 (0.997)	-3.28 (14.134)	-1.00 (2.059)
Median	-1.14	-0.57	0.00	0.00	-0.29	-0.71
Min, Max	-10.0, 5.4	-7.8, 5.3	-2.2, 25.0	-5.8, 1.3	-85.4, 13.2	-6.9, 3.0
Change from Baseline to Cycle 9 Day 1						
n	37	37	37	37	37	37
Mean (StdDev)	-2.19 (2.945)	-1.66 (2.707)	-0.07 (0.345)	-0.16 (0.912)	-4.71 (15.625)	-1.17 (2.014)
Median	-1.43	-0.86	0.00	0.00	-0.57	-0.71
Min, Max	-10.0, 5.4	-7.3, 5.1	-1.8, 0.4	-5.0, 1.3	-85.7, 2.3	-6.9, 2.9

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Scores	TSS (N=69)	Skin Domain (N=69)	GI Domain (N=69)	Q6 Fatigue (N=69)
Change from Baseline to Cycle 10 Day 1				
n	34	34	34	34
Mean (StdDev)	-9.69 (13.130)	-3.46 (6.813)	-4.71 (7.341)	-1.56 (2.773)
Median	-6.63	-1.64	-3.64	-1.00
Min, Max	-40.3, 14.8	-19.9, 8.2	-25.0, 15.6	-9.0, 3.2
Change from Baseline to Cycle 11 Day 1				
n	31	31	31	31
Mean (StdDev)	-10.26 (13.691)	-3.59 (7.215)	-5.28 (6.521)	-1.40 (2.974)
95% CIs of Mean	(-15.28 - -5.24)	(-6.23 - -0.94)	(-7.67 - -2.89)	(-2.49 - -0.31)
p-value [1]	<0.001***	0.0096**	<0.001***	0.0134*
Median	-5.14	-2.14	-4.43	-0.43
Min, Max	-37.2, 10.4	-20.6, 7.6	-23.7, 4.9	-9.0, 3.7
Change from Baseline to Cycle 12 Day 1				
n	28	28	28	28
Mean (StdDev)	-9.64 (15.565)	-2.71 (7.911)	-5.63 (6.960)	-1.31 (2.763)
Median	-4.71	-1.00	-4.07	-0.63
Min, Max	-40.0, 25.3	-22.4, 11.9	-22.2, 10.4	-7.7, 3.5

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Scores	Q3 Spots (N=69)	Q4 Itching (N=69)	Q5 Flushing (N=69)
Change from Baseline to Cycle 10 Day 1			
n	34	34	34
Mean (StdDev)	-1.17 (2.338)	-0.80 (3.055)	-1.52 (2.854)
Median	-0.21	-0.14	-0.64
Min, Max	-6.0, 3.0	-10.0, 4.5	-8.5, 6.6
Change from Baseline to Cycle 11 Day 1			
n	31	31	31
Mean (StdDev)	-1.25 (2.480)	-0.89 (2.950)	-1.45 (3.142)
95% CIs of Mean	(-2.16 - -0.34)	(-1.97 - 0.19)	(-2.60 - -0.30)
p-value [1]	0.0089**	0.1033	0.0155*
Median	-0.43	-0.29	-0.57
Min, Max	-6.0, 3.0	-10.0, 5.0	-7.3, 7.7
Change from Baseline to Cycle 12 Day 1			
n	28	28	28
Mean (StdDev)	-0.96 (2.620)	-0.56 (3.159)	-1.19 (3.319)
Median	-0.07	-0.14	-0.50
Min, Max	-7.0, 3.8	-10.0, 5.7	-7.9, 8.9

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Scores	Q1 Abdominal Pain (N=69)	Q2 Nausea (N=69)	Q7 Vomitting Count (N=69)	Q8 Vomitting Severity (N=69)	Q9 Diarrhea Count (N=69)	Q10 Diarrhea Severity (N=69)
Change from Baseline to Cycle 10 Day 1						
n	34	34	34	34	34	34
Mean (StdDev)	-1.77 (3.547)	-1.55 (2.807)	-0.06 (0.469)	-0.16 (1.141)	-4.95 (15.850)	-1.23 (2.158)
Median	-1.36	-0.69	0.00	0.00	-0.54	-0.86
Min, Max	-10.0, 8.9	-7.8, 4.6	-2.2, 1.3	-5.8, 2.4	-85.4, 4.6	-7.0, 3.5
Change from Baseline to Cycle 11 Day 1						
n	31	31	31	31	31	31
Mean (StdDev)	-1.86 (3.234)	-1.81 (2.647)	-0.06 (0.485)	-0.16 (1.163)	-4.18 (15.473)	-1.45 (1.989)
95% CIs of Mean	(-3.05 - -0.68)	(-2.78 - -0.84)	(-0.24 - 0.12)	(-0.58 - 0.27)	(-9.86 - 1.49)	(-2.18 - -0.72)
p-value [1]	0.0032**	<0.001***	0.4919	0.4611	0.1426	<0.001***
Median	-1.14	-0.67	0.00	0.00	-0.50	-1.00
Min, Max	-10.0, 5.4	-7.9, 1.7	-2.2, 1.3	-5.8, 2.4	-85.7, 2.4	-7.0, 1.9
Change from Baseline to Cycle 12 Day 1						
n	28	28	28	28	28	28
Mean (StdDev)	-2.13 (3.321)	-1.74 (2.751)	-0.02 (0.356)	-0.14 (1.019)	-4.76 (16.214)	-1.63 (2.305)
Median	-1.36	-0.62	0.00	0.00	-0.54	-1.00
Min, Max	-10.0, 5.4	-7.3, 3.5	-1.0, 1.3	-4.6, 2.4	-85.7, 1.0	-7.6, 3.3

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Scores	TSS (N=69)	Skin Domain (N=69)	GI Domain (N=69)	Q6 Fatigue (N=69)
Change from Baseline to Cycle 13 Day 1				
n	21	21	21	21
Mean (StdDev)	-7.74 (11.352)	-2.01 (6.503)	-4.32 (4.392)	-1.43 (2.668)
Median	-4.14	-1.14	-3.14	-1.14
Min, Max	-35.7, 7.5	-22.1, 8.0	-13.7, 4.1	-7.7, 3.3
Change from Baseline to Cycle 14 Day 1				
n	19	19	20	20
Mean (StdDev)	-6.65 (10.968)	-1.72 (7.030)	-3.12 (4.985)	-0.88 (2.637)
Median	-4.00	0.00	-3.14	-0.60
Min, Max	-38.0, 8.2	-23.0, 9.5	-10.0, 10.9	-6.0, 3.3
Change from Baseline to Cycle 15 Day 1				
n	15	15	15	15
Mean (StdDev)	-4.07 (11.996)	-0.38 (7.415)	-2.91 (3.805)	-0.78 (2.705)
Median	-1.00	0.00	-3.14	-0.14
Min, Max	-39.6, 15.1	-22.6, 10.4	-10.0, 4.1	-7.0, 2.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Scores	Q3 Spots (N=69)	Q4 Itching (N=69)	Q5 Flushing (N=69)
Change from Baseline to Cycle 13 Day 1			
n	21	21	21
Mean (StdDev)	-0.55 (2.421)	-0.52 (2.892)	-0.95 (1.944)
Median	0.00	-0.14	-0.40
Min, Max	-6.8, 3.0	-10.0, 5.5	-6.3, 1.8
Change from Baseline to Cycle 14 Day 1			
n	20	20	19
Mean (StdDev)	-0.39 (2.471)	-0.37 (3.117)	-0.90 (2.052)
Median	0.00	-0.07	-0.40
Min, Max	-7.4, 3.7	-10.0, 6.4	-5.6, 2.9
Change from Baseline to Cycle 15 Day 1			
n	15	15	15
Mean (StdDev)	-0.09 (2.431)	0.00 (3.305)	-0.27 (2.826)
Median	0.00	0.00	0.00
Min, Max	-7.0, 3.0	-10.0, 5.7	-5.6, 8.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Scores	Q1 Abdominal Pain (N=69)	Q2 Nausea (N=69)	Q7 Vomitting Count (N=69)	Q8 Vomitting Severity (N=69)	Q9 Diarrhea Count (N=69)	Q10 Diarrhea Severity (N=69)
Change from Baseline to Cycle 13 Day 1						
n	21	21	21	21	21	21
Mean (StdDev)	-1.67 (3.099)	-1.46 (2.165)	0.04 (0.362)	0.06 (0.599)	-5.73 (18.707)	-1.26 (1.745)
Median	-0.83	-0.71	0.00	0.00	-0.50	-0.86
Min, Max	-10.0, 5.4	-7.3, 0.6	-0.9, 1.3	-0.9, 2.4	-85.7, 2.2	-4.7, 2.7
Change from Baseline to Cycle 14 Day 1						
n	20	20	20	20	20	20
Mean (StdDev)	-1.34 (3.326)	-0.88 (2.334)	0.12 (0.527)	0.23 (0.929)	-1.57 (3.700)	-1.14 (1.436)
Median	-0.63	-0.55	0.00	0.00	-0.40	-0.85
Min, Max	-10.0, 5.4	-6.0, 6.0	-0.9, 1.8	-0.9, 3.3	-16.0, 1.2	-4.7, 1.0
Change from Baseline to Cycle 15 Day 1						
n	15	15	15	15	15	15
Mean (StdDev)	-1.08 (3.196)	-0.84 (1.499)	0.03 (0.415)	0.09 (0.693)	-0.88 (1.745)	-1.08 (1.614)
Median	-0.43	-0.67	0.00	0.00	-0.29	-0.71
Min, Max	-10.0, 5.4	-4.1, 2.3	-0.9, 1.3	-0.9, 2.4	-5.4, 1.4	-4.7, 1.1

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Scores	TSS (N=69)	Skin Domain (N=69)	GI Domain (N=69)	Q6 Fatigue (N=69)
Change from Baseline to Cycle 16 Day 1				
n	16	16	16	16
Mean (StdDev)	-3.47 (12.656)	-0.30 (7.821)	-2.57 (4.023)	-0.60 (2.628)
Median	-0.64	0.21	-2.74	0.00
Min, Max	-39.7, 20.1	-24.4, 12.9	-10.0, 5.4	-5.3, 3.2
Change from Baseline to Cycle 17 Day 1				
n	15	15	15	15
Mean (StdDev)	-5.12 (11.416)	-1.19 (7.231)	-3.17 (3.702)	-0.78 (2.760)
Median	-1.00	0.00	-3.14	0.00
Min, Max	-39.6, 7.2	-24.6, 7.5	-10.0, 4.1	-5.7, 3.2
Change from Baseline to Cycle 18 Day 1				
n	14	14	14	14
Mean (StdDev)	-3.12 (12.755)	-0.75 (7.670)	-2.06 (4.094)	-0.31 (2.614)
Median	-0.57	0.21	-2.17	0.00
Min, Max	-39.4, 16.2	-24.4, 9.8	-10.0, 4.2	-5.1, 3.3

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Scores	Q3 Spots (N=69)	Q4 Itching (N=69)	Q5 Flushing (N=69)
Change from Baseline to Cycle 16 Day 1			
n	16	16	16
Mean (StdDev)	-0.19 (2.526)	0.16 (3.353)	-0.26 (2.945)
Median	0.00	0.00	-0.14
Min, Max	-8.0, 3.2	-10.0, 5.5	-6.4, 8.6
Change from Baseline to Cycle 17 Day 1			
n	15	15	15
Mean (StdDev)	-0.15 (2.575)	-0.13 (3.177)	-0.91 (1.853)
Median	0.00	0.00	-0.29
Min, Max	-8.0, 2.9	-10.0, 5.1	-6.6, 1.0
Change from Baseline to Cycle 18 Day 1			
n	14	14	14
Mean (StdDev)	-0.43 (2.555)	-0.19 (3.028)	-0.13 (3.244)
Median	0.00	0.00	0.00
Min, Max	-8.0, 2.9	-9.8, 2.9	-6.6, 8.9

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Scores	Q1 Abdominal Pain (N=69)	Q2 Nausea (N=69)	Q7 Vomitting Count (N=69)	Q8 Vomitting Severity (N=69)	Q9 Diarrhea Count (N=69)	Q10 Diarrhea Severity (N=69)
Change from Baseline to Cycle 16 Day 1						
n	16	16	16	16	16	16
Mean (StdDev)	-1.14 (3.187)	-0.71 (1.483)	0.04 (0.406)	0.08 (0.670)	-0.78 (1.765)	-0.81 (1.910)
Median	-0.36	-0.33	0.00	0.00	-0.36	-0.77
Min, Max	-10.0, 5.4	-4.1, 2.8	-0.9, 1.3	-0.9, 2.4	-5.4, 2.0	-4.7, 2.8
Change from Baseline to Cycle 17 Day 1						
n	15	15	15	15	15	15
Mean (StdDev)	-1.22 (3.240)	-0.99 (1.288)	0.03 (0.415)	0.09 (0.693)	-0.88 (1.746)	-1.05 (1.662)
Median	-0.43	-0.67	0.00	0.00	-0.43	-0.83
Min, Max	-10.0, 5.4	-4.1, 0.2	-0.9, 1.3	-0.9, 2.4	-5.4, 1.3	-4.7, 1.4
Change from Baseline to Cycle 18 Day 1						
n	14	14	14	14	14	14
Mean (StdDev)	-0.81 (3.190)	-0.79 (1.320)	0.04 (0.428)	0.12 (0.704)	-0.52 (1.318)	-0.58 (1.743)
Median	-0.21	-0.33	0.00	0.00	-0.36	-0.77
Min, Max	-10.0, 5.4	-4.1, 1.2	-0.9, 1.3	-0.9, 2.4	-3.9, 1.9	-3.9, 3.2

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Scores	TSS (N=69)	Skin Domain (N=69)	GI Domain (N=69)	Q6 Fatigue (N=69)
Change from Baseline to Cycle 19 Day 1				
n	1	1	1	1
Mean (StdDev)	11.40 (-)	8.60 (-)	1.02 (-)	1.79 (-)
Median	11.40	8.60	1.02	1.79
Min, Max	11.4, 11.4	8.6, 8.6	1.0, 1.0	1.8, 1.8

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Scores	Q3 Spots (N=69)	Q4 Itching (N=69)	Q5 Flushing (N=69)
Change from Baseline to Cycle 19 Day 1			
n	1	1	1
Mean (StdDev)	-1.62 (-)	1.19 (-)	9.02 (-)
Median	-1.62	1.19	9.02
Min, Max	-1.6, -1.6	1.2, 1.2	9.0, 9.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Scores	Q1 Abdominal Pain (N=69)	Q2 Nausea (N=69)	Q7 Vomitting Count (N=69)	Q8 Vomitting Severity (N=69)	Q9 Diarrhea Count (N=69)	Q10 Diarrhea Severity (N=69)
Change from Baseline to Cycle 19 Day 1						
n	1	1	1	1	1	1
Mean (StdDev)	0.02 (-)	0.00 (-)	0.00 (-)	0.00 (-)	0.62 (-)	1.00 (-)
Median	0.02	0.00	0.00	0.00	0.62	1.00
Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.6, 0.6	1.0, 1.0

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg				
Scores	TSS (N=52)	Skin Domain (N=52)	GI Domain (N=52)	Q6 Fatigue (N=52)
Baseline (C1D-7 to C1D-1)				
n	47	47	47	47
Mean (StdDev)	20.06 (12.820)	7.99 (7.171)	6.51 (5.703)	5.56 (2.955)
Median	19.29	7.00	5.86	6.29
Min, Max	0.0, 53.7	0.0, 28.6	0.0, 21.7	0.0, 10.0
Change from Baseline to Cycle 2 Day 1				
n	45	45	45	45
Mean (StdDev)	-7.35 (9.328)	-3.40 (5.000)	-3.07 (5.072)	-0.87 (1.870)
Median	-5.26	-2.00	-2.00	-0.57
Min, Max	-30.1, 10.7	-23.1, 4.9	-16.9, 6.4	-8.3, 2.3
Change from Baseline to Cycle 3 Day 1				
n	43	43	43	43
Mean (StdDev)	-7.81 (10.335)	-3.23 (6.024)	-3.63 (4.949)	-0.94 (2.387)
95% CIs of Mean	(-10.99 - -4.62)	(-5.08 - -1.38)	(-5.16 - -2.11)	(-1.68 - -0.21)
p-value [1]	<0.001***	0.0011**	<0.001***	0.0130*
Median	-6.86	-2.57	-2.86	-0.71
Min, Max	-32.9, 21.7	-21.6, 10.0	-13.0, 5.3	-7.6, 6.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg			
Scores	Q3 Spots (N=52)	Q4 Itching (N=52)	Q5 Flushing (N=52)
Baseline (C1D-7 to C1D-1)			
n	47	47	47
Mean (StdDev)	2.80 (2.796)	2.79 (2.870)	2.40 (2.553)
Median	2.57	1.57	1.86
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 8.6
Change from Baseline to Cycle 2 Day 1			
n	45	45	45
Mean (StdDev)	-0.78 (1.500)	-1.46 (2.331)	-1.17 (2.146)
Median	-0.14	-0.71	-0.43
Min, Max	-5.3, 1.6	-10.0, 2.1	-7.9, 2.7
Change from Baseline to Cycle 3 Day 1			
n	43	43	43
Mean (StdDev)	-0.85 (2.078)	-1.29 (2.835)	-1.09 (2.611)
95% CIs of Mean	(-1.49 - -0.21)	(-2.16 - -0.41)	(-1.90 - -0.29)
p-value [1]	0.0104*	0.0048**	0.0088**
Median	-0.43	-0.43	-0.57
Min, Max	-6.4, 5.0	-10.0, 4.6	-7.0, 4.1

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Scores	Q1 Abdominal Pain (N=52)	Q2 Nausea (N=52)	Q7 Vomitting Count (N=52)	Q8 Vomitting Severity (N=52)	Q9 Diarrhea Count (N=52)	Q10 Diarrhea Severity (N=52)
Baseline (C1D-7 to C1D-1)						
n	47	47	47	47	47	47
Mean (StdDev)	2.89 (2.791)	1.69 (2.229)	0.06 (0.172)	0.13 (0.363)	1.31 (1.871)	1.81 (2.153)
Median	2.43	0.67	0.00	0.00	0.43	0.86
Min, Max	0.0, 10.0	0.0, 7.3	0.0, 1.0	0.0, 1.7	0.0, 7.1	0.0, 7.6
Change from Baseline to Cycle 2 Day 1						
n	45	45	45	45	45	45
Mean (StdDev)	-1.32 (2.558)	-0.88 (1.824)	-0.01 (0.191)	-0.01 (0.489)	-0.55 (2.113)	-0.87 (2.182)
Median	-0.60	-0.43	0.00	0.00	-0.10	-0.20
Min, Max	-8.3, 5.6	-5.6, 3.9	-0.5, 1.0	-1.4, 2.7	-5.4, 6.1	-6.9, 2.9
Change from Baseline to Cycle 3 Day 1						
n	43	43	43	43	43	43
Mean (StdDev)	-1.61 (2.701)	-1.05 (1.815)	0.00 (0.233)	0.05 (0.590)	-0.77 (1.772)	-1.02 (1.902)
95% CIs of Mean	(-2.44 - -0.77)	(-1.61 - -0.49)	(-0.07 - 0.08)	(-0.14 - 0.23)	(-1.31 - -0.22)	(-1.61 - -0.44)
p-value [1]	<0.001***	<0.001***	0.9050	0.6149	0.0069**	0.0010**
Median	-0.86	-0.57	0.00	0.00	-0.29	-0.57
Min, Max	-10.0, 5.3	-6.9, 1.7	-0.7, 1.1	-1.4, 3.0	-5.4, 2.6	-6.3, 2.9

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Scores	TSS (N=52)	Skin Domain (N=52)	GI Domain (N=52)	Q6 Fatigue (N=52)
Change from Baseline to Cycle 4 Day 1				
n	41	41	41	41
Mean (StdDev)	-8.00 (11.437)	-3.28 (6.407)	-3.83 (5.258)	-0.90 (2.554)
Median	-9.00	-1.82	-3.14	-0.57
Min, Max	-34.9, 21.6	-19.7, 13.4	-18.5, 6.9	-9.0, 4.1
Change from Baseline to Cycle 5 Day 1				
n	37	37	37	37
Mean (StdDev)	-9.92 (10.293)	-4.62 (5.885)	-3.81 (5.002)	-1.49 (2.691)
Median	-11.29	-2.86	-3.43	-1.17
Min, Max	-30.9, 12.4	-19.0, 4.7	-13.7, 6.6	-9.0, 5.3
Change from Baseline to Cycle 6 Day 1				
n	31	31	31	31
Mean (StdDev)	-8.88 (10.946)	-3.57 (6.192)	-4.15 (4.895)	-1.16 (3.029)
Median	-7.83	-2.86	-2.33	-0.57
Min, Max	-30.6, 12.6	-18.9, 7.6	-14.0, 3.4	-9.0, 7.9

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Scores	Q3 Spots (N=52)	Q4 Itching (N=52)	Q5 Flushing (N=52)
Change from Baseline to Cycle 4 Day 1			
n	41	41	41
Mean (StdDev)	-0.92 (2.185)	-1.26 (3.066)	-1.10 (2.657)
Median	-0.14	-0.29	-0.57
Min, Max	-6.4, 3.6	-10.0, 7.6	-7.3, 3.6
Change from Baseline to Cycle 5 Day 1			
n	37	37	37
Mean (StdDev)	-1.30 (2.299)	-1.80 (2.843)	-1.52 (2.254)
Median	-0.67	-0.67	-0.71
Min, Max	-6.4, 3.6	-10.0, 2.0	-7.0, 2.1
Change from Baseline to Cycle 6 Day 1			
n	31	31	31
Mean (StdDev)	-0.96 (2.588)	-1.25 (2.836)	-1.35 (2.287)
Median	-0.43	-0.29	-0.57
Min, Max	-6.0, 6.9	-10.0, 2.0	-7.3, 2.1

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Scores	Q1 Abdominal Pain (N=52)	Q2 Nausea (N=52)	Q7 Vomitting Count (N=52)	Q8 Vomitting Severity (N=52)	Q9 Diarrhea Count (N=52)	Q10 Diarrhea Severity (N=52)
Change from Baseline to Cycle 4 Day 1						
n	41	41	41	41	41	41
Mean (StdDev)	-1.86 (2.722)	-0.98 (1.940)	0.08 (0.491)	0.15 (0.892)	-0.89 (1.734)	-1.14 (1.943)
Median	-1.29	-0.29	0.00	0.00	-0.40	-0.71
Min, Max	-9.6, 4.0	-7.3, 2.0	-0.9, 2.7	-1.4, 4.6	-5.4, 2.1	-6.4, 2.9
Change from Baseline to Cycle 5 Day 1						
n	37	37	37	37	37	37
Mean (StdDev)	-1.78 (2.556)	-1.09 (1.928)	0.06 (0.546)	0.08 (0.720)	-0.83 (1.910)	-1.00 (2.341)
Median	-1.00	-0.33	0.00	0.00	-0.55	-0.71
Min, Max	-10.0, 5.0	-6.6, 1.7	-0.9, 3.1	-1.4, 3.6	-5.0, 3.4	-6.6, 4.8
Change from Baseline to Cycle 6 Day 1						
n	31	31	31	31	31	31
Mean (StdDev)	-1.62 (2.716)	-1.36 (2.035)	0.02 (0.377)	0.02 (0.543)	-0.94 (1.606)	-1.19 (1.837)
Median	-0.86	-0.43	0.00	0.00	-0.50	-0.71
Min, Max	-10.0, 3.4	-6.6, 1.7	-0.9, 1.7	-1.4, 1.9	-5.4, 1.4	-6.7, 1.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg				
Scores	TSS (N=52)	Skin Domain (N=52)	GI Domain (N=52)	Q6 Fatigue (N=52)
Change from Baseline to Cycle 7 Day 1				
n	28	28	28	28
Mean (StdDev)	-9.90 (11.089)	-3.92 (6.126)	-4.36 (5.114)	-1.62 (2.737)
95% CIs of Mean	(-14.20 - -5.60)	(-6.29 - -1.54)	(-6.34 - -2.37)	(-2.68 - -0.56)
p-value [1]	<0.001***	0.0022**	<0.001***	0.0041**
Median	-8.56	-2.43	-2.74	-1.00
Min, Max	-31.4, 7.0	-18.6, 6.0	-14.4, 4.1	-9.0, 2.4
Change from Baseline to Cycle 8 Day 1				
n	28	28	28	28
Mean (StdDev)	-10.96 (10.725)	-4.51 (5.838)	-4.54 (5.316)	-1.91 (2.758)
Median	-10.07	-3.00	-2.74	-1.71
Min, Max	-34.6, 7.0	-18.6, 3.0	-17.3, 4.1	-9.0, 2.4
Change from Baseline to Cycle 9 Day 1				
n	26	26	26	26
Mean (StdDev)	-11.22 (10.865)	-4.32 (6.155)	-4.89 (5.328)	-2.01 (2.763)
Median	-10.00	-3.00	-3.79	-1.93
Min, Max	-32.6, 7.0	-18.6, 3.6	-15.3, 4.1	-9.0, 2.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg			
Scores	Q3 Spots (N=52)	Q4 Itching (N=52)	Q5 Flushing (N=52)
Change from Baseline to Cycle 7 Day 1			
n	28	28	28
Mean (StdDev)	-1.20 (2.259)	-1.27 (2.916)	-1.44 (2.349)
95% CIs of Mean	(-2.08 - -0.33)	(-2.40 - -0.14)	(-2.35 - -0.53)
p-value [1]	0.0089**	0.0287*	0.0031**
Median	-0.43	-0.36	-0.64
Min, Max	-6.0, 2.9	-10.0, 2.0	-7.3, 2.2
Change from Baseline to Cycle 8 Day 1			
n	28	28	28
Mean (StdDev)	-1.42 (2.214)	-1.44 (2.907)	-1.66 (2.146)
Median	-0.64	-0.46	-1.18
Min, Max	-6.0, 2.9	-10.0, 2.0	-7.3, 1.1
Change from Baseline to Cycle 9 Day 1			
n	26	26	26
Mean (StdDev)	-1.25 (2.295)	-1.39 (3.027)	-1.68 (2.329)
Median	-0.21	-0.21	-0.86
Min, Max	-6.0, 2.9	-10.0, 2.0	-7.3, 1.6

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas
Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Scores	Q1 Abdominal Pain (N=52)	Q2 Nausea (N=52)	Q7 Vomitting Count (N=52)	Q8 Vomitting Severity (N=52)	Q9 Diarrhea Count (N=52)	Q10 Diarrhea Severity (N=52)
Change from Baseline to Cycle 7 Day 1						
n	28	28	28	28	28	28
Mean (StdDev)	-1.68 (2.862)	-1.41 (2.182)	-0.06 (0.185)	-0.10 (0.314)	-1.09 (1.577)	-1.16 (1.878)
95% CIs of Mean	(-2.79 - -0.57)	(-2.26 - -0.57)	(-0.13 - 0.01)	(-0.22 - 0.02)	(-1.70 - -0.48)	(-1.89 - -0.44)
p-value [1]	0.0044**	0.0020**	0.1079	0.1070	0.0011**	0.0029**
Median	-0.92	-0.55	0.00	0.00	-0.46	-0.85
Min, Max	-10.0, 5.4	-7.3, 1.3	-0.9, 0.1	-1.4, 0.1	-4.6, 1.6	-6.9, 3.3
Change from Baseline to Cycle 8 Day 1						
n	28	28	28	28	28	28
Mean (StdDev)	-1.86 (2.920)	-1.46 (2.284)	-0.06 (0.185)	-0.14 (0.361)	-0.90 (1.905)	-1.08 (2.145)
Median	-0.92	-0.50	0.00	0.00	-0.44	-0.77
Min, Max	-10.0, 5.4	-7.3, 2.1	-0.9, 0.1	-1.4, 0.1	-4.9, 2.7	-6.9, 3.0
Change from Baseline to Cycle 9 Day 1						
n	26	26	26	26	26	26
Mean (StdDev)	-1.86 (2.961)	-1.57 (2.350)	-0.03 (0.215)	-0.06 (0.364)	-1.09 (1.930)	-1.40 (2.019)
Median	-1.21	-0.76	0.00	0.00	-0.57	-0.92
Min, Max	-10.0, 5.4	-7.3, 1.6	-0.9, 0.4	-1.4, 0.6	-5.4, 2.3	-6.9, 1.9

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg				
Scores	TSS (N=52)	Skin Domain (N=52)	GI Domain (N=52)	Q6 Fatigue (N=52)
Change from Baseline to Cycle 10 Day 1				
n	24	24	24	24
Mean (StdDev)	-10.17 (12.316)	-4.13 (6.377)	-4.35 (6.932)	-1.70 (2.871)
Median	-8.13	-2.21	-3.64	-0.93
Min, Max	-35.4, 8.7	-19.9, 3.4	-19.0, 15.6	-9.0, 2.4
Change from Baseline to Cycle 11 Day 1				
n	22	22	22	22
Mean (StdDev)	-10.34 (12.793)	-4.13 (6.778)	-4.61 (5.868)	-1.60 (2.972)
95% CIs of Mean	(-16.01 - -4.67)	(-7.13 - -1.12)	(-7.21 - -2.01)	(-2.91 - -0.28)
p-value [1]	0.0011**	0.0094**	0.0014**	0.0200*
Median	-5.99	-2.21	-3.79	-0.34
Min, Max	-35.4, 7.0	-20.6, 4.4	-17.4, 4.9	-9.0, 2.4
Change from Baseline to Cycle 12 Day 1				
n	19	19	19	19
Mean (StdDev)	-10.47 (14.074)	-3.37 (7.331)	-5.70 (6.137)	-1.40 (2.652)
Median	-4.14	-1.29	-4.00	-0.25
Min, Max	-39.7, 7.0	-22.4, 5.7	-21.7, 4.1	-7.7, 2.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg			
Scores	Q3 Spots (N=52)	Q4 Itching (N=52)	Q5 Flushing (N=52)
Change from Baseline to Cycle 10 Day 1			
n	24	24	24
Mean (StdDev)	-1.25 (2.402)	-1.30 (3.149)	-1.58 (2.229)
Median	-0.21	-0.29	-0.64
Min, Max	-6.0, 2.9	-10.0, 2.3	-7.0, 1.7
Change from Baseline to Cycle 11 Day 1			
n	22	22	22
Mean (StdDev)	-1.28 (2.540)	-1.24 (2.977)	-1.61 (2.555)
95% CIs of Mean	(-2.41 - -0.16)	(-2.56 - 0.08)	(-2.74 - -0.48)
p-value [1]	0.0276*	0.0648	0.0075**
Median	-0.43	-0.36	-0.57
Min, Max	-6.0, 2.9	-10.0, 2.0	-7.3, 2.3
Change from Baseline to Cycle 12 Day 1			
n	19	19	19
Mean (StdDev)	-0.94 (2.577)	-1.06 (3.085)	-1.38 (2.503)
Median	0.00	-0.14	-0.57
Min, Max	-7.0, 2.9	-10.0, 2.0	-7.3, 2.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Scores	Q1 Abdominal Pain (N=52)	Q2 Nausea (N=52)	Q7 Vomitting Count (N=52)	Q8 Vomitting Severity (N=52)	Q9 Diarrhea Count (N=52)	Q10 Diarrhea Severity (N=52)
Change from Baseline to Cycle 10 Day 1						
n	24	24	24	24	24	24
Mean (StdDev)	-1.48 (3.756)	-1.32 (2.703)	0.01 (0.339)	0.05 (0.640)	-1.09 (2.162)	-1.59 (2.072)
Median	-1.21	-0.54	0.00	0.00	-0.54	-0.93
Min, Max	-10.0, 8.9	-7.3, 4.6	-0.9, 1.3	-1.4, 2.4	-5.4, 4.6	-7.0, 1.7
Change from Baseline to Cycle 11 Day 1						
n	22	22	22	22	22	22
Mean (StdDev)	-1.56 (3.410)	-1.58 (2.377)	0.03 (0.340)	0.08 (0.567)	-1.16 (2.002)	-1.56 (2.101)
95% CIs of Mean	(-3.07 - -0.05)	(-2.63 - -0.52)	(-0.12 - 0.18)	(-0.17 - 0.34)	(-2.05 - -0.27)	(-2.49 - -0.63)
p-value [1]	0.0437*	0.0053**	0.7240	0.4930	0.0128*	0.0022**
Median	-0.85	-0.62	0.00	0.00	-0.46	-0.93
Min, Max	-10.0, 5.4	-7.3, 0.7	-0.9, 1.3	-0.9, 2.4	-5.4, 2.4	-7.0, 1.9
Change from Baseline to Cycle 12 Day 1						
n	19	19	19	19	19	19
Mean (StdDev)	-2.00 (3.418)	-1.67 (2.396)	0.02 (0.367)	0.08 (0.607)	-1.59 (2.067)	-2.11 (2.323)
Median	-1.29	-0.67	0.00	0.00	-0.57	-1.29
Min, Max	-10.0, 5.4	-7.3, 0.0	-0.9, 1.3	-0.9, 2.4	-5.4, 0.1	-7.6, 0.1

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg				
Scores	TSS (N=52)	Skin Domain (N=52)	GI Domain (N=52)	Q6 Fatigue (N=52)
Change from Baseline to Cycle 13 Day 1				
n	14	14	14	14
Mean (StdDev)	-7.50 (11.228)	-2.31 (6.353)	-3.87 (4.572)	-1.32 (2.310)
Median	-3.29	-0.64	-3.14	-0.57
Min, Max	-35.7, 7.0	-22.1, 3.4	-13.7, 4.1	-4.6, 2.4
Change from Baseline to Cycle 14 Day 1				
n	13	13	13	13
Mean (StdDev)	-6.24 (11.086)	-2.13 (6.805)	-2.94 (3.491)	-1.17 (2.337)
Median	-1.86	0.00	-3.14	-0.43
Min, Max	-38.0, 7.0	-23.0, 3.4	-10.0, 4.1	-5.0, 2.4
Change from Baseline to Cycle 15 Day 1				
n	12	12	12	12
Mean (StdDev)	-5.81 (11.918)	-1.75 (7.084)	-2.80 (3.623)	-1.26 (2.804)
Median	-2.00	0.00	-2.74	-0.34
Min, Max	-39.6, 7.0	-22.6, 4.0	-10.0, 4.1	-7.0, 2.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg			
Scores	Q3 Spots (N=52)	Q4 Itching (N=52)	Q5 Flushing (N=52)
Change from Baseline to Cycle 13 Day 1			
n	14	14	14
Mean (StdDev)	-0.53 (2.490)	-0.83 (2.842)	-0.95 (1.549)
Median	0.00	-0.21	-0.29
Min, Max	-6.8, 2.9	-10.0, 2.0	-5.2, 0.4
Change from Baseline to Cycle 14 Day 1			
n	13	13	13
Mean (StdDev)	-0.30 (2.477)	-0.94 (3.000)	-0.89 (1.612)
Median	0.00	-0.14	-0.14
Min, Max	-7.4, 2.9	-10.0, 2.0	-5.6, 0.4
Change from Baseline to Cycle 15 Day 1			
n	12	12	12
Mean (StdDev)	-0.20 (2.542)	-0.68 (3.131)	-0.87 (1.689)
Median	0.00	-0.07	0.00
Min, Max	-7.0, 2.9	-10.0, 2.0	-5.6, 0.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Scores	Q1 Abdominal Pain (N=52)	Q2 Nausea (N=52)	Q7 Vomitting Count (N=52)	Q8 Vomitting Severity (N=52)	Q9 Diarrhea Count (N=52)	Q10 Diarrhea Severity (N=52)
Change from Baseline to Cycle 13 Day 1						
n	14	14	14	14	14	14
Mean (StdDev)	-1.14 (3.336)	-1.28 (2.021)	0.04 (0.428)	0.12 (0.704)	-1.28 (1.823)	-1.58 (1.650)
Median	-0.36	-0.69	0.00	0.00	-0.54	-0.93
Min, Max	-10.0, 5.4	-6.9, 0.6	-0.9, 1.3	-0.9, 2.4	-5.4, 0.1	-4.7, 0.1
Change from Baseline to Cycle 14 Day 1						
n	13	13	13	13	13	13
Mean (StdDev)	-0.93 (3.334)	-0.85 (1.242)	0.04 (0.446)	0.13 (0.732)	-1.01 (1.679)	-1.29 (1.499)
Median	-0.29	-0.43	0.00	0.00	-0.43	-0.86
Min, Max	-10.0, 5.4	-4.1, 0.0	-0.9, 1.3	-0.9, 2.4	-5.4, 0.1	-4.7, 0.1
Change from Baseline to Cycle 15 Day 1						
n	12	12	12	12	12	12
Mean (StdDev)	-0.80 (3.398)	-0.90 (1.289)	0.05 (0.465)	0.14 (0.763)	-1.05 (1.748)	-1.25 (1.573)
Median	-0.36	-0.33	0.00	0.00	-0.39	-0.77
Min, Max	-10.0, 5.4	-4.1, 0.0	-0.9, 1.3	-0.9, 2.4	-5.4, 0.1	-4.7, 0.1

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg				
Scores	TSS (N=52)	Skin Domain (N=52)	GI Domain (N=52)	Q6 Fatigue (N=52)
Change from Baseline to Cycle 16 Day 1				
n	12	12	12	12
Mean (StdDev)	-6.13 (11.950)	-2.09 (7.449)	-2.85 (3.636)	-1.19 (2.678)
Median	-2.00	0.00	-2.74	-0.13
Min, Max	-39.7, 7.0	-24.4, 3.4	-10.0, 4.1	-5.3, 2.4
Change from Baseline to Cycle 17 Day 1				
n	12	12	12	12
Mean (StdDev)	-6.27 (12.009)	-2.06 (7.516)	-2.90 (3.680)	-1.32 (2.768)
Median	-2.00	0.00	-2.74	-0.34
Min, Max	-39.6, 7.0	-24.6, 3.4	-10.0, 4.1	-5.7, 2.4
Change from Baseline to Cycle 18 Day 1				
n	11	11	11	11
Mean (StdDev)	-5.45 (12.241)	-1.93 (7.855)	-2.59 (3.694)	-0.93 (2.537)
Median	-1.00	0.00	-2.33	-0.25
Min, Max	-39.4, 7.0	-24.4, 3.4	-10.0, 4.1	-5.1, 2.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg			
Scores	Q3 Spots (N=52)	Q4 Itching (N=52)	Q5 Flushing (N=52)
Change from Baseline to Cycle 16 Day 1			
n	12	12	12
Mean (StdDev)	-0.36 (2.730)	-0.77 (3.066)	-0.96 (1.899)
Median	0.00	-0.07	-0.14
Min, Max	-8.0, 2.9	-10.0, 2.0	-6.4, 0.4
Change from Baseline to Cycle 17 Day 1			
n	12	12	12
Mean (StdDev)	-0.36 (2.730)	-0.72 (3.100)	-0.97 (1.936)
Median	0.00	-0.07	-0.14
Min, Max	-8.0, 2.9	-10.0, 2.0	-6.6, 0.4
Change from Baseline to Cycle 18 Day 1			
n	11	11	11
Mean (StdDev)	-0.41 (2.854)	-0.63 (3.247)	-0.89 (2.010)
Median	0.00	0.00	0.00
Min, Max	-8.0, 2.9	-9.8, 2.1	-6.6, 0.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Scores	Q1 Abdominal Pain (N=52)	Q2 Nausea (N=52)	Q7 Vomitting Count (N=52)	Q8 Vomitting Severity (N=52)	Q9 Diarrhea Count (N=52)	Q10 Diarrhea Severity (N=52)
Change from Baseline to Cycle 16 Day 1						
n	12	12	12	12	12	12
Mean (StdDev)	-0.82 (3.399)	-0.90 (1.289)	0.07 (0.470)	0.14 (0.763)	-1.07 (1.743)	-1.27 (1.564)
Median	-0.36	-0.33	0.00	0.00	-0.46	-0.85
Min, Max	-10.0, 5.4	-4.1, 0.0	-0.9, 1.3	-0.9, 2.4	-5.4, 0.1	-4.7, 0.1
Change from Baseline to Cycle 17 Day 1						
n	12	12	12	12	12	12
Mean (StdDev)	-0.87 (3.405)	-0.90 (1.289)	0.05 (0.465)	0.14 (0.763)	-1.07 (1.743)	-1.27 (1.564)
Median	-0.36	-0.33	0.00	0.00	-0.46	-0.85
Min, Max	-10.0, 5.4	-4.1, 0.0	-0.9, 1.3	-0.9, 2.4	-5.4, 0.1	-4.7, 0.1
Change from Baseline to Cycle 18 Day 1						
n	11	11	11	11	11	11
Mean (StdDev)	-0.80 (3.564)	-0.98 (1.319)	0.05 (0.488)	0.16 (0.799)	-0.67 (1.124)	-0.96 (1.182)
Median	-0.29	-0.67	0.00	0.00	-0.43	-0.83
Min, Max	-10.0, 5.4	-4.1, 0.0	-0.9, 1.3	-0.9, 2.4	-3.9, 0.1	-3.9, 0.1

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg				
Scores	TSS (N=50)	Skin Domain (N=50)	GI Domain (N=50)	Q6 Fatigue (N=50)
Baseline (C1D-7 to C1D-1)				
n	45	45	45	45
Mean (StdDev)	19.96 (13.058)	7.89 (7.316)	6.61 (5.738)	5.46 (2.979)
Median	19.29	6.86	5.86	6.29
Min, Max	0.0, 53.7	0.0, 28.6	0.0, 21.7	0.0, 10.0
Change from Baseline to Cycle 2 Day 1				
n	44	44	44	44
Mean (StdDev)	-7.21 (9.391)	-3.36 (5.050)	-2.98 (5.086)	-0.88 (1.891)
Median	-5.20	-1.86	-1.86	-0.57
Min, Max	-30.1, 10.7	-23.1, 4.9	-16.9, 6.4	-8.3, 2.3
Change from Baseline to Cycle 3 Day 1				
n	42	42	42	42
Mean (StdDev)	-7.79 (10.460)	-3.32 (6.070)	-3.51 (4.948)	-0.96 (2.414)
95% CIs of Mean	(-11.05 - -4.53)	(-5.21 - -1.43)	(-5.06 - -1.97)	(-1.71 - -0.20)
p-value [1]	<0.001***	0.0010**	<0.001***	0.0140*
Median	-6.56	-2.71	-2.71	-0.86
Min, Max	-32.9, 21.7	-21.6, 10.0	-13.0, 5.3	-7.6, 6.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg			
Scores	Q3 Spots (N=50)	Q4 Itching (N=50)	Q5 Flushing (N=50)
Baseline (C1D-7 to C1D-1)			
n	45	45	45
Mean (StdDev)	2.75 (2.849)	2.69 (2.887)	2.45 (2.584)
Median	2.00	1.00	1.86
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 8.6
Change from Baseline to Cycle 2 Day 1			
n	44	44	44
Mean (StdDev)	-0.75 (1.508)	-1.44 (2.352)	-1.18 (2.170)
Median	-0.07	-0.57	-0.36
Min, Max	-5.3, 1.6	-10.0, 2.1	-7.9, 2.7
Change from Baseline to Cycle 3 Day 1			
n	42	42	42
Mean (StdDev)	-0.84 (2.101)	-1.37 (2.813)	-1.11 (2.641)
95% CIs of Mean	(-1.49 - -0.18)	(-2.25 - -0.50)	(-1.93 - -0.29)
p-value [1]	0.0136*	0.0030**	0.0094**
Median	-0.43	-0.50	-0.57
Min, Max	-6.4, 5.0	-10.0, 4.6	-7.0, 4.1

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Scores	Q1 Abdominal Pain (N=50)	Q2 Nausea (N=50)	Q7 Vomitting Count (N=50)	Q8 Vomitting Severity (N=50)	Q9 Diarrhea Count (N=50)	Q10 Diarrhea Severity (N=50)
Baseline (C1D-7 to C1D-1)						
n	45	45	45	45	45	45
Mean (StdDev)	2.91 (2.806)	1.74 (2.261)	0.06 (0.175)	0.13 (0.370)	1.35 (1.901)	1.82 (2.179)
Median	2.43	0.67	0.00	0.00	0.43	0.86
Min, Max	0.0, 10.0	0.0, 7.3	0.0, 1.0	0.0, 1.7	0.0, 7.1	0.0, 7.6
Change from Baseline to Cycle 2 Day 1						
n	44	44	44	44	44	44
Mean (StdDev)	-1.24 (2.540)	-0.88 (1.845)	-0.01 (0.194)	-0.02 (0.494)	-0.55 (2.138)	-0.84 (2.199)
Median	-0.58	-0.36	0.00	0.00	-0.05	-0.10
Min, Max	-8.3, 5.6	-5.6, 3.9	-0.5, 1.0	-1.4, 2.7	-5.4, 6.1	-6.9, 2.9
Change from Baseline to Cycle 3 Day 1						
n	42	42	42	42	42	42
Mean (StdDev)	-1.53 (2.687)	-1.05 (1.837)	0.00 (0.236)	0.05 (0.597)	-0.77 (1.794)	-0.98 (1.905)
95% CIs of Mean	(-2.37 - -0.69)	(-1.62 - -0.48)	(-0.07 - 0.08)	(-0.14 - 0.23)	(-1.33 - -0.21)	(-1.57 - -0.39)
p-value [1]	<0.001***	<0.001***	0.9050	0.6151	0.0084**	0.0018**
Median	-0.85	-0.47	0.00	0.00	-0.25	-0.56
Min, Max	-10.0, 5.3	-6.9, 1.7	-0.7, 1.1	-1.4, 3.0	-5.4, 2.6	-6.3, 2.9

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg				
Scores	TSS (N=50)	Skin Domain (N=50)	GI Domain (N=50)	Q6 Fatigue (N=50)
Change from Baseline to Cycle 4 Day 1				
n	40	40	40	40
Mean (StdDev)	-7.83 (11.524)	-3.23 (6.480)	-3.76 (5.304)	-0.84 (2.561)
Median	-8.52	-1.70	-3.00	-0.45
Min, Max	-34.9, 21.6	-19.7, 13.4	-18.5, 6.9	-9.0, 4.1
Change from Baseline to Cycle 5 Day 1				
n	36	36	36	36
Mean (StdDev)	-9.87 (10.435)	-4.68 (5.956)	-3.77 (5.067)	-1.43 (2.700)
Median	-11.00	-3.21	-3.29	-1.01
Min, Max	-30.9, 12.4	-19.0, 4.7	-13.7, 6.6	-9.0, 5.3
Change from Baseline to Cycle 6 Day 1				
n	30	30	30	30
Mean (StdDev)	-8.72 (11.097)	-3.59 (6.297)	-4.03 (4.932)	-1.10 (3.061)
Median	-6.99	-2.50	-2.17	-0.43
Min, Max	-30.6, 12.6	-18.9, 7.6	-14.0, 3.4	-9.0, 7.9

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg			
Scores	Q3 Spots (N=50)	Q4 Itching (N=50)	Q5 Flushing (N=50)
Change from Baseline to Cycle 4 Day 1			
n	40	40	40
Mean (StdDev)	-0.90 (2.209)	-1.24 (3.102)	-1.09 (2.690)
Median	-0.14	-0.29	-0.57
Min, Max	-6.4, 3.6	-10.0, 7.6	-7.3, 3.6
Change from Baseline to Cycle 5 Day 1			
n	36	36	36
Mean (StdDev)	-1.32 (2.329)	-1.82 (2.881)	-1.54 (2.281)
Median	-0.71	-0.62	-1.08
Min, Max	-6.4, 3.6	-10.0, 2.0	-7.0, 2.1
Change from Baseline to Cycle 6 Day 1			
n	30	30	30
Mean (StdDev)	-0.96 (2.632)	-1.30 (2.872)	-1.33 (2.323)
Median	-0.29	-0.36	-0.57
Min, Max	-6.0, 6.9	-10.0, 2.0	-7.3, 2.1

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Scores	Q1 Abdominal Pain (N=50)	Q2 Nausea (N=50)	Q7 Vomitting Count (N=50)	Q8 Vomitting Severity (N=50)	Q9 Diarrhea Count (N=50)	Q10 Diarrhea Severity (N=50)
Change from Baseline to Cycle 4 Day 1						
n	40	40	40	40	40	40
Mean (StdDev)	-1.79 (2.715)	-0.99 (1.963)	0.08 (0.497)	0.15 (0.903)	-0.91 (1.751)	-1.13 (1.967)
Median	-1.07	-0.29	0.00	0.00	-0.41	-0.71
Min, Max	-9.6, 4.0	-7.3, 2.0	-0.9, 2.7	-1.4, 4.6	-5.4, 2.1	-6.4, 2.9
Change from Baseline to Cycle 5 Day 1						
n	36	36	36	36	36	36
Mean (StdDev)	-1.75 (2.584)	-1.12 (1.948)	0.06 (0.554)	0.08 (0.730)	-0.85 (1.933)	-0.97 (2.367)
Median	-1.00	-0.38	0.00	0.00	-0.56	-0.71
Min, Max	-10.0, 5.0	-6.6, 1.7	-0.9, 3.1	-1.4, 3.6	-5.0, 3.4	-6.6, 4.8
Change from Baseline to Cycle 6 Day 1						
n	30	30	30	30	30	30
Mean (StdDev)	-1.52 (2.697)	-1.37 (2.069)	0.02 (0.384)	0.02 (0.552)	-0.97 (1.626)	-1.17 (1.863)
Median	-0.85	-0.36	0.00	0.00	-0.54	-0.71
Min, Max	-10.0, 3.4	-6.6, 1.7	-0.9, 1.7	-1.4, 1.9	-5.4, 1.4	-6.7, 1.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg				
Scores	TSS (N=50)	Skin Domain (N=50)	GI Domain (N=50)	Q6 Fatigue (N=50)
Change from Baseline to Cycle 7 Day 1				
n	27	27	27	27
Mean (StdDev)	-9.84 (11.297)	-4.05 (6.201)	-4.25 (5.178)	-1.54 (2.758)
95% CIs of Mean	(-14.31 - -5.38)	(-6.50 - -1.60)	(-6.30 - -2.20)	(-2.64 - -0.45)
p-value [1]	<0.001***	0.0022**	<0.001***	0.0073**
Median	-7.83	-2.43	-2.33	-0.86
Min, Max	-31.4, 7.0	-18.6, 6.0	-14.4, 4.1	-9.0, 2.4
Change from Baseline to Cycle 8 Day 1				
n	27	27	27	27
Mean (StdDev)	-10.80 (10.894)	-4.53 (5.948)	-4.43 (5.388)	-1.84 (2.780)
Median	-8.57	-2.86	-2.33	-1.71
Min, Max	-34.6, 7.0	-18.6, 3.0	-17.3, 4.1	-9.0, 2.4
Change from Baseline to Cycle 9 Day 1				
n	25	25	25	25
Mean (StdDev)	-11.04 (11.049)	-4.33 (6.281)	-4.74 (5.382)	-1.97 (2.812)
Median	-8.43	-2.86	-3.71	-1.86
Min, Max	-32.6, 7.0	-18.6, 3.6	-15.3, 4.1	-9.0, 2.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg			
Scores	Q3 Spots (N=50)	Q4 Itching (N=50)	Q5 Flushing (N=50)
Change from Baseline to Cycle 7 Day 1			
n	27	27	27
Mean (StdDev)	-1.23 (2.297)	-1.35 (2.941)	-1.47 (2.390)
95% CIs of Mean	(-2.14 - -0.32)	(-2.52 - -0.19)	(-2.41 - -0.52)
p-value [1]	0.0097**	0.0244*	0.0037**
Median	-0.43	-0.43	-0.57
Min, Max	-6.0, 2.9	-10.0, 2.0	-7.3, 2.2
Change from Baseline to Cycle 8 Day 1			
n	27	27	27
Mean (StdDev)	-1.40 (2.254)	-1.48 (2.951)	-1.65 (2.186)
Median	-0.57	-0.50	-1.14
Min, Max	-6.0, 2.9	-10.0, 2.0	-7.3, 1.1
Change from Baseline to Cycle 9 Day 1			
n	25	25	25
Mean (StdDev)	-1.23 (2.340)	-1.45 (3.076)	-1.65 (2.372)
Median	0.00	-0.29	-0.71
Min, Max	-6.0, 2.9	-10.0, 2.0	-7.3, 1.6

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Scores	Q1 Abdominal Pain (N=50)	Q2 Nausea (N=50)	Q7 Vomitting Count (N=50)	Q8 Vomitting Severity (N=50)	Q9 Diarrhea Count (N=50)	Q10 Diarrhea Severity (N=50)
Change from Baseline to Cycle 7 Day 1						
n	27	27	27	27	27	27
Mean (StdDev)	-1.59 (2.871)	-1.44 (2.219)	-0.06 (0.188)	-0.10 (0.319)	-1.11 (1.603)	-1.12 (1.898)
95% CIs of Mean	(-2.72 - -0.45)	(-2.32 - -0.56)	(-0.13 - 0.01)	(-0.23 - 0.02)	(-1.75 - -0.48)	(-1.87 - -0.37)
p-value [1]	0.0080**	0.0024**	0.1079	0.1070	0.0013**	0.0051**
Median	-0.83	-0.43	0.00	0.00	-0.43	-0.83
Min, Max	-10.0, 5.4	-7.3, 1.3	-0.9, 0.1	-1.4, 0.1	-4.6, 1.6	-6.9, 3.3
Change from Baseline to Cycle 8 Day 1						
n	27	27	27	27	27	27
Mean (StdDev)	-1.75 (2.917)	-1.51 (2.312)	-0.06 (0.188)	-0.14 (0.367)	-0.92 (1.939)	-1.03 (2.171)
Median	-0.83	-0.57	0.00	0.00	-0.50	-0.71
Min, Max	-10.0, 5.4	-7.3, 2.1	-0.9, 0.1	-1.4, 0.1	-4.9, 2.7	-6.9, 3.0
Change from Baseline to Cycle 9 Day 1						
n	25	25	25	25	25	25
Mean (StdDev)	-1.74 (2.959)	-1.59 (2.395)	-0.03 (0.219)	-0.06 (0.371)	-1.10 (1.969)	-1.35 (2.040)
Median	-1.00	-0.67	0.00	0.00	-0.57	-0.83
Min, Max	-10.0, 5.4	-7.3, 1.6	-0.9, 0.4	-1.4, 0.6	-5.4, 2.3	-6.9, 1.9

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg				
Scores	TSS (N=50)	Skin Domain (N=50)	GI Domain (N=50)	Q6 Fatigue (N=50)
Change from Baseline to Cycle 10 Day 1				
n	23	23	23	23
Mean (StdDev)	-9.91 (12.524)	-4.09 (6.517)	-4.23 (7.063)	-1.59 (2.887)
Median	-7.83	-1.57	-3.14	-0.43
Min, Max	-35.4, 8.7	-19.9, 3.4	-19.0, 15.6	-9.0, 2.4
Change from Baseline to Cycle 11 Day 1				
n	21	21	21	21
Mean (StdDev)	-10.02 (13.018)	-4.03 (6.929)	-4.51 (5.993)	-1.47 (2.990)
95% CIs of Mean	(-15.94 - -4.09)	(-7.19 - -0.88)	(-7.24 - -1.78)	(-2.84 - -0.11)
p-value [1]	0.0021**	0.0148*	0.0025**	0.0351*
Median	-4.14	-1.57	-3.14	-0.25
Min, Max	-35.4, 7.0	-20.6, 4.4	-17.4, 4.9	-9.0, 2.4
Change from Baseline to Cycle 12 Day 1				
n	18	18	18	18
Mean (StdDev)	-10.01 (14.339)	-3.18 (7.497)	-5.62 (6.305)	-1.21 (2.600)
Median	-4.14	-0.93	-4.00	-0.13
Min, Max	-39.7, 7.0	-22.4, 5.7	-21.7, 4.1	-7.7, 2.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg			
Scores	Q3 Spots (N=50)	Q4 Itching (N=50)	Q5 Flushing (N=50)
Change from Baseline to Cycle 10 Day 1			
n	23	23	23
Mean (StdDev)	-1.21 (2.450)	-1.34 (3.214)	-1.54 (2.268)
Median	0.00	-0.29	-0.57
Min, Max	-6.0, 2.9	-10.0, 2.3	-7.0, 1.7
Change from Baseline to Cycle 11 Day 1			
n	21	21	21
Mean (StdDev)	-1.25 (2.598)	-1.22 (3.049)	-1.56 (2.608)
95% CIs of Mean	(-2.43 - -0.07)	(-2.61 - 0.17)	(-2.75 - -0.38)
p-value [1]	0.0396*	0.0814	0.0125*
Median	-0.43	-0.29	-0.57
Min, Max	-6.0, 2.9	-10.0, 2.0	-7.3, 2.3
Change from Baseline to Cycle 12 Day 1			
n	18	18	18
Mean (StdDev)	-0.88 (2.638)	-1.00 (3.163)	-1.31 (2.558)
Median	0.00	-0.14	-0.43
Min, Max	-7.0, 2.9	-10.0, 2.0	-7.3, 2.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Scores	Q1 Abdominal Pain (N=50)	Q2 Nausea (N=50)	Q7 Vomitting Count (N=50)	Q8 Vomitting Severity (N=50)	Q9 Diarrhea Count (N=50)	Q10 Diarrhea Severity (N=50)
Change from Baseline to Cycle 10 Day 1						
n	23	23	23	23	23	23
Mean (StdDev)	-1.36 (3.794)	-1.35 (2.761)	0.01 (0.347)	0.05 (0.654)	-1.12 (2.205)	-1.57 (2.115)
Median	-1.14	-0.40	0.00	0.00	-0.57	-0.86
Min, Max	-10.0, 8.9	-7.3, 4.6	-0.9, 1.3	-1.4, 2.4	-5.4, 4.6	-7.0, 1.7
Change from Baseline to Cycle 11 Day 1						
n	21	21	21	21	21	21
Mean (StdDev)	-1.43 (3.441)	-1.62 (2.428)	0.03 (0.349)	0.09 (0.581)	-1.21 (2.040)	-1.55 (2.153)
95% CIs of Mean	(-3.00 - 0.13)	(-2.72 - -0.51)	(-0.13 - 0.19)	(-0.18 - 0.35)	(-2.13 - -0.28)	(-2.53 - -0.57)
p-value [1]	0.0707	0.0063**	0.7245	0.4936	0.0135*	0.0036**
Median	-0.83	-0.57	0.00	0.00	-0.50	-0.86
Min, Max	-10.0, 5.4	-7.3, 0.7	-0.9, 1.3	-0.9, 2.4	-5.4, 2.4	-7.0, 1.9
Change from Baseline to Cycle 12 Day 1						
n	18	18	18	18	18	18
Mean (StdDev)	-1.89 (3.483)	-1.73 (2.454)	0.02 (0.377)	0.08 (0.624)	-1.65 (2.114)	-2.09 (2.388)
Median	-1.06	-0.62	0.00	0.00	-0.57	-1.14
Min, Max	-10.0, 5.4	-7.3, 0.0	-0.9, 1.3	-0.9, 2.4	-5.4, 0.1	-7.6, 0.1

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg				
Scores	TSS (N=50)	Skin Domain (N=50)	GI Domain (N=50)	Q6 Fatigue (N=50)
Change from Baseline to Cycle 13 Day 1				
n	13	13	13	13
Mean (StdDev)	-6.74 (11.297)	-2.13 (6.577)	-3.53 (4.569)	-1.07 (2.198)
Median	-2.43	0.00	-3.14	-0.43
Min, Max	-35.7, 7.0	-22.1, 3.4	-13.7, 4.1	-4.4, 2.4
Change from Baseline to Cycle 14 Day 1				
n	12	12	12	12
Mean (StdDev)	-5.64 (11.354)	-1.95 (7.075)	-2.75 (3.578)	-0.94 (2.274)
Median	-1.43	0.00	-2.74	-0.34
Min, Max	-38.0, 7.0	-23.0, 3.4	-10.0, 4.1	-5.0, 2.4
Change from Baseline to Cycle 15 Day 1				
n	12	12	12	12
Mean (StdDev)	-5.81 (11.918)	-1.75 (7.084)	-2.80 (3.623)	-1.26 (2.804)
Median	-2.00	0.00	-2.74	-0.34
Min, Max	-39.6, 7.0	-22.6, 4.0	-10.0, 4.1	-7.0, 2.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg			
Scores	Q3 Spots (N=50)	Q4 Itching (N=50)	Q5 Flushing (N=50)
Change from Baseline to Cycle 13 Day 1			
n	13	13	13
Mean (StdDev)	-0.58 (2.587)	-0.74 (2.937)	-0.82 (1.534)
Median	0.00	-0.14	-0.29
Min, Max	-6.8, 2.9	-10.0, 2.0	-5.2, 0.4
Change from Baseline to Cycle 14 Day 1			
n	12	12	12
Mean (StdDev)	-0.30 (2.587)	-0.77 (3.066)	-0.88 (1.683)
Median	0.00	-0.07	-0.07
Min, Max	-7.4, 2.9	-10.0, 2.0	-5.6, 0.4
Change from Baseline to Cycle 15 Day 1			
n	12	12	12
Mean (StdDev)	-0.20 (2.542)	-0.68 (3.131)	-0.87 (1.689)
Median	0.00	-0.07	0.00
Min, Max	-7.0, 2.9	-10.0, 2.0	-5.6, 0.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Scores	Q1 Abdominal Pain (N=50)	Q2 Nausea (N=50)	Q7 Vomitting Count (N=50)	Q8 Vomitting Severity (N=50)	Q9 Diarrhea Count (N=50)	Q10 Diarrhea Severity (N=50)
Change from Baseline to Cycle 13 Day 1						
n	13	13	13	13	13	13
Mean (StdDev)	-0.88 (3.321)	-1.30 (2.102)	0.04 (0.446)	0.13 (0.732)	-1.31 (1.892)	-1.48 (1.677)
Median	-0.29	-0.67	0.00	0.00	-0.50	-0.86
Min, Max	-10.0, 5.4	-6.9, 0.6	-0.9, 1.3	-0.9, 2.4	-5.4, 0.1	-4.7, 0.1
Change from Baseline to Cycle 14 Day 1						
n	12	12	12	12	12	12
Mean (StdDev)	-0.74 (3.406)	-0.89 (1.290)	0.05 (0.465)	0.14 (0.763)	-1.07 (1.743)	-1.27 (1.564)
Median	-0.14	-0.33	0.00	0.00	-0.46	-0.85
Min, Max	-10.0, 5.4	-4.1, 0.0	-0.9, 1.3	-0.9, 2.4	-5.4, 0.1	-4.7, 0.1
Change from Baseline to Cycle 15 Day 1						
n	12	12	12	12	12	12
Mean (StdDev)	-0.80 (3.398)	-0.90 (1.289)	0.05 (0.465)	0.14 (0.763)	-1.05 (1.748)	-1.25 (1.573)
Median	-0.36	-0.33	0.00	0.00	-0.39	-0.77
Min, Max	-10.0, 5.4	-4.1, 0.0	-0.9, 1.3	-0.9, 2.4	-5.4, 0.1	-4.7, 0.1

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg				
Scores	TSS (N=50)	Skin Domain (N=50)	GI Domain (N=50)	Q6 Fatigue (N=50)
Change from Baseline to Cycle 16 Day 1				
n	12	12	12	12
Mean (StdDev)	-6.13 (11.950)	-2.09 (7.449)	-2.85 (3.636)	-1.19 (2.678)
Median	-2.00	0.00	-2.74	-0.13
Min, Max	-39.7, 7.0	-24.4, 3.4	-10.0, 4.1	-5.3, 2.4
Change from Baseline to Cycle 17 Day 1				
n	12	12	12	12
Mean (StdDev)	-6.27 (12.009)	-2.06 (7.516)	-2.90 (3.680)	-1.32 (2.768)
Median	-2.00	0.00	-2.74	-0.34
Min, Max	-39.6, 7.0	-24.6, 3.4	-10.0, 4.1	-5.7, 2.4
Change from Baseline to Cycle 18 Day 1				
n	11	11	11	11
Mean (StdDev)	-5.45 (12.241)	-1.93 (7.855)	-2.59 (3.694)	-0.93 (2.537)
Median	-1.00	0.00	-2.33	-0.25
Min, Max	-39.4, 7.0	-24.4, 3.4	-10.0, 4.1	-5.1, 2.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
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Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg			
Scores	Q3 Spots (N=50)	Q4 Itching (N=50)	Q5 Flushing (N=50)
Change from Baseline to Cycle 16 Day 1			
n	12	12	12
Mean (StdDev)	-0.36 (2.730)	-0.77 (3.066)	-0.96 (1.899)
Median	0.00	-0.07	-0.14
Min, Max	-8.0, 2.9	-10.0, 2.0	-6.4, 0.4
Change from Baseline to Cycle 17 Day 1			
n	12	12	12
Mean (StdDev)	-0.36 (2.730)	-0.72 (3.100)	-0.97 (1.936)
Median	0.00	-0.07	-0.14
Min, Max	-8.0, 2.9	-10.0, 2.0	-6.6, 0.4
Change from Baseline to Cycle 18 Day 1			
n	11	11	11
Mean (StdDev)	-0.41 (2.854)	-0.63 (3.247)	-0.89 (2.010)
Median	0.00	0.00	0.00
Min, Max	-8.0, 2.9	-9.8, 2.1	-6.6, 0.4

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas Date: 20:45/20OCT2021

Table 35.2.9.3
Summary of Systemic Mastocytosis Symptoms by AdvSM-SAF Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Scores	Q1 Abdominal Pain (N=50)	Q2 Nausea (N=50)	Q7 Vomitting Count (N=50)	Q8 Vomitting Severity (N=50)	Q9 Diarrhea Count (N=50)	Q10 Diarrhea Severity (N=50)
Change from Baseline to Cycle 16 Day 1						
n	12	12	12	12	12	12
Mean (StdDev)	-0.82 (3.399)	-0.90 (1.289)	0.07 (0.470)	0.14 (0.763)	-1.07 (1.743)	-1.27 (1.564)
Median	-0.36	-0.33	0.00	0.00	-0.46	-0.85
Min, Max	-10.0, 5.4	-4.1, 0.0	-0.9, 1.3	-0.9, 2.4	-5.4, 0.1	-4.7, 0.1
Change from Baseline to Cycle 17 Day 1						
n	12	12	12	12	12	12
Mean (StdDev)	-0.87 (3.405)	-0.90 (1.289)	0.05 (0.465)	0.14 (0.763)	-1.07 (1.743)	-1.27 (1.564)
Median	-0.36	-0.33	0.00	0.00	-0.46	-0.85
Min, Max	-10.0, 5.4	-4.1, 0.0	-0.9, 1.3	-0.9, 2.4	-5.4, 0.1	-4.7, 0.1
Change from Baseline to Cycle 18 Day 1						
n	11	11	11	11	11	11
Mean (StdDev)	-0.80 (3.564)	-0.98 (1.319)	0.05 (0.488)	0.16 (0.799)	-0.67 (1.124)	-0.96 (1.182)
Median	-0.29	-0.67	0.00	0.00	-0.43	-0.83
Min, Max	-10.0, 5.4	-4.1, 0.0	-0.9, 1.3	-0.9, 2.4	-3.9, 0.1	-3.9, 0.1

Source: Listing 16.3.11
Abbreviations: C=Cycle, CIs=Confidence intervals, D=Day, GI=Gastrointestinal, Q=Question, SAF=symptom assessment form, TSS=Total sympotom score
Notes: Diagnosis of AdvSM is by RAC (Study 2101) or SSC (Study 2202) adjudication. Skin domain is composed of Q3, Q4, and Q5. GI domain is composed of Q1, Q2, Q8, and Q10. TSS is composed of Q1, Q2, Q3, Q4, Q5, Q6, Q8, and Q10. A symptom/domain/TSS score for any given day is determined by the 7-day average prior to that day. Domain scores and TSS on any given day is only calculated if no symptom score within the domain or the TSS is missing. If a symptom/domain/TSS score is available on at least 4 or more days during the 7-day period (no consecutive requirement), the average score is calculated by the sum of the available scores divided by the number of days with available scores.
[1] Two-sided p-value of paired t test, The null hypothesis is that the mean change from baseline is 0.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-symp-chg.sas
Date: 20:45/20OCT2021

Table 35.2.10.1
Summary of Patient's Global Impression of Symptom Severity
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

PGIS	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Baseline				
n	4	14	6	24
Mean (StdDev)	2.3 (1.50)	2.2 (1.19)	1.3 (0.82)	2.0 (1.18)
Median	2.0	2.0	1.5	2.0
Min, Max	1, 4	0, 4	0, 2	0, 4
Cycle 2 Day 1				
n	3	15	5	23
Mean (StdDev)	1.7 (0.58)	1.7 (0.70)	1.2 (0.45)	1.6 (0.66)
Median	2.0	2.0	1.0	2.0
Min, Max	1, 2	0, 3	1, 2	0, 3
Cycle 3 Day 1				
n	3	14	5	22
Mean (StdDev)	1.7 (1.53)	1.5 (0.65)	1.6 (0.55)	1.5 (0.74)
Median	2.0	2.0	2.0	2.0
Min, Max	0, 3	0, 2	1, 2	0, 3
Cycle 4 Day 1				
n	2	14	6	22
Mean (StdDev)	1.0 (1.41)	1.4 (0.85)	1.0 (0.63)	1.3 (0.83)
Median	1.0	1.5	1.0	1.0
Min, Max	0, 2	0, 3	0, 2	0, 3

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp.sas Date: 14:58/29SEP2021

Table 35.2.10.1
Summary of Patient's Global Impression of Symptom Severity
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

PGIS	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Cycle 5 Day 1				
n	3	12	6	21
Mean (StdDev)	1.0 (1.00)	1.5 (0.80)	1.5 (0.84)	1.4 (0.81)
Median	1.0	1.5	1.0	1.0
Min, Max	0, 2	0, 3	1, 3	0, 3
Cycle 6 Day 1				
n	3	12	5	20
Mean (StdDev)	0.7 (0.58)	1.3 (0.75)	1.2 (0.45)	1.2 (0.67)
Median	1.0	1.0	1.0	1.0
Min, Max	0, 1	0, 2	1, 2	0, 2
Cycle 7 Day 1				
n	3	10	5	18
Mean (StdDev)	0.7 (0.58)	1.3 (0.82)	1.0 (0.71)	1.1 (0.76)
Median	1.0	1.0	1.0	1.0
Min, Max	0, 1	0, 3	0, 2	0, 3
Cycle 8 Day 1				
n	2	10	4	16
Mean (StdDev)	0.5 (0.71)	1.5 (0.71)	2.0 (1.41)	1.5 (0.97)
Median	0.5	1.0	1.5	1.0
Min, Max	0, 1	1, 3	1, 4	0, 4

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp.sas Date: 14:58/29SEP2021

Table 35.2.10.1
Summary of Patient's Global Impression of Symptom Severity
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

PGIS	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Cycle 9 Day 1				
n	3	9	4	16
Mean (StdDev)	0.7 (0.58)	1.2 (0.67)	1.8 (1.71)	1.3 (1.00)
Median	1.0	1.0	1.5	1.0
Min, Max	0, 1	0, 2	0, 4	0, 4
Cycle 10 Day 1				
n	3	10	3	16
Mean (StdDev)	1.0 (0.00)	1.4 (0.52)	1.7 (0.58)	1.4 (0.50)
Median	1.0	1.0	2.0	1.0
Min, Max	1, 1	1, 2	1, 2	1, 2
Cycle 11 Day 1				
n	3	11	3	17
Mean (StdDev)	0.7 (0.58)	1.0 (0.77)	0.7 (0.58)	0.9 (0.70)
Median	1.0	1.0	1.0	1.0
Min, Max	0, 1	0, 2	0, 1	0, 2
Cycle 12 Day 1				
n	2	7	3	12
Mean (StdDev)	0.5 (0.71)	0.7 (0.76)	0.7 (0.58)	0.7 (0.65)
Median	0.5	1.0	1.0	1.0
Min, Max	0, 1	0, 2	0, 1	0, 2

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp.sas Date: 14:58/29SEP2021

Table 35.2.10.1
Summary of Patient's Global Impression of Symptom Severity
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

PGIS	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	3.0 (-)	2.2 (1.48)	1.5 (0.58)	2.0 (1.15)
Median	3.0	2.0	1.5	2.0
Min, Max	3, 3	0, 4	1, 2	0, 4
Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		1.6 (1.14)	1.3 (0.58)	1.5 (0.93)
Median		2.0	1.0	1.5
Min, Max		0, 3	1, 2	0, 3
Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		1.3 (0.50)	1.7 (0.58)	1.4 (0.53)
Median		1.0	2.0	1.0
Min, Max		1, 2	1, 2	1, 2
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		1.8 (0.96)	1.3 (0.50)	1.5 (0.76)
Median		1.5	1.0	1.0
Min, Max		1, 3	1, 2	1, 3

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp.sas
Date: 14:58/29SEP2021

Table 35.2.10.1
Summary of Patient's Global Impression of Symptom Severity
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

PGIS	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		1.5 (0.71)	1.3 (0.50)	1.3 (0.52)
Median		1.5	1.0	1.0
Min, Max		1, 2	1, 2	1, 2
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		1.3 (0.58)	1.0 (0.00)	1.1 (0.38)
Median		1.0	1.0	1.0
Min, Max		1, 2	1, 1	1, 2
Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		1.3 (0.58)	1.0 (1.00)	1.2 (0.75)
Median		1.0	1.0	1.0
Min, Max		1, 2	0, 2	0, 2
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		1.5 (0.71)	1.5 (0.71)	1.5 (0.58)
Median		1.5	1.5	1.5
Min, Max		1, 2	1, 2	1, 2

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp.sas
Date: 14:58/29SEP2021

Table 35.2.10.1
Summary of Patient's Global Impression of Symptom Severity
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

PGIS	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		1.5 (0.71)	1.5 (0.71)	1.5 (0.58)
Median		1.5	1.5	1.5
Min, Max		1, 2	1, 2	1, 2
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		2.0 (-)	1.5 (0.71)	1.7 (0.58)
Median		2.0	1.5	2.0
Min, Max		2, 2	1, 2	1, 2
Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		0.5 (0.71)	0.5 (0.71)	0.5 (0.58)
Median		0.5	0.5	0.5
Min, Max		0, 1	0, 1	0, 1
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.0 (-)	0.5 (0.71)	0.3 (0.58)
Median		0.0	0.5	0.0
Min, Max		0, 0	0, 1	0, 1

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp.sas
Date: 14:58/29SEP2021

Table 35.2.10.1
Summary of Patient's Global Impression of Symptom Severity
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

PGIS	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	3.0 (-)	2.2 (1.48)	1.5 (0.58)	2.0 (1.15)
Median	3.0	2.0	1.5	2.0
Min, Max	3, 3	0, 4	1, 2	0, 4
Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		1.6 (1.14)	1.3 (0.58)	1.5 (0.93)
Median		2.0	1.0	1.5
Min, Max		0, 3	1, 2	0, 3
Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		1.3 (0.50)	1.7 (0.58)	1.4 (0.53)
Median		1.0	2.0	1.0
Min, Max		1, 2	1, 2	1, 2
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		1.8 (0.96)	1.3 (0.50)	1.5 (0.76)
Median		1.5	1.0	1.0
Min, Max		1, 3	1, 2	1, 3

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp.sas
Date: 14:58/29SEP2021

Table 35.2.10.1
Summary of Patient's Global Impression of Symptom Severity
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

PGIS	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		1.5 (0.71)	1.3 (0.50)	1.3 (0.52)
Median		1.5	1.0	1.0
Min, Max		1, 2	1, 2	1, 2
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		1.3 (0.58)	1.0 (0.00)	1.1 (0.38)
Median		1.0	1.0	1.0
Min, Max		1, 2	1, 1	1, 2
Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		1.3 (0.58)	1.0 (1.00)	1.2 (0.75)
Median		1.0	1.0	1.0
Min, Max		1, 2	0, 2	0, 2
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		1.5 (0.71)	1.5 (0.71)	1.5 (0.58)
Median		1.5	1.5	1.5
Min, Max		1, 2	1, 2	1, 2

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp.sas
Date: 14:58/29SEP2021

Table 35.2.10.1
Summary of Patient's Global Impression of Symptom Severity
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

PGIS	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		1.5 (0.71)	1.5 (0.71)	1.5 (0.58)
Median		1.5	1.5	1.5
Min, Max		1, 2	1, 2	1, 2
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		2.0 (-)	1.5 (0.71)	1.7 (0.58)
Median		2.0	1.5	2.0
Min, Max		2, 2	1, 2	1, 2
Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		0.5 (0.71)	0.5 (0.71)	0.5 (0.58)
Median		0.5	0.5	0.5
Min, Max		0, 1	0, 1	0, 1
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.0 (-)	0.5 (0.71)	0.3 (0.58)
Median		0.0	0.5	0.0
Min, Max		0, 0	0, 1	0, 1

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp.sas
Date: 14:58/29SEP2021

Table 35.2.10.1
Summary of Patient's Global Impression of Symptom Severity
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

PGIS	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Baseline				
n	3	24	8	35
Mean (StdDev)	2.3 (0.58)	2.9 (1.30)	2.6 (1.06)	2.8 (1.19)
Median	2.0	3.0	2.5	3.0
Min, Max	2, 3	0, 4	1, 4	0, 4
Cycle 1 Day 15				
n	4	21	7	32
Mean (StdDev)	2.5 (0.58)	1.7 (1.02)	1.6 (0.79)	1.8 (0.95)
Median	2.5	2.0	1.0	2.0
Min, Max	2, 3	0, 4	1, 3	0, 4
Cycle 2 Day 1				
n	2	23	8	33
Mean (StdDev)	2.5 (0.71)	1.7 (1.06)	1.5 (0.93)	1.7 (1.02)
Median	2.5	2.0	1.0	2.0
Min, Max	2, 3	0, 4	1, 3	0, 4
Cycle 3 Day 1				
n	4	22	6	32
Mean (StdDev)	2.3 (0.50)	1.5 (0.91)	1.3 (0.82)	1.6 (0.87)
Median	2.0	2.0	1.0	2.0
Min, Max	2, 3	0, 3	1, 3	0, 3

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp.sas Date: 14:58/29SEP2021

Table 35.2.10.1
Summary of Patient's Global Impression of Symptom Severity
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

PGIS	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Cycle 5 Day 1				
n	2	14	5	21
Mean (StdDev)	2.0 (0.00)	1.3 (0.73)	0.8 (0.45)	1.2 (0.70)
Median	2.0	1.0	1.0	1.0
Min, Max	2, 2	0, 2	0, 1	0, 2
Cycle 7 Day 1				
n	1	14	2	17
Mean (StdDev)	2.0 (-)	1.0 (0.78)	1.0 (0.00)	1.1 (0.75)
Median	2.0	1.0	1.0	1.0
Min, Max	2, 2	0, 2	1, 1	0, 2
Cycle 9 Day 1				
n	0	11	2	13
Mean (StdDev)		1.0 (0.77)	1.5 (0.71)	1.1 (0.76)
Median		1.0	1.5	1.0
Min, Max		0, 2	1, 2	0, 2
Cycle 11 Day 1				
n	0	6	1	7
Mean (StdDev)		1.0 (0.63)	1.0 (-)	1.0 (0.58)
Median		1.0	1.0	1.0
Min, Max		0, 2	1, 1	0, 2

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp.sas Date: 14:58/29SEP2021

Table 35.2.10.1
Summary of Patient's Global Impression of Symptom Severity
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

PGIS	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		0.3 (0.58)	0.0 (-)	0.3 (0.50)
Median		0.0	0.0	0.0
Min, Max		0, 1	0, 0	0, 1
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.0 (-)		0.0 (-)
Median		0.0		0.0
Min, Max		0, 0		0, 0

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp.sas Date: 14:58/29SEP2021

Table 35.2.10.1
Summary of Patient's Global Impression of Symptom Severity
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

PGIS	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Baseline				
n	3	23	8	34
Mean (StdDev)	2.3 (0.58)	2.8 (1.30)	2.6 (1.06)	2.7 (1.19)
Median	2.0	3.0	2.5	3.0
Min, Max	2, 3	0, 4	1, 4	0, 4
Cycle 1 Day 15				
n	4	20	7	31
Mean (StdDev)	2.5 (0.58)	1.6 (0.89)	1.6 (0.79)	1.7 (0.87)
Median	2.5	2.0	1.0	2.0
Min, Max	2, 3	0, 3	1, 3	0, 3
Cycle 2 Day 1				
n	2	22	8	32
Mean (StdDev)	2.5 (0.71)	1.7 (1.09)	1.5 (0.93)	1.7 (1.03)
Median	2.5	2.0	1.0	2.0
Min, Max	2, 3	0, 4	1, 3	0, 4
Cycle 3 Day 1				
n	4	21	6	31
Mean (StdDev)	2.3 (0.50)	1.5 (0.87)	1.3 (0.82)	1.5 (0.85)
Median	2.0	2.0	1.0	2.0
Min, Max	2, 3	0, 3	1, 3	0, 3

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp.sas Date: 14:58/29SEP2021

Table 35.2.10.1
Summary of Patient's Global Impression of Symptom Severity
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

PGIS	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Cycle 5 Day 1				
n	2	13	5	20
Mean (StdDev)	2.0 (0.00)	1.2 (0.73)	0.8 (0.45)	1.2 (0.70)
Median	2.0	1.0	1.0	1.0
Min, Max	2, 2	0, 2	0, 1	0, 2
Cycle 7 Day 1				
n	1	13	2	16
Mean (StdDev)	2.0 (-)	0.9 (0.76)	1.0 (0.00)	1.0 (0.73)
Median	2.0	1.0	1.0	1.0
Min, Max	2, 2	0, 2	1, 1	0, 2
Cycle 9 Day 1				
n	0	10	2	12
Mean (StdDev)		0.9 (0.74)	1.5 (0.71)	1.0 (0.74)
Median		1.0	1.5	1.0
Min, Max		0, 2	1, 2	0, 2
Cycle 11 Day 1				
n	0	5	1	6
Mean (StdDev)		0.8 (0.45)	1.0 (-)	0.8 (0.41)
Median		1.0	1.0	1.0
Min, Max		0, 1	1, 1	0, 1

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp.sas Date: 14:58/29SEP2021

Table 35.2.10.1
Summary of Patient's Global Impression of Symptom Severity
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg				
PGIS	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		0.3 (0.58)	0.0 (-)	0.3 (0.50)
Median		0.0	0.0	0.0
Min, Max		0, 1	0, 0	0, 1
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.0 (-)		0.0 (-)
Median		0.0		0.0
Min, Max		0, 0		0, 0

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp.sas Date: 14:58/29SEP2021

Table 35.2.10.1
Summary of Patient's Global Impression of Symptom Severity
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

PGIS	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Baseline				
n	7	38	14	59
Mean (StdDev)	2.3 (1.11)	2.6 (1.28)	2.1 (1.14)	2.5 (1.24)
Median	2.0	3.0	2.0	3.0
Min, Max	1, 4	0, 4	0, 4	0, 4
Cycle 1 Day 15				
n	4	21	7	32
Mean (StdDev)	2.5 (0.58)	1.7 (1.02)	1.6 (0.79)	1.8 (0.95)
Median	2.5	2.0	1.0	2.0
Min, Max	2, 3	0, 4	1, 3	0, 4
Cycle 2 Day 1				
n	5	38	13	56
Mean (StdDev)	2.0 (0.71)	1.7 (0.93)	1.4 (0.77)	1.7 (0.88)
Median	2.0	2.0	1.0	2.0
Min, Max	1, 3	0, 4	1, 3	0, 4
Cycle 3 Day 1				
n	7	36	11	54
Mean (StdDev)	2.0 (1.00)	1.5 (0.81)	1.5 (0.69)	1.6 (0.81)
Median	2.0	2.0	1.0	2.0
Min, Max	0, 3	0, 3	1, 3	0, 3

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp.sas Date: 14:58/29SEP2021

Table 35.2.10.1
Summary of Patient's Global Impression of Symptom Severity
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

PGIS	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 4 Day 1				
n	2	14	6	22
Mean (StdDev)	1.0 (1.41)	1.4 (0.85)	1.0 (0.63)	1.3 (0.83)
Median	1.0	1.5	1.0	1.0
Min, Max	0, 2	0, 3	0, 2	0, 3
Cycle 5 Day 1				
n	5	26	11	42
Mean (StdDev)	1.4 (0.89)	1.4 (0.75)	1.2 (0.75)	1.3 (0.75)
Median	2.0	1.0	1.0	1.0
Min, Max	0, 2	0, 3	0, 3	0, 3
Cycle 6 Day 1				
n	3	12	5	20
Mean (StdDev)	0.7 (0.58)	1.3 (0.75)	1.2 (0.45)	1.2 (0.67)
Median	1.0	1.0	1.0	1.0
Min, Max	0, 1	0, 2	1, 2	0, 2
Cycle 7 Day 1				
n	4	24	7	35
Mean (StdDev)	1.0 (0.82)	1.1 (0.80)	1.0 (0.58)	1.1 (0.74)
Median	1.0	1.0	1.0	1.0
Min, Max	0, 2	0, 3	0, 2	0, 3

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp.sas Date: 14:58/29SEP2021

Table 35.2.10.1
Summary of Patient's Global Impression of Symptom Severity
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

PGIS	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 8 Day 1				
n	2	10	4	16
Mean (StdDev)	0.5 (0.71)	1.5 (0.71)	2.0 (1.41)	1.5 (0.97)
Median	0.5	1.0	1.5	1.0
Min, Max	0, 1	1, 3	1, 4	0, 4
Cycle 9 Day 1				
n	3	20	6	29
Mean (StdDev)	0.7 (0.58)	1.1 (0.72)	1.7 (1.37)	1.2 (0.89)
Median	1.0	1.0	1.5	1.0
Min, Max	0, 1	0, 2	0, 4	0, 4
Cycle 10 Day 1				
n	3	10	3	16
Mean (StdDev)	1.0 (0.00)	1.4 (0.52)	1.7 (0.58)	1.4 (0.50)
Median	1.0	1.0	2.0	1.0
Min, Max	1, 1	1, 2	1, 2	1, 2
Cycle 11 Day 1				
n	3	17	4	24
Mean (StdDev)	0.7 (0.58)	1.0 (0.71)	0.8 (0.50)	0.9 (0.65)
Median	1.0	1.0	1.0	1.0
Min, Max	0, 1	0, 2	0, 1	0, 2

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp.sas Date: 14:58/29SEP2021

Table 35.2.10.1
Summary of Patient's Global Impression of Symptom Severity
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

PGIS	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 12 Day 1				
n	2	7	3	12
Mean (StdDev)	0.5 (0.71)	0.7 (0.76)	0.7 (0.58)	0.7 (0.65)
Median	0.5	1.0	1.0	1.0
Min, Max	0, 1	0, 2	0, 1	0, 2
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		0.3 (0.58)	0.0 (-)	0.3 (0.50)
Median		0.0	0.0	0.0
Min, Max		0, 1	0, 0	0, 1
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.0 (-)		0.0 (-)
Median		0.0		0.0
Min, Max		0, 0		0, 0

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp.sas Date: 14:58/29SEP2021

Table 35.2.10.1
Summary of Patient's Global Impression of Symptom Severity
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

PGIS	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Baseline				
n	4	29	12	45
Mean (StdDev)	2.5 (0.58)	2.8 (1.33)	2.3 (1.06)	2.6 (1.21)
Median	2.5	3.0	2.0	3.0
Min, Max	2, 3	0, 4	1, 4	0, 4
Cycle 1 Day 15				
n	4	21	7	32
Mean (StdDev)	2.5 (0.58)	1.7 (1.02)	1.6 (0.79)	1.8 (0.95)
Median	2.5	2.0	1.0	2.0
Min, Max	2, 3	0, 4	1, 3	0, 4
Cycle 2 Day 1				
n	2	28	11	41
Mean (StdDev)	2.5 (0.71)	1.7 (1.06)	1.5 (0.82)	1.7 (0.99)
Median	2.5	2.0	1.0	2.0
Min, Max	2, 3	0, 4	1, 3	0, 4
Cycle 3 Day 1				
n	4	26	9	39
Mean (StdDev)	2.3 (0.50)	1.5 (0.86)	1.4 (0.73)	1.6 (0.82)
Median	2.0	1.5	1.0	2.0
Min, Max	2, 3	0, 3	1, 3	0, 3

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp.sas Date: 14:58/29SEP2021

Table 35.2.10.1
Summary of Patient's Global Impression of Symptom Severity
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

PGIS	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		1.8 (0.96)	1.3 (0.50)	1.5 (0.76)
Median		1.5	1.0	1.0
Min, Max		1, 3	1, 2	1, 3
Cycle 5 Day 1				
n	2	16	9	27
Mean (StdDev)	2.0 (0.00)	1.3 (0.70)	1.0 (0.50)	1.3 (0.66)
Median	2.0	1.0	1.0	1.0
Min, Max	2, 2	0, 2	0, 2	0, 2
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		1.3 (0.58)	1.0 (0.00)	1.1 (0.38)
Median		1.0	1.0	1.0
Min, Max		1, 2	1, 1	1, 2
Cycle 7 Day 1				
n	1	17	5	23
Mean (StdDev)	2.0 (-)	1.1 (0.75)	1.0 (0.71)	1.1 (0.73)
Median	2.0	1.0	1.0	1.0
Min, Max	2, 2	0, 2	0, 2	0, 2

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp.sas Date: 14:58/29SEP2021

Table 35.2.10.1
Summary of Patient's Global Impression of Symptom Severity
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

PGIS	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		1.5 (0.71)	1.5 (0.71)	1.5 (0.58)
Median		1.5	1.5	1.5
Min, Max		1, 2	1, 2	1, 2
Cycle 9 Day 1				
n	0	13	4	17
Mean (StdDev)		1.1 (0.76)	1.5 (0.58)	1.2 (0.73)
Median		1.0	1.5	1.0
Min, Max		0, 2	1, 2	0, 2
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		2.0 (-)	1.5 (0.71)	1.7 (0.58)
Median		2.0	1.5	2.0
Min, Max		2, 2	1, 2	1, 2
Cycle 11 Day 1				
n	0	8	3	11
Mean (StdDev)		0.9 (0.64)	0.7 (0.58)	0.8 (0.60)
Median		1.0	1.0	1.0
Min, Max		0, 2	0, 1	0, 2

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp.sas Date: 14:58/29SEP2021

Table 35.2.10.1
Summary of Patient's Global Impression of Symptom Severity
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

PGIS	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.0 (-)	0.5 (0.71)	0.3 (0.58)
Median		0.0	0.5	0.0
Min, Max		0, 0	0, 1	0, 1
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		0.3 (0.58)	0.0 (-)	0.3 (0.50)
Median		0.0	0.0	0.0
Min, Max		0, 1	0, 0	0, 1
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.0 (-)		0.0 (-)
Median		0.0		0.0
Min, Max		0, 0		0, 0

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp.sas Date: 14:58/29SEP2021

Table 35.2.10.1
Summary of Patient's Global Impression of Symptom Severity
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

PGIS	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Baseline				
n	4	28	12	44
Mean (StdDev)	2.5 (0.58)	2.7 (1.33)	2.3 (1.06)	2.6 (1.21)
Median	2.5	3.0	2.0	3.0
Min, Max	2, 3	0, 4	1, 4	0, 4
Cycle 1 Day 15				
n	4	20	7	31
Mean (StdDev)	2.5 (0.58)	1.6 (0.89)	1.6 (0.79)	1.7 (0.87)
Median	2.5	2.0	1.0	2.0
Min, Max	2, 3	0, 3	1, 3	0, 3
Cycle 2 Day 1				
n	2	27	11	40
Mean (StdDev)	2.5 (0.71)	1.7 (1.07)	1.5 (0.82)	1.7 (1.00)
Median	2.5	2.0	1.0	2.0
Min, Max	2, 3	0, 4	1, 3	0, 4
Cycle 3 Day 1				
n	4	25	9	38
Mean (StdDev)	2.3 (0.50)	1.4 (0.82)	1.4 (0.73)	1.5 (0.80)
Median	2.0	1.0	1.0	1.5
Min, Max	2, 3	0, 3	1, 3	0, 3

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp.sas
Date: 14:58/29SEP2021

Table 35.2.10.1
Summary of Patient's Global Impression of Symptom Severity
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

PGIS	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		1.8 (0.96)	1.3 (0.50)	1.5 (0.76)
Median		1.5	1.0	1.0
Min, Max		1, 3	1, 2	1, 3
Cycle 5 Day 1				
n	2	15	9	26
Mean (StdDev)	2.0 (0.00)	1.3 (0.70)	1.0 (0.50)	1.2 (0.65)
Median	2.0	1.0	1.0	1.0
Min, Max	2, 2	0, 2	0, 2	0, 2
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		1.3 (0.58)	1.0 (0.00)	1.1 (0.38)
Median		1.0	1.0	1.0
Min, Max		1, 2	1, 1	1, 2
Cycle 7 Day 1				
n	1	16	5	22
Mean (StdDev)	2.0 (-)	1.0 (0.73)	1.0 (0.71)	1.0 (0.72)
Median	2.0	1.0	1.0	1.0
Min, Max	2, 2	0, 2	0, 2	0, 2

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp.sas
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Table 35.2.10.1
Summary of Patient's Global Impression of Symptom Severity
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

PGIS	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		1.5 (0.71)	1.5 (0.71)	1.5 (0.58)
Median		1.5	1.5	1.5
Min, Max		1, 2	1, 2	1, 2
Cycle 9 Day 1				
n	0	12	4	16
Mean (StdDev)		1.0 (0.74)	1.5 (0.58)	1.1 (0.72)
Median		1.0	1.5	1.0
Min, Max		0, 2	1, 2	0, 2
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		2.0 (-)	1.5 (0.71)	1.7 (0.58)
Median		2.0	1.5	2.0
Min, Max		2, 2	1, 2	1, 2
Cycle 11 Day 1				
n	0	7	3	10
Mean (StdDev)		0.7 (0.49)	0.7 (0.58)	0.7 (0.48)
Median		1.0	1.0	1.0
Min, Max		0, 1	0, 1	0, 1

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp.sas
Date: 14:58/29SEP2021

Table 35.2.10.1
Summary of Patient's Global Impression of Symptom Severity
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

PGIS	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.0 (-)	0.5 (0.71)	0.3 (0.58)
Median		0.0	0.5	0.0
Min, Max		0, 0	0, 1	0, 1
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		0.3 (0.58)	0.0 (-)	0.3 (0.50)
Median		0.0	0.0	0.0
Min, Max		0, 1	0, 0	0, 1
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.0 (-)		0.0 (-)
Median		0.0		0.0
Min, Max		0, 0		0, 0

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp.sas Date: 14:58/29SEP2021

Table 35.2.10.2
Summary of Patient's Global Impression of Symptom Severity Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

PGIS	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Baseline				
n	4	14	6	24
Mean (StdDev)	2.3 (1.50)	2.2 (1.19)	1.3 (0.82)	2.0 (1.18)
Median	2.0	2.0	1.5	2.0
Min, Max	1, 4	0, 4	0, 2	0, 4
Change from Baseline to Cycle 2 Day 1				
n	3	12	5	20
Mean (StdDev)	-0.3 (1.53)	-0.4 (1.31)	0.0 (1.00)	-0.3 (1.22)
Median	0.0	-0.5	0.0	0.0
Min, Max	-2, 1	-2, 2	-1, 1	-2, 2
Change from Baseline to Cycle 3 Day 1				
n	3	12	5	20
Mean (StdDev)	-0.3 (1.15)	-0.6 (1.16)	0.4 (0.55)	-0.3 (1.08)
Median	-1.0	-1.0	0.0	0.0
Min, Max	-1, 1	-2, 1	0, 1	-2, 1
Change from Baseline to Cycle 4 Day 1				
n	2	11	6	19
Mean (StdDev)	0.0 (1.41)	-0.6 (1.50)	-0.3 (0.82)	-0.5 (1.26)
Median	0.0	-1.0	-0.5	-1.0
Min, Max	-1, 1	-3, 2	-1, 1	-3, 2

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp-chg.sas Date: 20:49/20OCT2021

Table 35.2.10.2
Summary of Patient's Global Impression of Symptom Severity Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

PGIS	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Change from Baseline to Cycle 5 Day 1				
n	3	9	6	18
Mean (StdDev)	-1.0 (1.00)	-0.2 (1.39)	0.2 (1.60)	-0.2 (1.40)
Median	-1.0	0.0	-0.5	-0.5
Min, Max	-2, 0	-2, 2	-1, 3	-2, 3
Change from Baseline to Cycle 6 Day 1				
n	3	9	5	17
Mean (StdDev)	-1.3 (1.53)	-1.1 (1.36)	0.0 (1.22)	-0.8 (1.38)
Median	-1.0	-1.0	0.0	-1.0
Min, Max	-3, 0	-3, 1	-1, 2	-3, 2
Change from Baseline to Cycle 7 Day 1				
n	3	7	5	15
Mean (StdDev)	-1.3 (1.53)	-1.1 (1.35)	-0.2 (1.10)	-0.9 (1.30)
Median	-1.0	-1.0	-1.0	-1.0
Min, Max	-3, 0	-3, 1	-1, 1	-3, 1
Change from Baseline to Cycle 8 Day 1				
n	2	8	4	14
Mean (StdDev)	-0.5 (0.71)	-1.0 (1.07)	0.8 (2.22)	-0.4 (1.55)
Median	-0.5	-1.0	0.0	-1.0
Min, Max	-1, 0	-2, 1	-1, 4	-2, 4

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp-chg.sas Date: 20:49/20OCT2021

Table 35.2.10.2
Summary of Patient's Global Impression of Symptom Severity Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

PGIS	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Change from Baseline to Cycle 9 Day 1				
n	3	6	4	13
Mean (StdDev)	-1.3 (1.53)	-1.3 (0.82)	0.5 (2.52)	-0.8 (1.74)
Median	-1.0	-1.5	0.0	-1.0
Min, Max	-3, 0	-2, 0	-2, 4	-3, 4
Change from Baseline to Cycle 10 Day 1				
n	3	7	3	13
Mean (StdDev)	-1.0 (1.73)	-1.0 (1.00)	0.0 (0.00)	-0.8 (1.09)
Median	0.0	-1.0	0.0	0.0
Min, Max	-3, 0	-2, 0	0, 0	-3, 0
Change from Baseline to Cycle 11 Day 1				
n	3	8	3	14
Mean (StdDev)	-1.3 (1.53)	-1.4 (1.60)	-1.0 (1.00)	-1.3 (1.38)
Median	-1.0	-1.5	-1.0	-1.0
Min, Max	-3, 0	-3, 1	-2, 0	-3, 1
Change from Baseline to Cycle 12 Day 1				
n	2	4	3	9
Mean (StdDev)	-2.0 (2.83)	-2.3 (0.96)	-1.0 (1.00)	-1.8 (1.39)
Median	-2.0	-2.5	-1.0	-2.0
Min, Max	-4, 0	-3, -1	-2, 0	-4, 0

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp-chg.sas Date: 20:49/20OCT2021

Table 35.2.10.2
Summary of Patient's Global Impression of Symptom Severity Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg				
PGIS	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	3.0 (-)	2.2 (1.48)	1.5 (0.58)	2.0 (1.15)
Median	3.0	2.0	1.5	2.0
Min, Max	3, 3	0, 4	1, 2	0, 4
Change from Baseline to Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		-0.6 (1.67)	0.0 (1.00)	-0.4 (1.41)
Median		-1.0	0.0	-0.5
Min, Max		-2, 2	-1, 1	-2, 2
Change from Baseline to Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		-0.8 (1.26)	0.3 (0.58)	-0.3 (1.11)
Median		-1.0	0.0	0.0
Min, Max		-2, 1	0, 1	-2, 1
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		-0.3 (1.50)	-0.3 (0.96)	-0.3 (1.16)
Median		-1.0	-0.5	-1.0
Min, Max		-1, 2	-1, 1	-1, 2

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp-chg.sas Date: 20:49/20OCT2021

Table 35.2.10.2
Summary of Patient's Global Impression of Symptom Severity Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

PGIS	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		0.5 (2.12)	-0.3 (0.96)	0.0 (1.26)
Median		0.5	-0.5	-0.5
Min, Max		-1, 2	-1, 1	-1, 2
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		-0.7 (1.53)	-0.5 (0.58)	-0.6 (0.98)
Median		-1.0	-0.5	-1.0
Min, Max		-2, 1	-1, 0	-2, 1
Change from Baseline to Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		-0.7 (1.53)	-0.3 (1.15)	-0.5 (1.22)
Median		-1.0	-1.0	-1.0
Min, Max		-2, 1	-1, 1	-2, 1
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		-1.5 (0.71)	0.0 (0.00)	-0.8 (0.96)
Median		-1.5	0.0	-0.5
Min, Max		-2, -1	0, 0	-2, 0

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp-chg.sas Date: 20:49/20OCT2021

Table 35.2.10.2
Summary of Patient's Global Impression of Symptom Severity Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

PGIS	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		-1.5 (0.71)	0.0 (0.00)	-0.8 (0.96)
Median		-1.5	0.0	-0.5
Min, Max		-2, -1	0, 0	-2, 0
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		-2.0 (-)	0.0 (0.00)	-0.7 (1.15)
Median		-2.0	0.0	0.0
Min, Max		-2, -2	0, 0	-2, 0
Change from Baseline to Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		-2.5 (0.71)	-1.0 (1.41)	-1.8 (1.26)
Median		-2.5	-1.0	-2.0
Min, Max		-3, -2	-2, 0	-3, 0
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		-2.0 (-)	-1.0 (1.41)	-1.3 (1.15)
Median		-2.0	-1.0	-2.0
Min, Max		-2, -2	-2, 0	-2, 0

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp-chg.sas Date: 20:49/20OCT2021

Table 35.2.10.2
Summary of Patient's Global Impression of Symptom Severity Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg				
PGIS	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	3.0 (-)	2.2 (1.48)	1.5 (0.58)	2.0 (1.15)
Median	3.0	2.0	1.5	2.0
Min, Max	3, 3	0, 4	1, 2	0, 4
Change from Baseline to Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		-0.6 (1.67)	0.0 (1.00)	-0.4 (1.41)
Median		-1.0	0.0	-0.5
Min, Max		-2, 2	-1, 1	-2, 2
Change from Baseline to Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		-0.8 (1.26)	0.3 (0.58)	-0.3 (1.11)
Median		-1.0	0.0	0.0
Min, Max		-2, 1	0, 1	-2, 1
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		-0.3 (1.50)	-0.3 (0.96)	-0.3 (1.16)
Median		-1.0	-0.5	-1.0
Min, Max		-1, 2	-1, 1	-1, 2

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp-chg.sas Date: 20:49/20OCT2021

Table 35.2.10.2
Summary of Patient's Global Impression of Symptom Severity Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg				
PGIS	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		0.5 (2.12)	-0.3 (0.96)	0.0 (1.26)
Median		0.5	-0.5	-0.5
Min, Max		-1, 2	-1, 1	-1, 2
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		-0.7 (1.53)	-0.5 (0.58)	-0.6 (0.98)
Median		-1.0	-0.5	-1.0
Min, Max		-2, 1	-1, 0	-2, 1
Change from Baseline to Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		-0.7 (1.53)	-0.3 (1.15)	-0.5 (1.22)
Median		-1.0	-1.0	-1.0
Min, Max		-2, 1	-1, 1	-2, 1
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		-1.5 (0.71)	0.0 (0.00)	-0.8 (0.96)
Median		-1.5	0.0	-0.5
Min, Max		-2, -1	0, 0	-2, 0

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp-chg.sas
Date: 20:49/20OCT2021

Table 35.2.10.2
Summary of Patient's Global Impression of Symptom Severity Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg				
PGIS	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		-1.5 (0.71)	0.0 (0.00)	-0.8 (0.96)
Median		-1.5	0.0	-0.5
Min, Max		-2, -1	0, 0	-2, 0
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		-2.0 (-)	0.0 (0.00)	-0.7 (1.15)
Median		-2.0	0.0	0.0
Min, Max		-2, -2	0, 0	-2, 0
Change from Baseline to Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		-2.5 (0.71)	-1.0 (1.41)	-1.8 (1.26)
Median		-2.5	-1.0	-2.0
Min, Max		-3, -2	-2, 0	-3, 0
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		-2.0 (-)	-1.0 (1.41)	-1.3 (1.15)
Median		-2.0	-1.0	-2.0
Min, Max		-2, -2	-2, 0	-2, 0

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp-chg.sas Date: 20:49/20OCT2021

Table 35.2.10.2
Summary of Patient's Global Impression of Symptom Severity Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

PGIS	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Baseline				
n	3	24	8	35
Mean (StdDev)	2.3 (0.58)	2.9 (1.30)	2.6 (1.06)	2.8 (1.19)
Median	2.0	3.0	2.5	3.0
Min, Max	2, 3	0, 4	1, 4	0, 4
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	0.3 (0.58)	-1.2 (1.36)	-0.9 (1.21)	-1.0 (1.33)
Median	0.0	-1.0	-1.0	-1.0
Min, Max	0, 1	-4, 2	-2, 1	-4, 2
Change from Baseline to Cycle 2 Day 1				
n	2	21	8	31
Mean (StdDev)	0.0 (0.00)	-1.2 (1.18)	-1.1 (1.25)	-1.1 (1.18)
Median	0.0	-1.0	-1.0	-1.0
Min, Max	0, 0	-4, 1	-3, 1	-4, 1
Change from Baseline to Cycle 3 Day 1				
n	3	22	6	31
Mean (StdDev)	0.0 (1.00)	-1.3 (1.35)	-1.3 (1.03)	-1.2 (1.29)
Median	0.0	-1.0	-1.0	-1.0
Min, Max	-1, 1	-4, 1	-3, 0	-4, 1

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp-chg.sas
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Table 35.2.10.2
Summary of Patient's Global Impression of Symptom Severity Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

PGIS	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Change from Baseline to Cycle 5 Day 1				
n	1	14	5	20
Mean (StdDev)	0.0 (-)	-1.9 (0.92)	-1.6 (1.34)	-1.8 (1.07)
Median	0.0	-2.0	-1.0	-2.0
Min, Max	0, 0	-3, 0	-3, 0	-3, 0
Change from Baseline to Cycle 7 Day 1				
n	1	14	2	17
Mean (StdDev)	-1.0 (-)	-2.2 (0.97)	-2.0 (1.41)	-2.1 (0.99)
Median	-1.0	-2.0	-2.0	-2.0
Min, Max	-1, -1	-4, 0	-3, -1	-4, 0
Change from Baseline to Cycle 9 Day 1				
n	0	11	2	13
Mean (StdDev)		-2.1 (1.14)	-1.5 (2.12)	-2.0 (1.22)
Median		-2.0	-1.5	-2.0
Min, Max		-4, 0	-3, 0	-4, 0
Change from Baseline to Cycle 11 Day 1				
n	0	6	1	7
Mean (StdDev)		-2.2 (1.72)	-3.0 (-)	-2.3 (1.60)
Median		-2.5	-3.0	-3.0
Min, Max		-4, 1	-3, -3	-4, 1

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp-chg.sas
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Table 35.2.10.2
Summary of Patient's Global Impression of Symptom Severity Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

PGIS	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-2.3 (2.08)	-4.0 (-)	-2.8 (1.89)
Median		-3.0	-4.0	-3.5
Min, Max		-4, 0	-4, -4	-4, 0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.0 (-)		0.0 (-)
Median		0.0		0.0
Min, Max		0, 0		0, 0

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp-chg.sas Date: 20:49/20OCT2021

Table 35.2.10.2
Summary of Patient's Global Impression of Symptom Severity Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

PGIS	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Baseline				
n	3	23	8	34
Mean (StdDev)	2.3 (0.58)	2.8 (1.30)	2.6 (1.06)	2.7 (1.19)
Median	2.0	3.0	2.5	3.0
Min, Max	2, 3	0, 4	1, 4	0, 4
Change from Baseline to Cycle 1 Day 15				
n	3	19	7	29
Mean (StdDev)	0.3 (0.58)	-1.3 (1.37)	-0.9 (1.21)	-1.0 (1.34)
Median	0.0	-1.0	-1.0	-1.0
Min, Max	0, 1	-4, 2	-2, 1	-4, 2
Change from Baseline to Cycle 2 Day 1				
n	2	20	8	30
Mean (StdDev)	0.0 (0.00)	-1.2 (1.20)	-1.1 (1.25)	-1.1 (1.18)
Median	0.0	-1.0	-1.0	-1.0
Min, Max	0, 0	-4, 1	-3, 1	-4, 1
Change from Baseline to Cycle 3 Day 1				
n	3	21	6	30
Mean (StdDev)	0.0 (1.00)	-1.3 (1.38)	-1.3 (1.03)	-1.2 (1.32)
Median	0.0	-1.0	-1.0	-1.0
Min, Max	-1, 1	-4, 1	-3, 0	-4, 1

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp-chg.sas
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Table 35.2.10.2
Summary of Patient's Global Impression of Symptom Severity Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

PGIS	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Change from Baseline to Cycle 5 Day 1				
n	1	13	5	19
Mean (StdDev)	0.0 (-)	-1.9 (0.95)	-1.6 (1.34)	-1.7 (1.10)
Median	0.0	-2.0	-1.0	-2.0
Min, Max	0, 0	-3, 0	-3, 0	-3, 0
Change from Baseline to Cycle 7 Day 1				
n	1	13	2	16
Mean (StdDev)	-1.0 (-)	-2.2 (1.01)	-2.0 (1.41)	-2.1 (1.02)
Median	-1.0	-2.0	-2.0	-2.0
Min, Max	-1, -1	-4, 0	-3, -1	-4, 0
Change from Baseline to Cycle 9 Day 1				
n	0	10	2	12
Mean (StdDev)		-2.1 (1.20)	-1.5 (2.12)	-2.0 (1.28)
Median		-2.0	-1.5	-2.0
Min, Max		-4, 0	-3, 0	-4, 0
Change from Baseline to Cycle 11 Day 1				
n	0	5	1	6
Mean (StdDev)		-2.2 (1.92)	-3.0 (-)	-2.3 (1.75)
Median		-3.0	-3.0	-3.0
Min, Max		-4, 1	-3, -3	-4, 1

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp-chg.sas
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Table 35.2.10.2
Summary of Patient's Global Impression of Symptom Severity Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg				
PGIS	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-2.3 (2.08)	-4.0 (-)	-2.8 (1.89)
Median		-3.0	-4.0	-3.5
Min, Max		-4, 0	-4, -4	-4, 0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.0 (-)		0.0 (-)
Median		0.0		0.0
Min, Max		0, 0		0, 0

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp-chg.sas Date: 20:49/20OCT2021

Table 35.2.10.2
Summary of Patient's Global Impression of Symptom Severity Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

PGIS	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Baseline				
n	7	38	14	59
Mean (StdDev)	2.3 (1.11)	2.6 (1.28)	2.1 (1.14)	2.5 (1.24)
Median	2.0	3.0	2.0	3.0
Min, Max	1, 4	0, 4	0, 4	0, 4
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	0.3 (0.58)	-1.2 (1.36)	-0.9 (1.21)	-1.0 (1.33)
Median	0.0	-1.0	-1.0	-1.0
Min, Max	0, 1	-4, 2	-2, 1	-4, 2
Change from Baseline to Cycle 2 Day 1				
n	5	33	13	51
Mean (StdDev)	-0.2 (1.10)	-0.9 (1.27)	-0.7 (1.25)	-0.8 (1.25)
Median	0.0	-1.0	-1.0	-1.0
Min, Max	-2, 1	-4, 2	-3, 1	-4, 2
Change from Baseline to Cycle 3 Day 1				
n	6	34	11	51
Mean (StdDev)	-0.2 (0.98)	-1.0 (1.31)	-0.5 (1.21)	-0.8 (1.28)
Median	-0.5	-1.0	0.0	-1.0
Min, Max	-1, 1	-4, 1	-3, 1	-4, 1

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp-chg.sas Date: 20:49/20OCT2021

Table 35.2.10.2
Summary of Patient's Global Impression of Symptom Severity Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

PGIS	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 4 Day 1				
n	2	11	6	19
Mean (StdDev)	0.0 (1.41)	-0.6 (1.50)	-0.3 (0.82)	-0.5 (1.26)
Median	0.0	-1.0	-0.5	-1.0
Min, Max	-1, 1	-3, 2	-1, 1	-3, 2
Change from Baseline to Cycle 5 Day 1				
n	4	23	11	38
Mean (StdDev)	-0.8 (0.96)	-1.3 (1.39)	-0.6 (1.69)	-1.0 (1.44)
Median	-0.5	-2.0	-1.0	-1.0
Min, Max	-2, 0	-3, 2	-3, 3	-3, 3
Change from Baseline to Cycle 6 Day 1				
n	3	9	5	17
Mean (StdDev)	-1.3 (1.53)	-1.1 (1.36)	0.0 (1.22)	-0.8 (1.38)
Median	-1.0	-1.0	0.0	-1.0
Min, Max	-3, 0	-3, 1	-1, 2	-3, 2
Change from Baseline to Cycle 7 Day 1				
n	4	21	7	32
Mean (StdDev)	-1.3 (1.26)	-1.9 (1.20)	-0.7 (1.38)	-1.5 (1.29)
Median	-1.0	-2.0	-1.0	-2.0
Min, Max	-3, 0	-4, 1	-3, 1	-4, 1

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp-chg.sas
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Table 35.2.10.2
Summary of Patient's Global Impression of Symptom Severity Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

PGIS	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 8 Day 1				
n	2	8	4	14
Mean (StdDev)	-0.5 (0.71)	-1.0 (1.07)	0.8 (2.22)	-0.4 (1.55)
Median	-0.5	-1.0	0.0	-1.0
Min, Max	-1, 0	-2, 1	-1, 4	-2, 4
Change from Baseline to Cycle 9 Day 1				
n	3	17	6	26
Mean (StdDev)	-1.3 (1.53)	-1.8 (1.07)	-0.2 (2.40)	-1.4 (1.60)
Median	-1.0	-2.0	0.0	-2.0
Min, Max	-3, 0	-4, 0	-3, 4	-4, 4
Change from Baseline to Cycle 10 Day 1				
n	3	7	3	13
Mean (StdDev)	-1.0 (1.73)	-1.0 (1.00)	0.0 (0.00)	-0.8 (1.09)
Median	0.0	-1.0	0.0	0.0
Min, Max	-3, 0	-2, 0	0, 0	-3, 0
Change from Baseline to Cycle 11 Day 1				
n	3	14	4	21
Mean (StdDev)	-1.3 (1.53)	-1.7 (1.64)	-1.5 (1.29)	-1.6 (1.50)
Median	-1.0	-2.0	-1.5	-2.0
Min, Max	-3, 0	-4, 1	-3, 0	-4, 1

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp-chg.sas
Date: 20:49/20OCT2021

Table 35.2.10.2
Summary of Patient's Global Impression of Symptom Severity Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

PGIS	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 12 Day 1				
n	2	4	3	9
Mean (StdDev)	-2.0 (2.83)	-2.3 (0.96)	-1.0 (1.00)	-1.8 (1.39)
Median	-2.0	-2.5	-1.0	-2.0
Min, Max	-4, 0	-3, -1	-2, 0	-4, 0
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-2.3 (2.08)	-4.0 (-)	-2.8 (1.89)
Median		-3.0	-4.0	-3.5
Min, Max		-4, 0	-4, -4	-4, 0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.0 (-)		0.0 (-)
Median		0.0		0.0
Min, Max		0, 0		0, 0

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp-chg.sas Date: 20:49/20OCT2021

Table 35.2.10.2
Summary of Patient's Global Impression of Symptom Severity Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

PGIS	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Baseline				
n	4	29	12	45
Mean (StdDev)	2.5 (0.58)	2.8 (1.33)	2.3 (1.06)	2.6 (1.21)
Median	2.5	3.0	2.0	3.0
Min, Max	2, 3	0, 4	1, 4	0, 4
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	0.3 (0.58)	-1.2 (1.36)	-0.9 (1.21)	-1.0 (1.33)
Median	0.0	-1.0	-1.0	-1.0
Min, Max	0, 1	-4, 2	-2, 1	-4, 2
Change from Baseline to Cycle 2 Day 1				
n	2	26	11	39
Mean (StdDev)	0.0 (0.00)	-1.1 (1.28)	-0.8 (1.25)	-1.0 (1.25)
Median	0.0	-1.0	-1.0	-1.0
Min, Max	0, 0	-4, 2	-3, 1	-4, 2
Change from Baseline to Cycle 3 Day 1				
n	3	26	9	38
Mean (StdDev)	0.0 (1.00)	-1.2 (1.33)	-0.8 (1.20)	-1.0 (1.29)
Median	0.0	-1.0	-1.0	-1.0
Min, Max	-1, 1	-4, 1	-3, 1	-4, 1

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp-chg.sas
Date: 20:49/20OCT2021

Table 35.2.10.2
Summary of Patient's Global Impression of Symptom Severity Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

PGIS	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		-0.3 (1.50)	-0.3 (0.96)	-0.3 (1.16)
Median		-1.0	-0.5	-1.0
Min, Max		-1, 2	-1, 1	-1, 2
Change from Baseline to Cycle 5 Day 1				
n	1	16	9	26
Mean (StdDev)	0.0 (-)	-1.6 (1.31)	-1.0 (1.32)	-1.3 (1.32)
Median	0.0	-2.0	-1.0	-1.0
Min, Max	0, 0	-3, 2	-3, 1	-3, 2
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		-0.7 (1.53)	-0.5 (0.58)	-0.6 (0.98)
Median		-1.0	-0.5	-1.0
Min, Max		-2, 1	-1, 0	-2, 1
Change from Baseline to Cycle 7 Day 1				
n	1	17	5	23
Mean (StdDev)	-1.0 (-)	-1.9 (1.20)	-1.0 (1.41)	-1.7 (1.26)
Median	-1.0	-2.0	-1.0	-2.0
Min, Max	-1, -1	-4, 1	-3, 1	-4, 1

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp-chg.sas
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Table 35.2.10.2
Summary of Patient's Global Impression of Symptom Severity Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

PGIS	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		-1.5 (0.71)	0.0 (0.00)	-0.8 (0.96)
Median		-1.5	0.0	-0.5
Min, Max		-2, -1	0, 0	-2, 0
Change from Baseline to Cycle 9 Day 1				
n	0	13	4	17
Mean (StdDev)		-2.0 (1.08)	-0.8 (1.50)	-1.7 (1.26)
Median		-2.0	0.0	-2.0
Min, Max		-4, 0	-3, 0	-4, 0
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		-2.0 (-)	0.0 (0.00)	-0.7 (1.15)
Median		-2.0	0.0	0.0
Min, Max		-2, -2	0, 0	-2, 0
Change from Baseline to Cycle 11 Day 1				
n	0	8	3	11
Mean (StdDev)		-2.3 (1.49)	-1.7 (1.53)	-2.1 (1.45)
Median		-2.5	-2.0	-2.0
Min, Max		-4, 1	-3, 0	-4, 1

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp-chg.sas
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Table 35.2.10.2
Summary of Patient's Global Impression of Symptom Severity Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg				
PGIS	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		-2.0 (-)	-1.0 (1.41)	-1.3 (1.15)
Median		-2.0	-1.0	-2.0
Min, Max		-2, -2	-2, 0	-2, 0
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-2.3 (2.08)	-4.0 (-)	-2.8 (1.89)
Median		-3.0	-4.0	-3.5
Min, Max		-4, 0	-4, -4	-4, 0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.0 (-)		0.0 (-)
Median		0.0		0.0
Min, Max		0, 0		0, 0

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp-chg.sas Date: 20:49/20OCT2021

Table 35.2.10.2
Summary of Patient's Global Impression of Symptom Severity Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg				
PGIS	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Baseline				
n	4	28	12	44
Mean (StdDev)	2.5 (0.58)	2.7 (1.33)	2.3 (1.06)	2.6 (1.21)
Median	2.5	3.0	2.0	3.0
Min, Max	2, 3	0, 4	1, 4	0, 4
Change from Baseline to Cycle 1 Day 15				
n	3	19	7	29
Mean (StdDev)	0.3 (0.58)	-1.3 (1.37)	-0.9 (1.21)	-1.0 (1.34)
Median	0.0	-1.0	-1.0	-1.0
Min, Max	0, 1	-4, 2	-2, 1	-4, 2
Change from Baseline to Cycle 2 Day 1				
n	2	25	11	38
Mean (StdDev)	0.0 (0.00)	-1.1 (1.29)	-0.8 (1.25)	-0.9 (1.25)
Median	0.0	-1.0	-1.0	-1.0
Min, Max	0, 0	-4, 2	-3, 1	-4, 2
Change from Baseline to Cycle 3 Day 1				
n	3	25	9	37
Mean (StdDev)	0.0 (1.00)	-1.2 (1.35)	-0.8 (1.20)	-1.0 (1.31)
Median	0.0	-1.0	-1.0	-1.0
Min, Max	-1, 1	-4, 1	-3, 1	-4, 1

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp-chg.sas
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Table 35.2.10.2
Summary of Patient's Global Impression of Symptom Severity Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

PGIS	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		-0.3 (1.50)	-0.3 (0.96)	-0.3 (1.16)
Median		-1.0	-0.5	-1.0
Min, Max		-1, 2	-1, 1	-1, 2
Change from Baseline to Cycle 5 Day 1				
n	1	15	9	25
Mean (StdDev)	0.0 (-)	-1.6 (1.35)	-1.0 (1.32)	-1.3 (1.35)
Median	0.0	-2.0	-1.0	-1.0
Min, Max	0, 0	-3, 2	-3, 1	-3, 2
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		-0.7 (1.53)	-0.5 (0.58)	-0.6 (0.98)
Median		-1.0	-0.5	-1.0
Min, Max		-2, 1	-1, 0	-2, 1
Change from Baseline to Cycle 7 Day 1				
n	1	16	5	22
Mean (StdDev)	-1.0 (-)	-1.9 (1.24)	-1.0 (1.41)	-1.7 (1.29)
Median	-1.0	-2.0	-1.0	-2.0
Min, Max	-1, -1	-4, 1	-3, 1	-4, 1

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp-chg.sas
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Table 35.2.10.2
Summary of Patient's Global Impression of Symptom Severity Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

PGIS	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		-1.5 (0.71)	0.0 (0.00)	-0.8 (0.96)
Median		-1.5	0.0	-0.5
Min, Max		-2, -1	0, 0	-2, 0
Change from Baseline to Cycle 9 Day 1				
n	0	12	4	16
Mean (StdDev)		-2.0 (1.13)	-0.8 (1.50)	-1.7 (1.30)
Median		-2.0	0.0	-2.0
Min, Max		-4, 0	-3, 0	-4, 0
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		-2.0 (-)	0.0 (0.00)	-0.7 (1.15)
Median		-2.0	0.0	0.0
Min, Max		-2, -2	0, 0	-2, 0
Change from Baseline to Cycle 11 Day 1				
n	0	7	3	10
Mean (StdDev)		-2.3 (1.60)	-1.7 (1.53)	-2.1 (1.52)
Median		-3.0	-2.0	-2.5
Min, Max		-4, 1	-3, 0	-4, 1

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp-chg.sas
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Table 35.2.10.2
Summary of Patient's Global Impression of Symptom Severity Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg				
PGIS	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		-2.0 (-)	-1.0 (1.41)	-1.3 (1.15)
Median		-2.0	-1.0	-2.0
Min, Max		-2, -2	-2, 0	-2, 0
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-2.3 (2.08)	-4.0 (-)	-2.8 (1.89)
Median		-3.0	-4.0	-3.5
Min, Max		-4, 0	-4, -4	-4, 0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.0 (-)		0.0 (-)
Median		0.0		0.0
Min, Max		0, 0		0, 0

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-imp-chg.sas Date: 20:49/20OCT2021

Table 35.2.10.1a
Summary of Compliance - Patient's Global Impression of Symptom Severity
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses	Baseline (N=27)	C2D1 (N=27)	C3D1 (N=27)	C4D1 (N=27)	C5D1 (N=27)	C6D1 (N=27)	C7D1 (N=27)	C8D1 (N=27)
Treated	27	27	26	26	25	24	24	23
PGIS	24 (88.9)	23 (85.2)	22 (84.6)	22 (84.6)	21 (84.0)	20 (83.3)	18 (75.0)	16 (69.6)

All Doses	C9D1 (N=27)	C10D1 (N=27)	C11D1 (N=27)	C12D1 (N=27)
Treated	23	19	18	17
PGIS	16 (69.6)	16 (84.2)	17 (94.4)	12 (70.6)

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-pgis.sas Date: 15:14/18JAN2022

Table 35.2.10.1a
Summary of Compliance - Patient's Global Impression of Symptom Severity
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg	Baseline (N=10)	C2D1 (N=10)	C3D1 (N=10)	C4D1 (N=10)	C5D1 (N=10)	C6D1 (N=10)	C7D1 (N=10)	C8D1 (N=10)
Treated	10	10	9	9	8	8	8	7
PGIS	10 (100)	8 (80.0)	7 (77.8)	8 (88.9)	6 (75.0)	7 (87.5)	6 (75.0)	4 (57.1)

Starting Dose: <= 200 mg	C9D1 (N=10)	C10D1 (N=10)	C11D1 (N=10)	C12D1 (N=10)
Treated	7	6	5	4
PGIS	4 (57.1)	3 (50.0)	4 (80.0)	3 (75.0)

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-pgis.sas Date: 15:14/18JAN2022

Table 35.2.10.1a
Summary of Compliance - Patient's Global Impression of Symptom Severity
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg	Baseline (N=10)	C2D1 (N=10)	C3D1 (N=10)	C4D1 (N=10)	C5D1 (N=10)	C6D1 (N=10)	C7D1 (N=10)	C8D1 (N=10)
Treated	10	10	9	9	8	8	8	7
PGIS	10 (100)	8 (80.0)	7 (77.8)	8 (88.9)	6 (75.0)	7 (87.5)	6 (75.0)	4 (57.1)

Starting Dose: 200 mg	C9D1 (N=10)	C10D1 (N=10)	C11D1 (N=10)	C12D1 (N=10)
Treated	7	6	5	4
PGIS	4 (57.1)	3 (50.0)	4 (80.0)	3 (75.0)

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-pgis.sas Date: 15:14/18JAN2022

Table 35.2.10.1a
Summary of Compliance - Patient's Global Impression of Symptom Severity
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses	Baseline (N=42)	C1D15 (N=42)	C2D1 (N=42)	C3D1 (N=42)	C5D1 (N=42)	C7D1 (N=42)	C9D1 (N=42)	C11D1 (N=42)
Treated	42	42	40	37	32	22	18	12
PGIS	35 (83.3)	32 (76.2)	33 (82.5)	32 (86.5)	21 (65.6)	17 (77.3)	13 (72.2)	7 (58.3)

All Doses	C14D1 (N=42)	C17D1 (N=42)
Treated	6	5
PGIS	4 (66.7)	1 (20.0)

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-pgis.sas Date: 15:14/18JAN2022

Table 35.2.10.1a
Summary of Compliance - Patient's Global Impression of Symptom Severity
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg								
	Baseline (N=40)	C1D15 (N=40)	C2D1 (N=40)	C3D1 (N=40)	C5D1 (N=40)	C7D1 (N=40)	C9D1 (N=40)	C11D1 (N=40)
Treated	40	40	39	36	31	21	17	11
PGIS	34 (85.0)	31 (77.5)	32 (82.1)	31 (86.1)	20 (64.5)	16 (76.2)	12 (70.6)	6 (54.5)

Starting Dose: 200 mg		
	C14D1 (N=40)	C17D1 (N=40)
Treated	5	5
PGIS	4 (80.0)	1 (20.0)

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-pgis.sas Date: 15:14/18JAN2022

Table 35.2.10.1a
Summary of Compliance - Patient's Global Impression of Symptom Severity
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses	Baseline (N=69)	C1D15 (N=69)	C2D1 (N=69)	C3D1 (N=69)	C4D1 (N=69)	C5D1 (N=69)	C6D1 (N=69)	C7D1 (N=69)
Treated	69	42	67	63	63	57	49	46
PGIS	59 (85.5)	32 (76.2)	56 (83.6)	54 (85.7)	22 (34.9)	42 (73.7)	20 (40.8)	35 (76.1)

All Doses	C8D1 (N=69)	C9D1 (N=69)	C10D1 (N=69)	C11D1 (N=69)	C12D1 (N=69)	C14D1 (N=69)	C17D1 (N=69)
Treated	44	41	32	30	27	22	21
PGIS	16 (36.4)	29 (70.7)	16 (50.0)	24 (80.0)	12 (44.4)	4 (18.2)	1 (4.8)

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-pgis.sas Date: 15:14/18JAN2022

Table 35.2.10.1a
Summary of Compliance - Patient's Global Impression of Symptom Severity
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg								
	Baseline (N=52)	C1D15 (N=52)	C2D1 (N=52)	C3D1 (N=52)	C4D1 (N=52)	C5D1 (N=52)	C6D1 (N=52)	C7D1 (N=52)
Treated	52	42	50	46	46	40	33	30
PGIS	45 (86.5)	32 (76.2)	41 (82.0)	39 (84.8)	8 (17.4)	27 (67.5)	7 (21.2)	23 (76.7)

Starting Dose: <= 200 mg							
	C8D1 (N=52)	C9D1 (N=52)	C10D1 (N=52)	C11D1 (N=52)	C12D1 (N=52)	C14D1 (N=52)	C17D1 (N=52)
Treated	28	25	19	17	14	9	8
PGIS	4 (14.3)	17 (68.0)	3 (15.8)	11 (64.7)	3 (21.4)	4 (44.4)	1 (12.5)

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-pgis.sas Date: 15:14/18JAN2022

Table 35.2.10.1a
Summary of Compliance - Patient's Global Impression of Symptom Severity
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg								
	Baseline (N=50)	C1D15 (N=50)	C2D1 (N=50)	C3D1 (N=50)	C4D1 (N=50)	C5D1 (N=50)	C6D1 (N=50)	C7D1 (N=50)
Treated	50	40	49	45	45	39	32	29
PGIS	44 (88.0)	31 (77.5)	40 (81.6)	38 (84.4)	8 (17.8)	26 (66.7)	7 (21.9)	22 (75.9)

Starting Dose: 200 mg							
	C8D1 (N=50)	C9D1 (N=50)	C10D1 (N=50)	C11D1 (N=50)	C12D1 (N=50)	C14D1 (N=50)	C17D1 (N=50)
Treated	27	24	18	16	13	8	8
PGIS	4 (14.8)	16 (66.7)	3 (16.7)	10 (62.5)	3 (23.1)	4 (50.0)	1 (12.5)

Source: Listing 16.3.12
Abbreviations: PGIS= Patient's Global Impression of Symptom Severity
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-pgis.sas Date: 15:14/18JAN2022

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Global Health Status/QoL	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Baseline				
n	4	15	6	25
Mean (StdDev)	45.83 (8.333)	43.89 (26.252)	36.11 (18.758)	42.33 (22.298)
Median	50.00	50.00	37.50	50.00
Min, Max	33.3, 50.0	0.0, 83.3	16.7, 58.3	0.0, 83.3
Cycle 2 Day 1				
n	3	15	5	23
Mean (StdDev)	50.00 (28.868)	63.89 (15.957)	55.00 (24.721)	60.14 (19.455)
Median	66.67	66.67	58.33	66.67
Min, Max	16.7, 66.7	41.7, 83.3	16.7, 83.3	16.7, 83.3
Cycle 3 Day 1				
n	3	14	5	22
Mean (StdDev)	41.67 (22.048)	65.48 (15.965)	61.67 (13.944)	61.36 (17.545)
Median	50.00	66.67	58.33	58.33
Min, Max	16.7, 58.3	41.7, 100.0	50.0, 83.3	16.7, 100.0
Cycle 4 Day 1				
n	2	14	6	22
Mean (StdDev)	62.50 (29.463)	63.10 (18.979)	48.61 (17.808)	59.09 (19.570)
Median	62.50	66.67	50.00	62.50
Min, Max	41.7, 83.3	41.7, 100.0	25.0, 66.7	25.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Global Health Status/QoL	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Cycle 5 Day 1				
n	3	12	6	21
Mean (StdDev)	69.44 (12.729)	64.58 (19.824)	59.72 (13.351)	63.89 (16.942)
Median	66.67	66.67	54.17	66.67
Min, Max	58.3, 83.3	25.0, 100.0	50.0, 83.3	25.0, 100.0
Cycle 6 Day 1				
n	3	12	5	20
Mean (StdDev)	72.22 (9.623)	63.89 (20.515)	61.67 (7.454)	64.58 (16.639)
Median	66.67	58.33	66.67	66.67
Min, Max	66.7, 83.3	33.3, 100.0	50.0, 66.7	33.3, 100.0
Cycle 7 Day 1				
n	3	10	5	18
Mean (StdDev)	58.33 (14.434)	65.00 (17.916)	53.33 (4.564)	60.65 (15.072)
Median	66.67	58.33	50.00	58.33
Min, Max	41.7, 66.7	41.7, 100.0	50.0, 58.3	41.7, 100.0
Cycle 8 Day 1				
n	2	10	4	16
Mean (StdDev)	66.67 (35.355)	66.67 (17.568)	45.83 (31.549)	61.46 (23.546)
Median	66.67	66.67	58.33	66.67
Min, Max	41.7, 91.7	41.7, 100.0	0.0, 66.7	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Global Health Status/QoL	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Cycle 9 Day 1				
n	3	9	4	16
Mean (StdDev)	58.33 (14.434)	70.37 (16.724)	31.25 (37.500)	58.33 (27.217)
Median	66.67	66.67	25.00	66.67
Min, Max	41.7, 66.7	50.0, 100.0	0.0, 75.0	0.0, 100.0
Cycle 10 Day 1				
n	3	10	3	16
Mean (StdDev)	69.44 (9.623)	63.33 (17.656)	50.00 (44.096)	61.98 (22.354)
Median	75.00	62.50	66.67	66.67
Min, Max	58.3, 75.0	25.0, 83.3	0.0, 83.3	0.0, 83.3
Cycle 11 Day 1				
n	3	11	3	17
Mean (StdDev)	50.00 (25.000)	65.91 (18.803)	36.11 (31.549)	57.84 (23.839)
Median	50.00	66.67	50.00	58.33
Min, Max	25.0, 75.0	41.7, 100.0	0.0, 58.3	0.0, 100.0
Cycle 12 Day 1				
n	2	7	3	12
Mean (StdDev)	70.83 (17.678)	65.48 (17.631)	50.00 (44.096)	62.50 (24.746)
Median	70.83	66.67	66.67	66.67
Min, Max	58.3, 83.3	41.7, 100.0	0.0, 83.3	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Physical Functioning	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Baseline				
n	4	15	6	25
Mean (StdDev)	78.33 (6.383)	50.67 (24.791)	61.11 (27.782)	57.60 (25.084)
Median	76.67	53.33	73.33	66.67
Min, Max	73.3, 86.7	0.0, 86.7	20.0, 86.7	0.0, 86.7
Cycle 2 Day 1				
n	3	15	5	23
Mean (StdDev)	73.33 (11.547)	62.22 (23.993)	68.00 (28.829)	64.93 (23.374)
Median	80.00	66.67	73.33	73.33
Min, Max	60.0, 80.0	13.3, 93.3	26.7, 100.0	13.3, 100.0
Cycle 3 Day 1				
n	3	14	5	22
Mean (StdDev)	68.89 (19.245)	64.76 (22.100)	77.33 (25.647)	68.18 (22.152)
Median	80.00	70.00	86.67	73.33
Min, Max	46.7, 80.0	26.7, 100.0	46.7, 100.0	26.7, 100.0
Cycle 4 Day 1				
n	2	14	6	22
Mean (StdDev)	56.67 (14.142)	64.76 (24.866)	77.78 (16.689)	67.58 (22.471)
Median	56.67	66.67	76.67	70.00
Min, Max	46.7, 66.7	20.0, 100.0	60.0, 100.0	20.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Physical Functioning	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Cycle 5 Day 1				
n	3	12	6	21
Mean (StdDev)	68.89 (13.878)	65.56 (23.065)	73.33 (19.777)	68.25 (20.538)
Median	73.33	70.00	70.00	73.33
Min, Max	53.3, 80.0	20.0, 100.0	53.3, 100.0	20.0, 100.0
Cycle 6 Day 1				
n	3	12	5	20
Mean (StdDev)	64.44 (16.777)	60.00 (25.898)	68.00 (28.048)	62.67 (24.414)
Median	66.67	53.33	60.00	60.00
Min, Max	46.7, 80.0	20.0, 100.0	33.3, 100.0	20.0, 100.0
Cycle 7 Day 1				
n	3	10	5	18
Mean (StdDev)	80.00 (11.547)	58.00 (30.639)	62.67 (26.916)	62.96 (27.366)
Median	86.67	66.67	60.00	70.00
Min, Max	66.7, 86.7	13.3, 100.0	26.7, 100.0	13.3, 100.0
Cycle 8 Day 1				
n	2	10	4	16
Mean (StdDev)	76.67 (14.142)	68.67 (21.094)	63.33 (34.641)	68.33 (23.158)
Median	76.67	73.33	66.67	73.33
Min, Max	66.7, 86.7	40.0, 100.0	20.0, 100.0	20.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Physical Functioning	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Cycle 9 Day 1				
n	3	9	4	16
Mean (StdDev)	66.67 (26.667)	65.93 (26.341)	58.33 (35.434)	64.17 (26.984)
Median	66.67	53.33	56.67	60.00
Min, Max	40.0, 93.3	26.7, 100.0	20.0, 100.0	20.0, 100.0
Cycle 10 Day 1				
n	3	10	3	16
Mean (StdDev)	71.11 (13.878)	62.67 (25.181)	66.67 (41.633)	65.00 (25.473)
Median	66.67	66.67	80.00	70.00
Min, Max	60.0, 86.7	13.3, 100.0	20.0, 100.0	13.3, 100.0
Cycle 11 Day 1				
n	3	11	3	17
Mean (StdDev)	68.89 (15.396)	70.30 (22.184)	62.22 (44.389)	68.63 (24.354)
Median	60.00	66.67	73.33	66.67
Min, Max	60.0, 86.7	26.7, 100.0	13.3, 100.0	13.3, 100.0
Cycle 12 Day 1				
n	2	7	3	12
Mean (StdDev)	63.33 (4.714)	67.62 (25.943)	62.22 (44.389)	65.56 (27.093)
Median	63.33	73.33	73.33	70.00
Min, Max	60.0, 66.7	33.3, 100.0	13.3, 100.0	13.3, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Role Functioning	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Baseline				
n	4	15	6	25
Mean (StdDev)	58.33 (21.517)	41.11 (25.871)	33.33 (36.515)	42.00 (28.104)
Median	58.33	33.33	33.33	50.00
Min, Max	33.3, 83.3	0.0, 83.3	0.0, 66.7	0.0, 83.3
Cycle 2 Day 1				
n	3	15	5	23
Mean (StdDev)	55.56 (25.459)	57.78 (32.038)	63.33 (38.006)	58.70 (31.330)
Median	50.00	66.67	66.67	66.67
Min, Max	33.3, 83.3	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 3 Day 1				
n	3	14	5	22
Mean (StdDev)	55.56 (25.459)	60.71 (22.272)	63.33 (29.814)	60.61 (23.314)
Median	50.00	66.67	66.67	66.67
Min, Max	33.3, 83.3	33.3, 100.0	16.7, 100.0	16.7, 100.0
Cycle 4 Day 1				
n	2	14	6	22
Mean (StdDev)	33.33 (23.570)	57.14 (26.726)	66.67 (29.814)	57.58 (27.568)
Median	33.33	66.67	66.67	66.67
Min, Max	16.7, 50.0	0.0, 100.0	33.3, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Role Functioning	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Cycle 5 Day 1				
n	3	12	6	21
Mean (StdDev)	61.11 (19.245)	56.94 (30.533)	52.78 (34.021)	56.35 (29.096)
Median	50.00	66.67	58.33	66.67
Min, Max	50.0, 83.3	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 6 Day 1				
n	3	12	5	20
Mean (StdDev)	72.22 (9.623)	44.44 (33.585)	60.00 (36.515)	52.50 (32.568)
Median	66.67	33.33	66.67	66.67
Min, Max	66.7, 83.3	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 7 Day 1				
n	3	10	5	18
Mean (StdDev)	77.78 (19.245)	55.00 (34.292)	63.33 (29.814)	61.11 (30.785)
Median	66.67	58.33	66.67	66.67
Min, Max	66.7, 100.0	0.0, 100.0	16.7, 100.0	0.0, 100.0
Cycle 8 Day 1				
n	2	10	4	16
Mean (StdDev)	66.67 (0.000)	66.67 (26.058)	41.67 (50.000)	60.42 (32.131)
Median	66.67	66.67	33.33	66.67
Min, Max	66.7, 66.7	16.7, 100.0	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Role Functioning	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Cycle 9 Day 1				
n	3	9	4	16
Mean (StdDev)	66.67 (16.667)	55.56 (39.965)	25.00 (50.000)	50.00 (40.369)
Median	66.67	66.67	0.00	66.67
Min, Max	50.0, 83.3	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	3	10	3	16
Mean (StdDev)	66.67 (0.000)	50.00 (34.247)	55.56 (50.918)	54.17 (33.054)
Median	66.67	50.00	66.67	66.67
Min, Max	66.7, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 11 Day 1				
n	3	11	3	17
Mean (StdDev)	66.67 (0.000)	60.61 (34.378)	55.56 (50.918)	60.78 (32.777)
Median	66.67	66.67	66.67	66.67
Min, Max	66.7, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 12 Day 1				
n	2	7	3	12
Mean (StdDev)	58.33 (35.355)	64.29 (33.923)	50.00 (50.000)	59.72 (35.146)
Median	58.33	66.67	50.00	66.67
Min, Max	33.3, 83.3	0.0, 100.0	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Emotional Functioning	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Baseline				
n	4	15	6	25
Mean (StdDev)	68.75 (32.185)	66.67 (25.198)	65.28 (26.043)	66.67 (25.345)
Median	70.83	66.67	75.00	75.00
Min, Max	33.3, 100.0	25.0, 100.0	25.0, 91.7	25.0, 100.0
Cycle 2 Day 1				
n	3	15	5	23
Mean (StdDev)	63.89 (20.972)	68.33 (28.730)	70.00 (20.917)	68.12 (25.457)
Median	66.67	75.00	66.67	66.67
Min, Max	41.7, 83.3	8.3, 100.0	41.7, 100.0	8.3, 100.0
Cycle 3 Day 1				
n	3	14	5	22
Mean (StdDev)	55.56 (26.788)	74.60 (21.319)	75.00 (8.333)	72.10 (20.204)
Median	66.67	75.00	75.00	75.00
Min, Max	25.0, 75.0	25.0, 100.0	66.7, 83.3	25.0, 100.0
Cycle 4 Day 1				
n	2	14	6	22
Mean (StdDev)	83.33 (11.785)	77.38 (18.324)	76.39 (19.305)	77.65 (17.515)
Median	83.33	75.00	79.17	79.17
Min, Max	75.0, 91.7	41.7, 100.0	50.0, 100.0	41.7, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Emotional Functioning	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Cycle 5 Day 1				
n	3	12	6	21
Mean (StdDev)	66.67 (22.048)	69.44 (26.192)	72.22 (14.593)	69.84 (21.965)
Median	75.00	66.67	66.67	66.67
Min, Max	41.7, 83.3	8.3, 100.0	58.3, 100.0	8.3, 100.0
Cycle 6 Day 1				
n	3	12	5	20
Mean (StdDev)	66.67 (25.000)	75.00 (20.412)	70.00 (24.008)	72.50 (20.960)
Median	66.67	70.83	75.00	70.83
Min, Max	41.7, 91.7	41.7, 100.0	41.7, 100.0	41.7, 100.0
Cycle 7 Day 1				
n	3	10	5	18
Mean (StdDev)	61.11 (12.729)	77.50 (21.173)	66.67 (27.003)	71.76 (21.794)
Median	58.33	75.00	66.67	70.83
Min, Max	50.0, 75.0	33.3, 100.0	25.0, 100.0	25.0, 100.0
Cycle 8 Day 1				
n	2	10	4	16
Mean (StdDev)	75.00 (11.785)	76.94 (17.473)	58.33 (15.215)	72.05 (17.494)
Median	75.00	70.83	58.33	66.67
Min, Max	66.7, 83.3	50.0, 100.0	41.7, 75.0	41.7, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Emotional Functioning	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Cycle 9 Day 1				
n	3	9	4	16
Mean (StdDev)	69.44 (12.729)	76.85 (20.318)	58.33 (31.180)	70.83 (22.361)
Median	66.67	75.00	54.17	66.67
Min, Max	58.3, 83.3	50.0, 100.0	25.0, 100.0	25.0, 100.0
Cycle 10 Day 1				
n	3	10	3	16
Mean (StdDev)	66.67 (33.333)	72.50 (24.861)	47.22 (17.347)	66.67 (25.640)
Median	66.67	75.00	41.67	66.67
Min, Max	33.3, 100.0	33.3, 100.0	33.3, 66.7	33.3, 100.0
Cycle 11 Day 1				
n	3	11	3	17
Mean (StdDev)	55.56 (20.972)	71.21 (23.083)	55.56 (17.347)	65.69 (22.025)
Median	58.33	66.67	50.00	58.33
Min, Max	33.3, 75.0	33.3, 100.0	41.7, 75.0	33.3, 100.0
Cycle 12 Day 1				
n	2	7	3	12
Mean (StdDev)	50.00 (23.570)	70.24 (22.493)	44.44 (33.679)	60.42 (26.142)
Median	50.00	66.67	50.00	66.67
Min, Max	33.3, 66.7	41.7, 100.0	8.3, 75.0	8.3, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Cognitive Functioning	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Baseline				
n	4	15	6	25
Mean (StdDev)	70.83 (28.464)	64.44 (32.038)	72.22 (20.184)	67.33 (28.252)
Median	75.00	66.67	75.00	66.67
Min, Max	33.3, 100.0	0.0, 100.0	50.0, 100.0	0.0, 100.0
Cycle 2 Day 1				
n	3	15	5	23
Mean (StdDev)	50.00 (44.096)	70.00 (29.681)	80.00 (7.454)	69.57 (28.715)
Median	66.67	66.67	83.33	83.33
Min, Max	0.0, 83.3	0.0, 100.0	66.7, 83.3	0.0, 100.0
Cycle 3 Day 1				
n	3	14	5	22
Mean (StdDev)	55.56 (34.694)	69.05 (24.335)	76.67 (9.129)	68.94 (23.171)
Median	66.67	66.67	83.33	66.67
Min, Max	16.7, 83.3	33.3, 100.0	66.7, 83.3	16.7, 100.0
Cycle 4 Day 1				
n	2	14	6	22
Mean (StdDev)	83.33 (23.570)	76.19 (22.374)	77.78 (13.608)	77.27 (19.616)
Median	83.33	83.33	75.00	83.33
Min, Max	66.7, 100.0	33.3, 100.0	66.7, 100.0	33.3, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Cognitive Functioning	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Cycle 5 Day 1				
n	3	12	6	21
Mean (StdDev)	61.11 (34.694)	68.06 (30.533)	66.67 (21.082)	66.67 (27.386)
Median	50.00	75.00	58.33	66.67
Min, Max	33.3, 100.0	0.0, 100.0	50.0, 100.0	0.0, 100.0
Cycle 6 Day 1				
n	3	12	5	20
Mean (StdDev)	55.56 (41.944)	76.39 (20.669)	83.33 (11.785)	75.00 (23.258)
Median	50.00	83.33	83.33	83.33
Min, Max	16.7, 100.0	33.3, 100.0	66.7, 100.0	16.7, 100.0
Cycle 7 Day 1				
n	3	10	5	18
Mean (StdDev)	50.00 (0.000)	73.33 (22.498)	70.00 (18.257)	68.52 (20.523)
Median	50.00	66.67	66.67	66.67
Min, Max	50.0, 50.0	33.3, 100.0	50.0, 100.0	33.3, 100.0
Cycle 8 Day 1				
n	2	10	4	16
Mean (StdDev)	66.67 (0.000)	75.00 (22.567)	75.00 (9.623)	73.96 (18.226)
Median	66.67	75.00	75.00	66.67
Min, Max	66.7, 66.7	33.3, 100.0	66.7, 83.3	33.3, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Cognitive Functioning	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Cycle 9 Day 1				
n	3	9	4	16
Mean (StdDev)	50.00 (16.667)	72.22 (23.570)	79.17 (15.957)	69.79 (22.127)
Median	50.00	83.33	75.00	66.67
Min, Max	33.3, 66.7	33.3, 100.0	66.7, 100.0	33.3, 100.0
Cycle 10 Day 1				
n	3	10	3	16
Mean (StdDev)	38.89 (41.944)	66.67 (27.217)	61.11 (25.459)	60.42 (29.736)
Median	33.33	66.67	66.67	66.67
Min, Max	0.0, 83.3	16.7, 100.0	33.3, 83.3	0.0, 100.0
Cycle 11 Day 1				
n	3	11	3	17
Mean (StdDev)	55.56 (9.623)	69.70 (22.134)	61.11 (19.245)	65.69 (19.957)
Median	50.00	66.67	50.00	66.67
Min, Max	50.0, 66.7	33.3, 100.0	50.0, 83.3	33.3, 100.0
Cycle 12 Day 1				
n	2	7	3	12
Mean (StdDev)	41.67 (11.785)	64.29 (32.530)	55.56 (34.694)	58.33 (29.729)
Median	41.67	66.67	66.67	66.67
Min, Max	33.3, 50.0	0.0, 100.0	16.7, 83.3	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Social Function	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Baseline				
n	4	15	6	25
Mean (StdDev)	66.67 (30.429)	50.00 (28.868)	50.00 (40.825)	52.67 (31.432)
Median	66.67	50.00	66.67	50.00
Min, Max	33.3, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 2 Day 1				
n	3	15	5	23
Mean (StdDev)	66.67 (16.667)	62.22 (34.195)	43.33 (36.515)	58.70 (32.902)
Median	66.67	66.67	33.33	66.67
Min, Max	50.0, 83.3	16.7, 100.0	0.0, 100.0	0.0, 100.0
Cycle 3 Day 1				
n	3	14	5	22
Mean (StdDev)	66.67 (16.667)	61.90 (23.956)	60.00 (19.003)	62.12 (21.320)
Median	66.67	58.33	66.67	66.67
Min, Max	50.0, 83.3	16.7, 100.0	33.3, 83.3	16.7, 100.0
Cycle 4 Day 1				
n	2	14	6	22
Mean (StdDev)	75.00 (11.785)	65.48 (26.525)	58.33 (25.276)	64.39 (24.825)
Median	75.00	66.67	58.33	66.67
Min, Max	66.7, 83.3	0.0, 100.0	33.3, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Social Function	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Cycle 5 Day 1				
n	3	12	6	21
Mean (StdDev)	50.00 (16.667)	58.33 (30.567)	63.89 (16.387)	58.73 (25.066)
Median	50.00	66.67	66.67	66.67
Min, Max	33.3, 66.7	0.0, 100.0	33.3, 83.3	0.0, 100.0
Cycle 6 Day 1				
n	3	12	5	20
Mean (StdDev)	66.67 (33.333)	56.94 (32.144)	60.00 (9.129)	59.17 (27.293)
Median	66.67	58.33	66.67	66.67
Min, Max	33.3, 100.0	0.0, 100.0	50.0, 66.7	0.0, 100.0
Cycle 7 Day 1				
n	3	10	5	18
Mean (StdDev)	61.11 (9.623)	51.67 (38.046)	76.67 (9.129)	60.19 (30.324)
Median	66.67	58.33	83.33	66.67
Min, Max	50.0, 66.7	0.0, 100.0	66.7, 83.3	0.0, 100.0
Cycle 8 Day 1				
n	2	10	4	16
Mean (StdDev)	58.33 (11.785)	61.67 (29.450)	41.67 (16.667)	56.25 (25.730)
Median	58.33	66.67	33.33	58.33
Min, Max	50.0, 66.7	16.7, 100.0	33.3, 66.7	16.7, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Social Function	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Cycle 9 Day 1				
n	3	9	4	16
Mean (StdDev)	61.11 (25.459)	57.41 (37.371)	66.67 (30.429)	60.42 (32.131)
Median	66.67	66.67	66.67	66.67
Min, Max	33.3, 83.3	0.0, 100.0	33.3, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	3	10	3	16
Mean (StdDev)	66.67 (16.667)	58.33 (29.659)	44.44 (38.490)	57.29 (28.525)
Median	66.67	58.33	66.67	66.67
Min, Max	50.0, 83.3	16.7, 100.0	0.0, 66.7	0.0, 100.0
Cycle 11 Day 1				
n	3	11	3	17
Mean (StdDev)	50.00 (28.868)	62.12 (27.979)	55.56 (34.694)	58.82 (27.712)
Median	33.33	66.67	66.67	66.67
Min, Max	33.3, 83.3	16.7, 100.0	16.7, 83.3	16.7, 100.0
Cycle 12 Day 1				
n	2	7	3	12
Mean (StdDev)	91.67 (11.785)	64.29 (31.074)	50.00 (28.868)	65.28 (29.694)
Median	91.67	66.67	66.67	66.67
Min, Max	83.3, 100.0	16.7, 100.0	16.7, 66.7	16.7, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Fatigue	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Baseline				
n	4	15	6	25
Mean (StdDev)	63.89 (27.778)	68.15 (25.499)	70.37 (29.537)	68.00 (25.724)
Median	61.11	66.67	72.22	66.67
Min, Max	33.3, 100.0	11.1, 100.0	33.3, 100.0	11.1, 100.0
Cycle 2 Day 1				
n	3	15	5	23
Mean (StdDev)	59.26 (23.130)	52.59 (26.715)	53.33 (29.814)	53.62 (25.875)
Median	66.67	44.44	55.56	55.56
Min, Max	33.3, 77.8	11.1, 100.0	22.2, 100.0	11.1, 100.0
Cycle 3 Day 1				
n	3	14	5	22
Mean (StdDev)	55.56 (29.397)	50.00 (25.691)	48.89 (24.343)	50.51 (24.662)
Median	66.67	50.00	33.33	50.00
Min, Max	22.2, 77.8	0.0, 100.0	33.3, 88.9	0.0, 100.0
Cycle 4 Day 1				
n	2	14	6	22
Mean (StdDev)	44.44 (31.427)	51.59 (22.054)	48.15 (32.710)	50.00 (24.667)
Median	44.44	50.00	33.33	38.89
Min, Max	22.2, 66.7	22.2, 77.8	22.2, 100.0	22.2, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Fatigue	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Cycle 5 Day 1				
n	3	12	6	21
Mean (StdDev)	48.15 (23.130)	50.00 (29.777)	46.30 (19.138)	48.68 (25.209)
Median	55.56	33.33	55.56	55.56
Min, Max	22.2, 66.7	11.1, 100.0	22.2, 66.7	11.1, 100.0
Cycle 6 Day 1				
n	3	12	5	20
Mean (StdDev)	44.44 (19.245)	51.85 (35.243)	57.78 (24.088)	52.22 (29.966)
Median	33.33	55.56	66.67	55.56
Min, Max	33.3, 66.7	0.0, 100.0	33.3, 88.9	0.0, 100.0
Cycle 7 Day 1				
n	3	10	5	18
Mean (StdDev)	48.15 (16.973)	42.78 (29.635)	55.56 (23.570)	47.22 (25.725)
Median	44.44	38.89	55.56	44.44
Min, Max	33.3, 66.7	0.0, 100.0	33.3, 88.9	0.0, 100.0
Cycle 8 Day 1				
n	2	10	4	16
Mean (StdDev)	44.44 (0.000)	38.89 (22.376)	66.67 (27.217)	46.53 (24.417)
Median	44.44	33.33	66.67	44.44
Min, Max	44.4, 44.4	0.0, 66.7	33.3, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Fatigue	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Cycle 9 Day 1				
n	3	9	4	16
Mean (StdDev)	44.44 (11.111)	27.16 (22.299)	66.67 (39.545)	40.28 (29.780)
Median	44.44	22.22	77.78	38.89
Min, Max	33.3, 55.6	0.0, 66.7	11.1, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	3	10	3	16
Mean (StdDev)	66.67 (19.245)	43.33 (25.364)	55.56 (40.062)	50.00 (27.217)
Median	77.78	38.89	44.44	44.44
Min, Max	44.4, 77.8	0.0, 77.8	22.2, 100.0	0.0, 100.0
Cycle 11 Day 1				
n	3	11	3	17
Mean (StdDev)	55.56 (11.111)	42.42 (28.897)	59.26 (35.717)	47.71 (27.432)
Median	55.56	44.44	44.44	44.44
Min, Max	44.4, 66.7	0.0, 88.9	33.3, 100.0	0.0, 100.0
Cycle 12 Day 1				
n	2	7	3	12
Mean (StdDev)	61.11 (7.857)	38.10 (26.338)	51.85 (42.066)	45.37 (28.212)
Median	61.11	44.44	33.33	44.44
Min, Max	55.6, 66.7	0.0, 77.8	22.2, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Nausea and Vomiting	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Baseline				
n	4	15	6	25
Mean (StdDev)	50.00 (30.429)	17.78 (23.117)	16.67 (25.820)	22.67 (26.736)
Median	50.00	0.00	8.33	16.67
Min, Max	16.7, 83.3	0.0, 66.7	0.0, 66.7	0.0, 83.3
Cycle 2 Day 1				
n	3	15	5	23
Mean (StdDev)	38.89 (9.623)	13.33 (21.082)	20.00 (27.386)	18.12 (22.424)
Median	33.33	0.00	16.67	16.67
Min, Max	33.3, 50.0	0.0, 66.7	0.0, 66.7	0.0, 66.7
Cycle 3 Day 1				
n	3	14	5	22
Mean (StdDev)	38.89 (9.623)	17.86 (23.079)	13.33 (13.944)	19.70 (20.979)
Median	33.33	8.33	16.67	16.67
Min, Max	33.3, 50.0	0.0, 66.7	0.0, 33.3	0.0, 66.7
Cycle 4 Day 1				
n	2	14	6	22
Mean (StdDev)	16.67 (23.570)	17.86 (13.812)	8.33 (13.944)	15.15 (14.465)
Median	16.67	16.67	0.00	16.67
Min, Max	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Nausea and Vomiting	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Cycle 5 Day 1				
n	3	12	6	21
Mean (StdDev)	33.33 (0.000)	6.94 (11.143)	11.11 (13.608)	11.90 (14.086)
Median	33.33	0.00	8.33	0.00
Min, Max	33.3, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3
Cycle 6 Day 1				
n	3	12	5	20
Mean (StdDev)	16.67 (16.667)	12.50 (14.434)	3.33 (7.454)	10.83 (13.545)
Median	16.67	8.33	0.00	0.00
Min, Max	0.0, 33.3	0.0, 33.3	0.0, 16.7	0.0, 33.3
Cycle 7 Day 1				
n	3	10	5	18
Mean (StdDev)	33.33 (0.000)	13.33 (20.488)	10.00 (9.129)	15.74 (17.594)
Median	33.33	0.00	16.67	16.67
Min, Max	33.3, 33.3	0.0, 50.0	0.0, 16.7	0.0, 50.0
Cycle 8 Day 1				
n	2	10	4	16
Mean (StdDev)	33.33 (0.000)	5.00 (8.051)	8.33 (9.623)	9.38 (12.124)
Median	33.33	0.00	8.33	0.00
Min, Max	33.3, 33.3	0.0, 16.7	0.0, 16.7	0.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Nausea and Vomiting	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Cycle 9 Day 1				
n	3	9	4	16
Mean (StdDev)	33.33 (0.000)	7.41 (8.784)	12.50 (8.333)	13.54 (12.500)
Median	33.33	0.00	16.67	16.67
Min, Max	33.3, 33.3	0.0, 16.7	0.0, 16.7	0.0, 33.3
Cycle 10 Day 1				
n	3	10	3	16
Mean (StdDev)	33.33 (16.667)	16.67 (20.787)	11.11 (9.623)	18.75 (19.124)
Median	33.33	16.67	16.67	16.67
Min, Max	16.7, 50.0	0.0, 66.7	0.0, 16.7	0.0, 66.7
Cycle 11 Day 1				
n	3	11	3	17
Mean (StdDev)	22.22 (9.623)	7.58 (13.670)	5.56 (9.623)	9.80 (13.253)
Median	16.67	0.00	0.00	0.00
Min, Max	16.7, 33.3	0.0, 33.3	0.0, 16.7	0.0, 33.3
Cycle 12 Day 1				
n	2	7	3	12
Mean (StdDev)	41.67 (11.785)	11.90 (12.599)	16.67 (16.667)	18.06 (16.603)
Median	41.67	16.67	16.67	16.67
Min, Max	33.3, 50.0	0.0, 33.3	0.0, 33.3	0.0, 50.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Pain	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Baseline				
n	4	15	6	25
Mean (StdDev)	58.33 (31.914)	43.33 (33.806)	50.00 (45.947)	47.33 (35.577)
Median	66.67	33.33	50.00	50.00
Min, Max	16.7, 83.3	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 2 Day 1				
n	3	15	5	23
Mean (StdDev)	38.89 (41.944)	24.44 (29.457)	30.00 (27.386)	27.54 (29.563)
Median	33.33	16.67	16.67	16.67
Min, Max	0.0, 83.3	0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 3 Day 1				
n	3	14	5	22
Mean (StdDev)	38.89 (38.490)	21.43 (26.497)	33.33 (26.352)	26.52 (27.535)
Median	16.67	16.67	33.33	16.67
Min, Max	16.7, 83.3	0.0, 83.3	0.0, 66.7	0.0, 83.3
Cycle 4 Day 1				
n	2	14	6	22
Mean (StdDev)	33.33 (23.570)	13.10 (23.732)	44.44 (32.773)	23.48 (28.940)
Median	33.33	0.00	33.33	16.67
Min, Max	16.7, 50.0	0.0, 83.3	16.7, 83.3	0.0, 83.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Pain	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Cycle 5 Day 1				
n	3	12	6	21
Mean (StdDev)	50.00 (44.096)	20.83 (22.613)	22.22 (25.092)	25.40 (27.192)
Median	33.33	16.67	16.67	16.67
Min, Max	16.7, 100.0	0.0, 66.7	0.0, 66.7	0.0, 100.0
Cycle 6 Day 1				
n	3	12	5	20
Mean (StdDev)	38.89 (38.490)	31.94 (30.533)	33.33 (26.352)	33.33 (29.120)
Median	16.67	33.33	33.33	33.33
Min, Max	16.7, 83.3	0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 7 Day 1				
n	3	10	5	18
Mean (StdDev)	38.89 (53.576)	40.00 (37.019)	40.00 (30.277)	39.81 (35.764)
Median	16.67	25.00	50.00	25.00
Min, Max	0.0, 100.0	0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 8 Day 1				
n	2	10	4	16
Mean (StdDev)	41.67 (35.355)	30.00 (28.109)	66.67 (40.825)	40.63 (33.867)
Median	41.67	33.33	75.00	33.33
Min, Max	16.7, 66.7	0.0, 83.3	16.7, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Pain	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Cycle 9 Day 1				
n	3	9	4	16
Mean (StdDev)	33.33 (44.096)	27.78 (34.359)	70.83 (39.382)	39.58 (39.382)
Median	16.67	16.67	83.33	25.00
Min, Max	0.0, 83.3	0.0, 100.0	16.7, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	3	10	3	16
Mean (StdDev)	22.22 (38.490)	35.00 (31.866)	55.56 (41.944)	36.46 (34.004)
Median	0.00	25.00	50.00	25.00
Min, Max	0.0, 66.7	0.0, 100.0	16.7, 100.0	0.0, 100.0
Cycle 11 Day 1				
n	3	11	3	17
Mean (StdDev)	44.44 (41.944)	19.70 (23.355)	50.00 (44.096)	29.41 (31.474)
Median	50.00	16.67	33.33	16.67
Min, Max	0.0, 83.3	0.0, 66.7	16.7, 100.0	0.0, 100.0
Cycle 12 Day 1				
n	2	7	3	12
Mean (StdDev)	41.67 (11.785)	23.81 (18.898)	44.44 (50.918)	31.94 (27.941)
Median	41.67	33.33	33.33	33.33
Min, Max	33.3, 50.0	0.0, 50.0	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Dyspnea	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Baseline				
n	4	15	6	25
Mean (StdDev)	41.67 (16.667)	48.89 (33.014)	44.44 (34.427)	46.67 (30.429)
Median	33.33	33.33	33.33	33.33
Min, Max	33.3, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 2 Day 1				
n	3	15	5	23
Mean (StdDev)	55.56 (38.490)	24.44 (29.457)	26.67 (14.907)	28.99 (28.962)
Median	33.33	33.33	33.33	33.33
Min, Max	33.3, 100.0	0.0, 100.0	0.0, 33.3	0.0, 100.0
Cycle 3 Day 1				
n	3	14	5	22
Mean (StdDev)	66.67 (33.333)	33.33 (29.235)	13.33 (18.257)	33.33 (30.861)
Median	66.67	33.33	0.00	33.33
Min, Max	33.3, 100.0	0.0, 100.0	0.0, 33.3	0.0, 100.0
Cycle 4 Day 1				
n	2	14	6	22
Mean (StdDev)	50.00 (23.570)	28.57 (28.815)	33.33 (21.082)	31.82 (26.181)
Median	50.00	33.33	33.33	33.33
Min, Max	33.3, 66.7	0.0, 100.0	0.0, 66.7	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Dyspnea	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Cycle 5 Day 1				
n	3	12	6	21
Mean (StdDev)	44.44 (19.245)	33.33 (31.782)	33.33 (42.164)	34.92 (32.449)
Median	33.33	33.33	16.67	33.33
Min, Max	33.3, 66.7	0.0, 66.7	0.0, 100.0	0.0, 100.0
Cycle 6 Day 1				
n	3	12	5	20
Mean (StdDev)	33.33 (0.000)	33.33 (31.782)	46.67 (38.006)	36.67 (30.397)
Median	33.33	33.33	33.33	33.33
Min, Max	33.3, 33.3	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 7 Day 1				
n	3	10	5	18
Mean (StdDev)	33.33 (0.000)	30.00 (36.683)	40.00 (43.461)	33.33 (34.300)
Median	33.33	16.67	33.33	33.33
Min, Max	33.3, 33.3	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 8 Day 1				
n	2	10	4	16
Mean (StdDev)	33.33 (0.000)	13.33 (23.307)	41.67 (50.000)	22.92 (31.549)
Median	33.33	0.00	33.33	0.00
Min, Max	33.3, 33.3	0.0, 66.7	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Dyspnea	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Cycle 9 Day 1				
n	3	9	4	16
Mean (StdDev)	55.56 (19.245)	14.81 (33.793)	58.33 (41.944)	33.33 (38.490)
Median	66.67	0.00	66.67	16.67
Min, Max	33.3, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	3	10	3	16
Mean (StdDev)	55.56 (19.245)	33.33 (35.136)	44.44 (50.918)	39.58 (34.894)
Median	66.67	33.33	33.33	33.33
Min, Max	33.3, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 11 Day 1				
n	3	11	3	17
Mean (StdDev)	44.44 (19.245)	24.24 (33.635)	33.33 (57.735)	29.41 (35.123)
Median	33.33	0.00	0.00	33.33
Min, Max	33.3, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 12 Day 1				
n	2	6	3	11
Mean (StdDev)	50.00 (23.570)	27.78 (44.305)	33.33 (57.735)	33.33 (42.164)
Median	50.00	0.00	0.00	0.00
Min, Max	33.3, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Insomnia	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Baseline				
n	4	15	6	25
Mean (StdDev)	50.00 (43.033)	46.67 (35.187)	55.56 (40.369)	49.33 (36.158)
Median	50.00	66.67	50.00	66.67
Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 2 Day 1				
n	3	15	5	23
Mean (StdDev)	55.56 (38.490)	35.56 (29.457)	33.33 (47.140)	37.68 (33.791)
Median	33.33	33.33	0.00	33.33
Min, Max	33.3, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 3 Day 1				
n	3	14	5	22
Mean (StdDev)	33.33 (33.333)	40.48 (29.753)	33.33 (33.333)	37.88 (29.628)
Median	33.33	33.33	33.33	33.33
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 4 Day 1				
n	2	14	6	22
Mean (StdDev)	33.33 (0.000)	40.48 (32.499)	55.56 (40.369)	43.94 (33.152)
Median	33.33	33.33	50.00	33.33
Min, Max	33.3, 33.3	0.0, 100.0	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Insomnia	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Cycle 5 Day 1				
n	3	12	6	21
Mean (StdDev)	33.33 (33.333)	47.22 (33.207)	22.22 (40.369)	38.10 (35.411)
Median	33.33	33.33	0.00	33.33
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 6 Day 1				
n	3	12	5	20
Mean (StdDev)	33.33 (33.333)	44.44 (25.950)	46.67 (38.006)	43.33 (28.817)
Median	33.33	33.33	33.33	33.33
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 7 Day 1				
n	3	10	5	18
Mean (StdDev)	44.44 (19.245)	50.00 (28.328)	53.33 (44.721)	50.00 (30.785)
Median	33.33	33.33	33.33	33.33
Min, Max	33.3, 66.7	33.3, 100.0	0.0, 100.0	0.0, 100.0
Cycle 8 Day 1				
n	2	10	4	16
Mean (StdDev)	33.33 (0.000)	43.33 (35.312)	50.00 (33.333)	43.75 (31.549)
Median	33.33	33.33	33.33	33.33
Min, Max	33.3, 33.3	0.0, 100.0	33.3, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Insomnia	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Cycle 9 Day 1				
n	3	9	4	16
Mean (StdDev)	55.56 (19.245)	33.33 (28.868)	58.33 (31.914)	43.75 (29.107)
Median	66.67	33.33	50.00	33.33
Min, Max	33.3, 66.7	0.0, 100.0	33.3, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	3	10	3	16
Mean (StdDev)	44.44 (50.918)	53.33 (32.203)	44.44 (50.918)	50.00 (36.515)
Median	33.33	50.00	33.33	33.33
Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 11 Day 1				
n	3	11	3	17
Mean (StdDev)	66.67 (33.333)	45.45 (40.202)	66.67 (33.333)	52.94 (37.377)
Median	66.67	33.33	66.67	33.33
Min, Max	33.3, 100.0	0.0, 100.0	33.3, 100.0	0.0, 100.0
Cycle 12 Day 1				
n	2	7	3	12
Mean (StdDev)	83.33 (23.570)	38.10 (35.635)	55.56 (50.918)	50.00 (38.925)
Median	83.33	33.33	66.67	50.00
Min, Max	66.7, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Appetite Loss	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Baseline				
n	4	15	6	25
Mean (StdDev)	25.00 (31.914)	51.11 (30.516)	50.00 (34.960)	46.67 (31.914)
Median	16.67	66.67	50.00	33.33
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 2 Day 1				
n	3	15	5	23
Mean (StdDev)	44.44 (50.918)	22.22 (24.125)	33.33 (23.570)	27.54 (27.802)
Median	33.33	33.33	33.33	33.33
Min, Max	0.0, 100.0	0.0, 66.7	0.0, 66.7	0.0, 100.0
Cycle 3 Day 1				
n	3	14	5	22
Mean (StdDev)	33.33 (33.333)	19.05 (25.198)	33.33 (23.570)	24.24 (25.577)
Median	33.33	0.00	33.33	33.33
Min, Max	0.0, 66.7	0.0, 66.7	0.0, 66.7	0.0, 66.7
Cycle 4 Day 1				
n	2	14	6	22
Mean (StdDev)	16.67 (23.570)	23.81 (20.375)	27.78 (32.773)	24.24 (23.417)
Median	16.67	33.33	16.67	33.33
Min, Max	0.0, 33.3	0.0, 66.7	0.0, 66.7	0.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Appetite Loss	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Cycle 5 Day 1				
n	3	12	6	21
Mean (StdDev)	44.44 (19.245)	27.78 (27.828)	27.78 (25.092)	30.16 (25.614)
Median	33.33	33.33	33.33	33.33
Min, Max	33.3, 66.7	0.0, 66.7	0.0, 66.7	0.0, 66.7
Cycle 6 Day 1				
n	3	12	5	20
Mean (StdDev)	33.33 (33.333)	25.00 (32.177)	20.00 (18.257)	25.00 (28.357)
Median	33.33	16.67	33.33	33.33
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 33.3	0.0, 100.0
Cycle 7 Day 1				
n	3	10	5	18
Mean (StdDev)	33.33 (33.333)	16.67 (28.328)	20.00 (29.814)	20.37 (28.328)
Median	33.33	0.00	0.00	0.00
Min, Max	0.0, 66.7	0.0, 66.7	0.0, 66.7	0.0, 66.7
Cycle 8 Day 1				
n	2	10	4	16
Mean (StdDev)	33.33 (0.000)	13.33 (23.307)	25.00 (31.914)	18.75 (24.248)
Median	33.33	0.00	16.67	0.00
Min, Max	33.3, 33.3	0.0, 66.7	0.0, 66.7	0.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Appetite Loss	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Cycle 9 Day 1				
n	3	9	4	16
Mean (StdDev)	33.33 (0.000)	7.41 (14.699)	50.00 (43.033)	22.92 (29.107)
Median	33.33	0.00	50.00	16.67
Min, Max	33.3, 33.3	0.0, 33.3	0.0, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	3	10	3	16
Mean (StdDev)	22.22 (38.490)	20.00 (23.307)	55.56 (38.490)	27.08 (30.353)
Median	0.00	16.67	33.33	33.33
Min, Max	0.0, 66.7	0.0, 66.7	33.3, 100.0	0.0, 100.0
Cycle 11 Day 1				
n	3	11	3	17
Mean (StdDev)	22.22 (19.245)	15.15 (22.918)	55.56 (38.490)	23.53 (28.296)
Median	33.33	0.00	33.33	33.33
Min, Max	0.0, 33.3	0.0, 66.7	33.3, 100.0	0.0, 100.0
Cycle 12 Day 1				
n	2	7	3	12
Mean (StdDev)	66.67 (47.140)	14.29 (17.817)	44.44 (50.918)	30.56 (36.121)
Median	66.67	0.00	33.33	33.33
Min, Max	33.3, 100.0	0.0, 33.3	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Constipation	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Baseline				
n	4	15	6	25
Mean (StdDev)	16.67 (19.245)	26.67 (31.371)	16.67 (27.889)	22.67 (28.415)
Median	16.67	33.33	0.00	0.00
Min, Max	0.0, 33.3	0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 2 Day 1				
n	3	15	5	23
Mean (StdDev)	66.67 (57.735)	22.22 (32.530)	13.33 (29.814)	26.09 (37.547)
Median	100.00	0.00	0.00	0.00
Min, Max	0.0, 100.0	0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 3 Day 1				
n	3	14	5	22
Mean (StdDev)	44.44 (50.918)	19.05 (25.198)	20.00 (29.814)	22.73 (29.790)
Median	33.33	0.00	0.00	0.00
Min, Max	0.0, 100.0	0.0, 66.7	0.0, 66.7	0.0, 100.0
Cycle 4 Day 1				
n	2	14	6	22
Mean (StdDev)	16.67 (23.570)	14.29 (31.254)	5.56 (13.608)	12.12 (26.318)
Median	16.67	0.00	0.00	0.00
Min, Max	0.0, 33.3	0.0, 100.0	0.0, 33.3	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Constipation	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Cycle 5 Day 1				
n	3	12	6	21
Mean (StdDev)	44.44 (50.918)	16.67 (26.591)	11.11 (27.217)	19.05 (30.861)
Median	33.33	0.00	0.00	0.00
Min, Max	0.0, 100.0	0.0, 66.7	0.0, 66.7	0.0, 100.0
Cycle 6 Day 1				
n	3	12	5	20
Mean (StdDev)	33.33 (33.333)	13.89 (26.432)	6.67 (14.907)	15.00 (25.305)
Median	33.33	0.00	0.00	0.00
Min, Max	0.0, 66.7	0.0, 66.7	0.0, 33.3	0.0, 66.7
Cycle 7 Day 1				
n	3	10	5	18
Mean (StdDev)	55.56 (50.918)	26.67 (40.976)	26.67 (43.461)	31.48 (41.965)
Median	66.67	0.00	0.00	0.00
Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 8 Day 1				
n	2	10	4	16
Mean (StdDev)	16.67 (23.570)	10.00 (22.498)	8.33 (16.667)	10.42 (20.069)
Median	16.67	0.00	0.00	0.00
Min, Max	0.0, 33.3	0.0, 66.7	0.0, 33.3	0.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Constipation	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Cycle 9 Day 1				
n	3	9	4	16
Mean (StdDev)	33.33 (33.333)	7.41 (14.699)	8.33 (16.667)	12.50 (20.638)
Median	33.33	0.00	0.00	0.00
Min, Max	0.0, 66.7	0.0, 33.3	0.0, 33.3	0.0, 66.7
Cycle 10 Day 1				
n	3	10	3	16
Mean (StdDev)	44.44 (50.918)	20.00 (28.109)	0.00 (0.000)	20.83 (31.914)
Median	33.33	0.00	0.00	0.00
Min, Max	0.0, 100.0	0.0, 66.7	0.0, 0.0	0.0, 100.0
Cycle 11 Day 1				
n	3	11	3	17
Mean (StdDev)	22.22 (19.245)	12.12 (22.473)	11.11 (19.245)	13.73 (20.612)
Median	33.33	0.00	0.00	0.00
Min, Max	0.0, 33.3	0.0, 66.7	0.0, 33.3	0.0, 66.7
Cycle 12 Day 1				
n	2	7	3	12
Mean (StdDev)	66.67 (0.000)	19.05 (26.227)	0.00 (0.000)	22.22 (29.588)
Median	66.67	0.00	0.00	0.00
Min, Max	66.7, 66.7	0.0, 66.7	0.0, 0.0	0.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Diarrhea	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Baseline				
n	4	15	6	25
Mean (StdDev)	75.00 (31.914)	33.33 (30.861)	44.44 (40.369)	42.67 (35.382)
Median	83.33	33.33	50.00	33.33
Min, Max	33.3, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 2 Day 1				
n	3	15	5	23
Mean (StdDev)	55.56 (38.490)	33.33 (25.198)	33.33 (23.570)	36.23 (26.425)
Median	33.33	33.33	33.33	33.33
Min, Max	33.3, 100.0	0.0, 66.7	0.0, 66.7	0.0, 100.0
Cycle 3 Day 1				
n	3	14	5	22
Mean (StdDev)	66.67 (33.333)	28.57 (28.815)	40.00 (36.515)	36.36 (32.382)
Median	66.67	33.33	66.67	33.33
Min, Max	33.3, 100.0	0.0, 66.7	0.0, 66.7	0.0, 100.0
Cycle 4 Day 1				
n	2	13	6	21
Mean (StdDev)	50.00 (70.711)	33.33 (27.217)	16.67 (27.889)	30.16 (31.455)
Median	50.00	33.33	0.00	33.33
Min, Max	0.0, 100.0	0.0, 66.7	0.0, 66.7	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Diarrhea	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Cycle 5 Day 1				
n	3	12	6	21
Mean (StdDev)	55.56 (38.490)	33.33 (28.427)	38.89 (25.092)	38.10 (28.452)
Median	33.33	33.33	33.33	33.33
Min, Max	33.3, 100.0	0.0, 66.7	0.0, 66.7	0.0, 100.0
Cycle 6 Day 1				
n	3	12	5	20
Mean (StdDev)	55.56 (38.490)	30.56 (33.207)	26.67 (27.889)	33.33 (32.444)
Median	33.33	33.33	33.33	33.33
Min, Max	33.3, 100.0	0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 7 Day 1				
n	3	10	5	18
Mean (StdDev)	55.56 (38.490)	23.33 (22.498)	20.00 (18.257)	27.78 (26.197)
Median	33.33	33.33	33.33	33.33
Min, Max	33.3, 100.0	0.0, 66.7	0.0, 33.3	0.0, 100.0
Cycle 8 Day 1				
n	2	10	4	16
Mean (StdDev)	66.67 (47.140)	33.33 (22.222)	8.33 (16.667)	31.25 (28.464)
Median	66.67	33.33	0.00	33.33
Min, Max	33.3, 100.0	0.0, 66.7	0.0, 33.3	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Diarrhea	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Cycle 9 Day 1				
n	3	9	4	16
Mean (StdDev)	44.44 (19.245)	18.52 (17.568)	41.67 (31.914)	29.17 (23.960)
Median	33.33	33.33	50.00	33.33
Min, Max	33.3, 66.7	0.0, 33.3	0.0, 66.7	0.0, 66.7
Cycle 10 Day 1				
n	3	10	3	16
Mean (StdDev)	11.11 (19.245)	36.67 (18.922)	55.56 (50.918)	35.42 (28.464)
Median	0.00	33.33	66.67	33.33
Min, Max	0.0, 33.3	0.0, 66.7	0.0, 100.0	0.0, 100.0
Cycle 11 Day 1				
n	3	11	3	17
Mean (StdDev)	33.33 (0.000)	36.36 (27.707)	33.33 (33.333)	35.29 (24.918)
Median	33.33	33.33	33.33	33.33
Min, Max	33.3, 33.3	0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 12 Day 1				
n	2	7	3	12
Mean (StdDev)	33.33 (0.000)	28.57 (23.002)	33.33 (33.333)	30.56 (22.285)
Median	33.33	33.33	33.33	33.33
Min, Max	33.3, 33.3	0.0, 66.7	0.0, 66.7	0.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Financial Difficulties	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Baseline				
n	4	15	6	25
Mean (StdDev)	66.67 (47.140)	37.78 (37.515)	61.11 (38.968)	48.00 (39.768)
Median	83.33	33.33	66.67	33.33
Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 2 Day 1				
n	3	15	5	23
Mean (StdDev)	77.78 (38.490)	35.56 (36.659)	66.67 (40.825)	47.83 (39.982)
Median	100.00	33.33	66.67	33.33
Min, Max	33.3, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 3 Day 1				
n	3	14	5	22
Mean (StdDev)	77.78 (19.245)	38.10 (34.237)	53.33 (38.006)	46.97 (35.125)
Median	66.67	33.33	66.67	33.33
Min, Max	66.7, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 4 Day 1				
n	2	14	6	22
Mean (StdDev)	66.67 (47.140)	30.95 (40.222)	50.00 (45.947)	39.39 (41.958)
Median	66.67	16.67	50.00	33.33
Min, Max	33.3, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Financial Difficulties	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Cycle 5 Day 1				
n	3	12	6	21
Mean (StdDev)	77.78 (38.490)	27.78 (31.248)	44.44 (40.369)	39.68 (37.445)
Median	100.00	33.33	50.00	33.33
Min, Max	33.3, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 6 Day 1				
n	3	12	5	20
Mean (StdDev)	44.44 (19.245)	22.22 (32.824)	40.00 (36.515)	30.00 (32.264)
Median	33.33	0.00	33.33	33.33
Min, Max	33.3, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 7 Day 1				
n	3	10	5	18
Mean (StdDev)	55.56 (38.490)	26.67 (30.631)	33.33 (40.825)	33.33 (34.300)
Median	33.33	33.33	33.33	33.33
Min, Max	33.3, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 8 Day 1				
n	2	10	4	16
Mean (StdDev)	50.00 (23.570)	26.67 (30.631)	50.00 (43.033)	35.42 (33.264)
Median	50.00	33.33	50.00	33.33
Min, Max	33.3, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Financial Difficulties	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Cycle 9 Day 1				
n	3	9	4	16
Mean (StdDev)	55.56 (19.245)	25.93 (27.778)	50.00 (43.033)	37.50 (31.914)
Median	66.67	33.33	50.00	33.33
Min, Max	33.3, 66.7	0.0, 66.7	0.0, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	3	10	3	16
Mean (StdDev)	55.56 (19.245)	43.33 (41.722)	66.67 (33.333)	50.00 (36.515)
Median	66.67	33.33	66.67	33.33
Min, Max	33.3, 66.7	0.0, 100.0	33.3, 100.0	0.0, 100.0
Cycle 11 Day 1				
n	3	11	3	17
Mean (StdDev)	55.56 (19.245)	36.36 (34.816)	66.67 (33.333)	45.10 (33.211)
Median	66.67	33.33	66.67	33.33
Min, Max	33.3, 66.7	0.0, 100.0	33.3, 100.0	0.0, 100.0
Cycle 12 Day 1				
n	2	7	3	12
Mean (StdDev)	50.00 (23.570)	28.57 (35.635)	55.56 (38.490)	38.89 (34.329)
Median	50.00	33.33	33.33	33.33
Min, Max	33.3, 66.7	0.0, 100.0	33.3, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Global Health Status/QoL	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	33.33 (-)	51.67 (34.561)	37.50 (19.837)	44.17 (26.946)
Median	33.33	50.00	37.50	45.83
Min, Max	33.3, 33.3	0.0, 83.3	16.7, 58.3	0.0, 83.3
Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		70.00 (17.280)	69.44 (12.729)	69.79 (14.731)
Median		75.00	66.67	70.83
Min, Max		41.7, 83.3	58.3, 83.3	41.7, 83.3
Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		72.92 (7.979)	66.67 (16.667)	70.24 (11.644)
Median		70.83	66.67	66.67
Min, Max		66.7, 83.3	50.0, 83.3	50.0, 83.3
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		70.83 (20.972)	56.25 (15.775)	63.54 (18.865)
Median		66.67	62.50	66.67
Min, Max		50.0, 100.0	33.3, 66.7	33.3, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Global Health Status/QoL	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		83.33 (23.570)	64.58 (14.232)	70.83 (18.066)
Median		83.33	62.50	66.67
Min, Max		66.7, 100.0	50.0, 83.3	50.0, 100.0
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		75.00 (22.048)	60.42 (7.979)	66.67 (15.957)
Median		66.67	62.50	66.67
Min, Max		58.3, 100.0	50.0, 66.7	50.0, 100.0
Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		75.00 (22.048)	52.78 (4.811)	63.89 (18.758)
Median		66.67	50.00	58.33
Min, Max		58.3, 100.0	50.0, 58.3	50.0, 100.0
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		83.33 (23.570)	33.33 (47.140)	58.33 (41.944)
Median		83.33	33.33	66.67
Min, Max		66.7, 100.0	0.0, 66.7	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Global Health Status/QoL	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		83.33 (23.570)	25.00 (35.355)	54.17 (41.667)
Median		83.33	25.00	58.33
Min, Max		66.7, 100.0	0.0, 50.0	0.0, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		58.33 (-)	33.33 (47.140)	41.67 (36.324)
Median		58.33	33.33	58.33
Min, Max		58.3, 58.3	0.0, 66.7	0.0, 66.7
Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		75.00 (35.355)	25.00 (35.355)	50.00 (40.825)
Median		75.00	25.00	50.00
Min, Max		50.0, 100.0	0.0, 50.0	0.0, 100.0
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		100.00 (-)	41.67 (58.926)	61.11 (53.576)
Median		100.00	41.67	83.33
Min, Max		100.0, 100.0	0.0, 83.3	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Physical Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	86.67 (-)	46.67 (29.059)	70.00 (24.646)	60.00 (28.284)
Median	86.67	53.33	80.00	66.67
Min, Max	86.7, 86.7	0.0, 80.0	33.3, 86.7	0.0, 86.7
Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		70.67 (13.824)	86.67 (13.333)	76.67 (15.119)
Median		73.33	86.67	76.67
Min, Max		53.3, 86.7	73.3, 100.0	53.3, 100.0
Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		70.00 (17.638)	95.56 (7.698)	80.95 (19.024)
Median		66.67	100.00	86.67
Min, Max		53.3, 93.3	86.7, 100.0	53.3, 100.0
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		71.67 (17.533)	86.67 (12.172)	79.17 (16.110)
Median		73.33	86.67	83.33
Min, Max		53.3, 86.7	73.3, 100.0	53.3, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Physical Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		66.67 (28.284)	78.33 (22.027)	74.44 (22.077)
Median		66.67	80.00	76.67
Min, Max		46.7, 86.7	53.3, 100.0	46.7, 100.0
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		55.56 (26.943)	71.67 (30.972)	64.76 (28.209)
Median		40.00	76.67	60.00
Min, Max		40.0, 86.7	33.3, 100.0	33.3, 100.0
Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		48.89 (32.886)	62.22 (36.717)	55.56 (32.019)
Median		33.33	60.00	46.67
Min, Max		26.7, 86.7	26.7, 100.0	26.7, 100.0
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		70.00 (23.570)	60.00 (56.569)	65.00 (35.849)
Median		70.00	60.00	70.00
Min, Max		53.3, 86.7	20.0, 100.0	20.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Physical Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		73.33 (37.712)	60.00 (56.569)	66.67 (40.000)
Median		73.33	60.00	73.33
Min, Max		46.7, 100.0	20.0, 100.0	20.0, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		46.67 (-)	60.00 (56.569)	55.56 (40.734)
Median		46.67	60.00	46.67
Min, Max		46.7, 46.7	20.0, 100.0	20.0, 100.0
Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		80.00 (28.284)	56.67 (61.283)	68.33 (41.231)
Median		80.00	56.67	80.00
Min, Max		60.0, 100.0	13.3, 100.0	13.3, 100.0
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		100.00 (-)	56.67 (61.283)	71.11 (50.037)
Median		100.00	56.67	100.00
Min, Max		100.0, 100.0	13.3, 100.0	13.3, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Role Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	33.33 (-)	56.67 (22.361)	33.33 (38.490)	45.00 (29.450)
Median	33.33	66.67	33.33	50.00
Min, Max	33.3, 33.3	33.3, 83.3	0.0, 66.7	0.0, 83.3
Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		76.67 (27.889)	83.33 (16.667)	79.17 (23.146)
Median		83.33	83.33	83.33
Min, Max		33.3, 100.0	66.7, 100.0	33.3, 100.0
Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		62.50 (25.000)	77.78 (19.245)	69.05 (22.420)
Median		66.67	66.67	66.67
Min, Max		33.3, 83.3	66.7, 100.0	33.3, 100.0
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		62.50 (20.972)	75.00 (31.914)	68.75 (25.877)
Median		66.67	83.33	66.67
Min, Max		33.3, 83.3	33.3, 100.0	33.3, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Role Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		58.33 (35.355)	54.17 (41.667)	55.56 (36.004)
Median		58.33	58.33	58.33
Min, Max		33.3, 83.3	0.0, 100.0	0.0, 100.0
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		55.56 (38.490)	58.33 (41.944)	57.14 (37.090)
Median		33.33	66.67	66.67
Min, Max		33.3, 100.0	0.0, 100.0	0.0, 100.0
Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		61.11 (34.694)	61.11 (41.944)	61.11 (34.427)
Median		50.00	66.67	58.33
Min, Max		33.3, 100.0	16.7, 100.0	16.7, 100.0
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		83.33 (23.570)	50.00 (70.711)	66.67 (47.140)
Median		83.33	50.00	83.33
Min, Max		66.7, 100.0	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Role Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		83.33 (23.570)	50.00 (70.711)	66.67 (47.140)
Median		83.33	50.00	83.33
Min, Max		66.7, 100.0	0.0, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		50.00 (-)	50.00 (70.711)	50.00 (50.000)
Median		50.00	50.00	50.00
Min, Max		50.0, 50.0	0.0, 100.0	0.0, 100.0
Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		75.00 (35.355)	50.00 (70.711)	62.50 (47.871)
Median		75.00	50.00	75.00
Min, Max		50.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		100.00 (-)	50.00 (70.711)	66.67 (57.735)
Median		100.00	50.00	100.00
Min, Max		100.0, 100.0	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Emotional Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	100.00 (-)	66.67 (29.463)	70.83 (20.972)	71.67 (25.215)
Median	100.00	75.00	75.00	75.00
Min, Max	100.0, 100.0	25.0, 100.0	41.7, 91.7	25.0, 100.0
Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		78.33 (24.721)	77.78 (19.245)	78.13 (21.333)
Median		83.33	66.67	75.00
Min, Max		41.7, 100.0	66.7, 100.0	41.7, 100.0
Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		84.03 (20.079)	75.00 (8.333)	80.16 (15.749)
Median		88.89	75.00	77.78
Min, Max		58.3, 100.0	66.7, 83.3	58.3, 100.0
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		87.50 (15.957)	79.17 (17.347)	83.33 (16.060)
Median		91.67	79.17	83.33
Min, Max		66.7, 100.0	58.3, 100.0	58.3, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Emotional Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		83.33 (23.570)	75.00 (18.002)	77.78 (18.002)
Median		83.33	70.83	70.83
Min, Max		66.7, 100.0	58.3, 100.0	58.3, 100.0
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		91.67 (14.434)	68.75 (27.534)	78.57 (24.465)
Median		100.00	66.67	83.33
Min, Max		75.0, 100.0	41.7, 100.0	41.7, 100.0
Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		88.89 (12.729)	55.56 (26.788)	72.22 (26.176)
Median		91.67	66.67	75.00
Min, Max		75.0, 100.0	25.0, 75.0	25.0, 100.0
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		87.50 (17.678)	45.83 (5.893)	66.67 (26.352)
Median		87.50	45.83	62.50
Min, Max		75.0, 100.0	41.7, 50.0	41.7, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Emotional Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		87.50 (17.678)	37.50 (17.678)	62.50 (32.275)
Median		87.50	37.50	62.50
Min, Max		75.0, 100.0	25.0, 50.0	25.0, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		91.67 (-)	37.50 (5.893)	55.56 (31.549)
Median		91.67	37.50	41.67
Min, Max		91.7, 91.7	33.3, 41.7	33.3, 91.7
Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		95.83 (5.893)	45.83 (5.893)	70.83 (29.266)
Median		95.83	45.83	70.83
Min, Max		91.7, 100.0	41.7, 50.0	41.7, 100.0
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		100.00 (-)	29.17 (29.463)	52.78 (45.896)
Median		100.00	29.17	50.00
Min, Max		100.0, 100.0	8.3, 50.0	8.3, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Cognitive Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	66.67 (-)	76.67 (19.003)	70.83 (15.957)	73.33 (16.102)
Median	66.67	83.33	75.00	75.00
Min, Max	66.7, 66.7	50.0, 100.0	50.0, 83.3	50.0, 100.0
Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		83.33 (23.570)	83.33 (0.000)	83.33 (17.817)
Median		100.00	83.33	83.33
Min, Max		50.0, 100.0	83.3, 83.3	50.0, 100.0
Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		91.67 (9.623)	77.78 (9.623)	85.71 (11.501)
Median		91.67	83.33	83.33
Min, Max		83.3, 100.0	66.7, 83.3	66.7, 100.0
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		87.50 (15.957)	79.17 (15.957)	83.33 (15.430)
Median		91.67	75.00	83.33
Min, Max		66.7, 100.0	66.7, 100.0	66.7, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Cognitive Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		83.33 (23.570)	70.83 (25.000)	75.00 (22.973)
Median		83.33	66.67	75.00
Min, Max		66.7, 100.0	50.0, 100.0	50.0, 100.0
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		94.44 (9.623)	83.33 (13.608)	88.10 (12.599)
Median		100.00	83.33	83.33
Min, Max		83.3, 100.0	66.7, 100.0	66.7, 100.0
Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		88.89 (19.245)	61.11 (9.623)	75.00 (20.412)
Median		100.00	66.67	66.67
Min, Max		66.7, 100.0	50.0, 66.7	50.0, 100.0
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		100.00 (0.000)	75.00 (11.785)	87.50 (15.957)
Median		100.00	75.00	91.67
Min, Max		100.0, 100.0	66.7, 83.3	66.7, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Cognitive Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		91.67 (11.785)	75.00 (11.785)	83.33 (13.608)
Median		91.67	75.00	83.33
Min, Max		83.3, 100.0	66.7, 83.3	66.7, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		100.00 (-)	58.33 (35.355)	72.22 (34.694)
Median		100.00	58.33	83.33
Min, Max		100.0, 100.0	33.3, 83.3	33.3, 100.0
Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		91.67 (11.785)	66.67 (23.570)	79.17 (20.972)
Median		91.67	66.67	83.33
Min, Max		83.3, 100.0	50.0, 83.3	50.0, 100.0
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		100.00 (-)	50.00 (47.140)	66.67 (44.096)
Median		100.00	50.00	83.33
Min, Max		100.0, 100.0	16.7, 83.3	16.7, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Social Function	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	33.33 (-)	60.00 (30.277)	58.33 (41.944)	56.67 (32.584)
Median	33.33	66.67	66.67	66.67
Min, Max	33.3, 33.3	16.7, 100.0	0.0, 100.0	0.0, 100.0
Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		80.00 (27.386)	55.56 (38.490)	70.83 (31.810)
Median		83.33	33.33	83.33
Min, Max		33.3, 100.0	33.3, 100.0	33.3, 100.0
Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		75.00 (21.517)	61.11 (25.459)	69.05 (22.420)
Median		75.00	66.67	66.67
Min, Max		50.0, 100.0	33.3, 83.3	33.3, 100.0
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		79.17 (15.957)	66.67 (27.217)	72.92 (21.708)
Median		75.00	66.67	66.67
Min, Max		66.7, 100.0	33.3, 100.0	33.3, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Social Function	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		83.33 (23.570)	62.50 (20.972)	69.44 (22.153)
Median		83.33	66.67	66.67
Min, Max		66.7, 100.0	33.3, 83.3	33.3, 100.0
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		72.22 (34.694)	58.33 (9.623)	64.29 (22.420)
Median		83.33	58.33	66.67
Min, Max		33.3, 100.0	50.0, 66.7	33.3, 100.0
Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		72.22 (34.694)	72.22 (9.623)	72.22 (22.771)
Median		83.33	66.67	75.00
Min, Max		33.3, 100.0	66.7, 83.3	33.3, 100.0
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		83.33 (23.570)	50.00 (23.570)	66.67 (27.217)
Median		83.33	50.00	66.67
Min, Max		66.7, 100.0	33.3, 66.7	33.3, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Social Function	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		91.67 (11.785)	58.33 (35.355)	75.00 (28.868)
Median		91.67	58.33	83.33
Min, Max		83.3, 100.0	33.3, 83.3	33.3, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		83.33 (-)	33.33 (47.140)	50.00 (44.096)
Median		83.33	33.33	66.67
Min, Max		83.3, 83.3	0.0, 66.7	0.0, 83.3
Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		75.00 (35.355)	50.00 (47.140)	62.50 (36.956)
Median		75.00	50.00	66.67
Min, Max		50.0, 100.0	16.7, 83.3	16.7, 100.0
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		100.00 (-)	41.67 (35.355)	61.11 (41.944)
Median		100.00	41.67	66.67
Min, Max		100.0, 100.0	16.7, 66.7	16.7, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Fatigue	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	100.00 (-)	55.56 (32.394)	69.44 (30.598)	65.56 (31.186)
Median	100.00	55.56	72.22	61.11
Min, Max	100.0, 100.0	11.1, 100.0	33.3, 100.0	11.1, 100.0
Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		35.56 (16.480)	37.04 (16.973)	36.11 (15.430)
Median		33.33	33.33	33.33
Min, Max		11.1, 55.6	22.2, 55.6	11.1, 55.6
Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		38.89 (14.344)	33.33 (0.000)	36.51 (10.569)
Median		38.89	33.33	33.33
Min, Max		22.2, 55.6	33.3, 33.3	22.2, 55.6
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		52.78 (22.906)	38.89 (26.450)	45.83 (24.079)
Median		50.00	27.78	33.33
Min, Max		33.3, 77.8	22.2, 77.8	22.2, 77.8

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Fatigue	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		66.67 (47.140)	41.67 (22.906)	50.00 (30.429)
Median		66.67	38.89	44.44
Min, Max		33.3, 100.0	22.2, 66.7	22.2, 100.0
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		59.26 (33.945)	55.56 (27.217)	57.14 (27.539)
Median		66.67	50.00	66.67
Min, Max		22.2, 88.9	33.3, 88.9	22.2, 88.9
Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		44.44 (22.222)	62.96 (27.962)	53.70 (24.762)
Median		44.44	66.67	55.56
Min, Max		22.2, 66.7	33.3, 88.9	22.2, 88.9
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		33.33 (15.713)	66.67 (47.140)	50.00 (34.546)
Median		33.33	66.67	38.89
Min, Max		22.2, 44.4	33.3, 100.0	22.2, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Fatigue	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		11.11 (15.713)	55.56 (62.854)	33.33 (45.361)
Median		11.11	55.56	16.67
Min, Max		0.0, 22.2	11.1, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		44.44 (-)	61.11 (54.997)	55.56 (40.062)
Median		44.44	61.11	44.44
Min, Max		44.4, 44.4	22.2, 100.0	22.2, 100.0
Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		27.78 (39.284)	66.67 (47.140)	47.22 (41.944)
Median		27.78	66.67	44.44
Min, Max		0.0, 55.6	33.3, 100.0	0.0, 100.0
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	61.11 (54.997)	40.74 (52.509)
Median		0.00	61.11	22.22
Min, Max		0.0, 0.0	22.2, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Nausea and Vomiting	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	66.67 (-)	10.00 (22.361)	8.33 (9.623)	15.00 (24.152)
Median	66.67	0.00	8.33	0.00
Min, Max	66.7, 66.7	0.0, 50.0	0.0, 16.7	0.0, 66.7
Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		13.33 (13.944)	11.11 (9.623)	12.50 (11.785)
Median		16.67	16.67	16.67
Min, Max		0.0, 33.3	0.0, 16.7	0.0, 33.3
Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		20.83 (25.000)	11.11 (9.623)	16.67 (19.245)
Median		16.67	16.67	16.67
Min, Max		0.0, 50.0	0.0, 16.7	0.0, 50.0
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		20.83 (15.957)	4.17 (8.333)	12.50 (14.773)
Median		25.00	0.00	8.33
Min, Max		0.0, 33.3	0.0, 16.7	0.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Nausea and Vomiting	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		16.67 (23.570)	8.33 (9.623)	11.11 (13.608)
Median		16.67	8.33	8.33
Min, Max		0.0, 33.3	0.0, 16.7	0.0, 33.3
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		5.56 (9.623)	4.17 (8.333)	4.76 (8.133)
Median		0.00	0.00	0.00
Min, Max		0.0, 16.7	0.0, 16.7	0.0, 16.7
Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		5.56 (9.623)	11.11 (9.623)	8.33 (9.129)
Median		0.00	16.67	8.33
Min, Max		0.0, 16.7	0.0, 16.7	0.0, 16.7
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		8.33 (11.785)	8.33 (11.785)	8.33 (9.623)
Median		8.33	8.33	8.33
Min, Max		0.0, 16.7	0.0, 16.7	0.0, 16.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Nausea and Vomiting	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		8.33 (11.785)	8.33 (11.785)	8.33 (9.623)
Median		8.33	8.33	8.33
Min, Max		0.0, 16.7	0.0, 16.7	0.0, 16.7
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		16.67 (-)	8.33 (11.785)	11.11 (9.623)
Median		16.67	8.33	16.67
Min, Max		16.7, 16.7	0.0, 16.7	0.0, 16.7
Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
Median		0.00	0.00	0.00
Min, Max		0.0, 0.0	0.0, 0.0	0.0, 0.0
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	8.33 (11.785)	5.56 (9.623)
Median		0.00	8.33	0.00
Min, Max		0.0, 0.0	0.0, 16.7	0.0, 16.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Pain	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	83.33 (-)	26.67 (19.003)	50.00 (43.033)	41.67 (33.564)
Median	83.33	33.33	50.00	33.33
Min, Max	83.3, 83.3	0.0, 50.0	0.0, 100.0	0.0, 100.0
Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		16.67 (20.412)	11.11 (9.623)	14.58 (16.517)
Median		16.67	16.67	16.67
Min, Max		0.0, 50.0	0.0, 16.7	0.0, 50.0
Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		25.00 (9.623)	16.67 (16.667)	21.43 (12.599)
Median		25.00	16.67	16.67
Min, Max		16.7, 33.3	0.0, 33.3	0.0, 33.3
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		8.33 (9.623)	25.00 (16.667)	16.67 (15.430)
Median		8.33	16.67	16.67
Min, Max		0.0, 16.7	16.7, 50.0	0.0, 50.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Pain	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		8.33 (11.785)	12.50 (15.957)	11.11 (13.608)
Median		8.33	8.33	8.33
Min, Max		0.0, 16.7	0.0, 33.3	0.0, 33.3
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		0.00 (0.000)	29.17 (28.464)	16.67 (25.459)
Median		0.00	25.00	0.00
Min, Max		0.0, 0.0	0.0, 66.7	0.0, 66.7
Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		11.11 (9.623)	27.78 (34.694)	19.44 (24.533)
Median		16.67	16.67	16.67
Min, Max		0.0, 16.7	0.0, 66.7	0.0, 66.7
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		8.33 (11.785)	58.33 (58.926)	33.33 (45.134)
Median		8.33	58.33	16.67
Min, Max		0.0, 16.7	16.7, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Pain	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	58.33 (58.926)	29.17 (47.871)
Median		0.00	58.33	8.33
Min, Max		0.0, 0.0	16.7, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		16.67 (-)	58.33 (58.926)	44.44 (48.113)
Median		16.67	58.33	16.67
Min, Max		16.7, 16.7	16.7, 100.0	16.7, 100.0
Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		8.33 (11.785)	58.33 (58.926)	33.33 (45.134)
Median		8.33	58.33	16.67
Min, Max		0.0, 16.7	16.7, 100.0	0.0, 100.0
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	50.00 (70.711)	33.33 (57.735)
Median		0.00	50.00	0.00
Min, Max		0.0, 0.0	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Dyspnea	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	33.33 (-)	40.00 (36.515)	50.00 (43.033)	43.33 (35.312)
Median	33.33	33.33	50.00	33.33
Min, Max	33.3, 33.3	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		13.33 (29.814)	22.22 (19.245)	16.67 (25.198)
Median		0.00	33.33	0.00
Min, Max		0.0, 66.7	0.0, 33.3	0.0, 66.7
Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		25.00 (16.667)	0.00 (0.000)	14.29 (17.817)
Median		33.33	0.00	0.00
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		16.67 (19.245)	25.00 (16.667)	20.83 (17.252)
Median		16.67	33.33	33.33
Min, Max		0.0, 33.3	0.0, 33.3	0.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Dyspnea	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		33.33 (47.140)	33.33 (47.140)	33.33 (42.164)
Median		33.33	16.67	16.67
Min, Max		0.0, 66.7	0.0, 100.0	0.0, 100.0
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		22.22 (19.245)	41.67 (41.944)	33.33 (33.333)
Median		33.33	33.33	33.33
Min, Max		0.0, 33.3	0.0, 100.0	0.0, 100.0
Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		22.22 (38.490)	55.56 (50.918)	38.89 (44.305)
Median		0.00	66.67	33.33
Min, Max		0.0, 66.7	0.0, 100.0	0.0, 100.0
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	50.00 (70.711)	25.00 (50.000)
Median		0.00	50.00	0.00
Min, Max		0.0, 0.0	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Dyspnea	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	50.00 (70.711)	25.00 (50.000)
Median		0.00	50.00	0.00
Min, Max		0.0, 0.0	0.0, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	50.00 (70.711)	33.33 (57.735)
Median		0.00	50.00	0.00
Min, Max		0.0, 0.0	0.0, 100.0	0.0, 100.0
Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	50.00 (70.711)	25.00 (50.000)
Median		0.00	50.00	0.00
Min, Max		0.0, 0.0	0.0, 100.0	0.0, 100.0
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	50.00 (70.711)	33.33 (57.735)
Median		0.00	50.00	0.00
Min, Max		0.0, 0.0	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Insomnia	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	100.00 (-)	26.67 (27.889)	58.33 (50.000)	46.67 (42.164)
Median	100.00	33.33	66.67	33.33
Min, Max	100.0, 100.0	0.0, 66.7	0.0, 100.0	0.0, 100.0
Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		20.00 (18.257)	22.22 (38.490)	20.83 (24.801)
Median		33.33	0.00	16.67
Min, Max		0.0, 33.3	0.0, 66.7	0.0, 66.7
Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		33.33 (27.217)	33.33 (33.333)	33.33 (27.217)
Median		33.33	33.33	33.33
Min, Max		0.0, 66.7	0.0, 66.7	0.0, 66.7
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		25.00 (31.914)	41.67 (41.944)	33.33 (35.635)
Median		16.67	33.33	33.33
Min, Max		0.0, 66.7	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Insomnia	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		50.00 (23.570)	33.33 (47.140)	38.89 (38.968)
Median		50.00	16.67	33.33
Min, Max		33.3, 66.7	0.0, 100.0	0.0, 100.0
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		33.33 (33.333)	41.67 (41.944)	38.10 (35.635)
Median		33.33	33.33	33.33
Min, Max		0.0, 66.7	0.0, 100.0	0.0, 100.0
Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		44.44 (19.245)	55.56 (38.490)	50.00 (27.889)
Median		33.33	33.33	33.33
Min, Max		33.3, 66.7	33.3, 100.0	33.3, 100.0
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	66.67 (47.140)	33.33 (47.140)
Median		0.00	66.67	16.67
Min, Max		0.0, 0.0	33.3, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Insomnia	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	66.67 (47.140)	33.33 (47.140)
Median		0.00	66.67	16.67
Min, Max		0.0, 0.0	33.3, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	66.67 (47.140)	44.44 (50.918)
Median		0.00	66.67	33.33
Min, Max		0.0, 0.0	33.3, 100.0	0.0, 100.0
Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	83.33 (23.570)	41.67 (50.000)
Median		0.00	83.33	33.33
Min, Max		0.0, 0.0	66.7, 100.0	0.0, 100.0
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	83.33 (23.570)	55.56 (50.918)
Median		0.00	83.33	66.67
Min, Max		0.0, 0.0	66.7, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Appetite Loss	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	0.00 (-)	40.00 (43.461)	41.67 (41.944)	36.67 (39.907)
Median	0.00	33.33	33.33	33.33
Min, Max	0.0, 0.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		20.00 (29.814)	33.33 (0.000)	25.00 (23.570)
Median		0.00	33.33	33.33
Min, Max		0.0, 66.7	33.3, 33.3	0.0, 66.7
Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		0.00 (0.000)	44.44 (19.245)	19.05 (26.227)
Median		0.00	33.33	0.00
Min, Max		0.0, 0.0	33.3, 66.7	0.0, 66.7
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		25.00 (16.667)	33.33 (38.490)	29.17 (27.817)
Median		33.33	33.33	33.33
Min, Max		0.0, 33.3	0.0, 66.7	0.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Appetite Loss	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		16.67 (23.570)	33.33 (27.217)	27.78 (25.092)
Median		16.67	33.33	33.33
Min, Max		0.0, 33.3	0.0, 66.7	0.0, 66.7
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		11.11 (19.245)	25.00 (16.667)	19.05 (17.817)
Median		0.00	33.33	33.33
Min, Max		0.0, 33.3	0.0, 33.3	0.0, 33.3
Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		22.22 (38.490)	33.33 (33.333)	27.78 (32.773)
Median		0.00	33.33	16.67
Min, Max		0.0, 66.7	0.0, 66.7	0.0, 66.7
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	33.33 (47.140)	16.67 (33.333)
Median		0.00	33.33	0.00
Min, Max		0.0, 0.0	0.0, 66.7	0.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Appetite Loss	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	50.00 (70.711)	25.00 (50.000)
Median		0.00	50.00	0.00
Min, Max		0.0, 0.0	0.0, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	66.67 (47.140)	44.44 (50.918)
Median		0.00	66.67	33.33
Min, Max		0.0, 0.0	33.3, 100.0	0.0, 100.0
Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	66.67 (47.140)	33.33 (47.140)
Median		0.00	66.67	16.67
Min, Max		0.0, 0.0	33.3, 100.0	0.0, 100.0
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	66.67 (47.140)	44.44 (50.918)
Median		0.00	66.67	33.33
Min, Max		0.0, 0.0	33.3, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Constipation	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	0.00 (-)	20.00 (29.814)	16.67 (33.333)	16.67 (28.328)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 0.0	0.0, 66.7	0.0, 66.7	0.0, 66.7
Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		13.33 (18.257)	0.00 (0.000)	8.33 (15.430)
Median		0.00	0.00	0.00
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3
Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		8.33 (16.667)	11.11 (19.245)	9.52 (16.265)
Median		0.00	0.00	0.00
Min, Max		0.0, 33.3	0.0, 33.3	0.0, 33.3
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		8.33 (16.667)	0.00 (0.000)	4.17 (11.785)
Median		0.00	0.00	0.00
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Constipation	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		16.67 (23.570)	0.00 (0.000)	5.56 (13.608)
Median		16.67	0.00	0.00
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		0.00 (0.000)	8.33 (16.667)	4.76 (12.599)
Median		0.00	0.00	0.00
Min, Max		0.0, 0.0	0.0, 33.3	0.0, 33.3
Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		11.11 (19.245)	0.00 (0.000)	5.56 (13.608)
Median		0.00	0.00	0.00
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
Median		0.00	0.00	0.00
Min, Max		0.0, 0.0	0.0, 0.0	0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Constipation	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
Median		0.00	0.00	0.00
Min, Max		0.0, 0.0	0.0, 0.0	0.0, 0.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	0.00 (0.000)	0.00 (0.000)
Median		0.00	0.00	0.00
Min, Max		0.0, 0.0	0.0, 0.0	0.0, 0.0
Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
Median		0.00	0.00	0.00
Min, Max		0.0, 0.0	0.0, 0.0	0.0, 0.0
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	0.00 (0.000)	0.00 (0.000)
Median		0.00	0.00	0.00
Min, Max		0.0, 0.0	0.0, 0.0	0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Diarrhea	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	100.00 (-)	33.33 (47.140)	58.33 (41.944)	50.00 (45.134)
Median	100.00	0.00	66.67	66.67
Min, Max	100.0, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		26.67 (27.889)	44.44 (19.245)	33.33 (25.198)
Median		33.33	33.33	33.33
Min, Max		0.0, 66.7	33.3, 66.7	0.0, 66.7
Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		25.00 (16.667)	66.67 (0.000)	42.86 (25.198)
Median		33.33	66.67	33.33
Min, Max		0.0, 33.3	66.7, 66.7	0.0, 66.7
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		41.67 (16.667)	25.00 (31.914)	33.33 (25.198)
Median		33.33	16.67	33.33
Min, Max		33.3, 66.7	0.0, 66.7	0.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Diarrhea	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		50.00 (23.570)	50.00 (19.245)	50.00 (18.257)
Median		50.00	50.00	50.00
Min, Max		33.3, 66.7	33.3, 66.7	33.3, 66.7
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		44.44 (50.918)	33.33 (27.217)	38.10 (35.635)
Median		33.33	33.33	33.33
Min, Max		0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		44.44 (19.245)	22.22 (19.245)	33.33 (21.082)
Median		33.33	33.33	33.33
Min, Max		33.3, 66.7	0.0, 33.3	0.0, 66.7
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		33.33 (0.000)	16.67 (23.570)	25.00 (16.667)
Median		33.33	16.67	33.33
Min, Max		33.3, 33.3	0.0, 33.3	0.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Diarrhea	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		16.67 (23.570)	66.67 (0.000)	41.67 (31.914)
Median		16.67	66.67	50.00
Min, Max		0.0, 33.3	66.7, 66.7	0.0, 66.7
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		33.33 (-)	83.33 (23.570)	66.67 (33.333)
Median		33.33	83.33	66.67
Min, Max		33.3, 33.3	66.7, 100.0	33.3, 100.0
Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		33.33 (0.000)	50.00 (23.570)	41.67 (16.667)
Median		33.33	50.00	33.33
Min, Max		33.3, 33.3	33.3, 66.7	33.3, 66.7
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		33.33 (-)	50.00 (23.570)	44.44 (19.245)
Median		33.33	50.00	33.33
Min, Max		33.3, 33.3	33.3, 66.7	33.3, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Financial Difficulties	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	66.67 (-)	26.67 (43.461)	58.33 (41.944)	43.33 (41.722)
Median	66.67	0.00	66.67	50.00
Min, Max	66.7, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		33.33 (40.825)	55.56 (50.918)	41.67 (42.725)
Median		33.33	66.67	33.33
Min, Max		0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		41.67 (31.914)	66.67 (33.333)	52.38 (32.530)
Median		50.00	66.67	66.67
Min, Max		0.0, 66.7	33.3, 100.0	0.0, 100.0
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		25.00 (50.000)	50.00 (43.033)	37.50 (45.207)
Median		0.00	50.00	16.67
Min, Max		0.0, 100.0	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Financial Difficulties	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		0.00 (0.000)	58.33 (41.944)	38.89 (44.305)
Median		0.00	66.67	33.33
Min, Max		0.0, 0.0	0.0, 100.0	0.0, 100.0
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		0.00 (0.000)	50.00 (33.333)	28.57 (35.635)
Median		0.00	33.33	33.33
Min, Max		0.0, 0.0	33.3, 100.0	0.0, 100.0
Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		0.00 (0.000)	44.44 (50.918)	22.22 (40.369)
Median		0.00	33.33	0.00
Min, Max		0.0, 0.0	0.0, 100.0	0.0, 100.0
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		16.67 (23.570)	83.33 (23.570)	50.00 (43.033)
Median		16.67	83.33	50.00
Min, Max		0.0, 33.3	66.7, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Financial Difficulties	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	83.33 (23.570)	41.67 (50.000)
Median		0.00	83.33	33.33
Min, Max		0.0, 0.0	66.7, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	83.33 (23.570)	55.56 (50.918)
Median		0.00	83.33	66.67
Min, Max		0.0, 0.0	66.7, 100.0	0.0, 100.0
Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	83.33 (23.570)	41.67 (50.000)
Median		0.00	83.33	33.33
Min, Max		0.0, 0.0	66.7, 100.0	0.0, 100.0
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	66.67 (47.140)	44.44 (50.918)
Median		0.00	66.67	33.33
Min, Max		0.0, 0.0	33.3, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Global Health Status/QoL	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	33.33 (-)	51.67 (34.561)	37.50 (19.837)	44.17 (26.946)
Median	33.33	50.00	37.50	45.83
Min, Max	33.3, 33.3	0.0, 83.3	16.7, 58.3	0.0, 83.3
Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		70.00 (17.280)	69.44 (12.729)	69.79 (14.731)
Median		75.00	66.67	70.83
Min, Max		41.7, 83.3	58.3, 83.3	41.7, 83.3
Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		72.92 (7.979)	66.67 (16.667)	70.24 (11.644)
Median		70.83	66.67	66.67
Min, Max		66.7, 83.3	50.0, 83.3	50.0, 83.3
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		70.83 (20.972)	56.25 (15.775)	63.54 (18.865)
Median		66.67	62.50	66.67
Min, Max		50.0, 100.0	33.3, 66.7	33.3, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Global Health Status/QoL	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		83.33 (23.570)	64.58 (14.232)	70.83 (18.066)
Median		83.33	62.50	66.67
Min, Max		66.7, 100.0	50.0, 83.3	50.0, 100.0
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		75.00 (22.048)	60.42 (7.979)	66.67 (15.957)
Median		66.67	62.50	66.67
Min, Max		58.3, 100.0	50.0, 66.7	50.0, 100.0
Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		75.00 (22.048)	52.78 (4.811)	63.89 (18.758)
Median		66.67	50.00	58.33
Min, Max		58.3, 100.0	50.0, 58.3	50.0, 100.0
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		83.33 (23.570)	33.33 (47.140)	58.33 (41.944)
Median		83.33	33.33	66.67
Min, Max		66.7, 100.0	0.0, 66.7	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Global Health Status/QoL	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		83.33 (23.570)	25.00 (35.355)	54.17 (41.667)
Median		83.33	25.00	58.33
Min, Max		66.7, 100.0	0.0, 50.0	0.0, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		58.33 (-)	33.33 (47.140)	41.67 (36.324)
Median		58.33	33.33	58.33
Min, Max		58.3, 58.3	0.0, 66.7	0.0, 66.7
Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		75.00 (35.355)	25.00 (35.355)	50.00 (40.825)
Median		75.00	25.00	50.00
Min, Max		50.0, 100.0	0.0, 50.0	0.0, 100.0
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		100.00 (-)	41.67 (58.926)	61.11 (53.576)
Median		100.00	41.67	83.33
Min, Max		100.0, 100.0	0.0, 83.3	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Physical Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	86.67 (-)	46.67 (29.059)	70.00 (24.646)	60.00 (28.284)
Median	86.67	53.33	80.00	66.67
Min, Max	86.7, 86.7	0.0, 80.0	33.3, 86.7	0.0, 86.7
Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		70.67 (13.824)	86.67 (13.333)	76.67 (15.119)
Median		73.33	86.67	76.67
Min, Max		53.3, 86.7	73.3, 100.0	53.3, 100.0
Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		70.00 (17.638)	95.56 (7.698)	80.95 (19.024)
Median		66.67	100.00	86.67
Min, Max		53.3, 93.3	86.7, 100.0	53.3, 100.0
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		71.67 (17.533)	86.67 (12.172)	79.17 (16.110)
Median		73.33	86.67	83.33
Min, Max		53.3, 86.7	73.3, 100.0	53.3, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Physical Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		66.67 (28.284)	78.33 (22.027)	74.44 (22.077)
Median		66.67	80.00	76.67
Min, Max		46.7, 86.7	53.3, 100.0	46.7, 100.0
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		55.56 (26.943)	71.67 (30.972)	64.76 (28.209)
Median		40.00	76.67	60.00
Min, Max		40.0, 86.7	33.3, 100.0	33.3, 100.0
Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		48.89 (32.886)	62.22 (36.717)	55.56 (32.019)
Median		33.33	60.00	46.67
Min, Max		26.7, 86.7	26.7, 100.0	26.7, 100.0
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		70.00 (23.570)	60.00 (56.569)	65.00 (35.849)
Median		70.00	60.00	70.00
Min, Max		53.3, 86.7	20.0, 100.0	20.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Physical Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		73.33 (37.712)	60.00 (56.569)	66.67 (40.000)
Median		73.33	60.00	73.33
Min, Max		46.7, 100.0	20.0, 100.0	20.0, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		46.67 (-)	60.00 (56.569)	55.56 (40.734)
Median		46.67	60.00	46.67
Min, Max		46.7, 46.7	20.0, 100.0	20.0, 100.0
Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		80.00 (28.284)	56.67 (61.283)	68.33 (41.231)
Median		80.00	56.67	80.00
Min, Max		60.0, 100.0	13.3, 100.0	13.3, 100.0
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		100.00 (-)	56.67 (61.283)	71.11 (50.037)
Median		100.00	56.67	100.00
Min, Max		100.0, 100.0	13.3, 100.0	13.3, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Role Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	33.33 (-)	56.67 (22.361)	33.33 (38.490)	45.00 (29.450)
Median	33.33	66.67	33.33	50.00
Min, Max	33.3, 33.3	33.3, 83.3	0.0, 66.7	0.0, 83.3
Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		76.67 (27.889)	83.33 (16.667)	79.17 (23.146)
Median		83.33	83.33	83.33
Min, Max		33.3, 100.0	66.7, 100.0	33.3, 100.0
Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		62.50 (25.000)	77.78 (19.245)	69.05 (22.420)
Median		66.67	66.67	66.67
Min, Max		33.3, 83.3	66.7, 100.0	33.3, 100.0
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		62.50 (20.972)	75.00 (31.914)	68.75 (25.877)
Median		66.67	83.33	66.67
Min, Max		33.3, 83.3	33.3, 100.0	33.3, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Role Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		58.33 (35.355)	54.17 (41.667)	55.56 (36.004)
Median		58.33	58.33	58.33
Min, Max		33.3, 83.3	0.0, 100.0	0.0, 100.0
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		55.56 (38.490)	58.33 (41.944)	57.14 (37.090)
Median		33.33	66.67	66.67
Min, Max		33.3, 100.0	0.0, 100.0	0.0, 100.0
Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		61.11 (34.694)	61.11 (41.944)	61.11 (34.427)
Median		50.00	66.67	58.33
Min, Max		33.3, 100.0	16.7, 100.0	16.7, 100.0
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		83.33 (23.570)	50.00 (70.711)	66.67 (47.140)
Median		83.33	50.00	83.33
Min, Max		66.7, 100.0	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Role Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		83.33 (23.570)	50.00 (70.711)	66.67 (47.140)
Median		83.33	50.00	83.33
Min, Max		66.7, 100.0	0.0, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		50.00 (-)	50.00 (70.711)	50.00 (50.000)
Median		50.00	50.00	50.00
Min, Max		50.0, 50.0	0.0, 100.0	0.0, 100.0
Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		75.00 (35.355)	50.00 (70.711)	62.50 (47.871)
Median		75.00	50.00	75.00
Min, Max		50.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		100.00 (-)	50.00 (70.711)	66.67 (57.735)
Median		100.00	50.00	100.00
Min, Max		100.0, 100.0	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Emotional Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	100.00 (-)	66.67 (29.463)	70.83 (20.972)	71.67 (25.215)
Median	100.00	75.00	75.00	75.00
Min, Max	100.0, 100.0	25.0, 100.0	41.7, 91.7	25.0, 100.0
Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		78.33 (24.721)	77.78 (19.245)	78.13 (21.333)
Median		83.33	66.67	75.00
Min, Max		41.7, 100.0	66.7, 100.0	41.7, 100.0
Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		84.03 (20.079)	75.00 (8.333)	80.16 (15.749)
Median		88.89	75.00	77.78
Min, Max		58.3, 100.0	66.7, 83.3	58.3, 100.0
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		87.50 (15.957)	79.17 (17.347)	83.33 (16.060)
Median		91.67	79.17	83.33
Min, Max		66.7, 100.0	58.3, 100.0	58.3, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Emotional Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		83.33 (23.570)	75.00 (18.002)	77.78 (18.002)
Median		83.33	70.83	70.83
Min, Max		66.7, 100.0	58.3, 100.0	58.3, 100.0
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		91.67 (14.434)	68.75 (27.534)	78.57 (24.465)
Median		100.00	66.67	83.33
Min, Max		75.0, 100.0	41.7, 100.0	41.7, 100.0
Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		88.89 (12.729)	55.56 (26.788)	72.22 (26.176)
Median		91.67	66.67	75.00
Min, Max		75.0, 100.0	25.0, 75.0	25.0, 100.0
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		87.50 (17.678)	45.83 (5.893)	66.67 (26.352)
Median		87.50	45.83	62.50
Min, Max		75.0, 100.0	41.7, 50.0	41.7, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Emotional Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		87.50 (17.678)	37.50 (17.678)	62.50 (32.275)
Median		87.50	37.50	62.50
Min, Max		75.0, 100.0	25.0, 50.0	25.0, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		91.67 (-)	37.50 (5.893)	55.56 (31.549)
Median		91.67	37.50	41.67
Min, Max		91.7, 91.7	33.3, 41.7	33.3, 91.7
Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		95.83 (5.893)	45.83 (5.893)	70.83 (29.266)
Median		95.83	45.83	70.83
Min, Max		91.7, 100.0	41.7, 50.0	41.7, 100.0
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		100.00 (-)	29.17 (29.463)	52.78 (45.896)
Median		100.00	29.17	50.00
Min, Max		100.0, 100.0	8.3, 50.0	8.3, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Cognitive Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	66.67 (-)	76.67 (19.003)	70.83 (15.957)	73.33 (16.102)
Median	66.67	83.33	75.00	75.00
Min, Max	66.7, 66.7	50.0, 100.0	50.0, 83.3	50.0, 100.0
Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		83.33 (23.570)	83.33 (0.000)	83.33 (17.817)
Median		100.00	83.33	83.33
Min, Max		50.0, 100.0	83.3, 83.3	50.0, 100.0
Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		91.67 (9.623)	77.78 (9.623)	85.71 (11.501)
Median		91.67	83.33	83.33
Min, Max		83.3, 100.0	66.7, 83.3	66.7, 100.0
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		87.50 (15.957)	79.17 (15.957)	83.33 (15.430)
Median		91.67	75.00	83.33
Min, Max		66.7, 100.0	66.7, 100.0	66.7, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Cognitive Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		83.33 (23.570)	70.83 (25.000)	75.00 (22.973)
Median		83.33	66.67	75.00
Min, Max		66.7, 100.0	50.0, 100.0	50.0, 100.0
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		94.44 (9.623)	83.33 (13.608)	88.10 (12.599)
Median		100.00	83.33	83.33
Min, Max		83.3, 100.0	66.7, 100.0	66.7, 100.0
Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		88.89 (19.245)	61.11 (9.623)	75.00 (20.412)
Median		100.00	66.67	66.67
Min, Max		66.7, 100.0	50.0, 66.7	50.0, 100.0
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		100.00 (0.000)	75.00 (11.785)	87.50 (15.957)
Median		100.00	75.00	91.67
Min, Max		100.0, 100.0	66.7, 83.3	66.7, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Cognitive Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		91.67 (11.785)	75.00 (11.785)	83.33 (13.608)
Median		91.67	75.00	83.33
Min, Max		83.3, 100.0	66.7, 83.3	66.7, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		100.00 (-)	58.33 (35.355)	72.22 (34.694)
Median		100.00	58.33	83.33
Min, Max		100.0, 100.0	33.3, 83.3	33.3, 100.0
Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		91.67 (11.785)	66.67 (23.570)	79.17 (20.972)
Median		91.67	66.67	83.33
Min, Max		83.3, 100.0	50.0, 83.3	50.0, 100.0
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		100.00 (-)	50.00 (47.140)	66.67 (44.096)
Median		100.00	50.00	83.33
Min, Max		100.0, 100.0	16.7, 83.3	16.7, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Social Function	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	33.33 (-)	60.00 (30.277)	58.33 (41.944)	56.67 (32.584)
Median	33.33	66.67	66.67	66.67
Min, Max	33.3, 33.3	16.7, 100.0	0.0, 100.0	0.0, 100.0
Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		80.00 (27.386)	55.56 (38.490)	70.83 (31.810)
Median		83.33	33.33	83.33
Min, Max		33.3, 100.0	33.3, 100.0	33.3, 100.0
Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		75.00 (21.517)	61.11 (25.459)	69.05 (22.420)
Median		75.00	66.67	66.67
Min, Max		50.0, 100.0	33.3, 83.3	33.3, 100.0
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		79.17 (15.957)	66.67 (27.217)	72.92 (21.708)
Median		75.00	66.67	66.67
Min, Max		66.7, 100.0	33.3, 100.0	33.3, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Social Function	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		83.33 (23.570)	62.50 (20.972)	69.44 (22.153)
Median		83.33	66.67	66.67
Min, Max		66.7, 100.0	33.3, 83.3	33.3, 100.0
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		72.22 (34.694)	58.33 (9.623)	64.29 (22.420)
Median		83.33	58.33	66.67
Min, Max		33.3, 100.0	50.0, 66.7	33.3, 100.0
Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		72.22 (34.694)	72.22 (9.623)	72.22 (22.771)
Median		83.33	66.67	75.00
Min, Max		33.3, 100.0	66.7, 83.3	33.3, 100.0
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		83.33 (23.570)	50.00 (23.570)	66.67 (27.217)
Median		83.33	50.00	66.67
Min, Max		66.7, 100.0	33.3, 66.7	33.3, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Social Function	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		91.67 (11.785)	58.33 (35.355)	75.00 (28.868)
Median		91.67	58.33	83.33
Min, Max		83.3, 100.0	33.3, 83.3	33.3, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		83.33 (-)	33.33 (47.140)	50.00 (44.096)
Median		83.33	33.33	66.67
Min, Max		83.3, 83.3	0.0, 66.7	0.0, 83.3
Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		75.00 (35.355)	50.00 (47.140)	62.50 (36.956)
Median		75.00	50.00	66.67
Min, Max		50.0, 100.0	16.7, 83.3	16.7, 100.0
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		100.00 (-)	41.67 (35.355)	61.11 (41.944)
Median		100.00	41.67	66.67
Min, Max		100.0, 100.0	16.7, 66.7	16.7, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Fatigue	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	100.00 (-)	55.56 (32.394)	69.44 (30.598)	65.56 (31.186)
Median	100.00	55.56	72.22	61.11
Min, Max	100.0, 100.0	11.1, 100.0	33.3, 100.0	11.1, 100.0
Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		35.56 (16.480)	37.04 (16.973)	36.11 (15.430)
Median		33.33	33.33	33.33
Min, Max		11.1, 55.6	22.2, 55.6	11.1, 55.6
Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		38.89 (14.344)	33.33 (0.000)	36.51 (10.569)
Median		38.89	33.33	33.33
Min, Max		22.2, 55.6	33.3, 33.3	22.2, 55.6
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		52.78 (22.906)	38.89 (26.450)	45.83 (24.079)
Median		50.00	27.78	33.33
Min, Max		33.3, 77.8	22.2, 77.8	22.2, 77.8

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Fatigue	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		66.67 (47.140)	41.67 (22.906)	50.00 (30.429)
Median		66.67	38.89	44.44
Min, Max		33.3, 100.0	22.2, 66.7	22.2, 100.0
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		59.26 (33.945)	55.56 (27.217)	57.14 (27.539)
Median		66.67	50.00	66.67
Min, Max		22.2, 88.9	33.3, 88.9	22.2, 88.9
Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		44.44 (22.222)	62.96 (27.962)	53.70 (24.762)
Median		44.44	66.67	55.56
Min, Max		22.2, 66.7	33.3, 88.9	22.2, 88.9
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		33.33 (15.713)	66.67 (47.140)	50.00 (34.546)
Median		33.33	66.67	38.89
Min, Max		22.2, 44.4	33.3, 100.0	22.2, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Fatigue	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		11.11 (15.713)	55.56 (62.854)	33.33 (45.361)
Median		11.11	55.56	16.67
Min, Max		0.0, 22.2	11.1, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		44.44 (-)	61.11 (54.997)	55.56 (40.062)
Median		44.44	61.11	44.44
Min, Max		44.4, 44.4	22.2, 100.0	22.2, 100.0
Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		27.78 (39.284)	66.67 (47.140)	47.22 (41.944)
Median		27.78	66.67	44.44
Min, Max		0.0, 55.6	33.3, 100.0	0.0, 100.0
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	61.11 (54.997)	40.74 (52.509)
Median		0.00	61.11	22.22
Min, Max		0.0, 0.0	22.2, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Nausea and Vomiting	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	66.67 (-)	10.00 (22.361)	8.33 (9.623)	15.00 (24.152)
Median	66.67	0.00	8.33	0.00
Min, Max	66.7, 66.7	0.0, 50.0	0.0, 16.7	0.0, 66.7
Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		13.33 (13.944)	11.11 (9.623)	12.50 (11.785)
Median		16.67	16.67	16.67
Min, Max		0.0, 33.3	0.0, 16.7	0.0, 33.3
Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		20.83 (25.000)	11.11 (9.623)	16.67 (19.245)
Median		16.67	16.67	16.67
Min, Max		0.0, 50.0	0.0, 16.7	0.0, 50.0
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		20.83 (15.957)	4.17 (8.333)	12.50 (14.773)
Median		25.00	0.00	8.33
Min, Max		0.0, 33.3	0.0, 16.7	0.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Nausea and Vomiting	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		16.67 (23.570)	8.33 (9.623)	11.11 (13.608)
Median		16.67	8.33	8.33
Min, Max		0.0, 33.3	0.0, 16.7	0.0, 33.3
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		5.56 (9.623)	4.17 (8.333)	4.76 (8.133)
Median		0.00	0.00	0.00
Min, Max		0.0, 16.7	0.0, 16.7	0.0, 16.7
Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		5.56 (9.623)	11.11 (9.623)	8.33 (9.129)
Median		0.00	16.67	8.33
Min, Max		0.0, 16.7	0.0, 16.7	0.0, 16.7
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		8.33 (11.785)	8.33 (11.785)	8.33 (9.623)
Median		8.33	8.33	8.33
Min, Max		0.0, 16.7	0.0, 16.7	0.0, 16.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Nausea and Vomiting	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		8.33 (11.785)	8.33 (11.785)	8.33 (9.623)
Median		8.33	8.33	8.33
Min, Max		0.0, 16.7	0.0, 16.7	0.0, 16.7
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		16.67 (-)	8.33 (11.785)	11.11 (9.623)
Median		16.67	8.33	16.67
Min, Max		16.7, 16.7	0.0, 16.7	0.0, 16.7
Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
Median		0.00	0.00	0.00
Min, Max		0.0, 0.0	0.0, 0.0	0.0, 0.0
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	8.33 (11.785)	5.56 (9.623)
Median		0.00	8.33	0.00
Min, Max		0.0, 0.0	0.0, 16.7	0.0, 16.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Pain	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	83.33 (-)	26.67 (19.003)	50.00 (43.033)	41.67 (33.564)
Median	83.33	33.33	50.00	33.33
Min, Max	83.3, 83.3	0.0, 50.0	0.0, 100.0	0.0, 100.0
Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		16.67 (20.412)	11.11 (9.623)	14.58 (16.517)
Median		16.67	16.67	16.67
Min, Max		0.0, 50.0	0.0, 16.7	0.0, 50.0
Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		25.00 (9.623)	16.67 (16.667)	21.43 (12.599)
Median		25.00	16.67	16.67
Min, Max		16.7, 33.3	0.0, 33.3	0.0, 33.3
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		8.33 (9.623)	25.00 (16.667)	16.67 (15.430)
Median		8.33	16.67	16.67
Min, Max		0.0, 16.7	16.7, 50.0	0.0, 50.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Pain	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		8.33 (11.785)	12.50 (15.957)	11.11 (13.608)
Median		8.33	8.33	8.33
Min, Max		0.0, 16.7	0.0, 33.3	0.0, 33.3
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		0.00 (0.000)	29.17 (28.464)	16.67 (25.459)
Median		0.00	25.00	0.00
Min, Max		0.0, 0.0	0.0, 66.7	0.0, 66.7
Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		11.11 (9.623)	27.78 (34.694)	19.44 (24.533)
Median		16.67	16.67	16.67
Min, Max		0.0, 16.7	0.0, 66.7	0.0, 66.7
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		8.33 (11.785)	58.33 (58.926)	33.33 (45.134)
Median		8.33	58.33	16.67
Min, Max		0.0, 16.7	16.7, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Pain	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	58.33 (58.926)	29.17 (47.871)
Median		0.00	58.33	8.33
Min, Max		0.0, 0.0	16.7, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		16.67 (-)	58.33 (58.926)	44.44 (48.113)
Median		16.67	58.33	16.67
Min, Max		16.7, 16.7	16.7, 100.0	16.7, 100.0
Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		8.33 (11.785)	58.33 (58.926)	33.33 (45.134)
Median		8.33	58.33	16.67
Min, Max		0.0, 16.7	16.7, 100.0	0.0, 100.0
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	50.00 (70.711)	33.33 (57.735)
Median		0.00	50.00	0.00
Min, Max		0.0, 0.0	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Dyspnea	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	33.33 (-)	40.00 (36.515)	50.00 (43.033)	43.33 (35.312)
Median	33.33	33.33	50.00	33.33
Min, Max	33.3, 33.3	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		13.33 (29.814)	22.22 (19.245)	16.67 (25.198)
Median		0.00	33.33	0.00
Min, Max		0.0, 66.7	0.0, 33.3	0.0, 66.7
Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		25.00 (16.667)	0.00 (0.000)	14.29 (17.817)
Median		33.33	0.00	0.00
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		16.67 (19.245)	25.00 (16.667)	20.83 (17.252)
Median		16.67	33.33	33.33
Min, Max		0.0, 33.3	0.0, 33.3	0.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Dyspnea	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		33.33 (47.140)	33.33 (47.140)	33.33 (42.164)
Median		33.33	16.67	16.67
Min, Max		0.0, 66.7	0.0, 100.0	0.0, 100.0
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		22.22 (19.245)	41.67 (41.944)	33.33 (33.333)
Median		33.33	33.33	33.33
Min, Max		0.0, 33.3	0.0, 100.0	0.0, 100.0
Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		22.22 (38.490)	55.56 (50.918)	38.89 (44.305)
Median		0.00	66.67	33.33
Min, Max		0.0, 66.7	0.0, 100.0	0.0, 100.0
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	50.00 (70.711)	25.00 (50.000)
Median		0.00	50.00	0.00
Min, Max		0.0, 0.0	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Dyspnea	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	50.00 (70.711)	25.00 (50.000)
Median		0.00	50.00	0.00
Min, Max		0.0, 0.0	0.0, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	50.00 (70.711)	33.33 (57.735)
Median		0.00	50.00	0.00
Min, Max		0.0, 0.0	0.0, 100.0	0.0, 100.0
Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	50.00 (70.711)	25.00 (50.000)
Median		0.00	50.00	0.00
Min, Max		0.0, 0.0	0.0, 100.0	0.0, 100.0
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	50.00 (70.711)	33.33 (57.735)
Median		0.00	50.00	0.00
Min, Max		0.0, 0.0	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Insomnia	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	100.00 (-)	26.67 (27.889)	58.33 (50.000)	46.67 (42.164)
Median	100.00	33.33	66.67	33.33
Min, Max	100.0, 100.0	0.0, 66.7	0.0, 100.0	0.0, 100.0
Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		20.00 (18.257)	22.22 (38.490)	20.83 (24.801)
Median		33.33	0.00	16.67
Min, Max		0.0, 33.3	0.0, 66.7	0.0, 66.7
Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		33.33 (27.217)	33.33 (33.333)	33.33 (27.217)
Median		33.33	33.33	33.33
Min, Max		0.0, 66.7	0.0, 66.7	0.0, 66.7
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		25.00 (31.914)	41.67 (41.944)	33.33 (35.635)
Median		16.67	33.33	33.33
Min, Max		0.0, 66.7	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Insomnia	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		50.00 (23.570)	33.33 (47.140)	38.89 (38.968)
Median		50.00	16.67	33.33
Min, Max		33.3, 66.7	0.0, 100.0	0.0, 100.0
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		33.33 (33.333)	41.67 (41.944)	38.10 (35.635)
Median		33.33	33.33	33.33
Min, Max		0.0, 66.7	0.0, 100.0	0.0, 100.0
Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		44.44 (19.245)	55.56 (38.490)	50.00 (27.889)
Median		33.33	33.33	33.33
Min, Max		33.3, 66.7	33.3, 100.0	33.3, 100.0
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	66.67 (47.140)	33.33 (47.140)
Median		0.00	66.67	16.67
Min, Max		0.0, 0.0	33.3, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Insomnia	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	66.67 (47.140)	33.33 (47.140)
Median		0.00	66.67	16.67
Min, Max		0.0, 0.0	33.3, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	66.67 (47.140)	44.44 (50.918)
Median		0.00	66.67	33.33
Min, Max		0.0, 0.0	33.3, 100.0	0.0, 100.0
Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	83.33 (23.570)	41.67 (50.000)
Median		0.00	83.33	33.33
Min, Max		0.0, 0.0	66.7, 100.0	0.0, 100.0
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	83.33 (23.570)	55.56 (50.918)
Median		0.00	83.33	66.67
Min, Max		0.0, 0.0	66.7, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Appetite Loss	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	0.00 (-)	40.00 (43.461)	41.67 (41.944)	36.67 (39.907)
Median	0.00	33.33	33.33	33.33
Min, Max	0.0, 0.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		20.00 (29.814)	33.33 (0.000)	25.00 (23.570)
Median		0.00	33.33	33.33
Min, Max		0.0, 66.7	33.3, 33.3	0.0, 66.7
Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		0.00 (0.000)	44.44 (19.245)	19.05 (26.227)
Median		0.00	33.33	0.00
Min, Max		0.0, 0.0	33.3, 66.7	0.0, 66.7
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		25.00 (16.667)	33.33 (38.490)	29.17 (27.817)
Median		33.33	33.33	33.33
Min, Max		0.0, 33.3	0.0, 66.7	0.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Appetite Loss	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		16.67 (23.570)	33.33 (27.217)	27.78 (25.092)
Median		16.67	33.33	33.33
Min, Max		0.0, 33.3	0.0, 66.7	0.0, 66.7
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		11.11 (19.245)	25.00 (16.667)	19.05 (17.817)
Median		0.00	33.33	33.33
Min, Max		0.0, 33.3	0.0, 33.3	0.0, 33.3
Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		22.22 (38.490)	33.33 (33.333)	27.78 (32.773)
Median		0.00	33.33	16.67
Min, Max		0.0, 66.7	0.0, 66.7	0.0, 66.7
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	33.33 (47.140)	16.67 (33.333)
Median		0.00	33.33	0.00
Min, Max		0.0, 0.0	0.0, 66.7	0.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Appetite Loss	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	50.00 (70.711)	25.00 (50.000)
Median		0.00	50.00	0.00
Min, Max		0.0, 0.0	0.0, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	66.67 (47.140)	44.44 (50.918)
Median		0.00	66.67	33.33
Min, Max		0.0, 0.0	33.3, 100.0	0.0, 100.0
Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	66.67 (47.140)	33.33 (47.140)
Median		0.00	66.67	16.67
Min, Max		0.0, 0.0	33.3, 100.0	0.0, 100.0
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	66.67 (47.140)	44.44 (50.918)
Median		0.00	66.67	33.33
Min, Max		0.0, 0.0	33.3, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Constipation	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	0.00 (-)	20.00 (29.814)	16.67 (33.333)	16.67 (28.328)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 0.0	0.0, 66.7	0.0, 66.7	0.0, 66.7
Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		13.33 (18.257)	0.00 (0.000)	8.33 (15.430)
Median		0.00	0.00	0.00
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3
Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		8.33 (16.667)	11.11 (19.245)	9.52 (16.265)
Median		0.00	0.00	0.00
Min, Max		0.0, 33.3	0.0, 33.3	0.0, 33.3
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		8.33 (16.667)	0.00 (0.000)	4.17 (11.785)
Median		0.00	0.00	0.00
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Constipation	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		16.67 (23.570)	0.00 (0.000)	5.56 (13.608)
Median		16.67	0.00	0.00
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		0.00 (0.000)	8.33 (16.667)	4.76 (12.599)
Median		0.00	0.00	0.00
Min, Max		0.0, 0.0	0.0, 33.3	0.0, 33.3
Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		11.11 (19.245)	0.00 (0.000)	5.56 (13.608)
Median		0.00	0.00	0.00
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
Median		0.00	0.00	0.00
Min, Max		0.0, 0.0	0.0, 0.0	0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Constipation	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
Median		0.00	0.00	0.00
Min, Max		0.0, 0.0	0.0, 0.0	0.0, 0.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	0.00 (0.000)	0.00 (0.000)
Median		0.00	0.00	0.00
Min, Max		0.0, 0.0	0.0, 0.0	0.0, 0.0
Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
Median		0.00	0.00	0.00
Min, Max		0.0, 0.0	0.0, 0.0	0.0, 0.0
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	0.00 (0.000)	0.00 (0.000)
Median		0.00	0.00	0.00
Min, Max		0.0, 0.0	0.0, 0.0	0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Diarrhea	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	100.00 (-)	33.33 (47.140)	58.33 (41.944)	50.00 (45.134)
Median	100.00	0.00	66.67	66.67
Min, Max	100.0, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		26.67 (27.889)	44.44 (19.245)	33.33 (25.198)
Median		33.33	33.33	33.33
Min, Max		0.0, 66.7	33.3, 66.7	0.0, 66.7
Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		25.00 (16.667)	66.67 (0.000)	42.86 (25.198)
Median		33.33	66.67	33.33
Min, Max		0.0, 33.3	66.7, 66.7	0.0, 66.7
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		41.67 (16.667)	25.00 (31.914)	33.33 (25.198)
Median		33.33	16.67	33.33
Min, Max		33.3, 66.7	0.0, 66.7	0.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Diarrhea	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		50.00 (23.570)	50.00 (19.245)	50.00 (18.257)
Median		50.00	50.00	50.00
Min, Max		33.3, 66.7	33.3, 66.7	33.3, 66.7
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		44.44 (50.918)	33.33 (27.217)	38.10 (35.635)
Median		33.33	33.33	33.33
Min, Max		0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		44.44 (19.245)	22.22 (19.245)	33.33 (21.082)
Median		33.33	33.33	33.33
Min, Max		33.3, 66.7	0.0, 33.3	0.0, 66.7
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		33.33 (0.000)	16.67 (23.570)	25.00 (16.667)
Median		33.33	16.67	33.33
Min, Max		33.3, 33.3	0.0, 33.3	0.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Diarrhea	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		16.67 (23.570)	66.67 (0.000)	41.67 (31.914)
Median		16.67	66.67	50.00
Min, Max		0.0, 33.3	66.7, 66.7	0.0, 66.7
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		33.33 (-)	83.33 (23.570)	66.67 (33.333)
Median		33.33	83.33	66.67
Min, Max		33.3, 33.3	66.7, 100.0	33.3, 100.0
Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		33.33 (0.000)	50.00 (23.570)	41.67 (16.667)
Median		33.33	50.00	33.33
Min, Max		33.3, 33.3	33.3, 66.7	33.3, 66.7
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		33.33 (-)	50.00 (23.570)	44.44 (19.245)
Median		33.33	50.00	33.33
Min, Max		33.3, 33.3	33.3, 66.7	33.3, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg				
Financial Difficulties	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	66.67 (-)	26.67 (43.461)	58.33 (41.944)	43.33 (41.722)
Median	66.67	0.00	66.67	50.00
Min, Max	66.7, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		33.33 (40.825)	55.56 (50.918)	41.67 (42.725)
Median		33.33	66.67	33.33
Min, Max		0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		41.67 (31.914)	66.67 (33.333)	52.38 (32.530)
Median		50.00	66.67	66.67
Min, Max		0.0, 66.7	33.3, 100.0	0.0, 100.0
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		25.00 (50.000)	50.00 (43.033)	37.50 (45.207)
Median		0.00	50.00	16.67
Min, Max		0.0, 100.0	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Financial Difficulties	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		0.00 (0.000)	58.33 (41.944)	38.89 (44.305)
Median		0.00	66.67	33.33
Min, Max		0.0, 0.0	0.0, 100.0	0.0, 100.0
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		0.00 (0.000)	50.00 (33.333)	28.57 (35.635)
Median		0.00	33.33	33.33
Min, Max		0.0, 0.0	33.3, 100.0	0.0, 100.0
Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		0.00 (0.000)	44.44 (50.918)	22.22 (40.369)
Median		0.00	33.33	0.00
Min, Max		0.0, 0.0	0.0, 100.0	0.0, 100.0
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		16.67 (23.570)	83.33 (23.570)	50.00 (43.033)
Median		16.67	83.33	50.00
Min, Max		0.0, 33.3	66.7, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Financial Difficulties	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	83.33 (23.570)	41.67 (50.000)
Median		0.00	83.33	33.33
Min, Max		0.0, 0.0	66.7, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	83.33 (23.570)	55.56 (50.918)
Median		0.00	83.33	66.67
Min, Max		0.0, 0.0	66.7, 100.0	0.0, 100.0
Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	83.33 (23.570)	41.67 (50.000)
Median		0.00	83.33	33.33
Min, Max		0.0, 0.0	66.7, 100.0	0.0, 100.0
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	66.67 (47.140)	44.44 (50.918)
Median		0.00	66.67	33.33
Min, Max		0.0, 0.0	33.3, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Global Health Status/QoL	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Baseline				
n	3	24	8	35
Mean (StdDev)	55.56 (20.972)	31.94 (25.616)	36.46 (13.317)	35.00 (23.466)
Median	58.33	33.33	33.33	33.33
Min, Max	33.3, 75.0	0.0, 100.0	16.7, 58.3	0.0, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	60.42 (12.500)	53.03 (23.365)	51.19 (21.746)	53.54 (21.654)
Median	66.67	50.00	50.00	50.00
Min, Max	41.7, 66.7	16.7, 100.0	25.0, 75.0	16.7, 100.0
Cycle 2 Day 1				
n	2	24	8	34
Mean (StdDev)	66.67 (0.000)	54.17 (20.412)	50.00 (24.801)	53.92 (20.844)
Median	66.67	54.17	58.33	62.50
Min, Max	66.7, 66.7	16.7, 91.7	0.0, 75.0	0.0, 91.7
Cycle 3 Day 1				
n	4	22	6	32
Mean (StdDev)	60.42 (15.775)	59.47 (16.325)	40.28 (12.266)	55.99 (16.964)
Median	54.17	66.67	37.50	58.33
Min, Max	50.0, 83.3	33.3, 83.3	25.0, 58.3	25.0, 83.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Global Health Status/QoL	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Cycle 5 Day 1				
n	2	14	5	21
Mean (StdDev)	58.33 (11.785)	54.76 (21.857)	43.33 (21.570)	52.38 (20.940)
Median	58.33	58.33	50.00	50.00
Min, Max	50.0, 66.7	0.0, 83.3	8.3, 66.7	0.0, 83.3
Cycle 7 Day 1				
n	1	14	2	17
Mean (StdDev)	41.67 (-)	63.10 (15.578)	54.17 (17.678)	60.78 (15.802)
Median	41.67	66.67	54.17	66.67
Min, Max	41.7, 41.7	25.0, 83.3	41.7, 66.7	25.0, 83.3
Cycle 9 Day 1				
n	0	11	2	13
Mean (StdDev)		55.30 (19.462)	62.50 (5.893)	56.41 (18.051)
Median		58.33	62.50	58.33
Min, Max		25.0, 83.3	58.3, 66.7	25.0, 83.3
Cycle 11 Day 1				
n	0	6	1	7
Mean (StdDev)		65.28 (9.742)	66.67 (-)	65.48 (8.909)
Median		66.67	66.67	66.67
Min, Max		50.0, 75.0	66.7, 66.7	50.0, 75.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Global Health Status/QoL	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		75.00 (14.434)	83.33 (-)	77.08 (12.500)
Median		83.33	83.33	83.33
Min, Max		58.3, 83.3	83.3, 83.3	58.3, 83.3
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		66.67 (-)		66.67 (-)
Median		66.67		66.67
Min, Max		66.7, 66.7		66.7, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Physical Functioning	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Baseline				
n	3	24	8	35
Mean (StdDev)	62.22 (36.717)	51.11 (29.137)	60.00 (24.944)	54.10 (28.320)
Median	80.00	46.67	60.00	46.67
Min, Max	20.0, 86.7	0.0, 100.0	26.7, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	58.33 (29.502)	61.52 (25.773)	77.14 (20.676)	64.44 (25.368)
Median	60.00	53.33	80.00	73.33
Min, Max	26.7, 86.7	0.0, 100.0	40.0, 100.0	0.0, 100.0
Cycle 2 Day 1				
n	2	24	8	34
Mean (StdDev)	83.33 (4.714)	65.28 (26.953)	71.67 (16.619)	67.84 (24.258)
Median	83.33	70.00	73.33	73.33
Min, Max	80.0, 86.7	0.0, 100.0	40.0, 93.3	0.0, 100.0
Cycle 3 Day 1				
n	4	22	6	32
Mean (StdDev)	55.00 (28.480)	72.12 (19.150)	65.56 (18.579)	68.75 (20.421)
Median	66.67	73.33	63.33	73.33
Min, Max	13.3, 73.3	26.7, 100.0	46.7, 100.0	13.3, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Physical Functioning	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Cycle 5 Day 1				
n	2	14	5	21
Mean (StdDev)	66.67 (28.284)	80.48 (15.790)	62.67 (23.851)	74.92 (19.540)
Median	66.67	83.33	60.00	80.00
Min, Max	46.7, 86.7	46.7, 100.0	40.0, 93.3	40.0, 100.0
Cycle 7 Day 1				
n	1	14	2	17
Mean (StdDev)	40.00 (-)	76.19 (15.844)	66.67 (0.000)	72.94 (16.910)
Median	40.00	76.67	66.67	73.33
Min, Max	40.0, 40.0	53.3, 100.0	66.7, 66.7	40.0, 100.0
Cycle 9 Day 1				
n	0	11	2	13
Mean (StdDev)		78.79 (14.242)	63.33 (4.714)	76.41 (14.302)
Median		80.00	63.33	73.33
Min, Max		53.3, 100.0	60.0, 66.7	53.3, 100.0
Cycle 11 Day 1				
n	0	6	1	7
Mean (StdDev)		77.78 (9.108)	86.67 (-)	79.05 (8.968)
Median		76.67	86.67	80.00
Min, Max		66.7, 93.3	86.7, 86.7	66.7, 93.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Physical Functioning	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		88.89 (10.184)	86.67 (-)	88.33 (8.389)
Median		86.67	86.67	86.67
Min, Max		80.0, 100.0	86.7, 86.7	80.0, 100.0
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		100.00 (-)		100.00 (-)
Median		100.00		100.00
Min, Max		100.0, 100.0		100.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Role Functioning	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Baseline				
n	3	24	8	35
Mean (StdDev)	50.00 (44.096)	38.89 (37.644)	27.08 (26.633)	37.14 (35.490)
Median	66.67	33.33	25.00	33.33
Min, Max	0.0, 83.3	0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	45.83 (31.549)	50.00 (31.706)	50.00 (21.517)	49.49 (29.013)
Median	58.33	50.00	66.67	50.00
Min, Max	0.0, 66.7	0.0, 100.0	16.7, 66.7	0.0, 100.0
Cycle 2 Day 1				
n	2	24	8	34
Mean (StdDev)	58.33 (35.355)	54.17 (29.180)	45.83 (23.146)	52.45 (27.565)
Median	58.33	50.00	50.00	50.00
Min, Max	33.3, 83.3	0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 3 Day 1				
n	4	22	6	32
Mean (StdDev)	45.83 (31.549)	60.61 (26.500)	38.89 (38.968)	54.69 (30.004)
Median	58.33	66.67	33.33	58.33
Min, Max	0.0, 66.7	16.7, 100.0	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Role Functioning	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Cycle 5 Day 1				
n	2	14	5	21
Mean (StdDev)	50.00 (70.711)	59.52 (26.726)	36.67 (24.721)	53.17 (30.559)
Median	50.00	66.67	33.33	50.00
Min, Max	0.0, 100.0	0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 7 Day 1				
n	1	14	2	17
Mean (StdDev)	33.33 (-)	59.52 (22.374)	50.00 (23.570)	56.86 (22.094)
Median	33.33	66.67	50.00	66.67
Min, Max	33.3, 33.3	16.7, 100.0	33.3, 66.7	16.7, 100.0
Cycle 9 Day 1				
n	0	11	2	13
Mean (StdDev)		63.64 (25.624)	50.00 (23.570)	61.54 (24.893)
Median		66.67	50.00	66.67
Min, Max		16.7, 100.0	33.3, 66.7	16.7, 100.0
Cycle 11 Day 1				
n	0	6	1	7
Mean (StdDev)		72.22 (13.608)	100.00 (-)	76.19 (16.265)
Median		66.67	100.00	66.67
Min, Max		66.7, 100.0	100.0, 100.0	66.7, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Role Functioning	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		83.33 (16.667)	66.67 (-)	79.17 (15.957)
Median		83.33	66.67	75.00
Min, Max		66.7, 100.0	66.7, 66.7	66.7, 100.0
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		100.00 (-)		100.00 (-)
Median		100.00		100.00
Min, Max		100.0, 100.0		100.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Emotional Functioning	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Baseline				
n	3	24	8	35
Mean (StdDev)	69.44 (31.549)	59.38 (27.288)	56.25 (27.728)	59.52 (27.052)
Median	83.33	54.17	54.17	58.33
Min, Max	33.3, 91.7	8.3, 100.0	8.3, 100.0	8.3, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	66.67 (20.412)	70.83 (23.675)	58.33 (28.054)	67.68 (24.095)
Median	70.83	70.83	50.00	66.67
Min, Max	41.7, 83.3	25.0, 100.0	25.0, 100.0	25.0, 100.0
Cycle 2 Day 1				
n	2	24	8	34
Mean (StdDev)	75.00 (0.000)	73.96 (22.697)	67.71 (23.754)	72.55 (22.051)
Median	75.00	75.00	70.83	75.00
Min, Max	75.0, 75.0	25.0, 100.0	25.0, 100.0	25.0, 100.0
Cycle 3 Day 1				
n	4	22	6	32
Mean (StdDev)	64.58 (12.500)	74.24 (19.570)	59.72 (28.095)	70.31 (20.947)
Median	66.67	75.00	66.67	70.83
Min, Max	50.0, 75.0	33.3, 100.0	16.7, 100.0	16.7, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Emotional Functioning	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Cycle 5 Day 1				
n	2	14	5	21
Mean (StdDev)	58.33 (11.785)	83.33 (16.984)	55.00 (37.081)	74.21 (25.400)
Median	58.33	87.50	50.00	75.00
Min, Max	50.0, 66.7	50.0, 100.0	8.3, 100.0	8.3, 100.0
Cycle 7 Day 1				
n	1	14	2	17
Mean (StdDev)	83.33 (-)	77.98 (18.376)	83.33 (23.570)	78.92 (17.707)
Median	83.33	79.17	83.33	83.33
Min, Max	83.3, 83.3	41.7, 100.0	66.7, 100.0	41.7, 100.0
Cycle 9 Day 1				
n	0	11	2	13
Mean (StdDev)		77.27 (22.077)	83.33 (23.570)	78.21 (21.392)
Median		75.00	83.33	75.00
Min, Max		33.3, 100.0	66.7, 100.0	33.3, 100.0
Cycle 11 Day 1				
n	0	6	1	7
Mean (StdDev)		73.61 (16.173)	100.00 (-)	77.38 (17.817)
Median		79.17	100.00	83.33
Min, Max		50.0, 91.7	100.0, 100.0	50.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Emotional Functioning	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		100.00 (0.000)	100.00 (-)	100.00 (0.000)
Median		100.00	100.00	100.00
Min, Max		100.0, 100.0	100.0, 100.0	100.0, 100.0
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		100.00 (-)		100.00 (-)
Median		100.00		100.00
Min, Max		100.0, 100.0		100.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Cognitive Functioning	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Baseline				
n	3	24	8	35
Mean (StdDev)	83.33 (16.667)	70.83 (23.698)	62.50 (33.034)	70.00 (25.502)
Median	83.33	66.67	50.00	66.67
Min, Max	66.7, 100.0	33.3, 100.0	16.7, 100.0	16.7, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	83.33 (19.245)	74.24 (19.057)	59.52 (30.211)	72.22 (22.309)
Median	83.33	75.00	50.00	66.67
Min, Max	66.7, 100.0	33.3, 100.0	16.7, 100.0	16.7, 100.0
Cycle 2 Day 1				
n	2	24	8	34
Mean (StdDev)	75.00 (11.785)	77.08 (18.266)	64.58 (24.296)	74.02 (19.759)
Median	75.00	83.33	66.67	83.33
Min, Max	66.7, 83.3	33.3, 100.0	33.3, 100.0	33.3, 100.0
Cycle 3 Day 1				
n	4	22	6	32
Mean (StdDev)	87.50 (15.957)	76.52 (20.353)	66.67 (27.889)	76.04 (21.560)
Median	91.67	83.33	66.67	83.33
Min, Max	66.7, 100.0	33.3, 100.0	16.7, 100.0	16.7, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Cognitive Functioning	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Cycle 5 Day 1				
n	2	14	5	21
Mean (StdDev)	83.33 (0.000)	76.19 (14.194)	50.00 (40.825)	70.63 (24.667)
Median	83.33	75.00	33.33	83.33
Min, Max	83.3, 83.3	50.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 7 Day 1				
n	1	14	2	17
Mean (StdDev)	100.00 (-)	75.00 (10.841)	83.33 (23.570)	77.45 (13.098)
Median	100.00	66.67	83.33	66.67
Min, Max	100.0, 100.0	66.7, 100.0	66.7, 100.0	66.7, 100.0
Cycle 9 Day 1				
n	0	11	2	13
Mean (StdDev)		71.21 (15.076)	58.33 (35.355)	69.23 (17.803)
Median		66.67	58.33	66.67
Min, Max		50.0, 100.0	33.3, 83.3	33.3, 100.0
Cycle 11 Day 1				
n	0	6	1	7
Mean (StdDev)		80.56 (16.387)	66.67 (-)	78.57 (15.853)
Median		75.00	66.67	66.67
Min, Max		66.7, 100.0	66.7, 66.7	66.7, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Cognitive Functioning	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		83.33 (16.667)	66.67 (-)	79.17 (15.957)
Median		83.33	66.67	75.00
Min, Max		66.7, 100.0	66.7, 66.7	66.7, 100.0
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		83.33 (-)		83.33 (-)
Median		83.33		83.33
Min, Max		83.3, 83.3		83.3, 83.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Social Function	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Baseline				
n	3	24	8	35
Mean (StdDev)	55.56 (41.944)	47.92 (34.513)	45.83 (29.209)	48.10 (33.031)
Median	50.00	33.33	50.00	33.33
Min, Max	16.7, 100.0	0.0, 100.0	0.0, 83.3	0.0, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	62.50 (43.833)	61.36 (29.719)	66.67 (16.667)	62.63 (28.574)
Median	75.00	58.33	66.67	66.67
Min, Max	0.0, 100.0	0.0, 100.0	33.3, 83.3	0.0, 100.0
Cycle 2 Day 1				
n	2	24	8	34
Mean (StdDev)	66.67 (23.570)	63.19 (32.220)	64.58 (16.517)	63.73 (28.270)
Median	66.67	66.67	66.67	66.67
Min, Max	50.0, 83.3	0.0, 100.0	33.3, 83.3	0.0, 100.0
Cycle 3 Day 1				
n	4	22	6	32
Mean (StdDev)	54.17 (36.956)	62.88 (28.606)	44.44 (29.187)	58.33 (29.633)
Median	66.67	66.67	58.33	66.67
Min, Max	0.0, 83.3	0.0, 100.0	0.0, 66.7	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Social Function	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Cycle 5 Day 1				
n	2	14	5	21
Mean (StdDev)	66.67 (47.140)	66.67 (22.646)	40.00 (14.907)	60.32 (24.987)
Median	66.67	66.67	50.00	66.67
Min, Max	33.3, 100.0	16.7, 100.0	16.7, 50.0	16.7, 100.0
Cycle 7 Day 1				
n	1	14	2	17
Mean (StdDev)	83.33 (-)	70.24 (18.695)	33.33 (0.000)	66.67 (21.246)
Median	83.33	66.67	33.33	66.67
Min, Max	83.3, 83.3	33.3, 100.0	33.3, 33.3	33.3, 100.0
Cycle 9 Day 1				
n	0	11	2	13
Mean (StdDev)		68.18 (20.350)	50.00 (47.140)	65.38 (24.019)
Median		66.67	50.00	66.67
Min, Max		33.3, 100.0	16.7, 83.3	16.7, 100.0
Cycle 11 Day 1				
n	0	6	1	7
Mean (StdDev)		69.44 (19.484)	100.00 (-)	73.81 (21.207)
Median		66.67	100.00	66.67
Min, Max		50.0, 100.0	100.0, 100.0	50.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Social Function	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		88.89 (9.623)	100.00 (-)	91.67 (9.623)
Median		83.33	100.00	91.67
Min, Max		83.3, 100.0	100.0, 100.0	83.3, 100.0
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		100.00 (-)		100.00 (-)
Median		100.00		100.00
Min, Max		100.0, 100.0		100.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Fatigue	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Baseline				
n	3	24	8	35
Mean (StdDev)	48.15 (16.973)	73.15 (32.422)	73.61 (29.058)	71.11 (30.867)
Median	44.44	88.89	77.78	77.78
Min, Max	33.3, 66.7	0.0, 100.0	22.2, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	61.11 (26.450)	53.54 (27.780)	50.79 (24.727)	53.87 (26.370)
Median	61.11	55.56	44.44	55.56
Min, Max	33.3, 88.9	11.1, 100.0	22.2, 88.9	11.1, 100.0
Cycle 2 Day 1				
n	2	24	8	34
Mean (StdDev)	44.44 (15.713)	51.39 (22.656)	55.56 (24.488)	51.96 (22.343)
Median	44.44	55.56	55.56	55.56
Min, Max	33.3, 55.6	22.2, 100.0	22.2, 100.0	22.2, 100.0
Cycle 3 Day 1				
n	4	22	6	32
Mean (StdDev)	58.33 (24.637)	54.55 (28.670)	66.67 (28.974)	57.29 (27.811)
Median	55.56	55.56	72.22	61.11
Min, Max	33.3, 88.9	11.1, 100.0	22.2, 100.0	11.1, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Fatigue	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Cycle 5 Day 1				
n	2	14	5	21
Mean (StdDev)	38.89 (23.570)	42.86 (24.598)	57.78 (26.527)	46.03 (24.667)
Median	38.89	38.89	55.56	44.44
Min, Max	22.2, 55.6	0.0, 77.8	22.2, 88.9	0.0, 88.9
Cycle 7 Day 1				
n	1	14	2	17
Mean (StdDev)	44.44 (-)	40.48 (22.480)	50.00 (39.284)	41.83 (22.747)
Median	44.44	38.89	50.00	44.44
Min, Max	44.4, 44.4	0.0, 88.9	22.2, 77.8	0.0, 88.9
Cycle 9 Day 1				
n	0	11	2	13
Mean (StdDev)		42.42 (20.975)	55.56 (31.427)	44.44 (21.754)
Median		55.56	55.56	55.56
Min, Max		11.1, 66.7	33.3, 77.8	11.1, 77.8
Cycle 11 Day 1				
n	0	6	1	7
Mean (StdDev)		40.74 (13.456)	22.22 (-)	38.10 (14.138)
Median		33.33	22.22	33.33
Min, Max		33.3, 66.7	22.2, 22.2	22.2, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Fatigue	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		22.22 (11.111)	33.33 (-)	25.00 (10.638)
Median		22.22	33.33	27.78
Min, Max		11.1, 33.3	33.3, 33.3	11.1, 33.3
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		33.33 (-)		33.33 (-)
Median		33.33		33.33
Min, Max		33.3, 33.3		33.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Nausea and Vomiting	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Baseline				
n	3	24	8	35
Mean (StdDev)	22.22 (38.490)	23.61 (31.051)	16.67 (23.570)	21.90 (29.365)
Median	0.00	16.67	0.00	16.67
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 50.0	0.0, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	25.00 (28.868)	10.61 (15.891)	11.90 (12.599)	12.63 (17.195)
Median	16.67	0.00	16.67	0.00
Min, Max	0.0, 66.7	0.0, 50.0	0.0, 33.3	0.0, 66.7
Cycle 2 Day 1				
n	2	24	8	34
Mean (StdDev)	33.33 (47.140)	8.33 (13.003)	8.33 (17.817)	9.80 (16.976)
Median	33.33	0.00	0.00	0.00
Min, Max	0.0, 66.7	0.0, 33.3	0.0, 50.0	0.0, 66.7
Cycle 3 Day 1				
n	4	22	6	32
Mean (StdDev)	20.83 (15.957)	6.82 (14.235)	0.00 (0.000)	7.29 (14.000)
Median	25.00	0.00	0.00	0.00
Min, Max	0.0, 33.3	0.0, 50.0	0.0, 0.0	0.0, 50.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Nausea and Vomiting	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Cycle 5 Day 1				
n	2	14	5	21
Mean (StdDev)	0.00 (0.000)	7.14 (10.770)	3.33 (7.454)	5.56 (9.623)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 0.0	0.0, 33.3	0.0, 16.7	0.0, 33.3
Cycle 7 Day 1				
n	1	14	2	17
Mean (StdDev)	16.67 (-)	4.76 (10.187)	8.33 (11.785)	5.88 (10.106)
Median	16.67	0.00	8.33	0.00
Min, Max	16.7, 16.7	0.0, 33.3	0.0, 16.7	0.0, 33.3
Cycle 9 Day 1				
n	0	11	2	13
Mean (StdDev)		6.06 (11.237)	0.00 (0.000)	5.13 (10.507)
Median		0.00	0.00	0.00
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3
Cycle 11 Day 1				
n	0	6	1	7
Mean (StdDev)		2.78 (6.804)	0.00 (-)	2.38 (6.299)
Median		0.00	0.00	0.00
Min, Max		0.0, 16.7	0.0, 0.0	0.0, 16.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Nausea and Vomiting	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		11.11 (19.245)	0.00 (-)	8.33 (16.667)
Median		0.00	0.00	0.00
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Pain	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Baseline				
n	3	24	8	35
Mean (StdDev)	38.89 (25.459)	40.28 (37.078)	54.17 (29.209)	43.33 (34.347)
Median	33.33	33.33	50.00	33.33
Min, Max	16.7, 66.7	0.0, 100.0	16.7, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	41.67 (21.517)	18.18 (22.950)	33.33 (19.245)	24.24 (23.233)
Median	41.67	8.33	33.33	16.67
Min, Max	16.7, 66.7	0.0, 83.3	16.7, 66.7	0.0, 83.3
Cycle 2 Day 1				
n	2	24	8	34
Mean (StdDev)	41.67 (35.355)	16.67 (26.006)	25.00 (12.599)	20.10 (24.197)
Median	41.67	0.00	33.33	16.67
Min, Max	16.7, 66.7	0.0, 83.3	0.0, 33.3	0.0, 83.3
Cycle 3 Day 1				
n	4	22	6	32
Mean (StdDev)	33.33 (30.429)	17.42 (22.109)	25.00 (17.480)	20.83 (22.401)
Median	33.33	8.33	25.00	16.67
Min, Max	0.0, 66.7	0.0, 66.7	0.0, 50.0	0.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Pain	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Cycle 5 Day 1				
n	2	14	5	21
Mean (StdDev)	33.33 (23.570)	20.24 (25.469)	33.33 (20.412)	24.60 (23.932)
Median	33.33	8.33	33.33	16.67
Min, Max	16.7, 50.0	0.0, 66.7	16.7, 66.7	0.0, 66.7
Cycle 7 Day 1				
n	1	14	2	17
Mean (StdDev)	66.67 (-)	20.24 (28.629)	16.67 (23.570)	22.55 (28.832)
Median	66.67	0.00	16.67	0.00
Min, Max	66.7, 66.7	0.0, 83.3	0.0, 33.3	0.0, 83.3
Cycle 9 Day 1				
n	0	11	2	13
Mean (StdDev)		18.18 (21.672)	33.33 (0.000)	20.51 (20.586)
Median		0.00	33.33	33.33
Min, Max		0.0, 50.0	33.3, 33.3	0.0, 50.0
Cycle 11 Day 1				
n	0	6	1	7
Mean (StdDev)		11.11 (17.213)	16.67 (-)	11.90 (15.853)
Median		0.00	16.67	0.00
Min, Max		0.0, 33.3	16.7, 16.7	0.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Pain	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		0.00 (0.000)	16.67 (-)	4.17 (8.333)
Median		0.00	16.67	0.00
Min, Max		0.0, 0.0	16.7, 16.7	0.0, 16.7
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Dyspnea	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Baseline				
n	3	24	8	35
Mean (StdDev)	11.11 (19.245)	55.56 (34.983)	54.17 (35.355)	51.43 (35.556)
Median	0.00	50.00	50.00	33.33
Min, Max	0.0, 33.3	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	16.67 (33.333)	36.36 (33.976)	33.33 (38.490)	33.33 (34.359)
Median	0.00	33.33	33.33	33.33
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 2 Day 1				
n	2	24	8	34
Mean (StdDev)	0.00 (0.000)	33.33 (32.601)	33.33 (35.635)	31.37 (32.764)
Median	0.00	33.33	33.33	33.33
Min, Max	0.0, 0.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 3 Day 1				
n	4	22	6	32
Mean (StdDev)	33.33 (27.217)	21.21 (24.224)	33.33 (36.515)	25.00 (26.774)
Median	33.33	16.67	33.33	33.33
Min, Max	0.0, 66.7	0.0, 66.7	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Dyspnea	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Cycle 5 Day 1				
n	2	14	5	21
Mean (StdDev)	16.67 (23.570)	21.43 (24.832)	33.33 (40.825)	23.81 (28.172)
Median	16.67	16.67	33.33	33.33
Min, Max	0.0, 33.3	0.0, 66.7	0.0, 100.0	0.0, 100.0
Cycle 7 Day 1				
n	1	14	2	17
Mean (StdDev)	33.33 (-)	21.43 (21.111)	16.67 (23.570)	21.57 (20.211)
Median	33.33	33.33	16.67	33.33
Min, Max	33.3, 33.3	0.0, 66.7	0.0, 33.3	0.0, 66.7
Cycle 9 Day 1				
n	0	11	2	13
Mean (StdDev)		18.18 (17.408)	16.67 (23.570)	17.95 (17.296)
Median		33.33	16.67	33.33
Min, Max		0.0, 33.3	0.0, 33.3	0.0, 33.3
Cycle 11 Day 1				
n	0	6	1	7
Mean (StdDev)		22.22 (17.213)	0.00 (-)	19.05 (17.817)
Median		33.33	0.00	33.33
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Dyspnea	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		11.11 (19.245)	0.00 (-)	8.33 (16.667)
Median		0.00	0.00	0.00
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Insomnia	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Baseline				
n	3	24	8	35
Mean (StdDev)	66.67 (33.333)	54.17 (36.531)	87.50 (24.801)	62.86 (35.948)
Median	66.67	66.67	100.00	66.67
Min, Max	33.3, 100.0	0.0, 100.0	33.3, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	66.67 (27.217)	37.88 (31.363)	42.86 (25.198)	42.42 (30.360)
Median	66.67	33.33	33.33	33.33
Min, Max	33.3, 100.0	0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 2 Day 1				
n	2	24	8	34
Mean (StdDev)	50.00 (23.570)	38.89 (38.906)	20.83 (17.252)	35.29 (34.759)
Median	50.00	33.33	33.33	33.33
Min, Max	33.3, 66.7	0.0, 100.0	0.0, 33.3	0.0, 100.0
Cycle 3 Day 1				
n	4	22	6	32
Mean (StdDev)	58.33 (31.914)	34.85 (28.129)	22.22 (17.213)	35.42 (28.001)
Median	50.00	33.33	33.33	33.33
Min, Max	33.3, 100.0	0.0, 100.0	0.0, 33.3	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Insomnia	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Cycle 5 Day 1				
n	2	14	5	21
Mean (StdDev)	50.00 (23.570)	30.95 (20.524)	53.33 (29.814)	38.10 (24.234)
Median	50.00	33.33	33.33	33.33
Min, Max	33.3, 66.7	0.0, 66.7	33.3, 100.0	0.0, 100.0
Cycle 7 Day 1				
n	1	14	2	17
Mean (StdDev)	66.67 (-)	35.71 (30.562)	33.33 (0.000)	37.25 (28.583)
Median	66.67	33.33	33.33	33.33
Min, Max	66.7, 66.7	0.0, 100.0	33.3, 33.3	0.0, 100.0
Cycle 9 Day 1				
n	0	11	2	13
Mean (StdDev)		30.30 (34.816)	33.33 (0.000)	30.77 (31.802)
Median		33.33	33.33	33.33
Min, Max		0.0, 100.0	33.3, 33.3	0.0, 100.0
Cycle 11 Day 1				
n	0	6	1	7
Mean (StdDev)		22.22 (27.217)	0.00 (-)	19.05 (26.227)
Median		16.67	0.00	0.00
Min, Max		0.0, 66.7	0.0, 0.0	0.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Insomnia	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		22.22 (19.245)	0.00 (-)	16.67 (19.245)
Median		33.33	0.00	16.67
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		33.33 (-)		33.33 (-)
Median		33.33		33.33
Min, Max		33.3, 33.3		33.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Appetite Loss	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Baseline				
n	3	24	8	35
Mean (StdDev)	22.22 (38.490)	48.61 (35.412)	50.00 (35.635)	46.67 (35.425)
Median	0.00	33.33	33.33	33.33
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	8.33 (16.667)	21.21 (24.224)	19.05 (17.817)	19.19 (22.096)
Median	0.00	33.33	33.33	33.33
Min, Max	0.0, 33.3	0.0, 100.0	0.0, 33.3	0.0, 100.0
Cycle 2 Day 1				
n	2	24	8	34
Mean (StdDev)	16.67 (23.570)	22.22 (28.937)	16.67 (25.198)	20.59 (27.235)
Median	16.67	0.00	0.00	0.00
Min, Max	0.0, 33.3	0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 3 Day 1				
n	4	22	6	32
Mean (StdDev)	25.00 (31.914)	15.15 (22.366)	5.56 (13.608)	14.58 (22.300)
Median	16.67	0.00	0.00	0.00
Min, Max	0.0, 66.7	0.0, 66.7	0.0, 33.3	0.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Appetite Loss	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Cycle 5 Day 1				
n	2	14	5	21
Mean (StdDev)	0.00 (0.000)	14.29 (21.540)	33.33 (23.570)	17.46 (22.655)
Median	0.00	0.00	33.33	0.00
Min, Max	0.0, 0.0	0.0, 66.7	0.0, 66.7	0.0, 66.7
Cycle 7 Day 1				
n	1	14	2	17
Mean (StdDev)	66.67 (-)	14.29 (21.540)	0.00 (0.000)	15.69 (23.914)
Median	66.67	0.00	0.00	0.00
Min, Max	66.7, 66.7	0.0, 66.7	0.0, 0.0	0.0, 66.7
Cycle 9 Day 1				
n	0	11	2	13
Mean (StdDev)		27.27 (29.129)	0.00 (0.000)	23.08 (28.495)
Median		33.33	0.00	0.00
Min, Max		0.0, 66.7	0.0, 0.0	0.0, 66.7
Cycle 11 Day 1				
n	0	6	1	7
Mean (StdDev)		22.22 (27.217)	0.00 (-)	19.05 (26.227)
Median		16.67	0.00	0.00
Min, Max		0.0, 66.7	0.0, 0.0	0.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Appetite Loss	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		0.00 (0.000)	0.00 (-)	0.00 (0.000)
Median		0.00	0.00	0.00
Min, Max		0.0, 0.0	0.0, 0.0	0.0, 0.0
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		33.33 (-)		33.33 (-)
Median		33.33		33.33
Min, Max		33.3, 33.3		33.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Constipation	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Baseline				
n	3	24	8	35
Mean (StdDev)	33.33 (33.333)	25.00 (32.969)	20.83 (35.355)	24.76 (32.683)
Median	33.33	0.00	0.00	0.00
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	25.00 (31.914)	15.15 (24.618)	14.29 (17.817)	16.16 (23.748)
Median	16.67	0.00	0.00	0.00
Min, Max	0.0, 66.7	0.0, 66.7	0.0, 33.3	0.0, 66.7
Cycle 2 Day 1				
n	2	24	8	34
Mean (StdDev)	50.00 (23.570)	8.33 (20.264)	8.33 (15.430)	10.78 (21.274)
Median	50.00	0.00	0.00	0.00
Min, Max	33.3, 66.7	0.0, 66.7	0.0, 33.3	0.0, 66.7
Cycle 3 Day 1				
n	4	22	6	32
Mean (StdDev)	16.67 (33.333)	12.12 (26.318)	5.56 (13.608)	11.46 (24.843)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 33.3	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Constipation	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Cycle 5 Day 1				
n	2	14	5	21
Mean (StdDev)	0.00 (0.000)	16.67 (28.495)	0.00 (0.000)	11.11 (24.343)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 0.0	0.0, 66.7	0.0, 0.0	0.0, 66.7
Cycle 7 Day 1				
n	1	14	2	17
Mean (StdDev)	33.33 (-)	11.90 (16.575)	0.00 (0.000)	11.76 (16.420)
Median	33.33	0.00	0.00	0.00
Min, Max	33.3, 33.3	0.0, 33.3	0.0, 0.0	0.0, 33.3
Cycle 9 Day 1				
n	0	11	2	13
Mean (StdDev)		12.12 (16.817)	0.00 (0.000)	10.26 (16.013)
Median		0.00	0.00	0.00
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3
Cycle 11 Day 1				
n	0	6	1	7
Mean (StdDev)		11.11 (17.213)	0.00 (-)	9.52 (16.265)
Median		0.00	0.00	0.00
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Constipation	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		11.11 (19.245)	0.00 (-)	8.33 (16.667)
Median		0.00	0.00	0.00
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Diarrhea	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Baseline				
n	3	24	8	35
Mean (StdDev)	0.00 (0.000)	41.67 (39.624)	45.83 (43.416)	39.05 (40.005)
Median	0.00	33.33	50.00	33.33
Min, Max	0.0, 0.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	16.67 (19.245)	18.18 (26.681)	38.10 (35.635)	22.22 (28.464)
Median	16.67	0.00	33.33	0.00
Min, Max	0.0, 33.3	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 2 Day 1				
n	2	24	8	34
Mean (StdDev)	0.00 (0.000)	13.89 (21.795)	29.17 (21.362)	16.67 (22.096)
Median	0.00	0.00	33.33	0.00
Min, Max	0.0, 0.0	0.0, 66.7	0.0, 66.7	0.0, 66.7
Cycle 3 Day 1				
n	4	22	6	32
Mean (StdDev)	8.33 (16.667)	13.64 (22.204)	11.11 (17.213)	12.50 (20.302)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 33.3	0.0, 66.7	0.0, 33.3	0.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Diarrhea	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Cycle 5 Day 1				
n	2	14	5	21
Mean (StdDev)	16.67 (23.570)	21.43 (33.607)	20.00 (29.814)	20.63 (30.689)
Median	16.67	0.00	0.00	0.00
Min, Max	0.0, 33.3	0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 7 Day 1				
n	1	14	2	17
Mean (StdDev)	33.33 (-)	19.05 (25.198)	16.67 (23.570)	19.61 (23.743)
Median	33.33	0.00	16.67	0.00
Min, Max	33.3, 33.3	0.0, 66.7	0.0, 33.3	0.0, 66.7
Cycle 9 Day 1				
n	0	11	2	13
Mean (StdDev)		15.15 (22.918)	16.67 (23.570)	15.38 (22.008)
Median		0.00	16.67	0.00
Min, Max		0.0, 66.7	0.0, 33.3	0.0, 66.7
Cycle 11 Day 1				
n	0	6	1	7
Mean (StdDev)		5.56 (13.608)	0.00 (-)	4.76 (12.599)
Median		0.00	0.00	0.00
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Diarrhea	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		0.00 (0.000)	0.00 (-)	0.00 (0.000)
Median		0.00	0.00	0.00
Min, Max		0.0, 0.0	0.0, 0.0	0.0, 0.0
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Financial Difficulties	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Baseline				
n	3	24	8	35
Mean (StdDev)	33.33 (33.333)	23.61 (30.263)	25.00 (34.503)	24.76 (30.618)
Median	33.33	0.00	16.67	0.00
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	25.00 (16.667)	19.70 (24.471)	4.76 (12.599)	17.17 (22.238)
Median	33.33	0.00	0.00	0.00
Min, Max	0.0, 33.3	0.0, 66.7	0.0, 33.3	0.0, 66.7
Cycle 2 Day 1				
n	2	24	8	34
Mean (StdDev)	16.67 (23.570)	15.28 (21.934)	16.67 (25.198)	15.69 (22.073)
Median	16.67	0.00	0.00	0.00
Min, Max	0.0, 33.3	0.0, 66.7	0.0, 66.7	0.0, 66.7
Cycle 3 Day 1				
n	4	22	6	32
Mean (StdDev)	41.67 (16.667)	18.18 (22.366)	22.22 (27.217)	21.88 (23.355)
Median	33.33	0.00	16.67	33.33
Min, Max	33.3, 66.7	0.0, 66.7	0.0, 66.7	0.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Financial Difficulties	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Cycle 5 Day 1				
n	2	14	5	21
Mean (StdDev)	16.67 (23.570)	9.52 (15.627)	26.67 (43.461)	14.29 (24.881)
Median	16.67	0.00	0.00	0.00
Min, Max	0.0, 33.3	0.0, 33.3	0.0, 100.0	0.0, 100.0
Cycle 7 Day 1				
n	1	14	2	17
Mean (StdDev)	33.33 (-)	16.67 (17.296)	16.67 (23.570)	17.65 (17.150)
Median	33.33	16.67	16.67	33.33
Min, Max	33.3, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3
Cycle 9 Day 1				
n	0	11	2	13
Mean (StdDev)		27.27 (20.101)	0.00 (0.000)	23.08 (21.014)
Median		33.33	0.00	33.33
Min, Max		0.0, 66.7	0.0, 0.0	0.0, 66.7
Cycle 11 Day 1				
n	0	6	1	7
Mean (StdDev)		38.89 (32.773)	0.00 (-)	33.33 (33.333)
Median		33.33	0.00	33.33
Min, Max		0.0, 100.0	0.0, 0.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Financial Difficulties	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		22.22 (19.245)	0.00 (-)	16.67 (19.245)
Median		33.33	0.00	16.67
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Global Health Status/QoL	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Baseline				
n	3	23	8	34
Mean (StdDev)	55.56 (20.972)	33.33 (25.251)	36.46 (13.317)	36.03 (23.003)
Median	58.33	33.33	33.33	33.33
Min, Max	33.3, 75.0	0.0, 100.0	16.7, 58.3	0.0, 100.0
Cycle 1 Day 15				
n	4	21	7	32
Mean (StdDev)	60.42 (12.500)	53.57 (23.801)	51.19 (21.746)	53.91 (21.893)
Median	66.67	50.00	50.00	54.17
Min, Max	41.7, 66.7	16.7, 100.0	25.0, 75.0	16.7, 100.0
Cycle 2 Day 1				
n	2	23	8	33
Mean (StdDev)	66.67 (0.000)	54.71 (20.693)	50.00 (24.801)	54.29 (21.053)
Median	66.67	58.33	58.33	66.67
Min, Max	66.7, 66.7	16.7, 91.7	0.0, 75.0	0.0, 91.7
Cycle 3 Day 1				
n	4	21	6	31
Mean (StdDev)	60.42 (15.775)	60.71 (15.622)	40.28 (12.266)	56.72 (16.725)
Median	54.17	66.67	37.50	58.33
Min, Max	50.0, 83.3	33.3, 83.3	25.0, 58.3	25.0, 83.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Global Health Status/QoL	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Cycle 5 Day 1				
n	2	13	5	20
Mean (StdDev)	58.33 (11.785)	55.13 (22.704)	43.33 (21.570)	52.50 (21.477)
Median	58.33	58.33	50.00	54.17
Min, Max	50.0, 66.7	0.0, 83.3	8.3, 66.7	0.0, 83.3
Cycle 7 Day 1				
n	1	13	2	16
Mean (StdDev)	41.67 (-)	64.10 (15.732)	54.17 (17.678)	61.46 (16.066)
Median	41.67	66.67	54.17	66.67
Min, Max	41.7, 41.7	25.0, 83.3	41.7, 66.7	25.0, 83.3
Cycle 9 Day 1				
n	0	10	2	12
Mean (StdDev)		55.83 (20.431)	62.50 (5.893)	56.94 (18.746)
Median		58.33	62.50	58.33
Min, Max		25.0, 83.3	58.3, 66.7	25.0, 83.3
Cycle 11 Day 1				
n	0	5	1	6
Mean (StdDev)		66.67 (10.206)	66.67 (-)	66.67 (9.129)
Median		66.67	66.67	66.67
Min, Max		50.0, 75.0	66.7, 66.7	50.0, 75.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Global Health Status/QoL	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		75.00 (14.434)	83.33 (-)	77.08 (12.500)
Median		83.33	83.33	83.33
Min, Max		58.3, 83.3	83.3, 83.3	58.3, 83.3
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		66.67 (-)		66.67 (-)
Median		66.67		66.67
Min, Max		66.7, 66.7		66.7, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Physical Functioning	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Baseline				
n	3	23	8	34
Mean (StdDev)	62.22 (36.717)	51.88 (29.539)	60.00 (24.944)	54.71 (28.511)
Median	80.00	46.67	60.00	53.33
Min, Max	20.0, 86.7	0.0, 100.0	26.7, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	21	7	32
Mean (StdDev)	58.33 (29.502)	62.22 (26.190)	77.14 (20.676)	65.00 (25.569)
Median	60.00	53.33	80.00	73.33
Min, Max	26.7, 86.7	0.0, 100.0	40.0, 100.0	0.0, 100.0
Cycle 2 Day 1				
n	2	23	8	33
Mean (StdDev)	83.33 (4.714)	65.80 (27.436)	71.67 (16.619)	68.28 (24.497)
Median	83.33	73.33	73.33	73.33
Min, Max	80.0, 86.7	0.0, 100.0	40.0, 93.3	0.0, 100.0
Cycle 3 Day 1				
n	4	21	6	31
Mean (StdDev)	55.00 (28.480)	72.06 (19.621)	65.56 (18.579)	68.60 (20.741)
Median	66.67	73.33	63.33	73.33
Min, Max	13.3, 73.3	26.7, 100.0	46.7, 100.0	13.3, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Physical Functioning	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Cycle 5 Day 1				
n	2	13	5	20
Mean (StdDev)	66.67 (28.284)	81.03 (16.295)	62.67 (23.851)	75.00 (20.044)
Median	66.67	86.67	60.00	80.00
Min, Max	46.7, 86.7	46.7, 100.0	40.0, 93.3	40.0, 100.0
Cycle 7 Day 1				
n	1	13	2	16
Mean (StdDev)	40.00 (-)	77.44 (15.762)	66.67 (0.000)	73.75 (17.122)
Median	40.00	80.00	66.67	73.33
Min, Max	40.0, 40.0	53.3, 100.0	66.7, 66.7	40.0, 100.0
Cycle 9 Day 1				
n	0	10	2	12
Mean (StdDev)		79.33 (14.891)	63.33 (4.714)	76.67 (14.907)
Median		80.00	63.33	76.67
Min, Max		53.3, 100.0	60.0, 66.7	53.3, 100.0
Cycle 11 Day 1				
n	0	5	1	6
Mean (StdDev)		77.33 (10.111)	86.67 (-)	78.89 (9.813)
Median		73.33	86.67	76.67
Min, Max		66.7, 93.3	86.7, 86.7	66.7, 93.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Physical Functioning	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		88.89 (10.184)	86.67 (-)	88.33 (8.389)
Median		86.67	86.67	86.67
Min, Max		80.0, 100.0	86.7, 86.7	80.0, 100.0
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		100.00 (-)		100.00 (-)
Median		100.00		100.00
Min, Max		100.0, 100.0		100.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Role Functioning	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Baseline				
n	3	23	8	34
Mean (StdDev)	50.00 (44.096)	40.58 (37.547)	27.08 (26.633)	38.24 (35.422)
Median	66.67	50.00	25.00	41.67
Min, Max	0.0, 83.3	0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 1 Day 15				
n	4	21	7	32
Mean (StdDev)	45.83 (31.549)	51.59 (31.581)	50.00 (21.517)	50.52 (28.863)
Median	58.33	50.00	66.67	50.00
Min, Max	0.0, 66.7	0.0, 100.0	16.7, 66.7	0.0, 100.0
Cycle 2 Day 1				
n	2	23	8	33
Mean (StdDev)	58.33 (35.355)	55.07 (29.488)	45.83 (23.146)	53.03 (27.781)
Median	58.33	50.00	50.00	50.00
Min, Max	33.3, 83.3	0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 3 Day 1				
n	4	21	6	31
Mean (StdDev)	45.83 (31.549)	61.90 (26.427)	38.89 (38.968)	55.38 (30.242)
Median	58.33	66.67	33.33	66.67
Min, Max	0.0, 66.7	16.7, 100.0	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Role Functioning	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Cycle 5 Day 1				
n	2	13	5	20
Mean (StdDev)	50.00 (70.711)	60.26 (27.671)	36.67 (24.721)	53.33 (31.344)
Median	50.00	66.67	33.33	58.33
Min, Max	0.0, 100.0	0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 7 Day 1				
n	1	13	2	16
Mean (StdDev)	33.33 (-)	62.82 (19.429)	50.00 (23.570)	59.38 (20.156)
Median	33.33	66.67	50.00	66.67
Min, Max	33.3, 33.3	33.3, 100.0	33.3, 66.7	33.3, 100.0
Cycle 9 Day 1				
n	0	10	2	12
Mean (StdDev)		65.00 (26.586)	50.00 (23.570)	62.50 (25.746)
Median		66.67	50.00	66.67
Min, Max		16.7, 100.0	33.3, 66.7	16.7, 100.0
Cycle 11 Day 1				
n	0	5	1	6
Mean (StdDev)		73.33 (14.907)	100.00 (-)	77.78 (17.213)
Median		66.67	100.00	66.67
Min, Max		66.7, 100.0	100.0, 100.0	66.7, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Role Functioning	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		83.33 (16.667)	66.67 (-)	79.17 (15.957)
Median		83.33	66.67	75.00
Min, Max		66.7, 100.0	66.7, 66.7	66.7, 100.0
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		100.00 (-)		100.00 (-)
Median		100.00		100.00
Min, Max		100.0, 100.0		100.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Emotional Functioning	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Baseline				
n	3	23	8	34
Mean (StdDev)	69.44 (31.549)	59.78 (27.827)	56.25 (27.728)	59.80 (27.407)
Median	83.33	58.33	54.17	58.33
Min, Max	33.3, 91.7	8.3, 100.0	8.3, 100.0	8.3, 100.0
Cycle 1 Day 15				
n	4	21	7	32
Mean (StdDev)	66.67 (20.412)	71.03 (24.241)	58.33 (28.054)	67.71 (24.479)
Median	70.83	75.00	50.00	66.67
Min, Max	41.7, 83.3	25.0, 100.0	25.0, 100.0	25.0, 100.0
Cycle 2 Day 1				
n	2	23	8	33
Mean (StdDev)	75.00 (0.000)	73.91 (23.206)	67.71 (23.754)	72.47 (22.388)
Median	75.00	75.00	70.83	75.00
Min, Max	75.0, 75.0	25.0, 100.0	25.0, 100.0	25.0, 100.0
Cycle 3 Day 1				
n	4	21	6	31
Mean (StdDev)	64.58 (12.500)	74.60 (19.978)	59.72 (28.095)	70.43 (21.283)
Median	66.67	75.00	66.67	75.00
Min, Max	50.0, 75.0	33.3, 100.0	16.7, 100.0	16.7, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Emotional Functioning	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Cycle 5 Day 1				
n	2	13	5	20
Mean (StdDev)	58.33 (11.785)	85.26 (16.013)	55.00 (37.081)	75.00 (25.792)
Median	58.33	91.67	50.00	79.17
Min, Max	50.0, 66.7	50.0, 100.0	8.3, 100.0	8.3, 100.0
Cycle 7 Day 1				
n	1	13	2	16
Mean (StdDev)	83.33 (-)	78.85 (18.824)	83.33 (23.570)	79.69 (17.994)
Median	83.33	83.33	83.33	83.33
Min, Max	83.3, 83.3	41.7, 100.0	66.7, 100.0	41.7, 100.0
Cycle 9 Day 1				
n	0	10	2	12
Mean (StdDev)		77.50 (23.257)	83.33 (23.570)	78.47 (22.321)
Median		83.33	83.33	83.33
Min, Max		33.3, 100.0	66.7, 100.0	33.3, 100.0
Cycle 11 Day 1				
n	0	5	1	6
Mean (StdDev)		76.67 (16.029)	100.00 (-)	80.56 (17.213)
Median		83.33	100.00	83.33
Min, Max		50.0, 91.7	100.0, 100.0	50.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Emotional Functioning	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		100.00 (0.000)	100.00 (-)	100.00 (0.000)
Median		100.00	100.00	100.00
Min, Max		100.0, 100.0	100.0, 100.0	100.0, 100.0
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		100.00 (-)		100.00 (-)
Median		100.00		100.00
Min, Max		100.0, 100.0		100.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg				
Cognitive Functioning	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Baseline				
n	3	23	8	34
Mean (StdDev)	83.33 (16.667)	72.46 (22.813)	62.50 (33.034)	71.08 (25.062)
Median	83.33	66.67	50.00	66.67
Min, Max	66.7, 100.0	33.3, 100.0	16.7, 100.0	16.7, 100.0
Cycle 1 Day 15				
n	4	21	7	32
Mean (StdDev)	83.33 (19.245)	74.60 (19.450)	59.52 (30.211)	72.40 (22.643)
Median	83.33	83.33	50.00	75.00
Min, Max	66.7, 100.0	33.3, 100.0	16.7, 100.0	16.7, 100.0
Cycle 2 Day 1				
n	2	23	8	33
Mean (StdDev)	75.00 (11.785)	76.81 (18.627)	64.58 (24.296)	73.74 (19.996)
Median	75.00	83.33	66.67	83.33
Min, Max	66.7, 83.3	33.3, 100.0	33.3, 100.0	33.3, 100.0
Cycle 3 Day 1				
n	4	21	6	31
Mean (StdDev)	87.50 (15.957)	78.57 (18.366)	66.67 (27.889)	77.42 (20.434)
Median	91.67	83.33	66.67	83.33
Min, Max	66.7, 100.0	33.3, 100.0	16.7, 100.0	16.7, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Cognitive Functioning	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Cycle 5 Day 1				
n	2	13	5	20
Mean (StdDev)	83.33 (0.000)	76.92 (14.495)	50.00 (40.825)	70.83 (25.291)
Median	83.33	83.33	33.33	83.33
Min, Max	83.3, 83.3	50.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 7 Day 1				
n	1	13	2	16
Mean (StdDev)	100.00 (-)	75.64 (11.004)	83.33 (23.570)	78.13 (13.220)
Median	100.00	66.67	83.33	75.00
Min, Max	100.0, 100.0	66.7, 100.0	66.7, 100.0	66.7, 100.0
Cycle 9 Day 1				
n	0	10	2	12
Mean (StdDev)		71.67 (15.811)	58.33 (35.355)	69.44 (18.577)
Median		66.67	58.33	66.67
Min, Max		50.0, 100.0	33.3, 83.3	33.3, 100.0
Cycle 11 Day 1				
n	0	5	1	6
Mean (StdDev)		83.33 (16.667)	66.67 (-)	80.56 (16.387)
Median		83.33	66.67	75.00
Min, Max		66.7, 100.0	66.7, 66.7	66.7, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Cognitive Functioning	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		83.33 (16.667)	66.67 (-)	79.17 (15.957)
Median		83.33	66.67	75.00
Min, Max		66.7, 100.0	66.7, 66.7	66.7, 100.0
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		83.33 (-)		83.33 (-)
Median		83.33		83.33
Min, Max		83.3, 83.3		83.3, 83.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg				
Social Function	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Baseline				
n	3	23	8	34
Mean (StdDev)	55.56 (41.944)	49.28 (34.626)	45.83 (29.209)	49.02 (33.065)
Median	50.00	33.33	50.00	33.33
Min, Max	16.7, 100.0	0.0, 100.0	0.0, 83.3	0.0, 100.0
Cycle 1 Day 15				
n	4	21	7	32
Mean (StdDev)	62.50 (43.833)	61.11 (30.429)	66.67 (16.667)	62.50 (29.022)
Median	75.00	50.00	66.67	66.67
Min, Max	0.0, 100.0	0.0, 100.0	33.3, 83.3	0.0, 100.0
Cycle 2 Day 1				
n	2	23	8	33
Mean (StdDev)	66.67 (23.570)	63.04 (32.936)	64.58 (16.517)	63.64 (28.703)
Median	66.67	66.67	66.67	66.67
Min, Max	50.0, 83.3	0.0, 100.0	33.3, 83.3	0.0, 100.0
Cycle 3 Day 1				
n	4	21	6	31
Mean (StdDev)	54.17 (36.956)	62.70 (29.300)	44.44 (29.187)	58.06 (30.084)
Median	66.67	66.67	58.33	66.67
Min, Max	0.0, 83.3	0.0, 100.0	0.0, 66.7	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Social Function	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Cycle 5 Day 1				
n	2	13	5	20
Mean (StdDev)	66.67 (47.140)	66.67 (23.570)	40.00 (14.907)	60.00 (25.592)
Median	66.67	66.67	50.00	58.33
Min, Max	33.3, 100.0	16.7, 100.0	16.7, 50.0	16.7, 100.0
Cycle 7 Day 1				
n	1	13	2	16
Mean (StdDev)	83.33 (-)	70.51 (19.429)	33.33 (0.000)	66.67 (21.943)
Median	83.33	66.67	33.33	66.67
Min, Max	83.3, 83.3	33.3, 100.0	33.3, 33.3	33.3, 100.0
Cycle 9 Day 1				
n	0	10	2	12
Mean (StdDev)		68.33 (21.445)	50.00 (47.140)	65.28 (25.084)
Median		66.67	50.00	66.67
Min, Max		33.3, 100.0	16.7, 83.3	16.7, 100.0
Cycle 11 Day 1				
n	0	5	1	6
Mean (StdDev)		70.00 (21.731)	100.00 (-)	75.00 (22.973)
Median		66.67	100.00	75.00
Min, Max		50.0, 100.0	100.0, 100.0	50.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Social Function	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		88.89 (9.623)	100.00 (-)	91.67 (9.623)
Median		83.33	100.00	91.67
Min, Max		83.3, 100.0	100.0, 100.0	83.3, 100.0
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		100.00 (-)		100.00 (-)
Median		100.00		100.00
Min, Max		100.0, 100.0		100.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Fatigue	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Baseline				
n	3	23	8	34
Mean (StdDev)	48.15 (16.973)	71.98 (32.631)	73.61 (29.058)	70.26 (30.913)
Median	44.44	88.89	77.78	77.78
Min, Max	33.3, 66.7	0.0, 100.0	22.2, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	21	7	32
Mean (StdDev)	61.11 (26.450)	52.91 (28.307)	50.79 (24.727)	53.47 (26.690)
Median	61.11	55.56	44.44	50.00
Min, Max	33.3, 88.9	11.1, 100.0	22.2, 88.9	11.1, 100.0
Cycle 2 Day 1				
n	2	23	8	33
Mean (StdDev)	44.44 (15.713)	50.72 (22.925)	55.56 (24.488)	51.52 (22.536)
Median	44.44	55.56	55.56	55.56
Min, Max	33.3, 55.6	22.2, 100.0	22.2, 100.0	22.2, 100.0
Cycle 3 Day 1				
n	4	21	6	31
Mean (StdDev)	58.33 (24.637)	53.97 (29.247)	66.67 (28.974)	56.99 (28.218)
Median	55.56	55.56	72.22	55.56
Min, Max	33.3, 88.9	11.1, 100.0	22.2, 100.0	11.1, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Fatigue	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Cycle 5 Day 1				
n	2	13	5	20
Mean (StdDev)	38.89 (23.570)	43.59 (25.443)	57.78 (26.527)	46.67 (25.131)
Median	38.89	44.44	55.56	44.44
Min, Max	22.2, 55.6	0.0, 77.8	22.2, 88.9	0.0, 88.9
Cycle 7 Day 1				
n	1	13	2	16
Mean (StdDev)	44.44 (-)	38.46 (22.043)	50.00 (39.284)	40.28 (22.544)
Median	44.44	33.33	50.00	38.89
Min, Max	44.4, 44.4	0.0, 88.9	22.2, 77.8	0.0, 88.9
Cycle 9 Day 1				
n	0	10	2	12
Mean (StdDev)		41.11 (21.628)	55.56 (31.427)	43.52 (22.453)
Median		44.44	55.56	44.44
Min, Max		11.1, 66.7	33.3, 77.8	11.1, 77.8
Cycle 11 Day 1				
n	0	5	1	6
Mean (StdDev)		42.22 (14.487)	22.22 (-)	38.89 (15.316)
Median		33.33	22.22	33.33
Min, Max		33.3, 66.7	22.2, 22.2	22.2, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Fatigue	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		22.22 (11.111)	33.33 (-)	25.00 (10.638)
Median		22.22	33.33	27.78
Min, Max		11.1, 33.3	33.3, 33.3	11.1, 33.3
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		33.33 (-)		33.33 (-)
Median		33.33		33.33
Min, Max		33.3, 33.3		33.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Nausea and Vomiting	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Baseline				
n	3	23	8	34
Mean (StdDev)	22.22 (38.490)	23.19 (31.678)	16.67 (23.570)	21.57 (29.738)
Median	0.00	16.67	0.00	8.33
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 50.0	0.0, 100.0
Cycle 1 Day 15				
n	4	21	7	32
Mean (StdDev)	25.00 (28.868)	11.11 (16.102)	11.90 (12.599)	13.02 (17.318)
Median	16.67	0.00	16.67	0.00
Min, Max	0.0, 66.7	0.0, 50.0	0.0, 33.3	0.0, 66.7
Cycle 2 Day 1				
n	2	23	8	33
Mean (StdDev)	33.33 (47.140)	8.70 (13.171)	8.33 (17.817)	10.10 (17.149)
Median	33.33	0.00	0.00	0.00
Min, Max	0.0, 66.7	0.0, 33.3	0.0, 50.0	0.0, 66.7
Cycle 3 Day 1				
n	4	21	6	31
Mean (StdDev)	20.83 (15.957)	7.14 (14.502)	0.00 (0.000)	7.53 (14.167)
Median	25.00	0.00	0.00	0.00
Min, Max	0.0, 33.3	0.0, 50.0	0.0, 0.0	0.0, 50.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Nausea and Vomiting	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Cycle 5 Day 1				
n	2	13	5	20
Mean (StdDev)	0.00 (0.000)	6.41 (10.841)	3.33 (7.454)	5.00 (9.521)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 0.0	0.0, 33.3	0.0, 16.7	0.0, 33.3
Cycle 7 Day 1				
n	1	13	2	16
Mean (StdDev)	16.67 (-)	3.85 (9.986)	8.33 (11.785)	5.21 (10.035)
Median	16.67	0.00	8.33	0.00
Min, Max	16.7, 16.7	0.0, 33.3	0.0, 16.7	0.0, 33.3
Cycle 9 Day 1				
n	0	10	2	12
Mean (StdDev)		6.67 (11.653)	0.00 (0.000)	5.56 (10.856)
Median		0.00	0.00	0.00
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3
Cycle 11 Day 1				
n	0	5	1	6
Mean (StdDev)		3.33 (7.454)	0.00 (-)	2.78 (6.804)
Median		0.00	0.00	0.00
Min, Max		0.0, 16.7	0.0, 0.0	0.0, 16.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Nausea and Vomiting	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		11.11 (19.245)	0.00 (-)	8.33 (16.667)
Median		0.00	0.00	0.00
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Pain	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Baseline				
n	3	23	8	34
Mean (StdDev)	38.89 (25.459)	40.58 (37.881)	54.17 (29.209)	43.63 (34.819)
Median	33.33	33.33	50.00	33.33
Min, Max	16.7, 66.7	0.0, 100.0	16.7, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	21	7	32
Mean (StdDev)	41.67 (21.517)	17.46 (23.260)	33.33 (19.245)	23.96 (23.546)
Median	41.67	0.00	33.33	16.67
Min, Max	16.7, 66.7	0.0, 83.3	16.7, 66.7	0.0, 83.3
Cycle 2 Day 1				
n	2	23	8	33
Mean (StdDev)	41.67 (35.355)	15.22 (25.581)	25.00 (12.599)	19.19 (23.980)
Median	41.67	0.00	33.33	16.67
Min, Max	16.7, 66.7	0.0, 83.3	0.0, 33.3	0.0, 83.3
Cycle 3 Day 1				
n	4	21	6	31
Mean (StdDev)	33.33 (30.429)	15.87 (21.393)	25.00 (17.480)	19.89 (22.119)
Median	33.33	0.00	25.00	16.67
Min, Max	0.0, 66.7	0.0, 66.7	0.0, 50.0	0.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Pain	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Cycle 5 Day 1				
n	2	13	5	20
Mean (StdDev)	33.33 (23.570)	19.23 (26.217)	33.33 (20.412)	24.17 (24.468)
Median	33.33	0.00	33.33	16.67
Min, Max	16.7, 50.0	0.0, 66.7	16.7, 66.7	0.0, 66.7
Cycle 7 Day 1				
n	1	13	2	16
Mean (StdDev)	66.67 (-)	16.67 (26.352)	16.67 (23.570)	19.79 (27.365)
Median	66.67	0.00	16.67	0.00
Min, Max	66.7, 66.7	0.0, 83.3	0.0, 33.3	0.0, 83.3
Cycle 9 Day 1				
n	0	10	2	12
Mean (StdDev)		16.67 (22.222)	33.33 (0.000)	19.44 (21.122)
Median		0.00	33.33	16.67
Min, Max		0.0, 50.0	33.3, 33.3	0.0, 50.0
Cycle 11 Day 1				
n	0	5	1	6
Mean (StdDev)		6.67 (14.907)	16.67 (-)	8.33 (13.944)
Median		0.00	16.67	0.00
Min, Max		0.0, 33.3	16.7, 16.7	0.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Pain	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		0.00 (0.000)	16.67 (-)	4.17 (8.333)
Median		0.00	16.67	0.00
Min, Max		0.0, 0.0	16.7, 16.7	0.0, 16.7
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Dyspnea	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Baseline				
n	3	23	8	34
Mean (StdDev)	11.11 (19.245)	53.62 (34.435)	54.17 (35.355)	50.00 (35.056)
Median	0.00	33.33	50.00	33.33
Min, Max	0.0, 33.3	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	21	7	32
Mean (StdDev)	16.67 (33.333)	33.33 (31.623)	33.33 (38.490)	31.25 (32.723)
Median	0.00	33.33	33.33	33.33
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 2 Day 1				
n	2	23	8	33
Mean (StdDev)	0.00 (0.000)	31.88 (32.533)	33.33 (35.635)	30.30 (32.664)
Median	0.00	33.33	33.33	33.33
Min, Max	0.0, 0.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 3 Day 1				
n	4	21	6	31
Mean (StdDev)	33.33 (27.217)	19.05 (22.537)	33.33 (36.515)	23.66 (26.096)
Median	33.33	0.00	33.33	33.33
Min, Max	0.0, 66.7	0.0, 66.7	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Dyspnea	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Cycle 5 Day 1				
n	2	13	5	20
Mean (StdDev)	16.67 (23.570)	17.95 (22.008)	33.33 (40.825)	21.67 (27.091)
Median	16.67	0.00	33.33	16.67
Min, Max	0.0, 33.3	0.0, 66.7	0.0, 100.0	0.0, 100.0
Cycle 7 Day 1				
n	1	13	2	16
Mean (StdDev)	33.33 (-)	17.95 (17.296)	16.67 (23.570)	18.75 (17.078)
Median	33.33	33.33	16.67	33.33
Min, Max	33.3, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3
Cycle 9 Day 1				
n	0	10	2	12
Mean (StdDev)		16.67 (17.568)	16.67 (23.570)	16.67 (17.408)
Median		16.67	16.67	16.67
Min, Max		0.0, 33.3	0.0, 33.3	0.0, 33.3
Cycle 11 Day 1				
n	0	5	1	6
Mean (StdDev)		20.00 (18.257)	0.00 (-)	16.67 (18.257)
Median		33.33	0.00	16.67
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Dyspnea	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		11.11 (19.245)	0.00 (-)	8.33 (16.667)
Median		0.00	0.00	0.00
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg				
Insomnia	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Baseline				
n	3	23	8	34
Mean (StdDev)	66.67 (33.333)	53.62 (37.253)	87.50 (24.801)	62.75 (36.482)
Median	66.67	66.67	100.00	66.67
Min, Max	33.3, 100.0	0.0, 100.0	33.3, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	21	7	32
Mean (StdDev)	66.67 (27.217)	38.10 (32.121)	42.86 (25.198)	42.71 (30.801)
Median	66.67	33.33	33.33	33.33
Min, Max	33.3, 100.0	0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 2 Day 1				
n	2	23	8	33
Mean (StdDev)	50.00 (23.570)	40.58 (38.868)	20.83 (17.252)	36.36 (34.725)
Median	50.00	33.33	33.33	33.33
Min, Max	33.3, 66.7	0.0, 100.0	0.0, 33.3	0.0, 100.0
Cycle 3 Day 1				
n	4	21	6	31
Mean (StdDev)	58.33 (31.914)	34.92 (28.822)	22.22 (17.213)	35.48 (28.461)
Median	50.00	33.33	33.33	33.33
Min, Max	33.3, 100.0	0.0, 100.0	0.0, 33.3	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Insomnia	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Cycle 5 Day 1				
n	2	13	5	20
Mean (StdDev)	50.00 (23.570)	33.33 (19.245)	53.33 (29.814)	40.00 (23.195)
Median	50.00	33.33	33.33	33.33
Min, Max	33.3, 66.7	0.0, 66.7	33.3, 100.0	0.0, 100.0
Cycle 7 Day 1				
n	1	13	2	16
Mean (StdDev)	66.67 (-)	38.46 (29.957)	33.33 (0.000)	39.58 (27.806)
Median	66.67	33.33	33.33	33.33
Min, Max	66.7, 66.7	0.0, 100.0	33.3, 33.3	0.0, 100.0
Cycle 9 Day 1				
n	0	10	2	12
Mean (StdDev)		33.33 (35.136)	33.33 (0.000)	33.33 (31.782)
Median		33.33	33.33	33.33
Min, Max		0.0, 100.0	33.3, 33.3	0.0, 100.0
Cycle 11 Day 1				
n	0	5	1	6
Mean (StdDev)		26.67 (27.889)	0.00 (-)	22.22 (27.217)
Median		33.33	0.00	16.67
Min, Max		0.0, 66.7	0.0, 0.0	0.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Insomnia	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		22.22 (19.245)	0.00 (-)	16.67 (19.245)
Median		33.33	0.00	16.67
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		33.33 (-)		33.33 (-)
Median		33.33		33.33
Min, Max		33.3, 33.3		33.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Appetite Loss	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Baseline				
n	3	23	8	34
Mean (StdDev)	22.22 (38.490)	49.28 (36.055)	50.00 (35.635)	47.06 (35.880)
Median	0.00	33.33	33.33	33.33
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	21	7	32
Mean (StdDev)	8.33 (16.667)	22.22 (24.343)	19.05 (17.817)	19.79 (22.175)
Median	0.00	33.33	33.33	33.33
Min, Max	0.0, 33.3	0.0, 100.0	0.0, 33.3	0.0, 100.0
Cycle 2 Day 1				
n	2	23	8	33
Mean (StdDev)	16.67 (23.570)	23.19 (29.189)	16.67 (25.198)	21.21 (27.409)
Median	16.67	0.00	0.00	0.00
Min, Max	0.0, 33.3	0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 3 Day 1				
n	4	21	6	31
Mean (StdDev)	25.00 (31.914)	15.87 (22.655)	5.56 (13.608)	15.05 (22.507)
Median	16.67	0.00	0.00	0.00
Min, Max	0.0, 66.7	0.0, 66.7	0.0, 33.3	0.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Appetite Loss	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Cycle 5 Day 1				
n	2	13	5	20
Mean (StdDev)	0.00 (0.000)	15.38 (22.008)	33.33 (23.570)	18.33 (22.878)
Median	0.00	0.00	33.33	0.00
Min, Max	0.0, 0.0	0.0, 66.7	0.0, 66.7	0.0, 66.7
Cycle 7 Day 1				
n	1	13	2	16
Mean (StdDev)	66.67 (-)	15.38 (22.008)	0.00 (0.000)	16.67 (24.343)
Median	66.67	0.00	0.00	0.00
Min, Max	66.7, 66.7	0.0, 66.7	0.0, 0.0	0.0, 66.7
Cycle 9 Day 1				
n	0	10	2	12
Mean (StdDev)		23.33 (27.442)	0.00 (0.000)	19.44 (26.432)
Median		16.67	0.00	0.00
Min, Max		0.0, 66.7	0.0, 0.0	0.0, 66.7
Cycle 11 Day 1				
n	0	5	1	6
Mean (StdDev)		26.67 (27.889)	0.00 (-)	22.22 (27.217)
Median		33.33	0.00	16.67
Min, Max		0.0, 66.7	0.0, 0.0	0.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Appetite Loss	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		0.00 (0.000)	0.00 (-)	0.00 (0.000)
Median		0.00	0.00	0.00
Min, Max		0.0, 0.0	0.0, 0.0	0.0, 0.0
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		33.33 (-)		33.33 (-)
Median		33.33		33.33
Min, Max		33.3, 33.3		33.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Constipation	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Baseline				
n	3	23	8	34
Mean (StdDev)	33.33 (33.333)	24.64 (33.661)	20.83 (35.355)	24.51 (33.140)
Median	33.33	0.00	0.00	0.00
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	21	7	32
Mean (StdDev)	25.00 (31.914)	15.87 (24.987)	14.29 (17.817)	16.67 (23.947)
Median	16.67	0.00	0.00	0.00
Min, Max	0.0, 66.7	0.0, 66.7	0.0, 33.3	0.0, 66.7
Cycle 2 Day 1				
n	2	23	8	33
Mean (StdDev)	50.00 (23.570)	8.70 (20.640)	8.33 (15.430)	11.11 (21.517)
Median	50.00	0.00	0.00	0.00
Min, Max	33.3, 66.7	0.0, 66.7	0.0, 33.3	0.0, 66.7
Cycle 3 Day 1				
n	4	21	6	31
Mean (StdDev)	16.67 (33.333)	12.70 (26.825)	5.56 (13.608)	11.83 (25.164)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 33.3	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Constipation	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Cycle 5 Day 1				
n	2	13	5	20
Mean (StdDev)	0.00 (0.000)	17.95 (29.235)	0.00 (0.000)	11.67 (24.839)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 0.0	0.0, 66.7	0.0, 0.0	0.0, 66.7
Cycle 7 Day 1				
n	1	13	2	16
Mean (StdDev)	33.33 (-)	12.82 (16.879)	0.00 (0.000)	12.50 (16.667)
Median	33.33	0.00	0.00	0.00
Min, Max	33.3, 33.3	0.0, 33.3	0.0, 0.0	0.0, 33.3
Cycle 9 Day 1				
n	0	10	2	12
Mean (StdDev)		13.33 (17.213)	0.00 (0.000)	11.11 (16.412)
Median		0.00	0.00	0.00
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3
Cycle 11 Day 1				
n	0	5	1	6
Mean (StdDev)		13.33 (18.257)	0.00 (-)	11.11 (17.213)
Median		0.00	0.00	0.00
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg				
Constipation	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		11.11 (19.245)	0.00 (-)	8.33 (16.667)
Median		0.00	0.00	0.00
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Diarrhea	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Baseline				
n	3	23	8	34
Mean (StdDev)	0.00 (0.000)	40.58 (40.147)	45.83 (43.416)	38.24 (40.312)
Median	0.00	33.33	50.00	33.33
Min, Max	0.0, 0.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	21	7	32
Mean (StdDev)	16.67 (19.245)	15.87 (24.987)	38.10 (35.635)	20.83 (27.760)
Median	16.67	0.00	33.33	0.00
Min, Max	0.0, 33.3	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 2 Day 1				
n	2	23	8	33
Mean (StdDev)	0.00 (0.000)	14.49 (22.079)	29.17 (21.362)	17.17 (22.238)
Median	0.00	0.00	33.33	0.00
Min, Max	0.0, 0.0	0.0, 66.7	0.0, 66.7	0.0, 66.7
Cycle 3 Day 1				
n	4	21	6	31
Mean (StdDev)	8.33 (16.667)	14.29 (22.537)	11.11 (17.213)	12.90 (20.507)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 33.3	0.0, 66.7	0.0, 33.3	0.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Diarrhea	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Cycle 5 Day 1				
n	2	13	5	20
Mean (StdDev)	16.67 (23.570)	20.51 (34.797)	20.00 (29.814)	20.00 (31.344)
Median	16.67	0.00	0.00	0.00
Min, Max	0.0, 33.3	0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 7 Day 1				
n	1	13	2	16
Mean (StdDev)	33.33 (-)	17.95 (25.875)	16.67 (23.570)	18.75 (24.248)
Median	33.33	0.00	16.67	0.00
Min, Max	33.3, 33.3	0.0, 66.7	0.0, 33.3	0.0, 66.7
Cycle 9 Day 1				
n	0	10	2	12
Mean (StdDev)		16.67 (23.570)	16.67 (23.570)	16.67 (22.473)
Median		0.00	16.67	0.00
Min, Max		0.0, 66.7	0.0, 33.3	0.0, 66.7
Cycle 11 Day 1				
n	0	5	1	6
Mean (StdDev)		6.67 (14.907)	0.00 (-)	5.56 (13.608)
Median		0.00	0.00	0.00
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Diarrhea	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		0.00 (0.000)	0.00 (-)	0.00 (0.000)
Median		0.00	0.00	0.00
Min, Max		0.0, 0.0	0.0, 0.0	0.0, 0.0
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Financial Difficulties	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Baseline				
n	3	23	8	34
Mean (StdDev)	33.33 (33.333)	24.64 (30.513)	25.00 (34.503)	25.49 (30.769)
Median	33.33	0.00	16.67	16.67
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	21	7	32
Mean (StdDev)	25.00 (16.667)	20.63 (24.667)	4.76 (12.599)	17.71 (22.376)
Median	33.33	0.00	0.00	0.00
Min, Max	0.0, 33.3	0.0, 66.7	0.0, 33.3	0.0, 66.7
Cycle 2 Day 1				
n	2	23	8	33
Mean (StdDev)	16.67 (23.570)	15.94 (22.178)	16.67 (25.198)	16.16 (22.238)
Median	16.67	0.00	0.00	0.00
Min, Max	0.0, 33.3	0.0, 66.7	0.0, 66.7	0.0, 66.7
Cycle 3 Day 1				
n	4	21	6	31
Mean (StdDev)	41.67 (16.667)	17.46 (22.655)	22.22 (27.217)	21.51 (23.646)
Median	33.33	0.00	16.67	33.33
Min, Max	33.3, 66.7	0.0, 66.7	0.0, 66.7	0.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Financial Difficulties	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Cycle 5 Day 1				
n	2	13	5	20
Mean (StdDev)	16.67 (23.570)	10.26 (16.013)	26.67 (43.461)	15.00 (25.305)
Median	16.67	0.00	0.00	0.00
Min, Max	0.0, 33.3	0.0, 33.3	0.0, 100.0	0.0, 100.0
Cycle 7 Day 1				
n	1	13	2	16
Mean (StdDev)	33.33 (-)	15.38 (17.296)	16.67 (23.570)	16.67 (17.213)
Median	33.33	0.00	16.67	16.67
Min, Max	33.3, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3
Cycle 9 Day 1				
n	0	10	2	12
Mean (StdDev)		26.67 (21.082)	0.00 (0.000)	22.22 (21.711)
Median		33.33	0.00	33.33
Min, Max		0.0, 66.7	0.0, 0.0	0.0, 66.7
Cycle 11 Day 1				
n	0	5	1	6
Mean (StdDev)		40.00 (36.515)	0.00 (-)	33.33 (36.515)
Median		33.33	0.00	33.33
Min, Max		0.0, 100.0	0.0, 0.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg				
Financial Difficulties	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		22.22 (19.245)	0.00 (-)	16.67 (19.245)
Median		33.33	0.00	16.67
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Global Health Status/QoL	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Baseline				
n	7	39	14	60
Mean (StdDev)	50.00 (14.434)	36.54 (26.186)	36.31 (15.194)	38.06 (23.084)
Median	50.00	33.33	33.33	33.33
Min, Max	33.3, 75.0	0.0, 100.0	16.7, 58.3	0.0, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	60.42 (12.500)	53.03 (23.365)	51.19 (21.746)	53.54 (21.654)
Median	66.67	50.00	50.00	50.00
Min, Max	41.7, 66.7	16.7, 100.0	25.0, 75.0	16.7, 100.0
Cycle 2 Day 1				
n	5	39	13	57
Mean (StdDev)	56.67 (22.361)	57.91 (19.208)	51.92 (23.852)	56.43 (20.353)
Median	66.67	66.67	58.33	66.67
Min, Max	16.7, 66.7	16.7, 91.7	0.0, 83.3	0.0, 91.7
Cycle 3 Day 1				
n	7	36	11	54
Mean (StdDev)	52.38 (19.670)	61.81 (16.229)	50.00 (16.667)	58.18 (17.246)
Median	50.00	66.67	50.00	58.33
Min, Max	16.7, 83.3	33.3, 100.0	25.0, 83.3	16.7, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Global Health Status/QoL	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 4 Day 1				
n	2	14	6	22
Mean (StdDev)	62.50 (29.463)	63.10 (18.979)	48.61 (17.808)	59.09 (19.570)
Median	62.50	66.67	50.00	62.50
Min, Max	41.7, 83.3	41.7, 100.0	25.0, 66.7	25.0, 100.0
Cycle 5 Day 1				
n	5	26	11	42
Mean (StdDev)	65.00 (12.360)	59.29 (21.125)	52.27 (18.668)	58.13 (19.693)
Median	66.67	62.50	50.00	58.33
Min, Max	50.0, 83.3	0.0, 100.0	8.3, 83.3	0.0, 100.0
Cycle 6 Day 1				
n	3	12	5	20
Mean (StdDev)	72.22 (9.623)	63.89 (20.515)	61.67 (7.454)	64.58 (16.639)
Median	66.67	58.33	66.67	66.67
Min, Max	66.7, 83.3	33.3, 100.0	50.0, 66.7	33.3, 100.0
Cycle 7 Day 1				
n	4	24	7	35
Mean (StdDev)	54.17 (14.434)	63.89 (16.238)	53.57 (8.133)	60.71 (15.202)
Median	54.17	66.67	50.00	58.33
Min, Max	41.7, 66.7	25.0, 100.0	41.7, 66.7	25.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Global Health Status/QoL	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 8 Day 1				
n	2	10	4	16
Mean (StdDev)	66.67 (35.355)	66.67 (17.568)	45.83 (31.549)	61.46 (23.546)
Median	66.67	66.67	58.33	66.67
Min, Max	41.7, 91.7	41.7, 100.0	0.0, 66.7	0.0, 100.0
Cycle 9 Day 1				
n	3	20	6	29
Mean (StdDev)	58.33 (14.434)	62.08 (19.398)	41.67 (33.333)	57.47 (23.182)
Median	66.67	58.33	54.17	58.33
Min, Max	41.7, 66.7	25.0, 100.0	0.0, 75.0	0.0, 100.0
Cycle 10 Day 1				
n	3	10	3	16
Mean (StdDev)	69.44 (9.623)	63.33 (17.656)	50.00 (44.096)	61.98 (22.354)
Median	75.00	62.50	66.67	66.67
Min, Max	58.3, 75.0	25.0, 83.3	0.0, 83.3	0.0, 83.3
Cycle 11 Day 1				
n	3	17	4	24
Mean (StdDev)	50.00 (25.000)	65.69 (15.834)	43.75 (29.950)	60.07 (20.703)
Median	50.00	66.67	54.17	62.50
Min, Max	25.0, 75.0	41.7, 100.0	0.0, 66.7	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Global Health Status/QoL	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 12 Day 1				
n	2	7	3	12
Mean (StdDev)	70.83 (17.678)	65.48 (17.631)	50.00 (44.096)	62.50 (24.746)
Median	70.83	66.67	66.67	66.67
Min, Max	58.3, 83.3	41.7, 100.0	0.0, 83.3	0.0, 100.0
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		75.00 (14.434)	83.33 (-)	77.08 (12.500)
Median		83.33	83.33	83.33
Min, Max		58.3, 83.3	83.3, 83.3	58.3, 83.3
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		66.67 (-)		66.67 (-)
Median		66.67		66.67
Min, Max		66.7, 66.7		66.7, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Physical Functioning	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Baseline				
n	7	39	14	60
Mean (StdDev)	71.43 (23.322)	50.94 (27.209)	60.48 (25.144)	55.56 (26.854)
Median	80.00	46.67	63.33	60.00
Min, Max	20.0, 86.7	0.0, 100.0	20.0, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	58.33 (29.502)	61.52 (25.773)	77.14 (20.676)	64.44 (25.368)
Median	60.00	53.33	80.00	73.33
Min, Max	26.7, 86.7	0.0, 100.0	40.0, 100.0	0.0, 100.0
Cycle 2 Day 1				
n	5	39	13	57
Mean (StdDev)	77.33 (10.111)	64.10 (25.575)	70.26 (21.014)	66.67 (23.738)
Median	80.00	66.67	73.33	73.33
Min, Max	60.0, 86.7	0.0, 100.0	26.7, 100.0	0.0, 100.0
Cycle 3 Day 1				
n	7	36	11	54
Mean (StdDev)	60.95 (24.169)	69.26 (20.364)	70.91 (21.761)	68.52 (20.939)
Median	73.33	73.33	66.67	73.33
Min, Max	13.3, 80.0	26.7, 100.0	46.7, 100.0	13.3, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Physical Functioning	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 4 Day 1				
n	2	14	6	22
Mean (StdDev)	56.67 (14.142)	64.76 (24.866)	77.78 (16.689)	67.58 (22.471)
Median	56.67	66.67	76.67	70.00
Min, Max	46.7, 66.7	20.0, 100.0	60.0, 100.0	20.0, 100.0
Cycle 5 Day 1				
n	5	26	11	42
Mean (StdDev)	68.00 (17.256)	73.59 (20.525)	68.48 (21.311)	71.59 (20.084)
Median	73.33	80.00	66.67	76.67
Min, Max	46.7, 86.7	20.0, 100.0	40.0, 100.0	20.0, 100.0
Cycle 6 Day 1				
n	3	12	5	20
Mean (StdDev)	64.44 (16.777)	60.00 (25.898)	68.00 (28.048)	62.67 (24.414)
Median	66.67	53.33	60.00	60.00
Min, Max	46.7, 80.0	20.0, 100.0	33.3, 100.0	20.0, 100.0
Cycle 7 Day 1				
n	4	24	7	35
Mean (StdDev)	70.00 (22.111)	68.61 (24.355)	63.81 (22.063)	67.81 (23.121)
Median	76.67	73.33	66.67	73.33
Min, Max	40.0, 86.7	13.3, 100.0	26.7, 100.0	13.3, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Physical Functioning	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 8 Day 1				
n	2	10	4	16
Mean (StdDev)	76.67 (14.142)	68.67 (21.094)	63.33 (34.641)	68.33 (23.158)
Median	76.67	73.33	66.67	73.33
Min, Max	66.7, 86.7	40.0, 100.0	20.0, 100.0	20.0, 100.0
Cycle 9 Day 1				
n	3	20	6	29
Mean (StdDev)	66.67 (26.667)	73.00 (21.024)	60.00 (27.649)	69.66 (22.719)
Median	66.67	76.67	63.33	73.33
Min, Max	40.0, 93.3	26.7, 100.0	20.0, 100.0	20.0, 100.0
Cycle 10 Day 1				
n	3	10	3	16
Mean (StdDev)	71.11 (13.878)	62.67 (25.181)	66.67 (41.633)	65.00 (25.473)
Median	66.67	66.67	80.00	70.00
Min, Max	60.0, 86.7	13.3, 100.0	20.0, 100.0	13.3, 100.0
Cycle 11 Day 1				
n	3	17	4	24
Mean (StdDev)	68.89 (15.396)	72.94 (18.630)	68.33 (38.249)	71.67 (21.378)
Median	60.00	73.33	80.00	73.33
Min, Max	60.0, 86.7	26.7, 100.0	13.3, 100.0	13.3, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Physical Functioning	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 12 Day 1				
n	2	7	3	12
Mean (StdDev)	63.33 (4.714)	67.62 (25.943)	62.22 (44.389)	65.56 (27.093)
Median	63.33	73.33	73.33	70.00
Min, Max	60.0, 66.7	33.3, 100.0	13.3, 100.0	13.3, 100.0
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		88.89 (10.184)	86.67 (-)	88.33 (8.389)
Median		86.67	86.67	86.67
Min, Max		80.0, 100.0	86.7, 86.7	80.0, 100.0
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		100.00 (-)		100.00 (-)
Median		100.00		100.00
Min, Max		100.0, 100.0		100.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Role Functioning	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Baseline				
n	7	39	14	60
Mean (StdDev)	54.76 (29.991)	39.74 (33.249)	29.76 (30.084)	39.17 (32.449)
Median	66.67	33.33	25.00	41.67
Min, Max	0.0, 83.3	0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	45.83 (31.549)	50.00 (31.706)	50.00 (21.517)	49.49 (29.013)
Median	58.33	50.00	66.67	50.00
Min, Max	0.0, 66.7	0.0, 100.0	16.7, 66.7	0.0, 100.0
Cycle 2 Day 1				
n	5	39	13	57
Mean (StdDev)	56.67 (25.276)	55.56 (29.945)	52.56 (29.538)	54.97 (29.033)
Median	50.00	50.00	66.67	50.00
Min, Max	33.3, 83.3	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 3 Day 1				
n	7	36	11	54
Mean (StdDev)	50.00 (27.217)	60.65 (24.609)	50.00 (35.746)	57.10 (27.396)
Median	50.00	66.67	66.67	66.67
Min, Max	0.0, 83.3	16.7, 100.0	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Role Functioning	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 4 Day 1				
n	2	14	6	22
Mean (StdDev)	33.33 (23.570)	57.14 (26.726)	66.67 (29.814)	57.58 (27.568)
Median	33.33	66.67	66.67	66.67
Min, Max	16.7, 50.0	0.0, 100.0	33.3, 100.0	0.0, 100.0
Cycle 5 Day 1				
n	5	26	11	42
Mean (StdDev)	56.67 (38.370)	58.33 (27.988)	45.45 (29.899)	54.76 (29.514)
Median	50.00	66.67	50.00	58.33
Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 6 Day 1				
n	3	12	5	20
Mean (StdDev)	72.22 (9.623)	44.44 (33.585)	60.00 (36.515)	52.50 (32.568)
Median	66.67	33.33	66.67	66.67
Min, Max	66.7, 83.3	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 7 Day 1				
n	4	24	7	35
Mean (StdDev)	66.67 (27.217)	57.64 (27.355)	59.52 (26.972)	59.05 (26.612)
Median	66.67	66.67	66.67	66.67
Min, Max	33.3, 100.0	0.0, 100.0	16.7, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Role Functioning	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 8 Day 1				
n	2	10	4	16
Mean (StdDev)	66.67 (0.000)	66.67 (26.058)	41.67 (50.000)	60.42 (32.131)
Median	66.67	66.67	33.33	66.67
Min, Max	66.7, 66.7	16.7, 100.0	0.0, 100.0	0.0, 100.0
Cycle 9 Day 1				
n	3	20	6	29
Mean (StdDev)	66.67 (16.667)	60.00 (32.173)	33.33 (42.164)	55.17 (34.245)
Median	66.67	66.67	16.67	66.67
Min, Max	50.0, 83.3	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	3	10	3	16
Mean (StdDev)	66.67 (0.000)	50.00 (34.247)	55.56 (50.918)	54.17 (33.054)
Median	66.67	50.00	66.67	66.67
Min, Max	66.7, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 11 Day 1				
n	3	17	4	24
Mean (StdDev)	66.67 (0.000)	64.71 (28.797)	66.67 (47.140)	65.28 (29.454)
Median	66.67	66.67	83.33	66.67
Min, Max	66.7, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Role Functioning	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 12 Day 1				
n	2	7	3	12
Mean (StdDev)	58.33 (35.355)	64.29 (33.923)	50.00 (50.000)	59.72 (35.146)
Median	58.33	66.67	50.00	66.67
Min, Max	33.3, 83.3	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		83.33 (16.667)	66.67 (-)	79.17 (15.957)
Median		83.33	66.67	75.00
Min, Max		66.7, 100.0	66.7, 66.7	66.7, 100.0
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		100.00 (-)		100.00 (-)
Median		100.00		100.00
Min, Max		100.0, 100.0		100.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Emotional Functioning	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Baseline				
n	7	39	14	60
Mean (StdDev)	69.05 (29.152)	62.18 (26.411)	60.12 (26.388)	62.50 (26.375)
Median	83.33	66.67	66.67	66.67
Min, Max	33.3, 100.0	8.3, 100.0	8.3, 100.0	8.3, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	66.67 (20.412)	70.83 (23.675)	58.33 (28.054)	67.68 (24.095)
Median	70.83	70.83	50.00	66.67
Min, Max	41.7, 83.3	25.0, 100.0	25.0, 100.0	25.0, 100.0
Cycle 2 Day 1				
n	5	39	13	57
Mean (StdDev)	68.33 (16.029)	71.79 (24.972)	68.59 (21.825)	70.76 (23.365)
Median	75.00	75.00	66.67	75.00
Min, Max	41.7, 83.3	8.3, 100.0	25.0, 100.0	8.3, 100.0
Cycle 3 Day 1				
n	7	36	11	54
Mean (StdDev)	60.71 (18.456)	74.38 (19.966)	66.67 (22.048)	71.04 (20.474)
Median	66.67	75.00	66.67	75.00
Min, Max	25.0, 75.0	25.0, 100.0	16.7, 100.0	16.7, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Emotional Functioning	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 4 Day 1				
n	2	14	6	22
Mean (StdDev)	83.33 (11.785)	77.38 (18.324)	76.39 (19.305)	77.65 (17.515)
Median	83.33	75.00	79.17	79.17
Min, Max	75.0, 91.7	41.7, 100.0	50.0, 100.0	41.7, 100.0
Cycle 5 Day 1				
n	5	26	11	42
Mean (StdDev)	63.33 (17.280)	76.92 (22.399)	64.39 (27.155)	72.02 (23.557)
Median	66.67	75.00	66.67	70.83
Min, Max	41.7, 83.3	8.3, 100.0	8.3, 100.0	8.3, 100.0
Cycle 6 Day 1				
n	3	12	5	20
Mean (StdDev)	66.67 (25.000)	75.00 (20.412)	70.00 (24.008)	72.50 (20.960)
Median	66.67	70.83	75.00	70.83
Min, Max	41.7, 91.7	41.7, 100.0	41.7, 100.0	41.7, 100.0
Cycle 7 Day 1				
n	4	24	7	35
Mean (StdDev)	66.67 (15.215)	77.78 (19.140)	71.43 (25.394)	75.24 (19.956)
Median	66.67	75.00	66.67	75.00
Min, Max	50.0, 83.3	33.3, 100.0	25.0, 100.0	25.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Emotional Functioning	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 8 Day 1				
n	2	10	4	16
Mean (StdDev)	75.00 (11.785)	76.94 (17.473)	58.33 (15.215)	72.05 (17.494)
Median	75.00	70.83	58.33	66.67
Min, Max	66.7, 83.3	50.0, 100.0	41.7, 75.0	41.7, 100.0
Cycle 9 Day 1				
n	3	20	6	29
Mean (StdDev)	69.44 (12.729)	77.08 (20.745)	66.67 (29.345)	74.14 (21.861)
Median	66.67	75.00	62.50	75.00
Min, Max	58.3, 83.3	33.3, 100.0	25.0, 100.0	25.0, 100.0
Cycle 10 Day 1				
n	3	10	3	16
Mean (StdDev)	66.67 (33.333)	72.50 (24.861)	47.22 (17.347)	66.67 (25.640)
Median	66.67	75.00	41.67	66.67
Min, Max	33.3, 100.0	33.3, 100.0	33.3, 66.7	33.3, 100.0
Cycle 11 Day 1				
n	3	17	4	24
Mean (StdDev)	55.56 (20.972)	72.06 (20.400)	66.67 (26.352)	69.10 (21.207)
Median	58.33	66.67	62.50	66.67
Min, Max	33.3, 75.0	33.3, 100.0	41.7, 100.0	33.3, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Emotional Functioning	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 12 Day 1				
n	2	7	3	12
Mean (StdDev)	50.00 (23.570)	70.24 (22.493)	44.44 (33.679)	60.42 (26.142)
Median	50.00	66.67	50.00	66.67
Min, Max	33.3, 66.7	41.7, 100.0	8.3, 75.0	8.3, 100.0
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		100.00 (0.000)	100.00 (-)	100.00 (0.000)
Median		100.00	100.00	100.00
Min, Max		100.0, 100.0	100.0, 100.0	100.0, 100.0
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		100.00 (-)		100.00 (-)
Median		100.00		100.00
Min, Max		100.0, 100.0		100.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Cognitive Functioning	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Baseline				
n	7	39	14	60
Mean (StdDev)	76.19 (23.288)	68.38 (26.981)	66.67 (27.735)	68.89 (26.480)
Median	83.33	66.67	58.33	66.67
Min, Max	33.3, 100.0	0.0, 100.0	16.7, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	83.33 (19.245)	74.24 (19.057)	59.52 (30.211)	72.22 (22.309)
Median	83.33	75.00	50.00	66.67
Min, Max	66.7, 100.0	33.3, 100.0	16.7, 100.0	16.7, 100.0
Cycle 2 Day 1				
n	5	39	13	57
Mean (StdDev)	60.00 (34.561)	74.36 (23.210)	70.51 (20.586)	72.22 (23.640)
Median	66.67	83.33	83.33	83.33
Min, Max	0.0, 83.3	0.0, 100.0	33.3, 100.0	0.0, 100.0
Cycle 3 Day 1				
n	7	36	11	54
Mean (StdDev)	73.81 (28.637)	73.61 (21.958)	71.21 (21.201)	73.15 (22.294)
Median	83.33	75.00	66.67	75.00
Min, Max	16.7, 100.0	33.3, 100.0	16.7, 100.0	16.7, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Cognitive Functioning	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 4 Day 1				
n	2	14	6	22
Mean (StdDev)	83.33 (23.570)	76.19 (22.374)	77.78 (13.608)	77.27 (19.616)
Median	83.33	83.33	75.00	83.33
Min, Max	66.7, 100.0	33.3, 100.0	66.7, 100.0	33.3, 100.0
Cycle 5 Day 1				
n	5	26	11	42
Mean (StdDev)	70.00 (27.386)	72.44 (23.066)	59.09 (31.059)	68.65 (25.821)
Median	83.33	75.00	50.00	66.67
Min, Max	33.3, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 6 Day 1				
n	3	12	5	20
Mean (StdDev)	55.56 (41.944)	76.39 (20.669)	83.33 (11.785)	75.00 (23.258)
Median	50.00	83.33	83.33	83.33
Min, Max	16.7, 100.0	33.3, 100.0	66.7, 100.0	16.7, 100.0
Cycle 7 Day 1				
n	4	24	7	35
Mean (StdDev)	62.50 (25.000)	74.31 (16.285)	73.81 (18.898)	72.86 (17.660)
Median	50.00	66.67	66.67	66.67
Min, Max	50.0, 100.0	33.3, 100.0	50.0, 100.0	33.3, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Cognitive Functioning	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 8 Day 1				
n	2	10	4	16
Mean (StdDev)	66.67 (0.000)	75.00 (22.567)	75.00 (9.623)	73.96 (18.226)
Median	66.67	75.00	75.00	66.67
Min, Max	66.7, 66.7	33.3, 100.0	66.7, 83.3	33.3, 100.0
Cycle 9 Day 1				
n	3	20	6	29
Mean (StdDev)	50.00 (16.667)	71.67 (18.810)	72.22 (22.771)	69.54 (19.955)
Median	50.00	66.67	75.00	66.67
Min, Max	33.3, 66.7	33.3, 100.0	33.3, 100.0	33.3, 100.0
Cycle 10 Day 1				
n	3	10	3	16
Mean (StdDev)	38.89 (41.944)	66.67 (27.217)	61.11 (25.459)	60.42 (29.736)
Median	33.33	66.67	66.67	66.67
Min, Max	0.0, 83.3	16.7, 100.0	33.3, 83.3	0.0, 100.0
Cycle 11 Day 1				
n	3	17	4	24
Mean (StdDev)	55.56 (9.623)	73.53 (20.462)	62.50 (15.957)	69.44 (19.453)
Median	50.00	66.67	58.33	66.67
Min, Max	50.0, 66.7	33.3, 100.0	50.0, 83.3	33.3, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Cognitive Functioning	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 12 Day 1				
n	2	7	3	12
Mean (StdDev)	41.67 (11.785)	64.29 (32.530)	55.56 (34.694)	58.33 (29.729)
Median	41.67	66.67	66.67	66.67
Min, Max	33.3, 50.0	0.0, 100.0	16.7, 83.3	0.0, 100.0
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		83.33 (16.667)	66.67 (-)	79.17 (15.957)
Median		83.33	66.67	75.00
Min, Max		66.7, 100.0	66.7, 66.7	66.7, 100.0
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		83.33 (-)		83.33 (-)
Median		83.33		83.33
Min, Max		83.3, 83.3		83.3, 83.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Social Function	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Baseline				
n	7	39	14	60
Mean (StdDev)	61.90 (32.934)	48.72 (32.078)	47.62 (33.242)	50.00 (32.184)
Median	50.00	33.33	66.67	50.00
Min, Max	16.7, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	62.50 (43.833)	61.36 (29.719)	66.67 (16.667)	62.63 (28.574)
Median	75.00	58.33	66.67	66.67
Min, Max	0.0, 100.0	0.0, 100.0	33.3, 83.3	0.0, 100.0
Cycle 2 Day 1				
n	5	39	13	57
Mean (StdDev)	66.67 (16.667)	62.82 (32.548)	56.41 (26.821)	61.70 (30.040)
Median	66.67	66.67	66.67	66.67
Min, Max	50.0, 83.3	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 3 Day 1				
n	7	36	11	54
Mean (StdDev)	59.52 (28.637)	62.50 (26.540)	51.52 (25.226)	59.88 (26.406)
Median	66.67	66.67	66.67	66.67
Min, Max	0.0, 83.3	0.0, 100.0	0.0, 83.3	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Social Function	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 4 Day 1				
n	2	14	6	22
Mean (StdDev)	75.00 (11.785)	65.48 (26.525)	58.33 (25.276)	64.39 (24.825)
Median	75.00	66.67	58.33	66.67
Min, Max	66.7, 83.3	0.0, 100.0	33.3, 100.0	0.0, 100.0
Cycle 5 Day 1				
n	5	26	11	42
Mean (StdDev)	56.67 (27.889)	62.82 (26.377)	53.03 (19.462)	59.52 (24.732)
Median	50.00	66.67	50.00	66.67
Min, Max	33.3, 100.0	0.0, 100.0	16.7, 83.3	0.0, 100.0
Cycle 6 Day 1				
n	3	12	5	20
Mean (StdDev)	66.67 (33.333)	56.94 (32.144)	60.00 (9.129)	59.17 (27.293)
Median	66.67	58.33	66.67	66.67
Min, Max	33.3, 100.0	0.0, 100.0	50.0, 66.7	0.0, 100.0
Cycle 7 Day 1				
n	4	24	7	35
Mean (StdDev)	66.67 (13.608)	62.50 (29.180)	64.29 (22.420)	63.33 (26.134)
Median	66.67	66.67	66.67	66.67
Min, Max	50.0, 83.3	0.0, 100.0	33.3, 83.3	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Social Function	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 8 Day 1				
n	2	10	4	16
Mean (StdDev)	58.33 (11.785)	61.67 (29.450)	41.67 (16.667)	56.25 (25.730)
Median	58.33	66.67	33.33	58.33
Min, Max	50.0, 66.7	16.7, 100.0	33.3, 66.7	16.7, 100.0
Cycle 9 Day 1				
n	3	20	6	29
Mean (StdDev)	61.11 (25.459)	63.33 (28.918)	61.11 (32.773)	62.64 (28.402)
Median	66.67	66.67	66.67	66.67
Min, Max	33.3, 83.3	0.0, 100.0	16.7, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	3	10	3	16
Mean (StdDev)	66.67 (16.667)	58.33 (29.659)	44.44 (38.490)	57.29 (28.525)
Median	66.67	58.33	66.67	66.67
Min, Max	50.0, 83.3	16.7, 100.0	0.0, 66.7	0.0, 100.0
Cycle 11 Day 1				
n	3	17	4	24
Mean (StdDev)	50.00 (28.868)	64.71 (24.918)	66.67 (36.004)	63.19 (26.457)
Median	33.33	66.67	75.00	66.67
Min, Max	33.3, 83.3	16.7, 100.0	16.7, 100.0	16.7, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Social Function	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 12 Day 1				
n	2	7	3	12
Mean (StdDev)	91.67 (11.785)	64.29 (31.074)	50.00 (28.868)	65.28 (29.694)
Median	91.67	66.67	66.67	66.67
Min, Max	83.3, 100.0	16.7, 100.0	16.7, 66.7	16.7, 100.0
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		88.89 (9.623)	100.00 (-)	91.67 (9.623)
Median		83.33	100.00	91.67
Min, Max		83.3, 100.0	100.0, 100.0	83.3, 100.0
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		100.00 (-)		100.00 (-)
Median		100.00		100.00
Min, Max		100.0, 100.0		100.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Fatigue	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Baseline				
n	7	39	14	60
Mean (StdDev)	57.14 (23.508)	71.23 (29.696)	72.22 (28.160)	69.81 (28.647)
Median	55.56	77.78	77.78	66.67
Min, Max	33.3, 100.0	0.0, 100.0	22.2, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	61.11 (26.450)	53.54 (27.780)	50.79 (24.727)	53.87 (26.370)
Median	61.11	55.56	44.44	55.56
Min, Max	33.3, 88.9	11.1, 100.0	22.2, 88.9	11.1, 100.0
Cycle 2 Day 1				
n	5	39	13	57
Mean (StdDev)	53.33 (19.876)	51.85 (23.958)	54.70 (25.443)	52.63 (23.619)
Median	55.56	55.56	55.56	55.56
Min, Max	33.3, 77.8	11.1, 100.0	22.2, 100.0	11.1, 100.0
Cycle 3 Day 1				
n	7	36	11	54
Mean (StdDev)	57.14 (24.367)	52.78 (27.265)	58.59 (27.258)	54.53 (26.547)
Median	66.67	55.56	55.56	55.56
Min, Max	22.2, 88.9	0.0, 100.0	22.2, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Fatigue	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 4 Day 1				
n	2	14	6	22
Mean (StdDev)	44.44 (31.427)	51.59 (22.054)	48.15 (32.710)	50.00 (24.667)
Median	44.44	50.00	33.33	38.89
Min, Max	22.2, 66.7	22.2, 77.8	22.2, 100.0	22.2, 100.0
Cycle 5 Day 1				
n	5	26	11	42
Mean (StdDev)	44.44 (20.787)	46.15 (26.795)	51.52 (22.373)	47.35 (24.670)
Median	55.56	33.33	55.56	44.44
Min, Max	22.2, 66.7	0.0, 100.0	22.2, 88.9	0.0, 100.0
Cycle 6 Day 1				
n	3	12	5	20
Mean (StdDev)	44.44 (19.245)	51.85 (35.243)	57.78 (24.088)	52.22 (29.966)
Median	33.33	55.56	66.67	55.56
Min, Max	33.3, 66.7	0.0, 100.0	33.3, 88.9	0.0, 100.0
Cycle 7 Day 1				
n	4	24	7	35
Mean (StdDev)	47.22 (13.981)	41.44 (25.113)	53.97 (25.198)	44.60 (24.122)
Median	44.44	38.89	55.56	44.44
Min, Max	33.3, 66.7	0.0, 100.0	22.2, 88.9	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Fatigue	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 8 Day 1				
n	2	10	4	16
Mean (StdDev)	44.44 (0.000)	38.89 (22.376)	66.67 (27.217)	46.53 (24.417)
Median	44.44	33.33	66.67	44.44
Min, Max	44.4, 44.4	0.0, 66.7	33.3, 100.0	0.0, 100.0
Cycle 9 Day 1				
n	3	20	6	29
Mean (StdDev)	44.44 (11.111)	35.56 (22.397)	62.96 (34.187)	42.15 (26.122)
Median	44.44	33.33	72.22	44.44
Min, Max	33.3, 55.6	0.0, 66.7	11.1, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	3	10	3	16
Mean (StdDev)	66.67 (19.245)	43.33 (25.364)	55.56 (40.062)	50.00 (27.217)
Median	77.78	38.89	44.44	44.44
Min, Max	44.4, 77.8	0.0, 77.8	22.2, 100.0	0.0, 100.0
Cycle 11 Day 1				
n	3	17	4	24
Mean (StdDev)	55.56 (11.111)	41.83 (24.066)	50.00 (34.546)	44.91 (24.405)
Median	55.56	44.44	38.89	44.44
Min, Max	44.4, 66.7	0.0, 88.9	22.2, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Fatigue	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 12 Day 1				
n	2	7	3	12
Mean (StdDev)	61.11 (7.857)	38.10 (26.338)	51.85 (42.066)	45.37 (28.212)
Median	61.11	44.44	33.33	44.44
Min, Max	55.6, 66.7	0.0, 77.8	22.2, 100.0	0.0, 100.0
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		22.22 (11.111)	33.33 (-)	25.00 (10.638)
Median		22.22	33.33	27.78
Min, Max		11.1, 33.3	33.3, 33.3	11.1, 33.3
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		33.33 (-)		33.33 (-)
Median		33.33		33.33
Min, Max		33.3, 33.3		33.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Nausea and Vomiting	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Baseline				
n	7	39	14	60
Mean (StdDev)	38.10 (34.311)	21.37 (28.084)	16.67 (23.570)	22.22 (28.068)
Median	33.33	16.67	0.00	16.67
Min, Max	0.0, 83.3	0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	25.00 (28.868)	10.61 (15.891)	11.90 (12.599)	12.63 (17.195)
Median	16.67	0.00	16.67	0.00
Min, Max	0.0, 66.7	0.0, 50.0	0.0, 33.3	0.0, 66.7
Cycle 2 Day 1				
n	5	39	13	57
Mean (StdDev)	36.67 (24.721)	10.26 (16.497)	12.82 (21.681)	13.16 (19.603)
Median	33.33	0.00	0.00	0.00
Min, Max	0.0, 66.7	0.0, 66.7	0.0, 66.7	0.0, 66.7
Cycle 3 Day 1				
n	7	36	11	54
Mean (StdDev)	28.57 (15.853)	11.11 (18.687)	6.06 (11.237)	12.35 (18.080)
Median	33.33	0.00	0.00	0.00
Min, Max	0.0, 50.0	0.0, 66.7	0.0, 33.3	0.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Nausea and Vomiting	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 4 Day 1				
n	2	14	6	22
Mean (StdDev)	16.67 (23.570)	17.86 (13.812)	8.33 (13.944)	15.15 (14.465)
Median	16.67	16.67	0.00	16.67
Min, Max	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3
Cycle 5 Day 1				
n	5	26	11	42
Mean (StdDev)	20.00 (18.257)	7.05 (10.722)	7.58 (11.459)	8.73 (12.340)
Median	33.33	0.00	0.00	0.00
Min, Max	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3
Cycle 6 Day 1				
n	3	12	5	20
Mean (StdDev)	16.67 (16.667)	12.50 (14.434)	3.33 (7.454)	10.83 (13.545)
Median	16.67	8.33	0.00	0.00
Min, Max	0.0, 33.3	0.0, 33.3	0.0, 16.7	0.0, 33.3
Cycle 7 Day 1				
n	4	24	7	35
Mean (StdDev)	29.17 (8.333)	8.33 (15.542)	9.52 (8.909)	10.95 (15.094)
Median	33.33	0.00	16.67	0.00
Min, Max	16.7, 33.3	0.0, 50.0	0.0, 16.7	0.0, 50.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Nausea and Vomiting	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 8 Day 1				
n	2	10	4	16
Mean (StdDev)	33.33 (0.000)	5.00 (8.051)	8.33 (9.623)	9.38 (12.124)
Median	33.33	0.00	8.33	0.00
Min, Max	33.3, 33.3	0.0, 16.7	0.0, 16.7	0.0, 33.3
Cycle 9 Day 1				
n	3	20	6	29
Mean (StdDev)	33.33 (0.000)	6.67 (9.971)	8.33 (9.129)	9.77 (12.213)
Median	33.33	0.00	8.33	0.00
Min, Max	33.3, 33.3	0.0, 33.3	0.0, 16.7	0.0, 33.3
Cycle 10 Day 1				
n	3	10	3	16
Mean (StdDev)	33.33 (16.667)	16.67 (20.787)	11.11 (9.623)	18.75 (19.124)
Median	33.33	16.67	16.67	16.67
Min, Max	16.7, 50.0	0.0, 66.7	0.0, 16.7	0.0, 66.7
Cycle 11 Day 1				
n	3	17	4	24
Mean (StdDev)	22.22 (9.623)	5.88 (11.698)	4.17 (8.333)	7.64 (12.018)
Median	16.67	0.00	0.00	0.00
Min, Max	16.7, 33.3	0.0, 33.3	0.0, 16.7	0.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Nausea and Vomiting	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 12 Day 1				
n	2	7	3	12
Mean (StdDev)	41.67 (11.785)	11.90 (12.599)	16.67 (16.667)	18.06 (16.603)
Median	41.67	16.67	16.67	16.67
Min, Max	33.3, 50.0	0.0, 33.3	0.0, 33.3	0.0, 50.0
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		11.11 (19.245)	0.00 (-)	8.33 (16.667)
Median		0.00	0.00	0.00
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Pain	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Baseline				
n	7	39	14	60
Mean (StdDev)	50.00 (28.868)	41.45 (35.432)	52.38 (35.720)	45.00 (34.622)
Median	50.00	33.33	50.00	33.33
Min, Max	16.7, 83.3	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	41.67 (21.517)	18.18 (22.950)	33.33 (19.245)	24.24 (23.233)
Median	41.67	8.33	33.33	16.67
Min, Max	16.7, 66.7	0.0, 83.3	16.7, 66.7	0.0, 83.3
Cycle 2 Day 1				
n	5	39	13	57
Mean (StdDev)	40.00 (34.561)	19.66 (27.272)	26.92 (18.682)	23.10 (26.494)
Median	33.33	0.00	33.33	16.67
Min, Max	0.0, 83.3	0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 3 Day 1				
n	7	36	11	54
Mean (StdDev)	35.71 (31.074)	18.98 (23.622)	28.79 (21.201)	23.15 (24.533)
Median	16.67	16.67	33.33	16.67
Min, Max	0.0, 83.3	0.0, 83.3	0.0, 66.7	0.0, 83.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Pain	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 4 Day 1				
n	2	14	6	22
Mean (StdDev)	33.33 (23.570)	13.10 (23.732)	44.44 (32.773)	23.48 (28.940)
Median	33.33	0.00	33.33	16.67
Min, Max	16.7, 50.0	0.0, 83.3	16.7, 83.3	0.0, 83.3
Cycle 5 Day 1				
n	5	26	11	42
Mean (StdDev)	43.33 (34.561)	20.51 (23.715)	27.27 (22.697)	25.00 (25.303)
Median	33.33	16.67	16.67	16.67
Min, Max	16.7, 100.0	0.0, 66.7	0.0, 66.7	0.0, 100.0
Cycle 6 Day 1				
n	3	12	5	20
Mean (StdDev)	38.89 (38.490)	31.94 (30.533)	33.33 (26.352)	33.33 (29.120)
Median	16.67	33.33	33.33	33.33
Min, Max	16.7, 83.3	0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 7 Day 1				
n	4	24	7	35
Mean (StdDev)	45.83 (45.896)	28.47 (33.144)	33.33 (28.868)	31.43 (33.277)
Median	41.67	16.67	33.33	16.67
Min, Max	0.0, 100.0	0.0, 100.0	0.0, 66.7	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Pain	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 8 Day 1				
n	2	10	4	16
Mean (StdDev)	41.67 (35.355)	30.00 (28.109)	66.67 (40.825)	40.63 (33.867)
Median	41.67	33.33	75.00	33.33
Min, Max	16.7, 66.7	0.0, 83.3	16.7, 100.0	0.0, 100.0
Cycle 9 Day 1				
n	3	20	6	29
Mean (StdDev)	33.33 (44.096)	22.50 (27.718)	58.33 (36.132)	31.03 (33.251)
Median	16.67	8.33	50.00	33.33
Min, Max	0.0, 83.3	0.0, 100.0	16.7, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	3	10	3	16
Mean (StdDev)	22.22 (38.490)	35.00 (31.866)	55.56 (41.944)	36.46 (34.004)
Median	0.00	25.00	50.00	25.00
Min, Max	0.0, 66.7	0.0, 100.0	16.7, 100.0	0.0, 100.0
Cycle 11 Day 1				
n	3	17	4	24
Mean (StdDev)	44.44 (41.944)	16.67 (21.246)	41.67 (39.675)	24.31 (28.649)
Median	50.00	0.00	25.00	16.67
Min, Max	0.0, 83.3	0.0, 66.7	16.7, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Pain	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 12 Day 1				
n	2	7	3	12
Mean (StdDev)	41.67 (11.785)	23.81 (18.898)	44.44 (50.918)	31.94 (27.941)
Median	41.67	33.33	33.33	33.33
Min, Max	33.3, 50.0	0.0, 50.0	0.0, 100.0	0.0, 100.0
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		0.00 (0.000)	16.67 (-)	4.17 (8.333)
Median		0.00	16.67	0.00
Min, Max		0.0, 0.0	16.7, 16.7	0.0, 16.7
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Dyspnea	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Baseline				
n	7	39	14	60
Mean (StdDev)	28.57 (23.002)	52.99 (33.957)	50.00 (33.968)	49.44 (33.329)
Median	33.33	33.33	33.33	33.33
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	16.67 (33.333)	36.36 (33.976)	33.33 (38.490)	33.33 (34.359)
Median	0.00	33.33	33.33	33.33
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 2 Day 1				
n	5	39	13	57
Mean (StdDev)	33.33 (40.825)	29.91 (31.339)	30.77 (28.744)	30.41 (31.041)
Median	33.33	33.33	33.33	33.33
Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 3 Day 1				
n	7	36	11	54
Mean (StdDev)	47.62 (32.530)	25.93 (26.561)	24.24 (30.151)	28.40 (28.526)
Median	33.33	33.33	33.33	33.33
Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Dyspnea	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 4 Day 1				
n	2	14	6	22
Mean (StdDev)	50.00 (23.570)	28.57 (28.815)	33.33 (21.082)	31.82 (26.181)
Median	50.00	33.33	33.33	33.33
Min, Max	33.3, 66.7	0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 5 Day 1				
n	5	26	11	42
Mean (StdDev)	33.33 (23.570)	26.92 (28.314)	33.33 (39.441)	29.37 (30.535)
Median	33.33	33.33	33.33	33.33
Min, Max	0.0, 66.7	0.0, 66.7	0.0, 100.0	0.0, 100.0
Cycle 6 Day 1				
n	3	12	5	20
Mean (StdDev)	33.33 (0.000)	33.33 (31.782)	46.67 (38.006)	36.67 (30.397)
Median	33.33	33.33	33.33	33.33
Min, Max	33.3, 33.3	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 7 Day 1				
n	4	24	7	35
Mean (StdDev)	33.33 (0.000)	25.00 (28.233)	33.33 (38.490)	27.62 (28.567)
Median	33.33	33.33	33.33	33.33
Min, Max	33.3, 33.3	0.0, 100.0	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Dyspnea	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 8 Day 1				
n	2	10	4	16
Mean (StdDev)	33.33 (0.000)	13.33 (23.307)	41.67 (50.000)	22.92 (31.549)
Median	33.33	0.00	33.33	0.00
Min, Max	33.3, 33.3	0.0, 66.7	0.0, 100.0	0.0, 100.0
Cycle 9 Day 1				
n	3	20	6	29
Mean (StdDev)	55.56 (19.245)	16.67 (25.363)	44.44 (40.369)	26.44 (31.345)
Median	66.67	0.00	50.00	33.33
Min, Max	33.3, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	3	10	3	16
Mean (StdDev)	55.56 (19.245)	33.33 (35.136)	44.44 (50.918)	39.58 (34.894)
Median	66.67	33.33	33.33	33.33
Min, Max	33.3, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 11 Day 1				
n	3	17	4	24
Mean (StdDev)	44.44 (19.245)	23.53 (28.296)	25.00 (50.000)	26.39 (31.051)
Median	33.33	33.33	0.00	33.33
Min, Max	33.3, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Dyspnea	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 12 Day 1				
n	2	6	3	11
Mean (StdDev)	50.00 (23.570)	27.78 (44.305)	33.33 (57.735)	33.33 (42.164)
Median	50.00	0.00	0.00	0.00
Min, Max	33.3, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		11.11 (19.245)	0.00 (-)	8.33 (16.667)
Median		0.00	0.00	0.00
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Insomnia	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Baseline				
n	7	39	14	60
Mean (StdDev)	57.14 (37.090)	51.28 (35.743)	73.81 (35.030)	57.22 (36.355)
Median	66.67	66.67	100.00	66.67
Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	66.67 (27.217)	37.88 (31.363)	42.86 (25.198)	42.42 (30.360)
Median	66.67	33.33	33.33	33.33
Min, Max	33.3, 100.0	0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 2 Day 1				
n	5	39	13	57
Mean (StdDev)	53.33 (29.814)	37.61 (35.193)	25.64 (30.894)	36.26 (34.087)
Median	33.33	33.33	33.33	33.33
Min, Max	33.3, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 3 Day 1				
n	7	36	11	54
Mean (StdDev)	47.62 (32.530)	37.04 (28.483)	27.27 (25.025)	36.42 (28.424)
Median	33.33	33.33	33.33	33.33
Min, Max	0.0, 100.0	0.0, 100.0	0.0, 66.7	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Insomnia	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 4 Day 1				
n	2	14	6	22
Mean (StdDev)	33.33 (0.000)	40.48 (32.499)	55.56 (40.369)	43.94 (33.152)
Median	33.33	33.33	50.00	33.33
Min, Max	33.3, 33.3	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 5 Day 1				
n	5	26	11	42
Mean (StdDev)	40.00 (27.889)	38.46 (27.797)	36.36 (37.873)	38.10 (29.970)
Median	33.33	33.33	33.33	33.33
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 6 Day 1				
n	3	12	5	20
Mean (StdDev)	33.33 (33.333)	44.44 (25.950)	46.67 (38.006)	43.33 (28.817)
Median	33.33	33.33	33.33	33.33
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 7 Day 1				
n	4	24	7	35
Mean (StdDev)	50.00 (19.245)	41.67 (29.895)	47.62 (37.796)	43.81 (30.002)
Median	50.00	33.33	33.33	33.33
Min, Max	33.3, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Insomnia	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 8 Day 1				
n	2	10	4	16
Mean (StdDev)	33.33 (0.000)	43.33 (35.312)	50.00 (33.333)	43.75 (31.549)
Median	33.33	33.33	33.33	33.33
Min, Max	33.3, 33.3	0.0, 100.0	33.3, 100.0	0.0, 100.0
Cycle 9 Day 1				
n	3	20	6	29
Mean (StdDev)	55.56 (19.245)	31.67 (31.484)	50.00 (27.889)	37.93 (30.504)
Median	66.67	33.33	33.33	33.33
Min, Max	33.3, 66.7	0.0, 100.0	33.3, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	3	10	3	16
Mean (StdDev)	44.44 (50.918)	53.33 (32.203)	44.44 (50.918)	50.00 (36.515)
Median	33.33	50.00	33.33	33.33
Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 11 Day 1				
n	3	17	4	24
Mean (StdDev)	66.67 (33.333)	37.25 (37.048)	50.00 (43.033)	43.06 (37.403)
Median	66.67	33.33	50.00	33.33
Min, Max	33.3, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Insomnia	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 12 Day 1				
n	2	7	3	12
Mean (StdDev)	83.33 (23.570)	38.10 (35.635)	55.56 (50.918)	50.00 (38.925)
Median	83.33	33.33	66.67	50.00
Min, Max	66.7, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		22.22 (19.245)	0.00 (-)	16.67 (19.245)
Median		33.33	0.00	16.67
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		33.33 (-)		33.33 (-)
Median		33.33		33.33
Min, Max		33.3, 33.3		33.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Appetite Loss	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Baseline				
n	7	39	14	60
Mean (StdDev)	23.81 (31.706)	49.57 (33.221)	50.00 (33.968)	46.67 (33.726)
Median	0.00	33.33	33.33	33.33
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	8.33 (16.667)	21.21 (24.224)	19.05 (17.817)	19.19 (22.096)
Median	0.00	33.33	33.33	33.33
Min, Max	0.0, 33.3	0.0, 100.0	0.0, 33.3	0.0, 100.0
Cycle 2 Day 1				
n	5	39	13	57
Mean (StdDev)	33.33 (40.825)	22.22 (26.856)	23.08 (25.036)	23.39 (27.433)
Median	33.33	0.00	33.33	33.33
Min, Max	0.0, 100.0	0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 3 Day 1				
n	7	36	11	54
Mean (StdDev)	28.57 (29.991)	16.67 (23.231)	18.18 (22.918)	18.52 (23.938)
Median	33.33	0.00	0.00	0.00
Min, Max	0.0, 66.7	0.0, 66.7	0.0, 66.7	0.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Appetite Loss	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 4 Day 1				
n	2	14	6	22
Mean (StdDev)	16.67 (23.570)	23.81 (20.375)	27.78 (32.773)	24.24 (23.417)
Median	16.67	33.33	16.67	33.33
Min, Max	0.0, 33.3	0.0, 66.7	0.0, 66.7	0.0, 66.7
Cycle 5 Day 1				
n	5	26	11	42
Mean (StdDev)	26.67 (27.889)	20.51 (25.081)	30.30 (23.355)	23.81 (24.732)
Median	33.33	0.00	33.33	33.33
Min, Max	0.0, 66.7	0.0, 66.7	0.0, 66.7	0.0, 66.7
Cycle 6 Day 1				
n	3	12	5	20
Mean (StdDev)	33.33 (33.333)	25.00 (32.177)	20.00 (18.257)	25.00 (28.357)
Median	33.33	16.67	33.33	33.33
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 33.3	0.0, 100.0
Cycle 7 Day 1				
n	4	24	7	35
Mean (StdDev)	41.67 (31.914)	15.28 (24.035)	14.29 (26.227)	18.10 (26.000)
Median	50.00	0.00	0.00	0.00
Min, Max	0.0, 66.7	0.0, 66.7	0.0, 66.7	0.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Appetite Loss	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 8 Day 1				
n	2	10	4	16
Mean (StdDev)	33.33 (0.000)	13.33 (23.307)	25.00 (31.914)	18.75 (24.248)
Median	33.33	0.00	16.67	0.00
Min, Max	33.3, 33.3	0.0, 66.7	0.0, 66.7	0.0, 66.7
Cycle 9 Day 1				
n	3	20	6	29
Mean (StdDev)	33.33 (0.000)	18.33 (25.305)	33.33 (42.164)	22.99 (28.317)
Median	33.33	0.00	16.67	0.00
Min, Max	33.3, 33.3	0.0, 66.7	0.0, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	3	10	3	16
Mean (StdDev)	22.22 (38.490)	20.00 (23.307)	55.56 (38.490)	27.08 (30.353)
Median	0.00	16.67	33.33	33.33
Min, Max	0.0, 66.7	0.0, 66.7	33.3, 100.0	0.0, 100.0
Cycle 11 Day 1				
n	3	17	4	24
Mean (StdDev)	22.22 (19.245)	17.65 (23.914)	41.67 (41.944)	22.22 (27.217)
Median	33.33	0.00	33.33	16.67
Min, Max	0.0, 33.3	0.0, 66.7	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Appetite Loss	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 12 Day 1				
n	2	7	3	12
Mean (StdDev)	66.67 (47.140)	14.29 (17.817)	44.44 (50.918)	30.56 (36.121)
Median	66.67	0.00	33.33	33.33
Min, Max	33.3, 100.0	0.0, 33.3	0.0, 100.0	0.0, 100.0
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		0.00 (0.000)	0.00 (-)	0.00 (0.000)
Median		0.00	0.00	0.00
Min, Max		0.0, 0.0	0.0, 0.0	0.0, 0.0
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		33.33 (-)		33.33 (-)
Median		33.33		33.33
Min, Max		33.3, 33.3		33.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Constipation	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Baseline				
n	7	39	14	60
Mean (StdDev)	23.81 (25.198)	25.64 (31.955)	19.05 (31.254)	23.89 (30.742)
Median	33.33	0.00	0.00	0.00
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	25.00 (31.914)	15.15 (24.618)	14.29 (17.817)	16.16 (23.748)
Median	16.67	0.00	0.00	0.00
Min, Max	0.0, 66.7	0.0, 66.7	0.0, 33.3	0.0, 66.7
Cycle 2 Day 1				
n	5	39	13	57
Mean (StdDev)	60.00 (43.461)	13.68 (26.177)	10.26 (21.014)	16.96 (29.629)
Median	66.67	0.00	0.00	0.00
Min, Max	0.0, 100.0	0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 3 Day 1				
n	7	36	11	54
Mean (StdDev)	28.57 (40.500)	14.81 (25.751)	12.12 (22.473)	16.05 (27.274)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 100.0	0.0, 100.0	0.0, 66.7	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Constipation	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 4 Day 1				
n	2	14	6	22
Mean (StdDev)	16.67 (23.570)	14.29 (31.254)	5.56 (13.608)	12.12 (26.318)
Median	16.67	0.00	0.00	0.00
Min, Max	0.0, 33.3	0.0, 100.0	0.0, 33.3	0.0, 100.0
Cycle 5 Day 1				
n	5	26	11	42
Mean (StdDev)	26.67 (43.461)	16.67 (27.080)	6.06 (20.101)	15.08 (27.745)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 100.0	0.0, 66.7	0.0, 66.7	0.0, 100.0
Cycle 6 Day 1				
n	3	12	5	20
Mean (StdDev)	33.33 (33.333)	13.89 (26.432)	6.67 (14.907)	15.00 (25.305)
Median	33.33	0.00	0.00	0.00
Min, Max	0.0, 66.7	0.0, 66.7	0.0, 33.3	0.0, 66.7
Cycle 7 Day 1				
n	4	24	7	35
Mean (StdDev)	50.00 (43.033)	18.06 (29.454)	19.05 (37.796)	21.90 (33.277)
Median	50.00	0.00	0.00	0.00
Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Constipation	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 8 Day 1				
n	2	10	4	16
Mean (StdDev)	16.67 (23.570)	10.00 (22.498)	8.33 (16.667)	10.42 (20.069)
Median	16.67	0.00	0.00	0.00
Min, Max	0.0, 33.3	0.0, 66.7	0.0, 33.3	0.0, 66.7
Cycle 9 Day 1				
n	3	20	6	29
Mean (StdDev)	33.33 (33.333)	10.00 (15.672)	5.56 (13.608)	11.49 (18.422)
Median	33.33	0.00	0.00	0.00
Min, Max	0.0, 66.7	0.0, 33.3	0.0, 33.3	0.0, 66.7
Cycle 10 Day 1				
n	3	10	3	16
Mean (StdDev)	44.44 (50.918)	20.00 (28.109)	0.00 (0.000)	20.83 (31.914)
Median	33.33	0.00	0.00	0.00
Min, Max	0.0, 100.0	0.0, 66.7	0.0, 0.0	0.0, 100.0
Cycle 11 Day 1				
n	3	17	4	24
Mean (StdDev)	22.22 (19.245)	11.76 (20.211)	8.33 (16.667)	12.50 (19.193)
Median	33.33	0.00	0.00	0.00
Min, Max	0.0, 33.3	0.0, 66.7	0.0, 33.3	0.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Constipation	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 12 Day 1				
n	2	7	3	12
Mean (StdDev)	66.67 (0.000)	19.05 (26.227)	0.00 (0.000)	22.22 (29.588)
Median	66.67	0.00	0.00	0.00
Min, Max	66.7, 66.7	0.0, 66.7	0.0, 0.0	0.0, 66.7
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		11.11 (19.245)	0.00 (-)	8.33 (16.667)
Median		0.00	0.00	0.00
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Diarrhea	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Baseline				
n	7	39	14	60
Mean (StdDev)	42.86 (46.004)	38.46 (36.305)	45.24 (40.525)	40.56 (37.878)
Median	33.33	33.33	50.00	33.33
Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	16.67 (19.245)	18.18 (26.681)	38.10 (35.635)	22.22 (28.464)
Median	16.67	0.00	33.33	0.00
Min, Max	0.0, 33.3	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 2 Day 1				
n	5	39	13	57
Mean (StdDev)	33.33 (40.825)	21.37 (24.765)	30.77 (21.350)	24.56 (25.609)
Median	33.33	0.00	33.33	33.33
Min, Max	0.0, 100.0	0.0, 66.7	0.0, 66.7	0.0, 100.0
Cycle 3 Day 1				
n	7	36	11	54
Mean (StdDev)	33.33 (38.490)	19.44 (25.666)	24.24 (30.151)	22.22 (28.225)
Median	33.33	0.00	0.00	0.00
Min, Max	0.0, 100.0	0.0, 66.7	0.0, 66.7	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Diarrhea	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 4 Day 1				
n	2	13	6	21
Mean (StdDev)	50.00 (70.711)	33.33 (27.217)	16.67 (27.889)	30.16 (31.455)
Median	50.00	33.33	0.00	33.33
Min, Max	0.0, 100.0	0.0, 66.7	0.0, 66.7	0.0, 100.0
Cycle 5 Day 1				
n	5	26	11	42
Mean (StdDev)	40.00 (36.515)	26.92 (31.297)	30.30 (27.707)	29.37 (30.535)
Median	33.33	16.67	33.33	33.33
Min, Max	0.0, 100.0	0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 6 Day 1				
n	3	12	5	20
Mean (StdDev)	55.56 (38.490)	30.56 (33.207)	26.67 (27.889)	33.33 (32.444)
Median	33.33	33.33	33.33	33.33
Min, Max	33.3, 100.0	0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 7 Day 1				
n	4	24	7	35
Mean (StdDev)	50.00 (33.333)	20.83 (23.698)	19.05 (17.817)	23.81 (25.012)
Median	33.33	16.67	33.33	33.33
Min, Max	33.3, 100.0	0.0, 66.7	0.0, 33.3	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Diarrhea	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 8 Day 1				
n	2	10	4	16
Mean (StdDev)	66.67 (47.140)	33.33 (22.222)	8.33 (16.667)	31.25 (28.464)
Median	66.67	33.33	0.00	33.33
Min, Max	33.3, 100.0	0.0, 66.7	0.0, 33.3	0.0, 100.0
Cycle 9 Day 1				
n	3	20	6	29
Mean (StdDev)	44.44 (19.245)	16.67 (20.233)	33.33 (29.814)	22.99 (23.744)
Median	33.33	0.00	33.33	33.33
Min, Max	33.3, 66.7	0.0, 66.7	0.0, 66.7	0.0, 66.7
Cycle 10 Day 1				
n	3	10	3	16
Mean (StdDev)	11.11 (19.245)	36.67 (18.922)	55.56 (50.918)	35.42 (28.464)
Median	0.00	33.33	66.67	33.33
Min, Max	0.0, 33.3	0.0, 66.7	0.0, 100.0	0.0, 100.0
Cycle 11 Day 1				
n	3	17	4	24
Mean (StdDev)	33.33 (0.000)	25.49 (27.712)	25.00 (31.914)	26.39 (25.968)
Median	33.33	33.33	16.67	33.33
Min, Max	33.3, 33.3	0.0, 100.0	0.0, 66.7	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Diarrhea	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 12 Day 1				
n	2	7	3	12
Mean (StdDev)	33.33 (0.000)	28.57 (23.002)	33.33 (33.333)	30.56 (22.285)
Median	33.33	33.33	33.33	33.33
Min, Max	33.3, 33.3	0.0, 66.7	0.0, 66.7	0.0, 66.7
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		0.00 (0.000)	0.00 (-)	0.00 (0.000)
Median		0.00	0.00	0.00
Min, Max		0.0, 0.0	0.0, 0.0	0.0, 0.0
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Financial Difficulties	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Baseline				
n	7	39	14	60
Mean (StdDev)	52.38 (42.414)	29.06 (33.490)	40.48 (39.610)	34.44 (36.291)
Median	66.67	33.33	33.33	33.33
Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	25.00 (16.667)	19.70 (24.471)	4.76 (12.599)	17.17 (22.238)
Median	33.33	0.00	0.00	0.00
Min, Max	0.0, 33.3	0.0, 66.7	0.0, 33.3	0.0, 66.7
Cycle 2 Day 1				
n	5	39	13	57
Mean (StdDev)	53.33 (44.721)	23.08 (29.769)	35.90 (39.585)	28.65 (34.179)
Median	33.33	0.00	33.33	33.33
Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 3 Day 1				
n	7	36	11	54
Mean (StdDev)	57.14 (25.198)	25.93 (28.852)	36.36 (34.816)	32.10 (31.029)
Median	66.67	33.33	33.33	33.33
Min, Max	33.3, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Financial Difficulties	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 4 Day 1				
n	2	14	6	22
Mean (StdDev)	66.67 (47.140)	30.95 (40.222)	50.00 (45.947)	39.39 (41.958)
Median	66.67	16.67	50.00	33.33
Min, Max	33.3, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 5 Day 1				
n	5	26	11	42
Mean (StdDev)	53.33 (44.721)	17.95 (25.352)	36.36 (40.701)	26.98 (33.928)
Median	33.33	0.00	33.33	16.67
Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 6 Day 1				
n	3	12	5	20
Mean (StdDev)	44.44 (19.245)	22.22 (32.824)	40.00 (36.515)	30.00 (32.264)
Median	33.33	0.00	33.33	33.33
Min, Max	33.3, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 7 Day 1				
n	4	24	7	35
Mean (StdDev)	50.00 (33.333)	20.83 (23.698)	28.57 (35.635)	25.71 (28.105)
Median	33.33	33.33	33.33	33.33
Min, Max	33.3, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Financial Difficulties	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 8 Day 1				
n	2	10	4	16
Mean (StdDev)	50.00 (23.570)	26.67 (30.631)	50.00 (43.033)	35.42 (33.264)
Median	50.00	33.33	50.00	33.33
Min, Max	33.3, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 9 Day 1				
n	3	20	6	29
Mean (StdDev)	55.56 (19.245)	26.67 (23.195)	33.33 (42.164)	31.03 (28.074)
Median	66.67	33.33	16.67	33.33
Min, Max	33.3, 66.7	0.0, 66.7	0.0, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	3	10	3	16
Mean (StdDev)	55.56 (19.245)	43.33 (41.722)	66.67 (33.333)	50.00 (36.515)
Median	66.67	33.33	66.67	33.33
Min, Max	33.3, 66.7	0.0, 100.0	33.3, 100.0	0.0, 100.0
Cycle 11 Day 1				
n	3	17	4	24
Mean (StdDev)	55.56 (19.245)	37.25 (33.087)	50.00 (43.033)	41.67 (32.969)
Median	66.67	33.33	50.00	33.33
Min, Max	33.3, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Financial Difficulties	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Cycle 12 Day 1				
n	2	7	3	12
Mean (StdDev)	50.00 (23.570)	28.57 (35.635)	55.56 (38.490)	38.89 (34.329)
Median	50.00	33.33	33.33	33.33
Min, Max	33.3, 66.7	0.0, 100.0	33.3, 100.0	0.0, 100.0
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		22.22 (19.245)	0.00 (-)	16.67 (19.245)
Median		33.33	0.00	16.67
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Global Health Status/QoL	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Baseline				
n	4	29	12	45
Mean (StdDev)	50.00 (20.412)	35.34 (27.697)	36.81 (14.847)	37.04 (24.267)
Median	45.83	33.33	33.33	33.33
Min, Max	33.3, 75.0	0.0, 100.0	16.7, 58.3	0.0, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	60.42 (12.500)	53.03 (23.365)	51.19 (21.746)	53.54 (21.654)
Median	66.67	50.00	50.00	50.00
Min, Max	41.7, 66.7	16.7, 100.0	25.0, 75.0	16.7, 100.0
Cycle 2 Day 1				
n	2	29	11	42
Mean (StdDev)	66.67 (0.000)	56.90 (20.542)	55.30 (23.355)	56.94 (20.653)
Median	66.67	66.67	66.67	66.67
Min, Max	66.7, 66.7	16.7, 91.7	0.0, 83.3	0.0, 91.7
Cycle 3 Day 1				
n	4	26	9	39
Mean (StdDev)	60.42 (15.775)	61.54 (15.999)	49.07 (18.373)	58.55 (16.937)
Median	54.17	66.67	50.00	58.33
Min, Max	50.0, 83.3	33.3, 83.3	25.0, 83.3	25.0, 83.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Global Health Status/QoL	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		70.83 (20.972)	56.25 (15.775)	63.54 (18.865)
Median		66.67	62.50	66.67
Min, Max		50.0, 100.0	33.3, 66.7	33.3, 100.0
Cycle 5 Day 1				
n	2	16	9	27
Mean (StdDev)	58.33 (11.785)	58.33 (23.373)	52.78 (20.833)	56.48 (21.475)
Median	58.33	58.33	50.00	58.33
Min, Max	50.0, 66.7	0.0, 100.0	8.3, 83.3	0.0, 100.0
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		75.00 (22.048)	60.42 (7.979)	66.67 (15.957)
Median		66.67	62.50	66.67
Min, Max		58.3, 100.0	50.0, 66.7	50.0, 100.0
Cycle 7 Day 1				
n	1	17	5	23
Mean (StdDev)	41.67 (-)	65.20 (16.728)	53.33 (9.501)	61.59 (16.233)
Median	41.67	66.67	50.00	66.67
Min, Max	41.7, 41.7	25.0, 100.0	41.7, 66.7	25.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Global Health Status/QoL	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		83.33 (23.570)	33.33 (47.140)	58.33 (41.944)
Median		83.33	33.33	66.67
Min, Max		66.7, 100.0	0.0, 66.7	0.0, 100.0
Cycle 9 Day 1				
n	0	13	4	17
Mean (StdDev)		59.62 (21.743)	43.75 (29.950)	55.88 (23.893)
Median		58.33	54.17	58.33
Min, Max		25.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		58.33 (-)	33.33 (47.140)	41.67 (36.324)
Median		58.33	33.33	58.33
Min, Max		58.3, 58.3	0.0, 66.7	0.0, 66.7
Cycle 11 Day 1				
n	0	8	3	11
Mean (StdDev)		67.71 (16.328)	38.89 (34.694)	59.85 (24.670)
Median		66.67	50.00	66.67
Min, Max		50.0, 100.0	0.0, 66.7	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Global Health Status/QoL	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		100.00 (-)	41.67 (58.926)	61.11 (53.576)
Median		100.00	41.67	83.33
Min, Max		100.0, 100.0	0.0, 83.3	0.0, 100.0
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		75.00 (14.434)	83.33 (-)	77.08 (12.500)
Median		83.33	83.33	83.33
Min, Max		58.3, 83.3	83.3, 83.3	58.3, 83.3
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		66.67 (-)		66.67 (-)
Median		66.67		66.67
Min, Max		66.7, 66.7		66.7, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Physical Functioning	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Baseline				
n	4	29	12	45
Mean (StdDev)	68.33 (32.375)	50.34 (28.652)	63.33 (24.205)	55.41 (28.099)
Median	83.33	46.67	63.33	53.33
Min, Max	20.0, 86.7	0.0, 100.0	26.7, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	58.33 (29.502)	61.52 (25.773)	77.14 (20.676)	64.44 (25.368)
Median	60.00	53.33	80.00	73.33
Min, Max	26.7, 86.7	0.0, 100.0	40.0, 100.0	0.0, 100.0
Cycle 2 Day 1				
n	2	29	11	42
Mean (StdDev)	83.33 (4.714)	66.21 (25.067)	75.76 (16.673)	69.52 (22.912)
Median	83.33	73.33	73.33	73.33
Min, Max	80.0, 86.7	0.0, 100.0	40.0, 100.0	0.0, 100.0
Cycle 3 Day 1				
n	4	26	9	39
Mean (StdDev)	55.00 (28.480)	71.79 (18.601)	75.56 (21.344)	70.94 (20.490)
Median	66.67	73.33	66.67	73.33
Min, Max	13.3, 73.3	26.7, 100.0	46.7, 100.0	13.3, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Physical Functioning	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		71.67 (17.533)	86.67 (12.172)	79.17 (16.110)
Median		73.33	86.67	83.33
Min, Max		53.3, 86.7	73.3, 100.0	53.3, 100.0
Cycle 5 Day 1				
n	2	16	9	27
Mean (StdDev)	66.67 (28.284)	78.75 (17.078)	69.63 (23.121)	74.81 (19.684)
Median	66.67	83.33	66.67	80.00
Min, Max	46.7, 86.7	46.7, 100.0	40.0, 100.0	40.0, 100.0
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		55.56 (26.943)	71.67 (30.972)	64.76 (28.209)
Median		40.00	76.67	60.00
Min, Max		40.0, 86.7	33.3, 100.0	33.3, 100.0
Cycle 7 Day 1				
n	1	17	5	23
Mean (StdDev)	40.00 (-)	71.37 (21.313)	64.00 (26.077)	68.41 (22.403)
Median	40.00	73.33	66.67	66.67
Min, Max	40.0, 40.0	26.7, 100.0	26.7, 100.0	26.7, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Physical Functioning	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		70.00 (23.570)	60.00 (56.569)	65.00 (35.849)
Median		70.00	60.00	70.00
Min, Max		53.3, 86.7	20.0, 100.0	20.0, 100.0
Cycle 9 Day 1				
n	0	13	4	17
Mean (StdDev)		77.95 (17.080)	61.67 (32.830)	74.12 (21.716)
Median		80.00	63.33	73.33
Min, Max		46.7, 100.0	20.0, 100.0	20.0, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		46.67 (-)	60.00 (56.569)	55.56 (40.734)
Median		46.67	60.00	46.67
Min, Max		46.7, 46.7	20.0, 100.0	20.0, 100.0
Cycle 11 Day 1				
n	0	8	3	11
Mean (StdDev)		78.33 (13.214)	66.67 (46.667)	75.15 (24.238)
Median		76.67	86.67	80.00
Min, Max		60.0, 100.0	13.3, 100.0	13.3, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Physical Functioning	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		100.00 (-)	56.67 (61.283)	71.11 (50.037)
Median		100.00	56.67	100.00
Min, Max		100.0, 100.0	13.3, 100.0	13.3, 100.0
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		88.89 (10.184)	86.67 (-)	88.33 (8.389)
Median		86.67	86.67	86.67
Min, Max		80.0, 100.0	86.7, 86.7	80.0, 100.0
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		100.00 (-)		100.00 (-)
Median		100.00		100.00
Min, Max		100.0, 100.0		100.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Role Functioning	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Baseline				
n	4	29	12	45
Mean (StdDev)	45.83 (36.956)	41.95 (35.807)	29.17 (29.409)	38.89 (34.082)
Median	50.00	50.00	25.00	33.33
Min, Max	0.0, 83.3	0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	45.83 (31.549)	50.00 (31.706)	50.00 (21.517)	49.49 (29.013)
Median	58.33	50.00	66.67	50.00
Min, Max	0.0, 66.7	0.0, 100.0	16.7, 66.7	0.0, 100.0
Cycle 2 Day 1				
n	2	29	11	42
Mean (StdDev)	58.33 (35.355)	58.05 (29.755)	56.06 (27.155)	57.54 (28.561)
Median	58.33	66.67	66.67	66.67
Min, Max	33.3, 83.3	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 3 Day 1				
n	4	26	9	39
Mean (StdDev)	45.83 (31.549)	60.90 (25.795)	51.85 (37.680)	57.26 (29.068)
Median	58.33	66.67	66.67	66.67
Min, Max	0.0, 66.7	16.7, 100.0	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Role Functioning	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		62.50 (20.972)	75.00 (31.914)	68.75 (25.877)
Median		66.67	83.33	66.67
Min, Max		33.3, 83.3	33.3, 100.0	33.3, 100.0
Cycle 5 Day 1				
n	2	16	9	27
Mean (StdDev)	50.00 (70.711)	59.38 (26.506)	44.44 (32.275)	53.70 (31.123)
Median	50.00	66.67	50.00	50.00
Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		55.56 (38.490)	58.33 (41.944)	57.14 (37.090)
Median		33.33	66.67	66.67
Min, Max		33.3, 100.0	0.0, 100.0	0.0, 100.0
Cycle 7 Day 1				
n	1	17	5	23
Mean (StdDev)	33.33 (-)	59.80 (23.614)	56.67 (32.489)	57.97 (25.060)
Median	33.33	66.67	66.67	66.67
Min, Max	33.3, 33.3	16.7, 100.0	16.7, 100.0	16.7, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Role Functioning	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		83.33 (23.570)	50.00 (70.711)	66.67 (47.140)
Median		83.33	50.00	83.33
Min, Max		66.7, 100.0	0.0, 100.0	0.0, 100.0
Cycle 9 Day 1				
n	0	13	4	17
Mean (StdDev)		66.67 (25.459)	50.00 (43.033)	62.75 (29.773)
Median		66.67	50.00	66.67
Min, Max		16.7, 100.0	0.0, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		50.00 (-)	50.00 (70.711)	50.00 (50.000)
Median		50.00	50.00	50.00
Min, Max		50.0, 50.0	0.0, 100.0	0.0, 100.0
Cycle 11 Day 1				
n	0	8	3	11
Mean (StdDev)		72.92 (17.678)	66.67 (57.735)	71.21 (29.899)
Median		66.67	100.00	66.67
Min, Max		50.0, 100.0	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Role Functioning	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		100.00 (-)	50.00 (70.711)	66.67 (57.735)
Median		100.00	50.00	100.00
Min, Max		100.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		83.33 (16.667)	66.67 (-)	79.17 (15.957)
Median		83.33	66.67	75.00
Min, Max		66.7, 100.0	66.7, 66.7	66.7, 100.0
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		100.00 (-)		100.00 (-)
Median		100.00		100.00
Min, Max		100.0, 100.0		100.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Emotional Functioning	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Baseline				
n	4	29	12	45
Mean (StdDev)	77.08 (29.950)	60.63 (27.268)	61.11 (25.706)	62.22 (26.862)
Median	87.50	58.33	66.67	58.33
Min, Max	33.3, 100.0	8.3, 100.0	8.3, 100.0	8.3, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	66.67 (20.412)	70.83 (23.675)	58.33 (28.054)	67.68 (24.095)
Median	70.83	70.83	50.00	66.67
Min, Max	41.7, 83.3	25.0, 100.0	25.0, 100.0	25.0, 100.0
Cycle 2 Day 1				
n	2	29	11	42
Mean (StdDev)	75.00 (0.000)	74.71 (22.656)	70.45 (22.162)	73.61 (21.771)
Median	75.00	75.00	66.67	75.00
Min, Max	75.0, 75.0	25.0, 100.0	25.0, 100.0	25.0, 100.0
Cycle 3 Day 1				
n	4	26	9	39
Mean (StdDev)	64.58 (12.500)	75.75 (19.572)	64.81 (23.855)	72.08 (20.292)
Median	66.67	76.39	66.67	75.00
Min, Max	50.0, 75.0	33.3, 100.0	16.7, 100.0	16.7, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Emotional Functioning	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		87.50 (15.957)	79.17 (17.347)	83.33 (16.060)
Median		91.67	79.17	83.33
Min, Max		66.7, 100.0	58.3, 100.0	58.3, 100.0
Cycle 5 Day 1				
n	2	16	9	27
Mean (StdDev)	58.33 (11.785)	83.33 (16.942)	63.89 (30.334)	75.00 (23.683)
Median	58.33	87.50	66.67	75.00
Min, Max	50.0, 66.7	50.0, 100.0	8.3, 100.0	8.3, 100.0
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		91.67 (14.434)	68.75 (27.534)	78.57 (24.465)
Median		100.00	66.67	83.33
Min, Max		75.0, 100.0	41.7, 100.0	41.7, 100.0
Cycle 7 Day 1				
n	1	17	5	23
Mean (StdDev)	83.33 (-)	79.90 (17.692)	66.67 (27.003)	77.17 (19.819)
Median	83.33	83.33	66.67	75.00
Min, Max	83.3, 83.3	41.7, 100.0	25.0, 100.0	25.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Emotional Functioning	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		87.50 (17.678)	45.83 (5.893)	66.67 (26.352)
Median		87.50	45.83	62.50
Min, Max		75.0, 100.0	41.7, 50.0	41.7, 100.0
Cycle 9 Day 1				
n	0	13	4	17
Mean (StdDev)		78.85 (21.141)	60.42 (31.458)	74.51 (24.201)
Median		75.00	58.33	75.00
Min, Max		33.3, 100.0	25.0, 100.0	25.0, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		91.67 (-)	37.50 (5.893)	55.56 (31.549)
Median		91.67	37.50	41.67
Min, Max		91.7, 91.7	33.3, 41.7	33.3, 91.7
Cycle 11 Day 1				
n	0	8	3	11
Mean (StdDev)		79.17 (17.252)	63.89 (31.549)	75.00 (21.409)
Median		83.33	50.00	83.33
Min, Max		50.0, 100.0	41.7, 100.0	41.7, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Emotional Functioning	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		100.00 (-)	29.17 (29.463)	52.78 (45.896)
Median		100.00	29.17	50.00
Min, Max		100.0, 100.0	8.3, 50.0	8.3, 100.0
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		100.00 (0.000)	100.00 (-)	100.00 (0.000)
Median		100.00	100.00	100.00
Min, Max		100.0, 100.0	100.0, 100.0	100.0, 100.0
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		100.00 (-)		100.00 (-)
Median		100.00		100.00
Min, Max		100.0, 100.0		100.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Cognitive Functioning	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Baseline				
n	4	29	12	45
Mean (StdDev)	79.17 (15.957)	71.84 (22.758)	65.28 (27.941)	70.74 (23.612)
Median	75.00	66.67	58.33	66.67
Min, Max	66.7, 100.0	33.3, 100.0	16.7, 100.0	16.7, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	83.33 (19.245)	74.24 (19.057)	59.52 (30.211)	72.22 (22.309)
Median	83.33	75.00	50.00	66.67
Min, Max	66.7, 100.0	33.3, 100.0	16.7, 100.0	16.7, 100.0
Cycle 2 Day 1				
n	2	29	11	42
Mean (StdDev)	75.00 (11.785)	78.16 (18.952)	69.70 (22.134)	75.79 (19.549)
Median	75.00	83.33	83.33	83.33
Min, Max	66.7, 83.3	33.3, 100.0	33.3, 100.0	33.3, 100.0
Cycle 3 Day 1				
n	4	26	9	39
Mean (StdDev)	87.50 (15.957)	78.85 (19.753)	70.37 (23.241)	77.78 (20.353)
Median	91.67	83.33	66.67	83.33
Min, Max	66.7, 100.0	33.3, 100.0	16.7, 100.0	16.7, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Cognitive Functioning	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		87.50 (15.957)	79.17 (15.957)	83.33 (15.430)
Median		91.67	75.00	83.33
Min, Max		66.7, 100.0	66.7, 100.0	66.7, 100.0
Cycle 5 Day 1				
n	2	16	9	27
Mean (StdDev)	83.33 (0.000)	77.08 (14.751)	59.26 (34.471)	71.60 (23.937)
Median	83.33	75.00	50.00	83.33
Min, Max	83.3, 83.3	50.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		94.44 (9.623)	83.33 (13.608)	88.10 (12.599)
Median		100.00	83.33	83.33
Min, Max		83.3, 100.0	66.7, 100.0	66.7, 100.0
Cycle 7 Day 1				
n	1	17	5	23
Mean (StdDev)	100.00 (-)	77.45 (13.098)	70.00 (18.257)	76.81 (14.855)
Median	100.00	66.67	66.67	66.67
Min, Max	100.0, 100.0	66.7, 100.0	50.0, 100.0	50.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Cognitive Functioning	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		100.00 (0.000)	75.00 (11.785)	87.50 (15.957)
Median		100.00	75.00	91.67
Min, Max		100.0, 100.0	66.7, 83.3	66.7, 100.0
Cycle 9 Day 1				
n	0	13	4	17
Mean (StdDev)		74.36 (16.124)	66.67 (23.570)	72.55 (17.620)
Median		66.67	75.00	66.67
Min, Max		50.0, 100.0	33.3, 83.3	33.3, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		100.00 (-)	58.33 (35.355)	72.22 (34.694)
Median		100.00	58.33	83.33
Min, Max		100.0, 100.0	33.3, 83.3	33.3, 100.0
Cycle 11 Day 1				
n	0	8	3	11
Mean (StdDev)		83.33 (15.430)	66.67 (16.667)	78.79 (16.817)
Median		83.33	66.67	83.33
Min, Max		66.7, 100.0	50.0, 83.3	50.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Cognitive Functioning	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		100.00 (-)	50.00 (47.140)	66.67 (44.096)
Median		100.00	50.00	83.33
Min, Max		100.0, 100.0	16.7, 83.3	16.7, 100.0
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		83.33 (16.667)	66.67 (-)	79.17 (15.957)
Median		83.33	66.67	75.00
Min, Max		66.7, 100.0	66.7, 66.7	66.7, 100.0
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		83.33 (-)		83.33 (-)
Median		83.33		83.33
Min, Max		83.3, 83.3		83.3, 83.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Social Function	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Baseline				
n	4	29	12	45
Mean (StdDev)	50.00 (36.004)	50.00 (33.630)	50.00 (32.567)	50.00 (32.760)
Median	41.67	33.33	66.67	33.33
Min, Max	16.7, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	62.50 (43.833)	61.36 (29.719)	66.67 (16.667)	62.63 (28.574)
Median	75.00	58.33	66.67	66.67
Min, Max	0.0, 100.0	0.0, 100.0	33.3, 83.3	0.0, 100.0
Cycle 2 Day 1				
n	2	29	11	42
Mean (StdDev)	66.67 (23.570)	66.09 (31.649)	62.12 (22.473)	65.08 (28.705)
Median	66.67	66.67	66.67	66.67
Min, Max	50.0, 83.3	0.0, 100.0	33.3, 100.0	0.0, 100.0
Cycle 3 Day 1				
n	4	26	9	39
Mean (StdDev)	54.17 (36.956)	64.74 (27.619)	50.00 (27.639)	60.26 (28.515)
Median	66.67	66.67	66.67	66.67
Min, Max	0.0, 83.3	0.0, 100.0	0.0, 83.3	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Social Function	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		79.17 (15.957)	66.67 (27.217)	72.92 (21.708)
Median		75.00	66.67	66.67
Min, Max		66.7, 100.0	33.3, 100.0	33.3, 100.0
Cycle 5 Day 1				
n	2	16	9	27
Mean (StdDev)	66.67 (47.140)	68.75 (22.669)	50.00 (20.412)	62.35 (24.281)
Median	66.67	66.67	50.00	66.67
Min, Max	33.3, 100.0	16.7, 100.0	16.7, 83.3	16.7, 100.0
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		72.22 (34.694)	58.33 (9.623)	64.29 (22.420)
Median		83.33	58.33	66.67
Min, Max		33.3, 100.0	50.0, 66.7	33.3, 100.0
Cycle 7 Day 1				
n	1	17	5	23
Mean (StdDev)	83.33 (-)	70.59 (20.858)	56.67 (22.361)	68.12 (21.269)
Median	83.33	66.67	66.67	66.67
Min, Max	83.3, 83.3	33.3, 100.0	33.3, 83.3	33.3, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Social Function	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		83.33 (23.570)	50.00 (23.570)	66.67 (27.217)
Median		83.33	50.00	66.67
Min, Max		66.7, 100.0	33.3, 66.7	33.3, 100.0
Cycle 9 Day 1				
n	0	13	4	17
Mean (StdDev)		71.79 (20.844)	54.17 (34.359)	67.65 (24.630)
Median		66.67	58.33	66.67
Min, Max		33.3, 100.0	16.7, 83.3	16.7, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		83.33 (-)	33.33 (47.140)	50.00 (44.096)
Median		83.33	33.33	66.67
Min, Max		83.3, 83.3	0.0, 66.7	0.0, 83.3
Cycle 11 Day 1				
n	0	8	3	11
Mean (StdDev)		70.83 (21.362)	66.67 (44.096)	69.70 (26.686)
Median		66.67	83.33	66.67
Min, Max		50.0, 100.0	16.7, 100.0	16.7, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Social Function	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		100.00 (-)	41.67 (35.355)	61.11 (41.944)
Median		100.00	41.67	66.67
Min, Max		100.0, 100.0	16.7, 66.7	16.7, 100.0
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		88.89 (9.623)	100.00 (-)	91.67 (9.623)
Median		83.33	100.00	91.67
Min, Max		83.3, 100.0	100.0, 100.0	83.3, 100.0
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		100.00 (-)		100.00 (-)
Median		100.00		100.00
Min, Max		100.0, 100.0		100.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Fatigue	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Baseline				
n	4	29	12	45
Mean (StdDev)	61.11 (29.397)	70.11 (32.544)	72.22 (28.229)	69.88 (30.670)
Median	55.56	77.78	77.78	77.78
Min, Max	33.3, 100.0	0.0, 100.0	22.2, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	61.11 (26.450)	53.54 (27.780)	50.79 (24.727)	53.87 (26.370)
Median	61.11	55.56	44.44	55.56
Min, Max	33.3, 88.9	11.1, 100.0	22.2, 88.9	11.1, 100.0
Cycle 2 Day 1				
n	2	29	11	42
Mean (StdDev)	44.44 (15.713)	48.66 (22.304)	50.51 (23.499)	48.94 (21.958)
Median	44.44	44.44	55.56	50.00
Min, Max	33.3, 55.6	11.1, 100.0	22.2, 100.0	11.1, 100.0
Cycle 3 Day 1				
n	4	26	9	39
Mean (StdDev)	58.33 (24.637)	52.14 (27.356)	55.56 (28.328)	53.56 (26.719)
Median	55.56	50.00	44.44	44.44
Min, Max	33.3, 88.9	11.1, 100.0	22.2, 100.0	11.1, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Fatigue	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		52.78 (22.906)	38.89 (26.450)	45.83 (24.079)
Median		50.00	27.78	33.33
Min, Max		33.3, 77.8	22.2, 77.8	22.2, 77.8
Cycle 5 Day 1				
n	2	16	9	27
Mean (StdDev)	38.89 (23.570)	45.83 (27.179)	50.62 (24.914)	46.91 (25.474)
Median	38.89	38.89	55.56	44.44
Min, Max	22.2, 55.6	0.0, 100.0	22.2, 88.9	0.0, 100.0
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		59.26 (33.945)	55.56 (27.217)	57.14 (27.539)
Median		66.67	50.00	66.67
Min, Max		22.2, 88.9	33.3, 88.9	22.2, 88.9
Cycle 7 Day 1				
n	1	17	5	23
Mean (StdDev)	44.44 (-)	41.18 (21.789)	57.78 (28.760)	44.93 (23.326)
Median	44.44	44.44	66.67	44.44
Min, Max	44.4, 44.4	0.0, 88.9	22.2, 88.9	0.0, 88.9

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Fatigue	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		33.33 (15.713)	66.67 (47.140)	50.00 (34.546)
Median		33.33	66.67	38.89
Min, Max		22.2, 44.4	33.3, 100.0	22.2, 100.0
Cycle 9 Day 1				
n	0	13	4	17
Mean (StdDev)		37.61 (22.923)	55.56 (40.572)	41.83 (27.647)
Median		33.33	55.56	33.33
Min, Max		0.0, 66.7	11.1, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		44.44 (-)	61.11 (54.997)	55.56 (40.062)
Median		44.44	61.11	44.44
Min, Max		44.4, 44.4	22.2, 100.0	22.2, 100.0
Cycle 11 Day 1				
n	0	8	3	11
Mean (StdDev)		37.50 (19.642)	51.85 (42.066)	41.41 (25.863)
Median		33.33	33.33	33.33
Min, Max		0.0, 66.7	22.2, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Fatigue	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	61.11 (54.997)	40.74 (52.509)
Median		0.00	61.11	22.22
Min, Max		0.0, 0.0	22.2, 100.0	0.0, 100.0
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		22.22 (11.111)	33.33 (-)	25.00 (10.638)
Median		22.22	33.33	27.78
Min, Max		11.1, 33.3	33.3, 33.3	11.1, 33.3
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		33.33 (-)		33.33 (-)
Median		33.33		33.33
Min, Max		33.3, 33.3		33.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Nausea and Vomiting	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Baseline				
n	4	29	12	45
Mean (StdDev)	33.33 (38.490)	21.26 (29.846)	13.89 (19.890)	20.37 (28.179)
Median	33.33	16.67	0.00	0.00
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 50.0	0.0, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	25.00 (28.868)	10.61 (15.891)	11.90 (12.599)	12.63 (17.195)
Median	16.67	0.00	16.67	0.00
Min, Max	0.0, 66.7	0.0, 50.0	0.0, 33.3	0.0, 66.7
Cycle 2 Day 1				
n	2	29	11	42
Mean (StdDev)	33.33 (47.140)	9.20 (13.052)	9.09 (15.570)	10.32 (16.025)
Median	33.33	0.00	0.00	0.00
Min, Max	0.0, 66.7	0.0, 33.3	0.0, 50.0	0.0, 66.7
Cycle 3 Day 1				
n	4	26	9	39
Mean (StdDev)	20.83 (15.957)	8.97 (16.486)	3.70 (7.349)	8.97 (15.221)
Median	25.00	0.00	0.00	0.00
Min, Max	0.0, 33.3	0.0, 50.0	0.0, 16.7	0.0, 50.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Nausea and Vomiting	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		20.83 (15.957)	4.17 (8.333)	12.50 (14.773)
Median		25.00	0.00	8.33
Min, Max		0.0, 33.3	0.0, 16.7	0.0, 33.3
Cycle 5 Day 1				
n	2	16	9	27
Mean (StdDev)	0.00 (0.000)	8.33 (12.172)	5.56 (8.333)	6.79 (10.601)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 0.0	0.0, 33.3	0.0, 16.7	0.0, 33.3
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		5.56 (9.623)	4.17 (8.333)	4.76 (8.133)
Median		0.00	0.00	0.00
Min, Max		0.0, 16.7	0.0, 16.7	0.0, 16.7
Cycle 7 Day 1				
n	1	17	5	23
Mean (StdDev)	16.67 (-)	4.90 (9.798)	10.00 (9.129)	6.52 (9.717)
Median	16.67	0.00	16.67	0.00
Min, Max	16.7, 16.7	0.0, 33.3	0.0, 16.7	0.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Nausea and Vomiting	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		8.33 (11.785)	8.33 (11.785)	8.33 (9.623)
Median		8.33	8.33	8.33
Min, Max		0.0, 16.7	0.0, 16.7	0.0, 16.7
Cycle 9 Day 1				
n	0	13	4	17
Mean (StdDev)		6.41 (10.841)	4.17 (8.333)	5.88 (10.106)
Median		0.00	0.00	0.00
Min, Max		0.0, 33.3	0.0, 16.7	0.0, 33.3
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		16.67 (-)	8.33 (11.785)	11.11 (9.623)
Median		16.67	8.33	16.67
Min, Max		16.7, 16.7	0.0, 16.7	0.0, 16.7
Cycle 11 Day 1				
n	0	8	3	11
Mean (StdDev)		2.08 (5.893)	0.00 (0.000)	1.52 (5.025)
Median		0.00	0.00	0.00
Min, Max		0.0, 16.7	0.0, 0.0	0.0, 16.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Nausea and Vomiting	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	8.33 (11.785)	5.56 (9.623)
Median		0.00	8.33	0.00
Min, Max		0.0, 0.0	0.0, 16.7	0.0, 16.7
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		11.11 (19.245)	0.00 (-)	8.33 (16.667)
Median		0.00	0.00	0.00
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Pain	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Baseline				
n	4	29	12	45
Mean (StdDev)	50.00 (30.429)	37.93 (34.760)	52.78 (32.437)	42.96 (33.801)
Median	50.00	33.33	50.00	33.33
Min, Max	16.7, 83.3	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	41.67 (21.517)	18.18 (22.950)	33.33 (19.245)	24.24 (23.233)
Median	41.67	8.33	33.33	16.67
Min, Max	16.7, 66.7	0.0, 83.3	16.7, 66.7	0.0, 83.3
Cycle 2 Day 1				
n	2	29	11	42
Mean (StdDev)	41.67 (35.355)	16.67 (24.801)	21.21 (13.104)	19.05 (22.861)
Median	41.67	0.00	16.67	16.67
Min, Max	16.7, 66.7	0.0, 83.3	0.0, 33.3	0.0, 83.3
Cycle 3 Day 1				
n	4	26	9	39
Mean (StdDev)	33.33 (30.429)	18.59 (20.724)	22.22 (16.667)	20.94 (20.844)
Median	33.33	16.67	16.67	16.67
Min, Max	0.0, 66.7	0.0, 66.7	0.0, 50.0	0.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Pain	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		8.33 (9.623)	25.00 (16.667)	16.67 (15.430)
Median		8.33	16.67	16.67
Min, Max		0.0, 16.7	16.7, 50.0	0.0, 50.0
Cycle 5 Day 1				
n	2	16	9	27
Mean (StdDev)	33.33 (23.570)	18.75 (24.248)	24.07 (20.601)	21.60 (22.558)
Median	33.33	8.33	16.67	16.67
Min, Max	16.7, 50.0	0.0, 66.7	0.0, 66.7	0.0, 66.7
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		0.00 (0.000)	29.17 (28.464)	16.67 (25.459)
Median		0.00	25.00	0.00
Min, Max		0.0, 0.0	0.0, 66.7	0.0, 66.7
Cycle 7 Day 1				
n	1	17	5	23
Mean (StdDev)	66.67 (-)	18.63 (26.275)	23.33 (27.889)	21.74 (27.264)
Median	66.67	0.00	16.67	16.67
Min, Max	66.7, 66.7	0.0, 83.3	0.0, 66.7	0.0, 83.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Pain	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		8.33 (11.785)	58.33 (58.926)	33.33 (45.134)
Median		8.33	58.33	16.67
Min, Max		0.0, 16.7	16.7, 100.0	0.0, 100.0
Cycle 9 Day 1				
n	0	13	4	17
Mean (StdDev)		15.38 (20.929)	45.83 (36.956)	22.55 (27.602)
Median		0.00	33.33	16.67
Min, Max		0.0, 50.0	16.7, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		16.67 (-)	58.33 (58.926)	44.44 (48.113)
Median		16.67	58.33	16.67
Min, Max		16.7, 16.7	16.7, 100.0	16.7, 100.0
Cycle 11 Day 1				
n	0	8	3	11
Mean (StdDev)		10.42 (15.269)	44.44 (48.113)	19.70 (29.644)
Median		0.00	16.67	16.67
Min, Max		0.0, 33.3	16.7, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Pain	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	50.00 (70.711)	33.33 (57.735)
Median		0.00	50.00	0.00
Min, Max		0.0, 0.0	0.0, 100.0	0.0, 100.0
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		0.00 (0.000)	16.67 (-)	4.17 (8.333)
Median		0.00	16.67	0.00
Min, Max		0.0, 0.0	16.7, 16.7	0.0, 16.7
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Dyspnea	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Baseline				
n	4	29	12	45
Mean (StdDev)	16.67 (19.245)	52.87 (35.093)	52.78 (36.121)	49.63 (35.264)
Median	16.67	33.33	50.00	33.33
Min, Max	0.0, 33.3	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	16.67 (33.333)	36.36 (33.976)	33.33 (38.490)	33.33 (34.359)
Median	0.00	33.33	33.33	33.33
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 2 Day 1				
n	2	29	11	42
Mean (StdDev)	0.00 (0.000)	29.89 (32.544)	30.30 (31.463)	28.57 (31.727)
Median	0.00	33.33	33.33	33.33
Min, Max	0.0, 0.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 3 Day 1				
n	4	26	9	39
Mean (StdDev)	33.33 (27.217)	21.79 (22.983)	22.22 (33.333)	23.08 (25.540)
Median	33.33	33.33	0.00	33.33
Min, Max	0.0, 66.7	0.0, 66.7	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Dyspnea	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		16.67 (19.245)	25.00 (16.667)	20.83 (17.252)
Median		16.67	33.33	33.33
Min, Max		0.0, 33.3	0.0, 33.3	0.0, 33.3
Cycle 5 Day 1				
n	2	16	9	27
Mean (StdDev)	16.67 (23.570)	22.92 (26.440)	33.33 (40.825)	25.93 (31.123)
Median	16.67	16.67	33.33	33.33
Min, Max	0.0, 33.3	0.0, 66.7	0.0, 100.0	0.0, 100.0
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		22.22 (19.245)	41.67 (41.944)	33.33 (33.333)
Median		33.33	33.33	33.33
Min, Max		0.0, 33.3	0.0, 100.0	0.0, 100.0
Cycle 7 Day 1				
n	1	17	5	23
Mean (StdDev)	33.33 (-)	21.57 (23.396)	40.00 (43.461)	26.09 (28.349)
Median	33.33	33.33	33.33	33.33
Min, Max	33.3, 33.3	0.0, 66.7	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Dyspnea	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	50.00 (70.711)	25.00 (50.000)
Median		0.00	50.00	0.00
Min, Max		0.0, 0.0	0.0, 100.0	0.0, 100.0
Cycle 9 Day 1				
n	0	13	4	17
Mean (StdDev)		15.38 (17.296)	33.33 (47.140)	19.61 (26.507)
Median		0.00	16.67	0.00
Min, Max		0.0, 33.3	0.0, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	50.00 (70.711)	33.33 (57.735)
Median		0.00	50.00	0.00
Min, Max		0.0, 0.0	0.0, 100.0	0.0, 100.0
Cycle 11 Day 1				
n	0	8	3	11
Mean (StdDev)		16.67 (17.817)	33.33 (57.735)	21.21 (30.814)
Median		16.67	0.00	0.00
Min, Max		0.0, 33.3	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Dyspnea	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	50.00 (70.711)	33.33 (57.735)
Median		0.00	50.00	0.00
Min, Max		0.0, 0.0	0.0, 100.0	0.0, 100.0
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		11.11 (19.245)	0.00 (-)	8.33 (16.667)
Median		0.00	0.00	0.00
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Insomnia	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Baseline				
n	4	29	12	45
Mean (StdDev)	75.00 (31.914)	49.43 (36.319)	77.78 (35.770)	59.26 (37.530)
Median	83.33	66.67	100.00	66.67
Min, Max	33.3, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	66.67 (27.217)	37.88 (31.363)	42.86 (25.198)	42.42 (30.360)
Median	66.67	33.33	33.33	33.33
Min, Max	33.3, 100.0	0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 2 Day 1				
n	2	29	11	42
Mean (StdDev)	50.00 (23.570)	35.63 (36.657)	21.21 (22.473)	32.54 (33.324)
Median	50.00	33.33	33.33	33.33
Min, Max	33.3, 66.7	0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 3 Day 1				
n	4	26	9	39
Mean (StdDev)	58.33 (31.914)	34.62 (27.456)	25.93 (22.222)	35.04 (27.518)
Median	50.00	33.33	33.33	33.33
Min, Max	33.3, 100.0	0.0, 100.0	0.0, 66.7	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Insomnia	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		25.00 (31.914)	41.67 (41.944)	33.33 (35.635)
Median		16.67	33.33	33.33
Min, Max		0.0, 66.7	0.0, 100.0	0.0, 100.0
Cycle 5 Day 1				
n	2	16	9	27
Mean (StdDev)	50.00 (23.570)	33.33 (21.082)	44.44 (37.268)	38.27 (27.275)
Median	50.00	33.33	33.33	33.33
Min, Max	33.3, 66.7	0.0, 66.7	0.0, 100.0	0.0, 100.0
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		33.33 (33.333)	41.67 (41.944)	38.10 (35.635)
Median		33.33	33.33	33.33
Min, Max		0.0, 66.7	0.0, 100.0	0.0, 100.0
Cycle 7 Day 1				
n	1	17	5	23
Mean (StdDev)	66.67 (-)	37.25 (28.583)	46.67 (29.814)	40.58 (28.349)
Median	66.67	33.33	33.33	33.33
Min, Max	66.7, 66.7	0.0, 100.0	33.3, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Insomnia	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	66.67 (47.140)	33.33 (47.140)
Median		0.00	66.67	16.67
Min, Max		0.0, 0.0	33.3, 100.0	0.0, 100.0
Cycle 9 Day 1				
n	0	13	4	17
Mean (StdDev)		25.64 (33.758)	50.00 (33.333)	31.37 (34.300)
Median		0.00	33.33	33.33
Min, Max		0.0, 100.0	33.3, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	66.67 (47.140)	44.44 (50.918)
Median		0.00	66.67	33.33
Min, Max		0.0, 0.0	33.3, 100.0	0.0, 100.0
Cycle 11 Day 1				
n	0	8	3	11
Mean (StdDev)		16.67 (25.198)	55.56 (50.918)	27.27 (35.957)
Median		0.00	66.67	0.00
Min, Max		0.0, 66.7	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Insomnia	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	83.33 (23.570)	55.56 (50.918)
Median		0.00	83.33	66.67
Min, Max		0.0, 0.0	66.7, 100.0	0.0, 100.0
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		22.22 (19.245)	0.00 (-)	16.67 (19.245)
Median		33.33	0.00	16.67
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		33.33 (-)		33.33 (-)
Median		33.33		33.33
Min, Max		33.3, 33.3		33.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Appetite Loss	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Baseline				
n	4	29	12	45
Mean (StdDev)	16.67 (33.333)	47.13 (36.206)	47.22 (36.121)	44.44 (36.237)
Median	0.00	33.33	33.33	33.33
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	8.33 (16.667)	21.21 (24.224)	19.05 (17.817)	19.19 (22.096)
Median	0.00	33.33	33.33	33.33
Min, Max	0.0, 33.3	0.0, 100.0	0.0, 33.3	0.0, 100.0
Cycle 2 Day 1				
n	2	29	11	42
Mean (StdDev)	16.67 (23.570)	21.84 (28.558)	21.21 (22.473)	21.43 (26.361)
Median	16.67	0.00	33.33	0.00
Min, Max	0.0, 33.3	0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 3 Day 1				
n	4	26	9	39
Mean (StdDev)	25.00 (31.914)	12.82 (21.243)	18.52 (24.216)	15.38 (22.745)
Median	16.67	0.00	0.00	0.00
Min, Max	0.0, 66.7	0.0, 66.7	0.0, 66.7	0.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Appetite Loss	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		25.00 (16.667)	33.33 (38.490)	29.17 (27.817)
Median		33.33	33.33	33.33
Min, Max		0.0, 33.3	0.0, 66.7	0.0, 66.7
Cycle 5 Day 1				
n	2	16	9	27
Mean (StdDev)	0.00 (0.000)	14.58 (20.972)	33.33 (23.570)	19.75 (23.130)
Median	0.00	0.00	33.33	0.00
Min, Max	0.0, 0.0	0.0, 66.7	0.0, 66.7	0.0, 66.7
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		11.11 (19.245)	25.00 (16.667)	19.05 (17.817)
Median		0.00	33.33	33.33
Min, Max		0.0, 33.3	0.0, 33.3	0.0, 33.3
Cycle 7 Day 1				
n	1	17	5	23
Mean (StdDev)	66.67 (-)	15.69 (23.914)	20.00 (29.814)	18.84 (26.258)
Median	66.67	0.00	0.00	0.00
Min, Max	66.7, 66.7	0.0, 66.7	0.0, 66.7	0.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Appetite Loss	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	33.33 (47.140)	16.67 (33.333)
Median		0.00	33.33	0.00
Min, Max		0.0, 0.0	0.0, 66.7	0.0, 66.7
Cycle 9 Day 1				
n	0	13	4	17
Mean (StdDev)		23.08 (28.495)	25.00 (50.000)	23.53 (32.839)
Median		0.00	0.00	0.00
Min, Max		0.0, 66.7	0.0, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	66.67 (47.140)	44.44 (50.918)
Median		0.00	66.67	33.33
Min, Max		0.0, 0.0	33.3, 100.0	0.0, 100.0
Cycle 11 Day 1				
n	0	8	3	11
Mean (StdDev)		16.67 (25.198)	44.44 (50.918)	24.24 (33.635)
Median		0.00	33.33	0.00
Min, Max		0.0, 66.7	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Appetite Loss	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	66.67 (47.140)	44.44 (50.918)
Median		0.00	66.67	33.33
Min, Max		0.0, 0.0	33.3, 100.0	0.0, 100.0
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		0.00 (0.000)	0.00 (-)	0.00 (0.000)
Median		0.00	0.00	0.00
Min, Max		0.0, 0.0	0.0, 0.0	0.0, 0.0
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		33.33 (-)		33.33 (-)
Median		33.33		33.33
Min, Max		33.3, 33.3		33.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Constipation	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Baseline				
n	4	29	12	45
Mean (StdDev)	25.00 (31.914)	24.14 (31.993)	19.44 (33.207)	22.96 (31.641)
Median	16.67	0.00	0.00	0.00
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	25.00 (31.914)	15.15 (24.618)	14.29 (17.817)	16.16 (23.748)
Median	16.67	0.00	0.00	0.00
Min, Max	0.0, 66.7	0.0, 66.7	0.0, 33.3	0.0, 66.7
Cycle 2 Day 1				
n	2	29	11	42
Mean (StdDev)	50.00 (23.570)	9.20 (19.713)	6.06 (13.484)	10.32 (20.146)
Median	50.00	0.00	0.00	0.00
Min, Max	33.3, 66.7	0.0, 66.7	0.0, 33.3	0.0, 66.7
Cycle 3 Day 1				
n	4	26	9	39
Mean (StdDev)	16.67 (33.333)	11.54 (24.841)	7.41 (14.699)	11.11 (23.363)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 33.3	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Constipation	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		8.33 (16.667)	0.00 (0.000)	4.17 (11.785)
Median		0.00	0.00	0.00
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3
Cycle 5 Day 1				
n	2	16	9	27
Mean (StdDev)	0.00 (0.000)	16.67 (27.217)	0.00 (0.000)	9.88 (22.293)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 0.0	0.0, 66.7	0.0, 0.0	0.0, 66.7
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		0.00 (0.000)	8.33 (16.667)	4.76 (12.599)
Median		0.00	0.00	0.00
Min, Max		0.0, 0.0	0.0, 33.3	0.0, 33.3
Cycle 7 Day 1				
n	1	17	5	23
Mean (StdDev)	33.33 (-)	11.76 (16.420)	0.00 (0.000)	10.14 (15.682)
Median	33.33	0.00	0.00	0.00
Min, Max	33.3, 33.3	0.0, 33.3	0.0, 0.0	0.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Constipation	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
Median		0.00	0.00	0.00
Min, Max		0.0, 0.0	0.0, 0.0	0.0, 0.0
Cycle 9 Day 1				
n	0	13	4	17
Mean (StdDev)		10.26 (16.013)	0.00 (0.000)	7.84 (14.575)
Median		0.00	0.00	0.00
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	0.00 (0.000)	0.00 (0.000)
Median		0.00	0.00	0.00
Min, Max		0.0, 0.0	0.0, 0.0	0.0, 0.0
Cycle 11 Day 1				
n	0	8	3	11
Mean (StdDev)		8.33 (15.430)	0.00 (0.000)	6.06 (13.484)
Median		0.00	0.00	0.00
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Constipation	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	0.00 (0.000)	0.00 (0.000)
Median		0.00	0.00	0.00
Min, Max		0.0, 0.0	0.0, 0.0	0.0, 0.0
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		11.11 (19.245)	0.00 (-)	8.33 (16.667)
Median		0.00	0.00	0.00
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Diarrhea	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Baseline				
n	4	29	12	45
Mean (StdDev)	25.00 (50.000)	40.23 (40.217)	50.00 (41.439)	41.48 (40.921)
Median	0.00	33.33	66.67	33.33
Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	16.67 (19.245)	18.18 (26.681)	38.10 (35.635)	22.22 (28.464)
Median	16.67	0.00	33.33	0.00
Min, Max	0.0, 33.3	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 2 Day 1				
n	2	29	11	42
Mean (StdDev)	0.00 (0.000)	16.09 (22.923)	33.33 (21.082)	19.84 (23.350)
Median	0.00	0.00	33.33	0.00
Min, Max	0.0, 0.0	0.0, 66.7	0.0, 66.7	0.0, 66.7
Cycle 3 Day 1				
n	4	26	9	39
Mean (StdDev)	8.33 (16.667)	15.38 (21.563)	29.63 (30.932)	17.95 (23.996)
Median	0.00	0.00	33.33	0.00
Min, Max	0.0, 33.3	0.0, 66.7	0.0, 66.7	0.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Diarrhea	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		41.67 (16.667)	25.00 (31.914)	33.33 (25.198)
Median		33.33	16.67	33.33
Min, Max		33.3, 66.7	0.0, 66.7	0.0, 66.7
Cycle 5 Day 1				
n	2	16	9	27
Mean (StdDev)	16.67 (23.570)	25.00 (33.333)	33.33 (28.868)	27.16 (30.714)
Median	16.67	0.00	33.33	33.33
Min, Max	0.0, 33.3	0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		44.44 (50.918)	33.33 (27.217)	38.10 (35.635)
Median		33.33	33.33	33.33
Min, Max		0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 7 Day 1				
n	1	17	5	23
Mean (StdDev)	33.33 (-)	23.53 (25.725)	20.00 (18.257)	23.19 (23.430)
Median	33.33	33.33	33.33	33.33
Min, Max	33.3, 33.3	0.0, 66.7	0.0, 33.3	0.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Diarrhea	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		33.33 (0.000)	16.67 (23.570)	25.00 (16.667)
Median		33.33	16.67	33.33
Min, Max		33.3, 33.3	0.0, 33.3	0.0, 33.3
Cycle 9 Day 1				
n	0	13	4	17
Mean (StdDev)		15.38 (22.008)	41.67 (31.914)	21.57 (26.197)
Median		0.00	50.00	0.00
Min, Max		0.0, 66.7	0.0, 66.7	0.0, 66.7
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		33.33 (-)	83.33 (23.570)	66.67 (33.333)
Median		33.33	83.33	66.67
Min, Max		33.3, 33.3	66.7, 100.0	33.3, 100.0
Cycle 11 Day 1				
n	0	8	3	11
Mean (StdDev)		12.50 (17.252)	33.33 (33.333)	18.18 (22.918)
Median		0.00	33.33	0.00
Min, Max		0.0, 33.3	0.0, 66.7	0.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Diarrhea	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		33.33 (-)	50.00 (23.570)	44.44 (19.245)
Median		33.33	50.00	33.33
Min, Max		33.3, 33.3	33.3, 66.7	33.3, 66.7
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		0.00 (0.000)	0.00 (-)	0.00 (0.000)
Median		0.00	0.00	0.00
Min, Max		0.0, 0.0	0.0, 0.0	0.0, 0.0
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Financial Difficulties	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Baseline				
n	4	29	12	45
Mean (StdDev)	41.67 (31.914)	24.14 (31.993)	36.11 (38.817)	28.89 (33.785)
Median	50.00	0.00	33.33	33.33
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	22	7	33
Mean (StdDev)	25.00 (16.667)	19.70 (24.471)	4.76 (12.599)	17.17 (22.238)
Median	33.33	0.00	0.00	0.00
Min, Max	0.0, 33.3	0.0, 66.7	0.0, 33.3	0.0, 66.7
Cycle 2 Day 1				
n	2	29	11	42
Mean (StdDev)	16.67 (23.570)	18.39 (26.105)	27.27 (35.957)	20.63 (28.468)
Median	16.67	0.00	0.00	0.00
Min, Max	0.0, 33.3	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 3 Day 1				
n	4	26	9	39
Mean (StdDev)	41.67 (16.667)	21.79 (24.841)	37.04 (35.136)	27.35 (27.436)
Median	33.33	16.67	33.33	33.33
Min, Max	33.3, 66.7	0.0, 66.7	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Financial Difficulties	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		25.00 (50.000)	50.00 (43.033)	37.50 (45.207)
Median		0.00	50.00	16.67
Min, Max		0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 5 Day 1				
n	2	16	9	27
Mean (StdDev)	16.67 (23.570)	8.33 (14.907)	40.74 (43.390)	19.75 (31.021)
Median	16.67	0.00	33.33	0.00
Min, Max	0.0, 33.3	0.0, 33.3	0.0, 100.0	0.0, 100.0
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		0.00 (0.000)	50.00 (33.333)	28.57 (35.635)
Median		0.00	33.33	33.33
Min, Max		0.0, 0.0	33.3, 100.0	0.0, 100.0
Cycle 7 Day 1				
n	1	17	5	23
Mean (StdDev)	33.33 (-)	13.73 (16.910)	33.33 (40.825)	18.84 (24.259)
Median	33.33	0.00	33.33	0.00
Min, Max	33.3, 33.3	0.0, 33.3	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Financial Difficulties	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		16.67 (23.570)	83.33 (23.570)	50.00 (43.033)
Median		16.67	83.33	50.00
Min, Max		0.0, 33.3	66.7, 100.0	0.0, 100.0
Cycle 9 Day 1				
n	0	13	4	17
Mean (StdDev)		23.08 (21.014)	41.67 (50.000)	27.45 (29.428)
Median		33.33	33.33	33.33
Min, Max		0.0, 66.7	0.0, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	83.33 (23.570)	55.56 (50.918)
Median		0.00	83.33	66.67
Min, Max		0.0, 0.0	66.7, 100.0	0.0, 100.0
Cycle 11 Day 1				
n	0	8	3	11
Mean (StdDev)		29.17 (33.034)	55.56 (50.918)	36.36 (37.873)
Median		33.33	66.67	33.33
Min, Max		0.0, 100.0	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Financial Difficulties	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	66.67 (47.140)	44.44 (50.918)
Median		0.00	66.67	33.33
Min, Max		0.0, 0.0	33.3, 100.0	0.0, 100.0
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		22.22 (19.245)	0.00 (-)	16.67 (19.245)
Median		33.33	0.00	16.67
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Global Health Status/QoL	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Baseline				
n	4	28	12	44
Mean (StdDev)	50.00 (20.412)	36.61 (27.343)	36.81 (14.847)	37.88 (23.873)
Median	45.83	33.33	33.33	33.33
Min, Max	33.3, 75.0	0.0, 100.0	16.7, 58.3	0.0, 100.0
Cycle 1 Day 15				
n	4	21	7	32
Mean (StdDev)	60.42 (12.500)	53.57 (23.801)	51.19 (21.746)	53.91 (21.893)
Median	66.67	50.00	50.00	54.17
Min, Max	41.7, 66.7	16.7, 100.0	25.0, 75.0	16.7, 100.0
Cycle 2 Day 1				
n	2	28	11	41
Mean (StdDev)	66.67 (0.000)	57.44 (20.705)	55.30 (23.355)	57.32 (20.766)
Median	66.67	66.67	66.67	66.67
Min, Max	66.7, 66.7	16.7, 91.7	0.0, 83.3	0.0, 91.7
Cycle 3 Day 1				
n	4	25	9	38
Mean (StdDev)	60.42 (15.775)	62.67 (15.237)	49.07 (18.373)	59.21 (16.643)
Median	54.17	66.67	50.00	62.50
Min, Max	50.0, 83.3	33.3, 83.3	25.0, 83.3	25.0, 83.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Global Health Status/QoL	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		70.83 (20.972)	56.25 (15.775)	63.54 (18.865)
Median		66.67	62.50	66.67
Min, Max		50.0, 100.0	33.3, 66.7	33.3, 100.0
Cycle 5 Day 1				
n	2	15	9	26
Mean (StdDev)	58.33 (11.785)	58.89 (24.084)	52.78 (20.833)	56.73 (21.861)
Median	58.33	58.33	50.00	58.33
Min, Max	50.0, 66.7	0.0, 100.0	8.3, 83.3	0.0, 100.0
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		75.00 (22.048)	60.42 (7.979)	66.67 (15.957)
Median		66.67	62.50	66.67
Min, Max		58.3, 100.0	50.0, 66.7	50.0, 100.0
Cycle 7 Day 1				
n	1	16	5	22
Mean (StdDev)	41.67 (-)	66.15 (16.796)	53.33 (9.501)	62.12 (16.412)
Median	41.67	66.67	50.00	66.67
Min, Max	41.7, 41.7	25.0, 100.0	41.7, 66.7	25.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Global Health Status/QoL	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		83.33 (23.570)	33.33 (47.140)	58.33 (41.944)
Median		83.33	33.33	66.67
Min, Max		66.7, 100.0	0.0, 66.7	0.0, 100.0
Cycle 9 Day 1				
n	0	12	4	16
Mean (StdDev)		60.42 (22.508)	43.75 (29.950)	56.25 (24.627)
Median		58.33	54.17	58.33
Min, Max		25.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		58.33 (-)	33.33 (47.140)	41.67 (36.324)
Median		58.33	33.33	58.33
Min, Max		58.3, 58.3	0.0, 66.7	0.0, 66.7
Cycle 11 Day 1				
n	0	7	3	10
Mean (StdDev)		69.05 (17.156)	38.89 (34.694)	60.00 (25.999)
Median		66.67	50.00	66.67
Min, Max		50.0, 100.0	0.0, 66.7	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Global Health Status/QoL	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		100.00 (-)	41.67 (58.926)	61.11 (53.576)
Median		100.00	41.67	83.33
Min, Max		100.0, 100.0	0.0, 83.3	0.0, 100.0
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		75.00 (14.434)	83.33 (-)	77.08 (12.500)
Median		83.33	83.33	83.33
Min, Max		58.3, 83.3	83.3, 83.3	58.3, 83.3
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		66.67 (-)		66.67 (-)
Median		66.67		66.67
Min, Max		66.7, 66.7		66.7, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Physical Functioning	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Baseline				
n	4	28	12	44
Mean (StdDev)	68.33 (32.375)	50.95 (28.986)	63.33 (24.205)	55.91 (28.219)
Median	83.33	46.67	63.33	56.67
Min, Max	20.0, 86.7	0.0, 100.0	26.7, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	21	7	32
Mean (StdDev)	58.33 (29.502)	62.22 (26.190)	77.14 (20.676)	65.00 (25.569)
Median	60.00	53.33	80.00	73.33
Min, Max	26.7, 86.7	0.0, 100.0	40.0, 100.0	0.0, 100.0
Cycle 2 Day 1				
n	2	28	11	41
Mean (StdDev)	83.33 (4.714)	66.67 (25.402)	75.76 (16.673)	69.92 (23.052)
Median	83.33	73.33	73.33	73.33
Min, Max	80.0, 86.7	0.0, 100.0	40.0, 100.0	0.0, 100.0
Cycle 3 Day 1				
n	4	25	9	38
Mean (StdDev)	55.00 (28.480)	71.73 (18.981)	75.56 (21.344)	70.88 (20.762)
Median	66.67	73.33	66.67	73.33
Min, Max	13.3, 73.3	26.7, 100.0	46.7, 100.0	13.3, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Physical Functioning	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		71.67 (17.533)	86.67 (12.172)	79.17 (16.110)
Median		73.33	86.67	83.33
Min, Max		53.3, 86.7	73.3, 100.0	53.3, 100.0
Cycle 5 Day 1				
n	2	15	9	26
Mean (StdDev)	66.67 (28.284)	79.11 (17.614)	69.63 (23.121)	74.87 (20.072)
Median	66.67	86.67	66.67	80.00
Min, Max	46.7, 86.7	46.7, 100.0	40.0, 100.0	40.0, 100.0
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		55.56 (26.943)	71.67 (30.972)	64.76 (28.209)
Median		40.00	76.67	60.00
Min, Max		40.0, 86.7	33.3, 100.0	33.3, 100.0
Cycle 7 Day 1				
n	1	16	5	22
Mean (StdDev)	40.00 (-)	72.08 (21.803)	64.00 (26.077)	68.79 (22.853)
Median	40.00	76.67	66.67	70.00
Min, Max	40.0, 40.0	26.7, 100.0	26.7, 100.0	26.7, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Physical Functioning	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		70.00 (23.570)	60.00 (56.569)	65.00 (35.849)
Median		70.00	60.00	70.00
Min, Max		53.3, 86.7	20.0, 100.0	20.0, 100.0
Cycle 9 Day 1				
n	0	12	4	16
Mean (StdDev)		78.33 (17.781)	61.67 (32.830)	74.17 (22.427)
Median		80.00	63.33	76.67
Min, Max		46.7, 100.0	20.0, 100.0	20.0, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		46.67 (-)	60.00 (56.569)	55.56 (40.734)
Median		46.67	60.00	46.67
Min, Max		46.7, 46.7	20.0, 100.0	20.0, 100.0
Cycle 11 Day 1				
n	0	7	3	10
Mean (StdDev)		78.10 (14.254)	66.67 (46.667)	74.67 (25.493)
Median		73.33	86.67	76.67
Min, Max		60.0, 100.0	13.3, 100.0	13.3, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Physical Functioning	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		100.00 (-)	56.67 (61.283)	71.11 (50.037)
Median		100.00	56.67	100.00
Min, Max		100.0, 100.0	13.3, 100.0	13.3, 100.0
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		88.89 (10.184)	86.67 (-)	88.33 (8.389)
Median		86.67	86.67	86.67
Min, Max		80.0, 100.0	86.7, 86.7	80.0, 100.0
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		100.00 (-)		100.00 (-)
Median		100.00		100.00
Min, Max		100.0, 100.0		100.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Role Functioning	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Baseline				
n	4	28	12	44
Mean (StdDev)	45.83 (36.956)	43.45 (35.526)	29.17 (29.409)	39.77 (33.951)
Median	50.00	50.00	25.00	41.67
Min, Max	0.0, 83.3	0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 1 Day 15				
n	4	21	7	32
Mean (StdDev)	45.83 (31.549)	51.59 (31.581)	50.00 (21.517)	50.52 (28.863)
Median	58.33	50.00	66.67	50.00
Min, Max	0.0, 66.7	0.0, 100.0	16.7, 66.7	0.0, 100.0
Cycle 2 Day 1				
n	2	28	11	41
Mean (StdDev)	58.33 (35.355)	58.93 (29.911)	56.06 (27.155)	58.13 (28.656)
Median	58.33	66.67	66.67	66.67
Min, Max	33.3, 83.3	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 3 Day 1				
n	4	25	9	38
Mean (StdDev)	45.83 (31.549)	62.00 (25.694)	51.85 (37.680)	57.89 (29.187)
Median	58.33	66.67	66.67	66.67
Min, Max	0.0, 66.7	16.7, 100.0	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Role Functioning	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		62.50 (20.972)	75.00 (31.914)	68.75 (25.877)
Median		66.67	83.33	66.67
Min, Max		33.3, 83.3	33.3, 100.0	33.3, 100.0
Cycle 5 Day 1				
n	2	15	9	26
Mean (StdDev)	50.00 (70.711)	60.00 (27.314)	44.44 (32.275)	53.85 (31.731)
Median	50.00	66.67	50.00	58.33
Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		55.56 (38.490)	58.33 (41.944)	57.14 (37.090)
Median		33.33	66.67	66.67
Min, Max		33.3, 100.0	0.0, 100.0	0.0, 100.0
Cycle 7 Day 1				
n	1	16	5	22
Mean (StdDev)	33.33 (-)	62.50 (21.517)	56.67 (32.489)	59.85 (23.937)
Median	33.33	66.67	66.67	66.67
Min, Max	33.3, 33.3	33.3, 100.0	16.7, 100.0	16.7, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Role Functioning	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		83.33 (23.570)	50.00 (70.711)	66.67 (47.140)
Median		83.33	50.00	83.33
Min, Max		66.7, 100.0	0.0, 100.0	0.0, 100.0
Cycle 9 Day 1				
n	0	12	4	16
Mean (StdDev)		68.06 (26.071)	50.00 (43.033)	63.54 (30.562)
Median		66.67	50.00	66.67
Min, Max		16.7, 100.0	0.0, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		50.00 (-)	50.00 (70.711)	50.00 (50.000)
Median		50.00	50.00	50.00
Min, Max		50.0, 50.0	0.0, 100.0	0.0, 100.0
Cycle 11 Day 1				
n	0	7	3	10
Mean (StdDev)		73.81 (18.898)	66.67 (57.735)	71.67 (31.476)
Median		66.67	100.00	66.67
Min, Max		50.0, 100.0	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Role Functioning	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		100.00 (-)	50.00 (70.711)	66.67 (57.735)
Median		100.00	50.00	100.00
Min, Max		100.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		83.33 (16.667)	66.67 (-)	79.17 (15.957)
Median		83.33	66.67	75.00
Min, Max		66.7, 100.0	66.7, 66.7	66.7, 100.0
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		100.00 (-)		100.00 (-)
Median		100.00		100.00
Min, Max		100.0, 100.0		100.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Emotional Functioning	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Baseline				
n	4	28	12	44
Mean (StdDev)	77.08 (29.950)	61.01 (27.690)	61.11 (25.706)	62.50 (27.108)
Median	87.50	58.33	66.67	62.50
Min, Max	33.3, 100.0	8.3, 100.0	8.3, 100.0	8.3, 100.0
Cycle 1 Day 15				
n	4	21	7	32
Mean (StdDev)	66.67 (20.412)	71.03 (24.241)	58.33 (28.054)	67.71 (24.479)
Median	70.83	75.00	50.00	66.67
Min, Max	41.7, 83.3	25.0, 100.0	25.0, 100.0	25.0, 100.0
Cycle 2 Day 1				
n	2	28	11	41
Mean (StdDev)	75.00 (0.000)	74.70 (23.072)	70.45 (22.162)	73.58 (22.040)
Median	75.00	75.00	66.67	75.00
Min, Max	75.0, 75.0	25.0, 100.0	25.0, 100.0	25.0, 100.0
Cycle 3 Day 1				
n	4	25	9	38
Mean (StdDev)	64.58 (12.500)	76.11 (19.886)	64.81 (23.855)	72.22 (20.545)
Median	66.67	77.78	66.67	75.00
Min, Max	50.0, 75.0	33.3, 100.0	16.7, 100.0	16.7, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Emotional Functioning	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		87.50 (15.957)	79.17 (17.347)	83.33 (16.060)
Median		91.67	79.17	83.33
Min, Max		66.7, 100.0	58.3, 100.0	58.3, 100.0
Cycle 5 Day 1				
n	2	15	9	26
Mean (StdDev)	58.33 (11.785)	85.00 (16.122)	63.89 (30.334)	75.64 (23.912)
Median	58.33	91.67	66.67	75.00
Min, Max	50.0, 66.7	50.0, 100.0	8.3, 100.0	8.3, 100.0
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		91.67 (14.434)	68.75 (27.534)	78.57 (24.465)
Median		100.00	66.67	83.33
Min, Max		75.0, 100.0	41.7, 100.0	41.7, 100.0
Cycle 7 Day 1				
n	1	16	5	22
Mean (StdDev)	83.33 (-)	80.73 (17.930)	66.67 (27.003)	77.65 (20.149)
Median	83.33	83.33	66.67	79.17
Min, Max	83.3, 83.3	41.7, 100.0	25.0, 100.0	25.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Emotional Functioning	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		87.50 (17.678)	45.83 (5.893)	66.67 (26.352)
Median		87.50	45.83	62.50
Min, Max		75.0, 100.0	41.7, 50.0	41.7, 100.0
Cycle 9 Day 1				
n	0	12	4	16
Mean (StdDev)		79.17 (22.048)	60.42 (31.458)	74.48 (24.994)
Median		83.33	58.33	75.00
Min, Max		33.3, 100.0	25.0, 100.0	25.0, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		91.67 (-)	37.50 (5.893)	55.56 (31.549)
Median		91.67	37.50	41.67
Min, Max		91.7, 91.7	33.3, 41.7	33.3, 91.7
Cycle 11 Day 1				
n	0	7	3	10
Mean (StdDev)		82.14 (16.265)	63.89 (31.549)	76.67 (21.802)
Median		83.33	50.00	83.33
Min, Max		50.0, 100.0	41.7, 100.0	41.7, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Emotional Functioning	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		100.00 (-)	29.17 (29.463)	52.78 (45.896)
Median		100.00	29.17	50.00
Min, Max		100.0, 100.0	8.3, 50.0	8.3, 100.0
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		100.00 (0.000)	100.00 (-)	100.00 (0.000)
Median		100.00	100.00	100.00
Min, Max		100.0, 100.0	100.0, 100.0	100.0, 100.0
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		100.00 (-)		100.00 (-)
Median		100.00		100.00
Min, Max		100.0, 100.0		100.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Cognitive Functioning	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Baseline				
n	4	28	12	44
Mean (StdDev)	79.17 (15.957)	73.21 (21.914)	65.28 (27.941)	71.59 (23.178)
Median	75.00	75.00	58.33	66.67
Min, Max	66.7, 100.0	33.3, 100.0	16.7, 100.0	16.7, 100.0
Cycle 1 Day 15				
n	4	21	7	32
Mean (StdDev)	83.33 (19.245)	74.60 (19.450)	59.52 (30.211)	72.40 (22.643)
Median	83.33	83.33	50.00	75.00
Min, Max	66.7, 100.0	33.3, 100.0	16.7, 100.0	16.7, 100.0
Cycle 2 Day 1				
n	2	28	11	41
Mean (StdDev)	75.00 (11.785)	77.98 (19.274)	69.70 (22.134)	75.61 (19.755)
Median	75.00	83.33	83.33	83.33
Min, Max	66.7, 83.3	33.3, 100.0	33.3, 100.0	33.3, 100.0
Cycle 3 Day 1				
n	4	25	9	38
Mean (StdDev)	87.50 (15.957)	80.67 (17.795)	70.37 (23.241)	78.95 (19.252)
Median	91.67	83.33	66.67	83.33
Min, Max	66.7, 100.0	33.3, 100.0	16.7, 100.0	16.7, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Cognitive Functioning	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		87.50 (15.957)	79.17 (15.957)	83.33 (15.430)
Median		91.67	75.00	83.33
Min, Max		66.7, 100.0	66.7, 100.0	66.7, 100.0
Cycle 5 Day 1				
n	2	15	9	26
Mean (StdDev)	83.33 (0.000)	77.78 (14.996)	59.26 (34.471)	71.79 (24.390)
Median	83.33	83.33	50.00	83.33
Min, Max	83.3, 83.3	50.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		94.44 (9.623)	83.33 (13.608)	88.10 (12.599)
Median		100.00	83.33	83.33
Min, Max		83.3, 100.0	66.7, 100.0	66.7, 100.0
Cycle 7 Day 1				
n	1	16	5	22
Mean (StdDev)	100.00 (-)	78.13 (13.220)	70.00 (18.257)	77.27 (15.036)
Median	100.00	75.00	66.67	66.67
Min, Max	100.0, 100.0	66.7, 100.0	50.0, 100.0	50.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Cognitive Functioning	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		100.00 (0.000)	75.00 (11.785)	87.50 (15.957)
Median		100.00	75.00	91.67
Min, Max		100.0, 100.0	66.7, 83.3	66.7, 100.0
Cycle 9 Day 1				
n	0	12	4	16
Mean (StdDev)		75.00 (16.667)	66.67 (23.570)	72.92 (18.130)
Median		75.00	75.00	75.00
Min, Max		50.0, 100.0	33.3, 83.3	33.3, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		100.00 (-)	58.33 (35.355)	72.22 (34.694)
Median		100.00	58.33	83.33
Min, Max		100.0, 100.0	33.3, 83.3	33.3, 100.0
Cycle 11 Day 1				
n	0	7	3	10
Mean (StdDev)		85.71 (14.996)	66.67 (16.667)	80.00 (17.213)
Median		83.33	66.67	83.33
Min, Max		66.7, 100.0	50.0, 83.3	50.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Cognitive Functioning	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		100.00 (-)	50.00 (47.140)	66.67 (44.096)
Median		100.00	50.00	83.33
Min, Max		100.0, 100.0	16.7, 83.3	16.7, 100.0
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		83.33 (16.667)	66.67 (-)	79.17 (15.957)
Median		83.33	66.67	75.00
Min, Max		66.7, 100.0	66.7, 66.7	66.7, 100.0
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		83.33 (-)		83.33 (-)
Median		83.33		83.33
Min, Max		83.3, 83.3		83.3, 83.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Social Function	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Baseline				
n	4	28	12	44
Mean (StdDev)	50.00 (36.004)	51.19 (33.619)	50.00 (32.567)	50.76 (32.738)
Median	41.67	33.33	66.67	41.67
Min, Max	16.7, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	21	7	32
Mean (StdDev)	62.50 (43.833)	61.11 (30.429)	66.67 (16.667)	62.50 (29.022)
Median	75.00	50.00	66.67	66.67
Min, Max	0.0, 100.0	0.0, 100.0	33.3, 83.3	0.0, 100.0
Cycle 2 Day 1				
n	2	28	11	41
Mean (StdDev)	66.67 (23.570)	66.07 (32.229)	62.12 (22.473)	65.04 (29.060)
Median	66.67	66.67	66.67	66.67
Min, Max	50.0, 83.3	0.0, 100.0	33.3, 100.0	0.0, 100.0
Cycle 3 Day 1				
n	4	25	9	38
Mean (StdDev)	54.17 (36.956)	64.67 (28.186)	50.00 (27.639)	60.09 (28.878)
Median	66.67	66.67	66.67	66.67
Min, Max	0.0, 83.3	0.0, 100.0	0.0, 83.3	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Social Function	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		79.17 (15.957)	66.67 (27.217)	72.92 (21.708)
Median		75.00	66.67	66.67
Min, Max		66.7, 100.0	33.3, 100.0	33.3, 100.0
Cycle 5 Day 1				
n	2	15	9	26
Mean (StdDev)	66.67 (47.140)	68.89 (23.458)	50.00 (20.412)	62.18 (24.747)
Median	66.67	66.67	50.00	66.67
Min, Max	33.3, 100.0	16.7, 100.0	16.7, 83.3	16.7, 100.0
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		72.22 (34.694)	58.33 (9.623)	64.29 (22.420)
Median		83.33	58.33	66.67
Min, Max		33.3, 100.0	50.0, 66.7	33.3, 100.0
Cycle 7 Day 1				
n	1	16	5	22
Mean (StdDev)	83.33 (-)	70.83 (21.517)	56.67 (22.361)	68.18 (21.767)
Median	83.33	66.67	66.67	66.67
Min, Max	83.3, 83.3	33.3, 100.0	33.3, 83.3	33.3, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Social Function	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		83.33 (23.570)	50.00 (23.570)	66.67 (27.217)
Median		83.33	50.00	66.67
Min, Max		66.7, 100.0	33.3, 66.7	33.3, 100.0
Cycle 9 Day 1				
n	0	12	4	16
Mean (StdDev)		72.22 (21.711)	54.17 (34.359)	67.71 (25.436)
Median		66.67	58.33	66.67
Min, Max		33.3, 100.0	16.7, 83.3	16.7, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		83.33 (-)	33.33 (47.140)	50.00 (44.096)
Median		83.33	33.33	66.67
Min, Max		83.3, 83.3	0.0, 66.7	0.0, 83.3
Cycle 11 Day 1				
n	0	7	3	10
Mean (StdDev)		71.43 (23.002)	66.67 (44.096)	70.00 (28.109)
Median		66.67	83.33	75.00
Min, Max		50.0, 100.0	16.7, 100.0	16.7, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Social Function	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		100.00 (-)	41.67 (35.355)	61.11 (41.944)
Median		100.00	41.67	66.67
Min, Max		100.0, 100.0	16.7, 66.7	16.7, 100.0
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		88.89 (9.623)	100.00 (-)	91.67 (9.623)
Median		83.33	100.00	91.67
Min, Max		83.3, 100.0	100.0, 100.0	83.3, 100.0
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		100.00 (-)		100.00 (-)
Median		100.00		100.00
Min, Max		100.0, 100.0		100.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Fatigue	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Baseline				
n	4	28	12	44
Mean (StdDev)	61.11 (29.397)	69.05 (32.620)	72.22 (28.229)	69.19 (30.675)
Median	55.56	77.78	77.78	72.22
Min, Max	33.3, 100.0	0.0, 100.0	22.2, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	21	7	32
Mean (StdDev)	61.11 (26.450)	52.91 (28.307)	50.79 (24.727)	53.47 (26.690)
Median	61.11	55.56	44.44	50.00
Min, Max	33.3, 88.9	11.1, 100.0	22.2, 88.9	11.1, 100.0
Cycle 2 Day 1				
n	2	28	11	41
Mean (StdDev)	44.44 (15.713)	48.02 (22.438)	50.51 (23.499)	48.51 (22.049)
Median	44.44	44.44	55.56	44.44
Min, Max	33.3, 55.6	11.1, 100.0	22.2, 100.0	11.1, 100.0
Cycle 3 Day 1				
n	4	25	9	38
Mean (StdDev)	58.33 (24.637)	51.56 (27.756)	55.56 (28.328)	53.22 (26.990)
Median	55.56	44.44	44.44	44.44
Min, Max	33.3, 88.9	11.1, 100.0	22.2, 100.0	11.1, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Fatigue	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		52.78 (22.906)	38.89 (26.450)	45.83 (24.079)
Median		50.00	27.78	33.33
Min, Max		33.3, 77.8	22.2, 77.8	22.2, 77.8
Cycle 5 Day 1				
n	2	15	9	26
Mean (StdDev)	38.89 (23.570)	46.67 (27.920)	50.62 (24.914)	47.44 (25.831)
Median	38.89	44.44	55.56	44.44
Min, Max	22.2, 55.6	0.0, 100.0	22.2, 88.9	0.0, 100.0
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		59.26 (33.945)	55.56 (27.217)	57.14 (27.539)
Median		66.67	50.00	66.67
Min, Max		22.2, 88.9	33.3, 88.9	22.2, 88.9
Cycle 7 Day 1				
n	1	16	5	22
Mean (StdDev)	44.44 (-)	39.58 (21.457)	57.78 (28.760)	43.94 (23.377)
Median	44.44	38.89	66.67	44.44
Min, Max	44.4, 44.4	0.0, 88.9	22.2, 88.9	0.0, 88.9

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Fatigue	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		33.33 (15.713)	66.67 (47.140)	50.00 (34.546)
Median		33.33	66.67	38.89
Min, Max		22.2, 44.4	33.3, 100.0	22.2, 100.0
Cycle 9 Day 1				
n	0	12	4	16
Mean (StdDev)		36.11 (23.271)	55.56 (40.572)	40.97 (28.319)
Median		33.33	55.56	33.33
Min, Max		0.0, 66.7	11.1, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		44.44 (-)	61.11 (54.997)	55.56 (40.062)
Median		44.44	61.11	44.44
Min, Max		44.4, 44.4	22.2, 100.0	22.2, 100.0
Cycle 11 Day 1				
n	0	7	3	10
Mean (StdDev)		38.10 (21.138)	51.85 (42.066)	42.22 (27.116)
Median		33.33	33.33	33.33
Min, Max		0.0, 66.7	22.2, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Fatigue	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	61.11 (54.997)	40.74 (52.509)
Median		0.00	61.11	22.22
Min, Max		0.0, 0.0	22.2, 100.0	0.0, 100.0
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		22.22 (11.111)	33.33 (-)	25.00 (10.638)
Median		22.22	33.33	27.78
Min, Max		11.1, 33.3	33.3, 33.3	11.1, 33.3
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		33.33 (-)		33.33 (-)
Median		33.33		33.33
Min, Max		33.3, 33.3		33.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Nausea and Vomiting	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Baseline				
n	4	28	12	44
Mean (StdDev)	33.33 (38.490)	20.83 (30.302)	13.89 (19.890)	20.08 (28.435)
Median	33.33	8.33	0.00	0.00
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 50.0	0.0, 100.0
Cycle 1 Day 15				
n	4	21	7	32
Mean (StdDev)	25.00 (28.868)	11.11 (16.102)	11.90 (12.599)	13.02 (17.318)
Median	16.67	0.00	16.67	0.00
Min, Max	0.0, 66.7	0.0, 50.0	0.0, 33.3	0.0, 66.7
Cycle 2 Day 1				
n	2	28	11	41
Mean (StdDev)	33.33 (47.140)	9.52 (13.169)	9.09 (15.570)	10.57 (16.140)
Median	33.33	0.00	0.00	0.00
Min, Max	0.0, 66.7	0.0, 33.3	0.0, 50.0	0.0, 66.7
Cycle 3 Day 1				
n	4	25	9	38
Mean (StdDev)	20.83 (15.957)	9.33 (16.722)	3.70 (7.349)	9.21 (15.352)
Median	25.00	0.00	0.00	0.00
Min, Max	0.0, 33.3	0.0, 50.0	0.0, 16.7	0.0, 50.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Nausea and Vomiting	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		20.83 (15.957)	4.17 (8.333)	12.50 (14.773)
Median		25.00	0.00	8.33
Min, Max		0.0, 33.3	0.0, 16.7	0.0, 33.3
Cycle 5 Day 1				
n	2	15	9	26
Mean (StdDev)	0.00 (0.000)	7.78 (12.387)	5.56 (8.333)	6.41 (10.622)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 0.0	0.0, 33.3	0.0, 16.7	0.0, 33.3
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		5.56 (9.623)	4.17 (8.333)	4.76 (8.133)
Median		0.00	0.00	0.00
Min, Max		0.0, 16.7	0.0, 16.7	0.0, 16.7
Cycle 7 Day 1				
n	1	16	5	22
Mean (StdDev)	16.67 (-)	4.17 (9.623)	10.00 (9.129)	6.06 (9.685)
Median	16.67	0.00	16.67	0.00
Min, Max	16.7, 16.7	0.0, 33.3	0.0, 16.7	0.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Nausea and Vomiting	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		8.33 (11.785)	8.33 (11.785)	8.33 (9.623)
Median		8.33	8.33	8.33
Min, Max		0.0, 16.7	0.0, 16.7	0.0, 16.7
Cycle 9 Day 1				
n	0	12	4	16
Mean (StdDev)		6.94 (11.143)	4.17 (8.333)	6.25 (10.319)
Median		0.00	0.00	0.00
Min, Max		0.0, 33.3	0.0, 16.7	0.0, 33.3
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		16.67 (-)	8.33 (11.785)	11.11 (9.623)
Median		16.67	8.33	16.67
Min, Max		16.7, 16.7	0.0, 16.7	0.0, 16.7
Cycle 11 Day 1				
n	0	7	3	10
Mean (StdDev)		2.38 (6.299)	0.00 (0.000)	1.67 (5.270)
Median		0.00	0.00	0.00
Min, Max		0.0, 16.7	0.0, 0.0	0.0, 16.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Nausea and Vomiting	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	8.33 (11.785)	5.56 (9.623)
Median		0.00	8.33	0.00
Min, Max		0.0, 0.0	0.0, 16.7	0.0, 16.7
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		11.11 (19.245)	0.00 (-)	8.33 (16.667)
Median		0.00	0.00	0.00
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Pain	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Baseline				
n	4	28	12	44
Mean (StdDev)	50.00 (30.429)	38.10 (35.387)	52.78 (32.437)	43.18 (34.160)
Median	50.00	33.33	50.00	33.33
Min, Max	16.7, 83.3	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	21	7	32
Mean (StdDev)	41.67 (21.517)	17.46 (23.260)	33.33 (19.245)	23.96 (23.546)
Median	41.67	0.00	33.33	16.67
Min, Max	16.7, 66.7	0.0, 83.3	16.7, 66.7	0.0, 83.3
Cycle 2 Day 1				
n	2	28	11	41
Mean (StdDev)	41.67 (35.355)	15.48 (24.398)	21.21 (13.104)	18.29 (22.609)
Median	41.67	0.00	16.67	16.67
Min, Max	16.7, 66.7	0.0, 83.3	0.0, 33.3	0.0, 83.3
Cycle 3 Day 1				
n	4	25	9	38
Mean (StdDev)	33.33 (30.429)	17.33 (20.115)	22.22 (16.667)	20.18 (20.562)
Median	33.33	16.67	16.67	16.67
Min, Max	0.0, 66.7	0.0, 66.7	0.0, 50.0	0.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Pain	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		8.33 (9.623)	25.00 (16.667)	16.67 (15.430)
Median		8.33	16.67	16.67
Min, Max		0.0, 16.7	16.7, 50.0	0.0, 50.0
Cycle 5 Day 1				
n	2	15	9	26
Mean (StdDev)	33.33 (23.570)	17.78 (24.774)	24.07 (20.601)	21.15 (22.880)
Median	33.33	0.00	16.67	16.67
Min, Max	16.7, 50.0	0.0, 66.7	0.0, 66.7	0.0, 66.7
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		0.00 (0.000)	29.17 (28.464)	16.67 (25.459)
Median		0.00	25.00	0.00
Min, Max		0.0, 0.0	0.0, 66.7	0.0, 66.7
Cycle 7 Day 1				
n	1	16	5	22
Mean (StdDev)	66.67 (-)	15.63 (23.936)	23.33 (27.889)	19.70 (26.042)
Median	66.67	0.00	16.67	8.33
Min, Max	66.7, 66.7	0.0, 83.3	0.0, 66.7	0.0, 83.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Pain	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		8.33 (11.785)	58.33 (58.926)	33.33 (45.134)
Median		8.33	58.33	16.67
Min, Max		0.0, 16.7	16.7, 100.0	0.0, 100.0
Cycle 9 Day 1				
n	0	12	4	16
Mean (StdDev)		13.89 (21.122)	45.83 (36.956)	21.88 (28.362)
Median		0.00	33.33	8.33
Min, Max		0.0, 50.0	16.7, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		16.67 (-)	58.33 (58.926)	44.44 (48.113)
Median		16.67	58.33	16.67
Min, Max		16.7, 16.7	16.7, 100.0	16.7, 100.0
Cycle 11 Day 1				
n	0	7	3	10
Mean (StdDev)		7.14 (13.113)	44.44 (48.113)	18.33 (30.882)
Median		0.00	16.67	8.33
Min, Max		0.0, 33.3	16.7, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Pain	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	50.00 (70.711)	33.33 (57.735)
Median		0.00	50.00	0.00
Min, Max		0.0, 0.0	0.0, 100.0	0.0, 100.0
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		0.00 (0.000)	16.67 (-)	4.17 (8.333)
Median		0.00	16.67	0.00
Min, Max		0.0, 0.0	16.7, 16.7	0.0, 16.7
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Dyspnea	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Baseline				
n	4	28	12	44
Mean (StdDev)	16.67 (19.245)	51.19 (34.525)	52.78 (36.121)	48.48 (34.816)
Median	16.67	33.33	50.00	33.33
Min, Max	0.0, 33.3	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	21	7	32
Mean (StdDev)	16.67 (33.333)	33.33 (31.623)	33.33 (38.490)	31.25 (32.723)
Median	0.00	33.33	33.33	33.33
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 2 Day 1				
n	2	28	11	41
Mean (StdDev)	0.00 (0.000)	28.57 (32.349)	30.30 (31.463)	27.64 (31.537)
Median	0.00	33.33	33.33	33.33
Min, Max	0.0, 0.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 3 Day 1				
n	4	25	9	38
Mean (StdDev)	33.33 (27.217)	20.00 (21.517)	22.22 (33.333)	21.93 (24.843)
Median	33.33	33.33	0.00	33.33
Min, Max	0.0, 66.7	0.0, 66.7	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Dyspnea	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		16.67 (19.245)	25.00 (16.667)	20.83 (17.252)
Median		16.67	33.33	33.33
Min, Max		0.0, 33.3	0.0, 33.3	0.0, 33.3
Cycle 5 Day 1				
n	2	15	9	26
Mean (StdDev)	16.67 (23.570)	20.00 (24.560)	33.33 (40.825)	24.36 (30.634)
Median	16.67	0.00	33.33	16.67
Min, Max	0.0, 33.3	0.0, 66.7	0.0, 100.0	0.0, 100.0
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		22.22 (19.245)	41.67 (41.944)	33.33 (33.333)
Median		33.33	33.33	33.33
Min, Max		0.0, 33.3	0.0, 100.0	0.0, 100.0
Cycle 7 Day 1				
n	1	16	5	22
Mean (StdDev)	33.33 (-)	18.75 (20.972)	40.00 (43.461)	24.24 (27.568)
Median	33.33	16.67	33.33	33.33
Min, Max	33.3, 33.3	0.0, 66.7	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Dyspnea	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	50.00 (70.711)	25.00 (50.000)
Median		0.00	50.00	0.00
Min, Max		0.0, 0.0	0.0, 100.0	0.0, 100.0
Cycle 9 Day 1				
n	0	12	4	16
Mean (StdDev)		13.89 (17.164)	33.33 (47.140)	18.75 (27.131)
Median		0.00	16.67	0.00
Min, Max		0.0, 33.3	0.0, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	50.00 (70.711)	33.33 (57.735)
Median		0.00	50.00	0.00
Min, Max		0.0, 0.0	0.0, 100.0	0.0, 100.0
Cycle 11 Day 1				
n	0	7	3	10
Mean (StdDev)		14.29 (17.817)	33.33 (57.735)	20.00 (32.203)
Median		0.00	0.00	0.00
Min, Max		0.0, 33.3	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Dyspnea	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	50.00 (70.711)	33.33 (57.735)
Median		0.00	50.00	0.00
Min, Max		0.0, 0.0	0.0, 100.0	0.0, 100.0
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		11.11 (19.245)	0.00 (-)	8.33 (16.667)
Median		0.00	0.00	0.00
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Insomnia	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Baseline				
n	4	28	12	44
Mean (StdDev)	75.00 (31.914)	48.81 (36.831)	77.78 (35.770)	59.09 (37.947)
Median	83.33	50.00	100.00	66.67
Min, Max	33.3, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	21	7	32
Mean (StdDev)	66.67 (27.217)	38.10 (32.121)	42.86 (25.198)	42.71 (30.801)
Median	66.67	33.33	33.33	33.33
Min, Max	33.3, 100.0	0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 2 Day 1				
n	2	28	11	41
Mean (StdDev)	50.00 (23.570)	36.90 (36.671)	21.21 (22.473)	33.33 (33.333)
Median	50.00	33.33	33.33	33.33
Min, Max	33.3, 66.7	0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 3 Day 1				
n	4	25	9	38
Mean (StdDev)	58.33 (31.914)	34.67 (28.021)	25.93 (22.222)	35.09 (27.886)
Median	50.00	33.33	33.33	33.33
Min, Max	33.3, 100.0	0.0, 100.0	0.0, 66.7	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Insomnia	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		25.00 (31.914)	41.67 (41.944)	33.33 (35.635)
Median		16.67	33.33	33.33
Min, Max		0.0, 66.7	0.0, 100.0	0.0, 100.0
Cycle 5 Day 1				
n	2	15	9	26
Mean (StdDev)	50.00 (23.570)	35.56 (19.787)	44.44 (37.268)	39.74 (26.699)
Median	50.00	33.33	33.33	33.33
Min, Max	33.3, 66.7	0.0, 66.7	0.0, 100.0	0.0, 100.0
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		33.33 (33.333)	41.67 (41.944)	38.10 (35.635)
Median		33.33	33.33	33.33
Min, Max		0.0, 66.7	0.0, 100.0	0.0, 100.0
Cycle 7 Day 1				
n	1	16	5	22
Mean (StdDev)	66.67 (-)	39.58 (27.806)	46.67 (29.814)	42.42 (27.568)
Median	66.67	33.33	33.33	33.33
Min, Max	66.7, 66.7	0.0, 100.0	33.3, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Insomnia	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	66.67 (47.140)	33.33 (47.140)
Median		0.00	66.67	16.67
Min, Max		0.0, 0.0	33.3, 100.0	0.0, 100.0
Cycle 9 Day 1				
n	0	12	4	16
Mean (StdDev)		27.78 (34.329)	50.00 (33.333)	33.33 (34.427)
Median		16.67	33.33	33.33
Min, Max		0.0, 100.0	33.3, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	66.67 (47.140)	44.44 (50.918)
Median		0.00	66.67	33.33
Min, Max		0.0, 0.0	33.3, 100.0	0.0, 100.0
Cycle 11 Day 1				
n	0	7	3	10
Mean (StdDev)		19.05 (26.227)	55.56 (50.918)	30.00 (36.683)
Median		0.00	66.67	16.67
Min, Max		0.0, 66.7	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Insomnia	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	83.33 (23.570)	55.56 (50.918)
Median		0.00	83.33	66.67
Min, Max		0.0, 0.0	66.7, 100.0	0.0, 100.0
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		22.22 (19.245)	0.00 (-)	16.67 (19.245)
Median		33.33	0.00	16.67
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		33.33 (-)		33.33 (-)
Median		33.33		33.33
Min, Max		33.3, 33.3		33.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Appetite Loss	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Baseline				
n	4	28	12	44
Mean (StdDev)	16.67 (33.333)	47.62 (36.772)	47.22 (36.121)	44.70 (36.616)
Median	0.00	33.33	33.33	33.33
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	21	7	32
Mean (StdDev)	8.33 (16.667)	22.22 (24.343)	19.05 (17.817)	19.79 (22.175)
Median	0.00	33.33	33.33	33.33
Min, Max	0.0, 33.3	0.0, 100.0	0.0, 33.3	0.0, 100.0
Cycle 2 Day 1				
n	2	28	11	41
Mean (StdDev)	16.67 (23.570)	22.62 (28.766)	21.21 (22.473)	21.95 (26.468)
Median	16.67	0.00	33.33	0.00
Min, Max	0.0, 33.3	0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 3 Day 1				
n	4	25	9	38
Mean (StdDev)	25.00 (31.914)	13.33 (21.517)	18.52 (24.216)	15.79 (22.907)
Median	16.67	0.00	0.00	0.00
Min, Max	0.0, 66.7	0.0, 66.7	0.0, 66.7	0.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Appetite Loss	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		25.00 (16.667)	33.33 (38.490)	29.17 (27.817)
Median		33.33	33.33	33.33
Min, Max		0.0, 33.3	0.0, 66.7	0.0, 66.7
Cycle 5 Day 1				
n	2	15	9	26
Mean (StdDev)	0.00 (0.000)	15.56 (21.331)	33.33 (23.570)	20.51 (23.242)
Median	0.00	0.00	33.33	16.67
Min, Max	0.0, 0.0	0.0, 66.7	0.0, 66.7	0.0, 66.7
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		11.11 (19.245)	25.00 (16.667)	19.05 (17.817)
Median		0.00	33.33	33.33
Min, Max		0.0, 33.3	0.0, 33.3	0.0, 33.3
Cycle 7 Day 1				
n	1	16	5	22
Mean (StdDev)	66.67 (-)	16.67 (24.343)	20.00 (29.814)	19.70 (26.546)
Median	66.67	0.00	0.00	0.00
Min, Max	66.7, 66.7	0.0, 66.7	0.0, 66.7	0.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Appetite Loss	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	33.33 (47.140)	16.67 (33.333)
Median		0.00	33.33	0.00
Min, Max		0.0, 0.0	0.0, 66.7	0.0, 66.7
Cycle 9 Day 1				
n	0	12	4	16
Mean (StdDev)		19.44 (26.432)	25.00 (50.000)	20.83 (31.914)
Median		0.00	0.00	0.00
Min, Max		0.0, 66.7	0.0, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	66.67 (47.140)	44.44 (50.918)
Median		0.00	66.67	33.33
Min, Max		0.0, 0.0	33.3, 100.0	0.0, 100.0
Cycle 11 Day 1				
n	0	7	3	10
Mean (StdDev)		19.05 (26.227)	44.44 (50.918)	26.67 (34.427)
Median		0.00	33.33	16.67
Min, Max		0.0, 66.7	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Appetite Loss	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	66.67 (47.140)	44.44 (50.918)
Median		0.00	66.67	33.33
Min, Max		0.0, 0.0	33.3, 100.0	0.0, 100.0
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		0.00 (0.000)	0.00 (-)	0.00 (0.000)
Median		0.00	0.00	0.00
Min, Max		0.0, 0.0	0.0, 0.0	0.0, 0.0
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		33.33 (-)		33.33 (-)
Median		33.33		33.33
Min, Max		33.3, 33.3		33.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Constipation	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Baseline				
n	4	28	12	44
Mean (StdDev)	25.00 (31.914)	23.81 (32.530)	19.44 (33.207)	22.73 (31.966)
Median	16.67	0.00	0.00	0.00
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	21	7	32
Mean (StdDev)	25.00 (31.914)	15.87 (24.987)	14.29 (17.817)	16.67 (23.947)
Median	16.67	0.00	0.00	0.00
Min, Max	0.0, 66.7	0.0, 66.7	0.0, 33.3	0.0, 66.7
Cycle 2 Day 1				
n	2	28	11	41
Mean (StdDev)	50.00 (23.570)	9.52 (19.994)	6.06 (13.484)	10.57 (20.329)
Median	50.00	0.00	0.00	0.00
Min, Max	33.3, 66.7	0.0, 66.7	0.0, 33.3	0.0, 66.7
Cycle 3 Day 1				
n	4	25	9	38
Mean (StdDev)	16.67 (33.333)	12.00 (25.240)	7.41 (14.699)	11.40 (23.604)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 33.3	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Constipation	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		8.33 (16.667)	0.00 (0.000)	4.17 (11.785)
Median		0.00	0.00	0.00
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3
Cycle 5 Day 1				
n	2	15	9	26
Mean (StdDev)	0.00 (0.000)	17.78 (27.794)	0.00 (0.000)	10.26 (22.646)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 0.0	0.0, 66.7	0.0, 0.0	0.0, 66.7
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		0.00 (0.000)	8.33 (16.667)	4.76 (12.599)
Median		0.00	0.00	0.00
Min, Max		0.0, 0.0	0.0, 33.3	0.0, 33.3
Cycle 7 Day 1				
n	1	16	5	22
Mean (StdDev)	33.33 (-)	12.50 (16.667)	0.00 (0.000)	10.61 (15.891)
Median	33.33	0.00	0.00	0.00
Min, Max	33.3, 33.3	0.0, 33.3	0.0, 0.0	0.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Constipation	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
Median		0.00	0.00	0.00
Min, Max		0.0, 0.0	0.0, 0.0	0.0, 0.0
Cycle 9 Day 1				
n	0	12	4	16
Mean (StdDev)		11.11 (16.412)	0.00 (0.000)	8.33 (14.907)
Median		0.00	0.00	0.00
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	0.00 (0.000)	0.00 (0.000)
Median		0.00	0.00	0.00
Min, Max		0.0, 0.0	0.0, 0.0	0.0, 0.0
Cycle 11 Day 1				
n	0	7	3	10
Mean (StdDev)		9.52 (16.265)	0.00 (0.000)	6.67 (14.055)
Median		0.00	0.00	0.00
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Constipation	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	0.00 (0.000)	0.00 (0.000)
Median		0.00	0.00	0.00
Min, Max		0.0, 0.0	0.0, 0.0	0.0, 0.0
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		11.11 (19.245)	0.00 (-)	8.33 (16.667)
Median		0.00	0.00	0.00
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Diarrhea	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Baseline				
n	4	28	12	44
Mean (StdDev)	25.00 (50.000)	39.29 (40.626)	50.00 (41.439)	40.91 (41.211)
Median	0.00	33.33	66.67	33.33
Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	21	7	32
Mean (StdDev)	16.67 (19.245)	15.87 (24.987)	38.10 (35.635)	20.83 (27.760)
Median	16.67	0.00	33.33	0.00
Min, Max	0.0, 33.3	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 2 Day 1				
n	2	28	11	41
Mean (StdDev)	0.00 (0.000)	16.67 (23.130)	33.33 (21.082)	20.33 (23.426)
Median	0.00	0.00	33.33	0.00
Min, Max	0.0, 0.0	0.0, 66.7	0.0, 66.7	0.0, 66.7
Cycle 3 Day 1				
n	4	25	9	38
Mean (StdDev)	8.33 (16.667)	16.00 (21.773)	29.63 (30.932)	18.42 (24.133)
Median	0.00	0.00	33.33	0.00
Min, Max	0.0, 33.3	0.0, 66.7	0.0, 66.7	0.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
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Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Diarrhea	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		41.67 (16.667)	25.00 (31.914)	33.33 (25.198)
Median		33.33	16.67	33.33
Min, Max		33.3, 66.7	0.0, 66.7	0.0, 66.7
Cycle 5 Day 1				
n	2	15	9	26
Mean (StdDev)	16.67 (23.570)	24.44 (34.427)	33.33 (28.868)	26.92 (31.297)
Median	16.67	0.00	33.33	16.67
Min, Max	0.0, 33.3	0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		44.44 (50.918)	33.33 (27.217)	38.10 (35.635)
Median		33.33	33.33	33.33
Min, Max		0.0, 100.0	0.0, 66.7	0.0, 100.0
Cycle 7 Day 1				
n	1	16	5	22
Mean (StdDev)	33.33 (-)	22.92 (26.440)	20.00 (18.257)	22.73 (23.874)
Median	33.33	16.67	33.33	33.33
Min, Max	33.3, 33.3	0.0, 66.7	0.0, 33.3	0.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas
Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Diarrhea	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		33.33 (0.000)	16.67 (23.570)	25.00 (16.667)
Median		33.33	16.67	33.33
Min, Max		33.3, 33.3	0.0, 33.3	0.0, 33.3
Cycle 9 Day 1				
n	0	12	4	16
Mean (StdDev)		16.67 (22.473)	41.67 (31.914)	22.92 (26.440)
Median		0.00	50.00	16.67
Min, Max		0.0, 66.7	0.0, 66.7	0.0, 66.7
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		33.33 (-)	83.33 (23.570)	66.67 (33.333)
Median		33.33	83.33	66.67
Min, Max		33.3, 33.3	66.7, 100.0	33.3, 100.0
Cycle 11 Day 1				
n	0	7	3	10
Mean (StdDev)		14.29 (17.817)	33.33 (33.333)	20.00 (23.307)
Median		0.00	33.33	16.67
Min, Max		0.0, 33.3	0.0, 66.7	0.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Diarrhea	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		33.33 (-)	50.00 (23.570)	44.44 (19.245)
Median		33.33	50.00	33.33
Min, Max		33.3, 33.3	33.3, 66.7	33.3, 66.7
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		0.00 (0.000)	0.00 (-)	0.00 (0.000)
Median		0.00	0.00	0.00
Min, Max		0.0, 0.0	0.0, 0.0	0.0, 0.0
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Financial Difficulties	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Baseline				
n	4	28	12	44
Mean (StdDev)	41.67 (31.914)	25.00 (32.235)	36.11 (38.817)	29.55 (33.884)
Median	50.00	0.00	33.33	33.33
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 1 Day 15				
n	4	21	7	32
Mean (StdDev)	25.00 (16.667)	20.63 (24.667)	4.76 (12.599)	17.71 (22.376)
Median	33.33	0.00	0.00	0.00
Min, Max	0.0, 33.3	0.0, 66.7	0.0, 33.3	0.0, 66.7
Cycle 2 Day 1				
n	2	28	11	41
Mean (StdDev)	16.67 (23.570)	19.05 (26.338)	27.27 (35.957)	21.14 (28.632)
Median	16.67	0.00	0.00	0.00
Min, Max	0.0, 33.3	0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 3 Day 1				
n	4	25	9	38
Mean (StdDev)	41.67 (16.667)	21.33 (25.240)	37.04 (35.136)	27.19 (27.786)
Median	33.33	0.00	33.33	33.33
Min, Max	33.3, 66.7	0.0, 66.7	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Financial Difficulties	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		25.00 (50.000)	50.00 (43.033)	37.50 (45.207)
Median		0.00	50.00	16.67
Min, Max		0.0, 100.0	0.0, 100.0	0.0, 100.0
Cycle 5 Day 1				
n	2	15	9	26
Mean (StdDev)	16.67 (23.570)	8.89 (15.258)	40.74 (43.390)	20.51 (31.379)
Median	16.67	0.00	33.33	0.00
Min, Max	0.0, 33.3	0.0, 33.3	0.0, 100.0	0.0, 100.0
Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		0.00 (0.000)	50.00 (33.333)	28.57 (35.635)
Median		0.00	33.33	33.33
Min, Max		0.0, 0.0	33.3, 100.0	0.0, 100.0
Cycle 7 Day 1				
n	1	16	5	22
Mean (StdDev)	33.33 (-)	12.50 (16.667)	33.33 (40.825)	18.18 (24.618)
Median	33.33	0.00	33.33	0.00
Min, Max	33.3, 33.3	0.0, 33.3	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Financial Difficulties	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		16.67 (23.570)	83.33 (23.570)	50.00 (43.033)
Median		16.67	83.33	50.00
Min, Max		0.0, 33.3	66.7, 100.0	0.0, 100.0
Cycle 9 Day 1				
n	0	12	4	16
Mean (StdDev)		22.22 (21.711)	41.67 (50.000)	27.08 (30.353)
Median		33.33	33.33	33.33
Min, Max		0.0, 66.7	0.0, 100.0	0.0, 100.0
Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	83.33 (23.570)	55.56 (50.918)
Median		0.00	83.33	66.67
Min, Max		0.0, 0.0	66.7, 100.0	0.0, 100.0
Cycle 11 Day 1				
n	0	7	3	10
Mean (StdDev)		28.57 (35.635)	55.56 (50.918)	36.67 (39.907)
Median		33.33	66.67	33.33
Min, Max		0.0, 100.0	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.1
Summary of Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Financial Difficulties	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	66.67 (47.140)	44.44 (50.918)
Median		0.00	66.67	33.33
Min, Max		0.0, 0.0	33.3, 100.0	0.0, 100.0
Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		22.22 (19.245)	0.00 (-)	16.67 (19.245)
Median		33.33	0.00	16.67
Min, Max		0.0, 33.3	0.0, 0.0	0.0, 33.3
Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual.sas Date: 15:40/29SEP2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Global Health Status/QoL	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Baseline				
n	4	15	6	25
Mean (StdDev)	45.83 (8.333)	43.89 (26.252)	36.11 (18.758)	42.33 (22.298)
Median	50.00	50.00	37.50	50.00
Min, Max	33.3, 50.0	0.0, 83.3	16.7, 58.3	0.0, 83.3
Change from Baseline to Cycle 2 Day 1				
n	3	13	5	21
Mean (StdDev)	0.00 (28.868)	16.67 (20.972)	15.00 (34.561)	13.89 (24.907)
Median	16.67	16.67	16.67	16.67
Min, Max	-33.3, 16.7	-8.3, 66.7	-33.3, 58.3	-33.3, 66.7
Change from Baseline to Cycle 3 Day 1				
n	3	13	5	21
Mean (StdDev)	-8.33 (22.048)	17.31 (24.641)	21.67 (24.008)	14.68 (24.987)
Median	0.00	16.67	33.33	8.33
Min, Max	-33.3, 8.3	-16.7, 66.7	-8.3, 41.7	-33.3, 66.7
Change from Baseline to Cycle 4 Day 1				
n	2	12	6	20
Mean (StdDev)	12.50 (29.463)	15.28 (31.549)	12.50 (30.619)	14.17 (29.506)
Median	12.50	20.83	20.83	20.83
Min, Max	-8.3, 33.3	-33.3, 66.7	-25.0, 41.7	-33.3, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Global Health Status/QoL	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Change from Baseline to Cycle 5 Day 1				
n	3	10	6	19
Mean (StdDev)	19.44 (12.729)	15.83 (27.902)	23.61 (18.572)	18.86 (22.710)
Median	16.67	20.83	33.33	25.00
Min, Max	8.3, 33.3	-25.0, 58.3	0.0, 41.7	-25.0, 58.3
Change from Baseline to Cycle 6 Day 1				
n	3	10	5	18
Mean (StdDev)	22.22 (9.623)	27.50 (32.643)	21.67 (20.917)	25.00 (26.197)
Median	16.67	33.33	16.67	25.00
Min, Max	16.7, 33.3	-25.0, 66.7	-8.3, 41.7	-25.0, 66.7
Change from Baseline to Cycle 7 Day 1				
n	3	8	5	16
Mean (StdDev)	8.33 (14.434)	36.46 (28.846)	15.00 (24.580)	24.48 (27.126)
Median	16.67	37.50	0.00	29.17
Min, Max	-8.3, 16.7	-25.0, 66.7	-8.3, 41.7	-25.0, 66.7
Change from Baseline to Cycle 8 Day 1				
n	2	9	4	15
Mean (StdDev)	16.67 (35.355)	34.26 (26.824)	12.50 (28.464)	26.11 (27.972)
Median	16.67	33.33	8.33	25.00
Min, Max	-8.3, 41.7	-16.7, 66.7	-16.7, 50.0	-16.7, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Global Health Status/QoL	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Change from Baseline to Cycle 9 Day 1				
n	3	7	4	14
Mean (StdDev)	8.33 (14.434)	48.81 (20.086)	-2.08 (45.325)	25.60 (35.875)
Median	16.67	50.00	-8.33	25.00
Min, Max	-8.3, 16.7	16.7, 75.0	-50.0, 58.3	-50.0, 75.0
Change from Baseline to Cycle 10 Day 1				
n	3	8	3	14
Mean (StdDev)	19.44 (9.623)	33.33 (24.801)	22.22 (41.944)	27.98 (25.655)
Median	25.00	41.67	16.67	25.00
Min, Max	8.3, 25.0	0.0, 58.3	-16.7, 66.7	-16.7, 66.7
Change from Baseline to Cycle 11 Day 1				
n	3	9	3	15
Mean (StdDev)	0.00 (25.000)	32.41 (25.154)	8.33 (30.046)	21.11 (28.148)
Median	0.00	41.67	0.00	25.00
Min, Max	-25.0, 25.0	-8.3, 58.3	-16.7, 41.7	-25.0, 58.3
Change from Baseline to Cycle 12 Day 1				
n	2	5	3	10
Mean (StdDev)	20.83 (17.678)	35.00 (16.029)	22.22 (34.694)	28.33 (21.588)
Median	20.83	33.33	33.33	33.33
Min, Max	8.3, 33.3	16.7, 58.3	-16.7, 50.0	-16.7, 58.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Physical Functioning	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Baseline				
n	4	15	6	25
Mean (StdDev)	78.33 (6.383)	50.67 (24.791)	61.11 (27.782)	57.60 (25.084)
Median	76.67	53.33	73.33	66.67
Min, Max	73.3, 86.7	0.0, 86.7	20.0, 86.7	0.0, 86.7
Change from Baseline to Cycle 2 Day 1				
n	3	13	5	21
Mean (StdDev)	-2.22 (10.184)	11.28 (22.008)	1.33 (10.954)	6.98 (18.912)
Median	0.00	6.67	6.67	6.67
Min, Max	-13.3, 6.7	-20.0, 73.3	-13.3, 13.3	-20.0, 73.3
Change from Baseline to Cycle 3 Day 1				
n	3	13	5	21
Mean (StdDev)	-6.67 (17.638)	10.26 (20.479)	10.67 (19.777)	7.94 (19.958)
Median	0.00	6.67	13.33	6.67
Min, Max	-26.7, 6.7	-26.7, 53.3	-20.0, 33.3	-26.7, 53.3
Change from Baseline to Cycle 4 Day 1				
n	2	12	6	20
Mean (StdDev)	-20.00 (9.428)	15.00 (20.326)	16.67 (22.998)	12.00 (22.436)
Median	-20.00	10.00	13.33	6.67
Min, Max	-26.7, -13.3	-6.7, 60.0	-6.7, 46.7	-26.7, 60.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Physical Functioning	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Change from Baseline to Cycle 5 Day 1				
n	3	10	6	19
Mean (StdDev)	-6.67 (13.333)	12.67 (16.763)	12.22 (24.736)	9.47 (19.540)
Median	-6.67	13.33	13.33	13.33
Min, Max	-20.0, 6.7	-6.7, 40.0	-13.3, 53.3	-20.0, 53.3
Change from Baseline to Cycle 6 Day 1				
n	3	10	5	18
Mean (StdDev)	-11.11 (13.878)	16.67 (21.140)	-1.33 (15.202)	7.04 (21.140)
Median	-6.67	16.67	0.00	13.33
Min, Max	-26.7, 0.0	-20.0, 46.7	-20.0, 13.3	-26.7, 46.7
Change from Baseline to Cycle 7 Day 1				
n	3	8	5	16
Mean (StdDev)	4.44 (10.184)	19.17 (19.660)	5.33 (29.590)	12.08 (21.938)
Median	6.67	20.00	-6.67	13.33
Min, Max	-6.7, 13.3	-20.0, 46.7	-20.0, 53.3	-20.0, 53.3
Change from Baseline to Cycle 8 Day 1				
n	2	9	4	15
Mean (StdDev)	0.00 (9.428)	22.96 (18.889)	11.67 (34.588)	16.89 (23.213)
Median	0.00	20.00	0.00	13.33
Min, Max	-6.7, 6.7	-13.3, 53.3	-13.3, 60.0	-13.3, 60.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Physical Functioning	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Change from Baseline to Cycle 9 Day 1				
n	3	7	4	14
Mean (StdDev)	-8.89 (23.413)	32.38 (14.620)	6.67 (35.277)	16.19 (28.007)
Median	-6.67	33.33	0.00	16.67
Min, Max	-33.3, 13.3	13.3, 46.7	-26.7, 53.3	-33.3, 53.3
Change from Baseline to Cycle 10 Day 1				
n	3	8	3	14
Mean (StdDev)	-4.44 (10.184)	20.00 (21.082)	20.00 (37.118)	14.76 (23.991)
Median	-6.67	16.67	13.33	13.33
Min, Max	-13.3, 6.7	-6.7, 46.7	-13.3, 60.0	-13.3, 60.0
Change from Baseline to Cycle 11 Day 1				
n	3	9	3	15
Mean (StdDev)	-6.67 (11.547)	28.15 (22.798)	15.56 (36.717)	18.67 (26.571)
Median	-13.33	20.00	13.33	20.00
Min, Max	-13.3, 6.7	-13.3, 60.0	-20.0, 53.3	-20.0, 60.0
Change from Baseline to Cycle 12 Day 1				
n	2	5	3	10
Mean (StdDev)	-10.00 (4.714)	30.67 (19.206)	15.56 (36.717)	18.00 (27.044)
Median	-10.00	26.67	13.33	16.67
Min, Max	-13.3, -6.7	6.7, 53.3	-20.0, 53.3	-20.0, 53.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Role Functioning	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Baseline				
n	4	15	6	25
Mean (StdDev)	58.33 (21.517)	41.11 (25.871)	33.33 (36.515)	42.00 (28.104)
Median	58.33	33.33	33.33	50.00
Min, Max	33.3, 83.3	0.0, 83.3	0.0, 66.7	0.0, 83.3
Change from Baseline to Cycle 2 Day 1				
n	3	13	5	21
Mean (StdDev)	-11.11 (34.694)	16.67 (18.002)	23.33 (36.515)	14.29 (26.502)
Median	0.00	16.67	0.00	16.67
Min, Max	-50.0, 16.7	-16.7, 50.0	0.0, 83.3	-50.0, 83.3
Change from Baseline to Cycle 3 Day 1				
n	3	13	5	21
Mean (StdDev)	-11.11 (34.694)	15.38 (18.586)	23.33 (27.889)	13.49 (24.506)
Median	0.00	16.67	16.67	16.67
Min, Max	-50.0, 16.7	-16.7, 50.0	0.0, 66.7	-50.0, 66.7
Change from Baseline to Cycle 4 Day 1				
n	2	12	6	20
Mean (StdDev)	-25.00 (11.785)	13.89 (26.432)	33.33 (47.140)	15.83 (35.654)
Median	-25.00	16.67	33.33	16.67
Min, Max	-33.3, -16.7	-33.3, 66.7	-33.3, 100.0	-33.3, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Role Functioning	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Change from Baseline to Cycle 5 Day 1				
n	3	10	6	19
Mean (StdDev)	-5.56 (25.459)	15.00 (32.820)	19.44 (37.143)	13.16 (32.669)
Median	0.00	16.67	16.67	16.67
Min, Max	-33.3, 16.7	-33.3, 66.7	-33.3, 66.7	-33.3, 66.7
Change from Baseline to Cycle 6 Day 1				
n	3	10	5	18
Mean (StdDev)	5.56 (19.245)	8.33 (30.682)	20.00 (29.814)	11.11 (28.006)
Median	16.67	0.00	0.00	0.00
Min, Max	-16.7, 16.7	-33.3, 66.7	0.0, 66.7	-33.3, 66.7
Change from Baseline to Cycle 7 Day 1				
n	3	8	5	16
Mean (StdDev)	11.11 (25.459)	20.83 (33.034)	23.33 (27.889)	19.79 (28.687)
Median	16.67	16.67	16.67	16.67
Min, Max	-16.7, 33.3	-33.3, 83.3	0.0, 66.7	-33.3, 83.3
Change from Baseline to Cycle 8 Day 1				
n	2	9	4	15
Mean (StdDev)	8.33 (11.785)	29.63 (24.689)	8.33 (56.928)	21.11 (34.195)
Median	8.33	33.33	16.67	33.33
Min, Max	0.0, 16.7	0.0, 83.3	-66.7, 66.7	-66.7, 83.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Role Functioning	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Change from Baseline to Cycle 9 Day 1				
n	3	7	4	14
Mean (StdDev)	0.00 (28.868)	35.71 (17.817)	-8.33 (41.944)	15.48 (33.630)
Median	16.67	33.33	0.00	16.67
Min, Max	-33.3, 16.7	16.7, 66.7	-66.7, 33.3	-66.7, 66.7
Change from Baseline to Cycle 10 Day 1				
n	3	8	3	14
Mean (StdDev)	0.00 (16.667)	22.92 (36.664)	33.33 (33.333)	20.24 (32.803)
Median	0.00	25.00	33.33	16.67
Min, Max	-16.7, 16.7	-33.3, 83.3	0.0, 66.7	-33.3, 83.3
Change from Baseline to Cycle 11 Day 1				
n	3	9	3	15
Mean (StdDev)	0.00 (16.667)	25.93 (35.464)	33.33 (33.333)	22.22 (32.530)
Median	0.00	33.33	33.33	16.67
Min, Max	-16.7, 16.7	-33.3, 100.0	0.0, 66.7	-33.3, 100.0
Change from Baseline to Cycle 12 Day 1				
n	2	5	3	10
Mean (StdDev)	-16.67 (23.570)	46.67 (32.059)	27.78 (25.459)	28.33 (36.047)
Median	-16.67	33.33	33.33	33.33
Min, Max	-33.3, 0.0	16.7, 100.0	0.0, 50.0	-33.3, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Emotional Functioning	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Baseline				
n	4	15	6	25
Mean (StdDev)	68.75 (32.185)	66.67 (25.198)	65.28 (26.043)	66.67 (25.345)
Median	70.83	66.67	75.00	75.00
Min, Max	33.3, 100.0	25.0, 100.0	25.0, 91.7	25.0, 100.0
Change from Baseline to Cycle 2 Day 1				
n	3	13	5	21
Mean (StdDev)	5.56 (12.729)	3.85 (21.413)	10.00 (17.078)	5.56 (18.881)
Median	8.33	0.00	16.67	0.00
Min, Max	-8.3, 16.7	-25.0, 58.3	-8.3, 25.0	-25.0, 58.3
Change from Baseline to Cycle 3 Day 1				
n	3	13	5	21
Mean (StdDev)	-2.78 (17.347)	9.19 (21.014)	15.00 (21.570)	8.86 (20.443)
Median	-8.33	0.00	8.33	0.00
Min, Max	-16.7, 16.7	-16.7, 52.8	-8.3, 41.7	-16.7, 52.8
Change from Baseline to Cycle 4 Day 1				
n	2	12	6	20
Mean (StdDev)	12.50 (41.248)	9.03 (19.611)	11.11 (17.213)	10.00 (19.794)
Median	12.50	0.00	8.33	8.33
Min, Max	-16.7, 41.7	-8.3, 58.3	-16.7, 33.3	-16.7, 58.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Emotional Functioning	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Change from Baseline to Cycle 5 Day 1				
n	3	10	6	19
Mean (StdDev)	8.33 (16.667)	-2.50 (20.050)	6.94 (23.224)	2.19 (20.192)
Median	8.33	0.00	4.17	0.00
Min, Max	-8.3, 25.0	-33.3, 25.0	-16.7, 41.7	-33.3, 41.7
Change from Baseline to Cycle 6 Day 1				
n	3	10	5	18
Mean (StdDev)	8.33 (8.333)	10.00 (30.631)	-3.33 (21.731)	6.02 (25.534)
Median	8.33	4.17	-8.33	4.17
Min, Max	0.0, 16.7	-33.3, 75.0	-33.3, 25.0	-33.3, 75.0
Change from Baseline to Cycle 7 Day 1				
n	3	8	5	16
Mean (StdDev)	2.78 (17.347)	13.54 (27.795)	-3.33 (40.225)	6.25 (29.892)
Median	8.33	4.17	0.00	4.17
Min, Max	-16.7, 16.7	-25.0, 66.7	-66.7, 41.7	-66.7, 66.7
Change from Baseline to Cycle 8 Day 1				
n	2	9	4	15
Mean (StdDev)	4.17 (17.678)	13.27 (17.666)	-10.42 (38.715)	5.74 (25.164)
Median	4.17	8.33	-16.67	8.33
Min, Max	-8.3, 16.7	-8.3, 50.0	-50.0, 41.7	-50.0, 50.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Emotional Functioning	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Change from Baseline to Cycle 9 Day 1				
n	3	7	4	14
Mean (StdDev)	11.11 (17.347)	17.86 (17.631)	-10.42 (41.597)	8.33 (27.347)
Median	16.67	16.67	-12.50	16.67
Min, Max	-8.3, 25.0	0.0, 50.0	-50.0, 33.3	-50.0, 50.0
Change from Baseline to Cycle 10 Day 1				
n	3	8	3	14
Mean (StdDev)	8.33 (8.333)	13.54 (25.173)	-16.67 (50.690)	5.95 (30.034)
Median	8.33	8.33	-41.67	8.33
Min, Max	0.0, 16.7	-8.3, 66.7	-50.0, 41.7	-50.0, 66.7
Change from Baseline to Cycle 11 Day 1				
n	3	9	3	15
Mean (StdDev)	-2.78 (24.056)	16.67 (22.822)	-8.33 (50.690)	7.78 (29.625)
Median	-16.67	8.33	-33.33	8.33
Min, Max	-16.7, 25.0	-8.3, 66.7	-41.7, 50.0	-41.7, 66.7
Change from Baseline to Cycle 12 Day 1				
n	2	5	3	10
Mean (StdDev)	8.33 (11.785)	16.67 (11.785)	-19.44 (66.840)	4.17 (36.694)
Median	8.33	25.00	-25.00	12.50
Min, Max	0.0, 16.7	0.0, 25.0	-83.3, 50.0	-83.3, 50.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Cognitive Functioning	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Baseline				
n	4	15	6	25
Mean (StdDev)	70.83 (28.464)	64.44 (32.038)	72.22 (20.184)	67.33 (28.252)
Median	75.00	66.67	75.00	66.67
Min, Max	33.3, 100.0	0.0, 100.0	50.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 2 Day 1				
n	3	13	5	21
Mean (StdDev)	-22.22 (58.531)	0.00 (22.567)	10.00 (19.003)	-0.79 (28.614)
Median	-16.67	0.00	16.67	0.00
Min, Max	-83.3, 33.3	-33.3, 50.0	-16.7, 33.3	-83.3, 50.0
Change from Baseline to Cycle 3 Day 1				
n	3	13	5	21
Mean (StdDev)	-16.67 (50.000)	2.56 (24.387)	6.67 (14.907)	0.79 (26.602)
Median	-16.67	0.00	16.67	0.00
Min, Max	-66.7, 33.3	-50.0, 50.0	-16.7, 16.7	-66.7, 50.0
Change from Baseline to Cycle 4 Day 1				
n	2	12	6	20
Mean (StdDev)	16.67 (23.570)	2.78 (23.391)	5.56 (13.608)	5.00 (20.305)
Median	16.67	0.00	8.33	0.00
Min, Max	0.0, 33.3	-33.3, 50.0	-16.7, 16.7	-33.3, 50.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Cognitive Functioning	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Change from Baseline to Cycle 5 Day 1				
n	3	10	6	19
Mean (StdDev)	-11.11 (19.245)	-1.67 (19.954)	-5.56 (22.771)	-4.39 (19.909)
Median	0.00	0.00	0.00	0.00
Min, Max	-33.3, 0.0	-33.3, 33.3	-33.3, 16.7	-33.3, 33.3
Change from Baseline to Cycle 6 Day 1				
n	3	10	5	18
Mean (StdDev)	-16.67 (44.096)	16.67 (17.568)	6.67 (14.907)	8.33 (24.421)
Median	0.00	16.67	16.67	16.67
Min, Max	-66.7, 16.7	0.0, 50.0	-16.7, 16.7	-66.7, 50.0
Change from Baseline to Cycle 7 Day 1				
n	3	8	5	16
Mean (StdDev)	-22.22 (34.694)	12.50 (24.801)	-6.67 (19.003)	0.00 (27.217)
Median	-33.33	0.00	0.00	0.00
Min, Max	-50.0, 16.7	-16.7, 50.0	-33.3, 16.7	-50.0, 50.0
Change from Baseline to Cycle 8 Day 1				
n	2	9	4	15
Mean (StdDev)	0.00 (47.140)	14.81 (21.155)	-4.17 (15.957)	7.78 (23.458)
Median	0.00	16.67	-8.33	0.00
Min, Max	-33.3, 33.3	-16.7, 50.0	-16.7, 16.7	-33.3, 50.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Cognitive Functioning	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Change from Baseline to Cycle 9 Day 1				
n	3	7	4	14
Mean (StdDev)	-22.22 (34.694)	16.67 (28.868)	0.00 (13.608)	3.57 (29.365)
Median	-33.33	16.67	0.00	0.00
Min, Max	-50.0, 16.7	-16.7, 50.0	-16.7, 16.7	-50.0, 50.0
Change from Baseline to Cycle 10 Day 1				
n	3	8	3	14
Mean (StdDev)	-33.33 (16.667)	12.50 (23.146)	-11.11 (34.694)	-2.38 (29.855)
Median	-33.33	16.67	0.00	0.00
Min, Max	-50.0, -16.7	-16.7, 50.0	-50.0, 16.7	-50.0, 50.0
Change from Baseline to Cycle 11 Day 1				
n	3	9	3	15
Mean (StdDev)	-16.67 (28.868)	12.96 (18.215)	-11.11 (19.245)	2.22 (23.458)
Median	-33.33	16.67	0.00	0.00
Min, Max	-33.3, 16.7	-16.7, 33.3	-33.3, 0.0	-33.3, 33.3
Change from Baseline to Cycle 12 Day 1				
n	2	5	3	10
Mean (StdDev)	-16.67 (47.140)	6.67 (19.003)	-16.67 (44.096)	-5.00 (31.476)
Median	-16.67	0.00	0.00	0.00
Min, Max	-50.0, 16.7	-16.7, 33.3	-66.7, 16.7	-66.7, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Social Function	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Baseline				
n	4	15	6	25
Mean (StdDev)	66.67 (30.429)	50.00 (28.868)	50.00 (40.825)	52.67 (31.432)
Median	66.67	50.00	66.67	50.00
Min, Max	33.3, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 2 Day 1				
n	3	13	5	21
Mean (StdDev)	-11.11 (34.694)	11.54 (27.542)	3.33 (29.814)	6.35 (28.614)
Median	0.00	16.67	0.00	16.67
Min, Max	-50.0, 16.7	-33.3, 66.7	-33.3, 33.3	-50.0, 66.7
Change from Baseline to Cycle 3 Day 1				
n	3	13	5	21
Mean (StdDev)	-11.11 (41.944)	10.26 (16.013)	20.00 (21.731)	9.52 (22.713)
Median	-16.67	0.00	16.67	0.00
Min, Max	-50.0, 33.3	-16.7, 33.3	0.0, 50.0	-50.0, 50.0
Change from Baseline to Cycle 4 Day 1				
n	2	12	6	20
Mean (StdDev)	8.33 (11.785)	15.28 (20.669)	8.33 (20.412)	12.50 (19.403)
Median	8.33	16.67	0.00	8.33
Min, Max	0.0, 16.7	-16.7, 50.0	-16.7, 33.3	-16.7, 50.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Social Function	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Change from Baseline to Cycle 5 Day 1				
n	3	10	6	19
Mean (StdDev)	-27.78 (34.694)	15.00 (16.574)	13.89 (30.581)	7.89 (27.982)
Median	-16.67	16.67	0.00	0.00
Min, Max	-66.7, 0.0	-16.7, 33.3	-16.7, 66.7	-66.7, 66.7
Change from Baseline to Cycle 6 Day 1				
n	3	10	5	18
Mean (StdDev)	-11.11 (9.623)	18.33 (34.650)	0.00 (42.492)	8.33 (34.890)
Median	-16.67	25.00	0.00	0.00
Min, Max	-16.7, 0.0	-33.3, 66.7	-50.0, 66.7	-50.0, 66.7
Change from Baseline to Cycle 7 Day 1				
n	3	8	5	16
Mean (StdDev)	-16.67 (33.333)	14.58 (31.418)	16.67 (39.087)	9.38 (34.410)
Median	-16.67	16.67	0.00	8.33
Min, Max	-50.0, 16.7	-33.3, 66.7	-16.7, 83.3	-50.0, 83.3
Change from Baseline to Cycle 8 Day 1				
n	2	9	4	15
Mean (StdDev)	-8.33 (11.785)	16.67 (20.412)	-16.67 (43.033)	4.44 (29.859)
Median	-8.33	16.67	-16.67	0.00
Min, Max	-16.7, 0.0	-16.7, 50.0	-66.7, 33.3	-66.7, 50.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Social Function	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Change from Baseline to Cycle 9 Day 1				
n	3	7	4	14
Mean (StdDev)	-16.67 (0.000)	23.81 (26.972)	8.33 (70.053)	10.71 (41.658)
Median	-16.67	33.33	0.00	8.33
Min, Max	-16.7, -16.7	-16.7, 66.7	-66.7, 100.0	-66.7, 100.0
Change from Baseline to Cycle 10 Day 1				
n	3	8	3	14
Mean (StdDev)	-11.11 (19.245)	22.92 (33.259)	-11.11 (83.887)	8.33 (45.173)
Median	0.00	25.00	0.00	0.00
Min, Max	-33.3, 0.0	-16.7, 66.7	-100.0, 66.7	-100.0, 66.7
Change from Baseline to Cycle 11 Day 1				
n	3	9	3	15
Mean (StdDev)	-27.78 (34.694)	25.93 (27.778)	0.00 (76.376)	10.00 (44.006)
Median	-16.67	33.33	16.67	16.67
Min, Max	-66.7, 0.0	-16.7, 66.7	-83.3, 66.7	-83.3, 66.7
Change from Baseline to Cycle 12 Day 1				
n	2	5	3	10
Mean (StdDev)	16.67 (47.140)	36.67 (18.257)	-5.56 (75.154)	20.00 (44.997)
Median	16.67	33.33	0.00	33.33
Min, Max	-16.7, 50.0	16.7, 66.7	-83.3, 66.7	-83.3, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Fatigue	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Baseline				
n	4	15	6	25
Mean (StdDev)	63.89 (27.778)	68.15 (25.499)	70.37 (29.537)	68.00 (25.724)
Median	61.11	66.67	72.22	66.67
Min, Max	33.3, 100.0	11.1, 100.0	33.3, 100.0	11.1, 100.0
Change from Baseline to Cycle 2 Day 1				
n	3	13	5	21
Mean (StdDev)	7.41 (27.962)	-15.38 (20.557)	-11.11 (31.427)	-11.11 (24.343)
Median	11.11	-11.11	0.00	0.00
Min, Max	-22.2, 33.3	-66.7, 11.1	-66.7, 11.1	-66.7, 33.3
Change from Baseline to Cycle 3 Day 1				
n	3	13	5	21
Mean (StdDev)	3.70 (33.945)	-17.09 (19.038)	-15.56 (25.580)	-13.76 (22.745)
Median	11.11	-11.11	-11.11	-11.11
Min, Max	-33.3, 33.3	-44.4, 11.1	-55.6, 11.1	-55.6, 33.3
Change from Baseline to Cycle 4 Day 1				
n	2	12	6	20
Mean (StdDev)	0.00 (47.140)	-14.81 (21.883)	-22.22 (36.515)	-15.56 (28.017)
Median	0.00	-22.22	-11.11	-22.22
Min, Max	-33.3, 33.3	-44.4, 22.2	-66.7, 22.2	-66.7, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Fatigue	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Change from Baseline to Cycle 5 Day 1				
n	3	10	6	19
Mean (StdDev)	-3.70 (27.962)	-17.78 (30.180)	-24.07 (29.327)	-17.54 (28.764)
Median	0.00	-27.78	-22.22	-22.22
Min, Max	-33.3, 22.2	-55.6, 55.6	-66.7, 11.1	-66.7, 55.6
Change from Baseline to Cycle 6 Day 1				
n	3	10	5	18
Mean (StdDev)	-7.41 (12.830)	-24.44 (31.340)	-6.67 (30.021)	-16.67 (28.836)
Median	0.00	-33.33	0.00	-16.67
Min, Max	-22.2, 0.0	-55.6, 44.4	-55.6, 22.2	-55.6, 44.4
Change from Baseline to Cycle 7 Day 1				
n	3	8	5	16
Mean (StdDev)	-3.70 (6.415)	-35.42 (24.834)	-11.11 (20.787)	-21.88 (24.718)
Median	0.00	-41.67	-11.11	-22.22
Min, Max	-11.1, 0.0	-55.6, 22.2	-44.4, 11.1	-55.6, 22.2
Change from Baseline to Cycle 8 Day 1				
n	2	9	4	15
Mean (StdDev)	0.00 (15.713)	-39.51 (20.116)	-2.78 (22.906)	-24.44 (26.956)
Median	0.00	-44.44	0.00	-33.33
Min, Max	-11.1, 11.1	-66.7, 0.0	-33.3, 22.2	-66.7, 22.2

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Fatigue	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Change from Baseline to Cycle 9 Day 1				
n	3	7	4	14
Mean (StdDev)	-7.41 (6.415)	-57.14 (17.484)	-2.78 (34.397)	-30.95 (34.088)
Median	-11.11	-55.56	-11.11	-33.33
Min, Max	-11.1, 0.0	-77.8, -33.3	-33.3, 44.4	-77.8, 44.4
Change from Baseline to Cycle 10 Day 1				
n	3	8	3	14
Mean (StdDev)	14.81 (6.415)	-37.50 (22.954)	-22.22 (29.397)	-23.02 (29.707)
Median	11.11	-38.89	-11.11	-22.22
Min, Max	11.1, 22.2	-66.7, 0.0	-55.6, 0.0	-66.7, 22.2
Change from Baseline to Cycle 11 Day 1				
n	3	9	3	15
Mean (StdDev)	3.70 (6.415)	-40.74 (22.222)	-18.52 (32.075)	-27.41 (27.815)
Median	0.00	-44.44	0.00	-33.33
Min, Max	0.0, 11.1	-77.8, -11.1	-55.6, 0.0	-77.8, 11.1
Change from Baseline to Cycle 12 Day 1				
n	2	5	3	10
Mean (StdDev)	0.00 (0.000)	-53.33 (18.257)	-25.93 (35.717)	-34.44 (30.293)
Median	0.00	-44.44	-11.11	-38.89
Min, Max	0.0, 0.0	-77.8, -33.3	-66.7, 0.0	-77.8, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Nausea and Vomiting	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Baseline				
n	4	15	6	25
Mean (StdDev)	50.00 (30.429)	17.78 (23.117)	16.67 (25.820)	22.67 (26.736)
Median	50.00	0.00	8.33	16.67
Min, Max	16.7, 83.3	0.0, 66.7	0.0, 66.7	0.0, 83.3
Change from Baseline to Cycle 2 Day 1				
n	3	13	5	21
Mean (StdDev)	-5.56 (41.944)	-1.28 (24.019)	3.33 (7.454)	-0.79 (23.260)
Median	0.00	0.00	0.00	0.00
Min, Max	-50.0, 33.3	-50.0, 33.3	0.0, 16.7	-50.0, 33.3
Change from Baseline to Cycle 3 Day 1				
n	3	13	5	21
Mean (StdDev)	-5.56 (41.944)	1.28 (24.019)	-3.33 (18.257)	-0.79 (24.425)
Median	0.00	0.00	0.00	0.00
Min, Max	-50.0, 33.3	-50.0, 50.0	-33.3, 16.7	-50.0, 50.0
Change from Baseline to Cycle 4 Day 1				
n	2	12	6	20
Mean (StdDev)	-41.67 (58.926)	4.17 (20.257)	-8.33 (17.480)	-4.17 (26.422)
Median	-41.67	0.00	-8.33	0.00
Min, Max	-83.3, 0.0	-33.3, 33.3	-33.3, 16.7	-83.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Nausea and Vomiting	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Change from Baseline to Cycle 5 Day 1				
n	3	10	6	19
Mean (StdDev)	-11.11 (34.694)	-3.33 (21.943)	-5.56 (17.213)	-5.26 (21.554)
Median	0.00	0.00	0.00	0.00
Min, Max	-50.0, 16.7	-50.0, 33.3	-33.3, 16.7	-50.0, 33.3
Change from Baseline to Cycle 6 Day 1				
n	3	10	5	18
Mean (StdDev)	-27.78 (48.113)	-8.33 (19.642)	-3.33 (13.944)	-10.19 (24.347)
Median	0.00	-8.33	0.00	0.00
Min, Max	-83.3, 0.0	-50.0, 16.7	-16.7, 16.7	-83.3, 16.7
Change from Baseline to Cycle 7 Day 1				
n	3	8	5	16
Mean (StdDev)	-11.11 (34.694)	-8.33 (17.817)	-10.00 (25.276)	-9.38 (21.916)
Median	0.00	0.00	0.00	0.00
Min, Max	-50.0, 16.7	-33.3, 16.7	-50.0, 16.7	-50.0, 16.7
Change from Baseline to Cycle 8 Day 1				
n	2	9	4	15
Mean (StdDev)	-25.00 (35.355)	-16.67 (18.634)	-16.67 (23.570)	-17.78 (20.380)
Median	-25.00	-16.67	-8.33	-16.67
Min, Max	-50.0, 0.0	-50.0, 0.0	-50.0, 0.0	-50.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Nausea and Vomiting	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Change from Baseline to Cycle 9 Day 1				
n	3	7	4	14
Mean (StdDev)	-11.11 (34.694)	-11.90 (12.599)	-12.50 (28.464)	-11.90 (21.111)
Median	0.00	-16.67	-8.33	-8.33
Min, Max	-50.0, 16.7	-33.3, 0.0	-50.0, 16.7	-50.0, 16.7
Change from Baseline to Cycle 10 Day 1				
n	3	8	3	14
Mean (StdDev)	-11.11 (41.944)	-10.42 (12.400)	-22.22 (25.459)	-13.10 (21.857)
Median	-16.67	-8.33	-16.67	-16.67
Min, Max	-50.0, 33.3	-33.3, 0.0	-50.0, 0.0	-50.0, 33.3
Change from Baseline to Cycle 11 Day 1				
n	3	9	3	15
Mean (StdDev)	-22.22 (25.459)	-16.67 (18.634)	-27.78 (19.245)	-20.00 (19.107)
Median	-16.67	-16.67	-16.67	-16.67
Min, Max	-50.0, 0.0	-50.0, 0.0	-50.0, -16.7	-50.0, 0.0
Change from Baseline to Cycle 12 Day 1				
n	2	5	3	10
Mean (StdDev)	-8.33 (35.355)	-6.67 (9.129)	-16.67 (16.667)	-10.00 (16.102)
Median	-8.33	0.00	-16.67	-8.33
Min, Max	-33.3, 16.7	-16.7, 0.0	-33.3, 0.0	-33.3, 16.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Pain	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Baseline				
n	4	15	6	25
Mean (StdDev)	58.33 (31.914)	43.33 (33.806)	50.00 (45.947)	47.33 (35.577)
Median	66.67	33.33	50.00	50.00
Min, Max	16.7, 83.3	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 2 Day 1				
n	3	13	5	21
Mean (StdDev)	-11.11 (9.623)	-15.38 (23.035)	-16.67 (48.591)	-15.08 (28.336)
Median	-16.67	0.00	-16.67	-16.67
Min, Max	-16.7, 0.0	-50.0, 16.7	-83.3, 50.0	-83.3, 50.0
Change from Baseline to Cycle 3 Day 1				
n	3	13	5	21
Mean (StdDev)	-11.11 (19.245)	-15.38 (27.606)	-13.33 (43.141)	-14.29 (29.480)
Median	0.00	0.00	-16.67	0.00
Min, Max	-33.3, 0.0	-66.7, 33.3	-66.7, 50.0	-66.7, 50.0
Change from Baseline to Cycle 4 Day 1				
n	2	12	6	20
Mean (StdDev)	0.00 (0.000)	-23.61 (27.023)	-5.56 (62.063)	-15.83 (39.171)
Median	0.00	-16.67	-16.67	-16.67
Min, Max	0.0, 0.0	-83.3, 0.0	-83.3, 83.3	-83.3, 83.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Pain	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Change from Baseline to Cycle 5 Day 1				
n	3	10	6	19
Mean (StdDev)	0.00 (16.667)	-21.67 (27.273)	-27.78 (60.246)	-20.18 (38.721)
Median	0.00	-16.67	-25.00	-16.67
Min, Max	-16.7, 16.7	-66.7, 16.7	-100.0, 66.7	-100.0, 66.7
Change from Baseline to Cycle 6 Day 1				
n	3	10	5	18
Mean (StdDev)	-11.11 (19.245)	-26.67 (17.916)	-6.67 (48.016)	-18.52 (29.087)
Median	0.00	-33.33	0.00	-16.67
Min, Max	-33.3, 0.0	-50.0, 0.0	-83.3, 50.0	-83.3, 50.0
Change from Baseline to Cycle 7 Day 1				
n	3	8	5	16
Mean (StdDev)	-11.11 (25.459)	-20.83 (19.416)	0.00 (31.180)	-12.50 (24.721)
Median	-16.67	-16.67	0.00	-16.67
Min, Max	-33.3, 16.7	-50.0, 16.7	-33.3, 50.0	-50.0, 50.0
Change from Baseline to Cycle 8 Day 1				
n	2	9	4	15
Mean (StdDev)	8.33 (11.785)	-31.48 (21.155)	16.67 (65.263)	-13.33 (41.404)
Median	8.33	-33.33	8.33	-16.67
Min, Max	0.0, 16.7	-66.7, 0.0	-50.0, 100.0	-66.7, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Pain	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Change from Baseline to Cycle 9 Day 1				
n	3	7	4	14
Mean (StdDev)	-16.67 (16.667)	-40.48 (16.265)	20.83 (36.956)	-17.86 (34.877)
Median	-16.67	-33.33	16.67	-25.00
Min, Max	-33.3, 0.0	-66.7, -16.7	-16.7, 66.7	-66.7, 66.7
Change from Baseline to Cycle 10 Day 1				
n	3	8	3	14
Mean (StdDev)	-27.78 (19.245)	-27.08 (33.259)	-11.11 (41.944)	-23.81 (31.156)
Median	-16.67	-16.67	-16.67	-16.67
Min, Max	-50.0, -16.7	-66.7, 33.3	-50.0, 33.3	-66.7, 33.3
Change from Baseline to Cycle 11 Day 1				
n	3	9	3	15
Mean (StdDev)	-5.56 (9.623)	-37.04 (29.788)	-16.67 (50.000)	-26.67 (32.611)
Median	0.00	-33.33	-16.67	-16.67
Min, Max	-16.7, 0.0	-83.3, 0.0	-66.7, 33.3	-83.3, 33.3
Change from Baseline to Cycle 12 Day 1				
n	2	5	3	10
Mean (StdDev)	-25.00 (11.785)	-46.67 (13.944)	-22.22 (50.918)	-35.00 (28.814)
Median	-25.00	-50.00	-33.33	-33.33
Min, Max	-33.3, -16.7	-66.7, -33.3	-66.7, 33.3	-66.7, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Dyspnea	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Baseline				
n	4	15	6	25
Mean (StdDev)	41.67 (16.667)	48.89 (33.014)	44.44 (34.427)	46.67 (30.429)
Median	33.33	33.33	33.33	33.33
Min, Max	33.3, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 2 Day 1				
n	3	13	5	21
Mean (StdDev)	11.11 (50.918)	-23.08 (34.385)	-6.67 (14.907)	-14.29 (34.272)
Median	0.00	-33.33	0.00	0.00
Min, Max	-33.3, 66.7	-100.0, 33.3	-33.3, 0.0	-100.0, 66.7
Change from Baseline to Cycle 3 Day 1				
n	3	13	5	21
Mean (StdDev)	22.22 (50.918)	-12.82 (39.764)	-20.00 (29.814)	-9.52 (39.641)
Median	33.33	0.00	0.00	0.00
Min, Max	-33.3, 66.7	-100.0, 33.3	-66.7, 0.0	-100.0, 66.7
Change from Baseline to Cycle 4 Day 1				
n	2	12	6	20
Mean (StdDev)	0.00 (47.140)	-19.44 (26.432)	-11.11 (34.427)	-15.00 (29.568)
Median	0.00	0.00	0.00	0.00
Min, Max	-33.3, 33.3	-66.7, 0.0	-66.7, 33.3	-66.7, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Dyspnea	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Change from Baseline to Cycle 5 Day 1				
n	3	10	6	19
Mean (StdDev)	0.00 (33.333)	-10.00 (41.722)	-11.11 (34.427)	-8.77 (36.586)
Median	0.00	0.00	0.00	0.00
Min, Max	-33.3, 33.3	-100.0, 33.3	-66.7, 33.3	-100.0, 33.3
Change from Baseline to Cycle 6 Day 1				
n	3	10	5	18
Mean (StdDev)	-11.11 (19.245)	-23.33 (31.623)	0.00 (40.825)	-14.81 (32.784)
Median	0.00	-33.33	0.00	0.00
Min, Max	-33.3, 0.0	-66.7, 33.3	-66.7, 33.3	-66.7, 33.3
Change from Baseline to Cycle 7 Day 1				
n	3	8	5	16
Mean (StdDev)	-11.11 (19.245)	-29.17 (41.547)	-13.33 (38.006)	-20.83 (36.260)
Median	0.00	-33.33	0.00	-16.67
Min, Max	-33.3, 0.0	-100.0, 33.3	-66.7, 33.3	-100.0, 33.3
Change from Baseline to Cycle 8 Day 1				
n	2	9	4	15
Mean (StdDev)	-16.67 (23.570)	-37.04 (42.310)	-16.67 (43.033)	-28.89 (39.574)
Median	-16.67	-33.33	-16.67	-33.33
Min, Max	-33.3, 0.0	-100.0, 0.0	-66.7, 33.3	-100.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Dyspnea	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Change from Baseline to Cycle 9 Day 1				
n	3	7	4	14
Mean (StdDev)	11.11 (19.245)	-52.38 (37.796)	0.00 (47.140)	-23.81 (46.093)
Median	0.00	-33.33	16.67	-16.67
Min, Max	0.0, 33.3	-100.0, 0.0	-66.7, 33.3	-100.0, 33.3
Change from Baseline to Cycle 10 Day 1				
n	3	8	3	14
Mean (StdDev)	11.11 (19.245)	-20.83 (35.355)	-22.22 (38.490)	-14.29 (33.878)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 33.3	-100.0, 0.0	-66.7, 0.0	-100.0, 33.3
Change from Baseline to Cycle 11 Day 1				
n	3	9	3	15
Mean (StdDev)	0.00 (0.000)	-29.63 (35.136)	-33.33 (33.333)	-24.44 (32.038)
Median	0.00	-33.33	-33.33	0.00
Min, Max	0.0, 0.0	-100.0, 0.0	-66.7, 0.0	-100.0, 0.0
Change from Baseline to Cycle 12 Day 1				
n	2	4	3	9
Mean (StdDev)	0.00 (0.000)	-33.33 (27.217)	-33.33 (33.333)	-25.93 (27.778)
Median	0.00	-33.33	-33.33	-33.33
Min, Max	0.0, 0.0	-66.7, 0.0	-66.7, 0.0	-66.7, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Insomnia	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Baseline				
n	4	15	6	25
Mean (StdDev)	50.00 (43.033)	46.67 (35.187)	55.56 (40.369)	49.33 (36.158)
Median	50.00	66.67	50.00	66.67
Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 2 Day 1				
n	3	13	5	21
Mean (StdDev)	22.22 (19.245)	-10.26 (21.014)	-13.33 (64.979)	-6.35 (35.931)
Median	33.33	0.00	-33.33	0.00
Min, Max	0.0, 33.3	-33.3, 33.3	-100.0, 66.7	-100.0, 66.7
Change from Baseline to Cycle 3 Day 1				
n	3	13	5	21
Mean (StdDev)	0.00 (33.333)	-7.69 (33.758)	-13.33 (50.553)	-7.94 (36.370)
Median	0.00	0.00	-33.33	0.00
Min, Max	-33.3, 33.3	-66.7, 66.7	-66.7, 66.7	-66.7, 66.7
Change from Baseline to Cycle 4 Day 1				
n	2	12	6	20
Mean (StdDev)	16.67 (23.570)	-5.56 (27.828)	0.00 (47.140)	-1.67 (33.289)
Median	16.67	0.00	0.00	0.00
Min, Max	0.0, 33.3	-66.7, 33.3	-66.7, 66.7	-66.7, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Insomnia	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Change from Baseline to Cycle 5 Day 1				
n	3	10	6	19
Mean (StdDev)	0.00 (33.333)	-6.67 (37.843)	-33.33 (29.814)	-14.04 (35.687)
Median	0.00	-33.33	-33.33	-33.33
Min, Max	-33.3, 33.3	-33.3, 66.7	-66.7, 0.0	-66.7, 66.7
Change from Baseline to Cycle 6 Day 1				
n	3	10	5	18
Mean (StdDev)	0.00 (33.333)	-16.67 (36.004)	-13.33 (38.006)	-12.96 (34.563)
Median	0.00	-33.33	0.00	-16.67
Min, Max	-33.3, 33.3	-66.7, 66.7	-66.7, 33.3	-66.7, 66.7
Change from Baseline to Cycle 7 Day 1				
n	3	8	5	16
Mean (StdDev)	11.11 (19.245)	-4.17 (37.533)	6.67 (27.889)	2.08 (30.957)
Median	0.00	-16.67	0.00	0.00
Min, Max	0.0, 33.3	-33.3, 66.7	-33.3, 33.3	-33.3, 66.7
Change from Baseline to Cycle 8 Day 1				
n	2	9	4	15
Mean (StdDev)	16.67 (23.570)	-25.93 (27.778)	-8.33 (16.667)	-15.56 (27.794)
Median	16.67	-33.33	0.00	0.00
Min, Max	0.0, 33.3	-66.7, 0.0	-33.3, 0.0	-66.7, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Insomnia	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Change from Baseline to Cycle 9 Day 1				
n	3	7	4	14
Mean (StdDev)	22.22 (38.490)	-33.33 (27.217)	0.00 (0.000)	-11.90 (33.607)
Median	0.00	-33.33	0.00	0.00
Min, Max	0.0, 66.7	-66.7, 0.0	0.0, 0.0	-66.7, 66.7
Change from Baseline to Cycle 10 Day 1				
n	3	8	3	14
Mean (StdDev)	11.11 (38.490)	-8.33 (23.570)	-11.11 (19.245)	-4.76 (25.678)
Median	33.33	0.00	0.00	0.00
Min, Max	-33.3, 33.3	-33.3, 33.3	-33.3, 0.0	-33.3, 33.3
Change from Baseline to Cycle 11 Day 1				
n	3	9	3	15
Mean (StdDev)	33.33 (0.000)	-18.52 (33.793)	11.11 (19.245)	-2.22 (34.427)
Median	33.33	0.00	0.00	0.00
Min, Max	33.3, 33.3	-66.7, 33.3	0.0, 33.3	-66.7, 33.3
Change from Baseline to Cycle 12 Day 1				
n	2	5	3	10
Mean (StdDev)	33.33 (0.000)	-33.33 (33.333)	0.00 (33.333)	-10.00 (38.650)
Median	33.33	-33.33	0.00	0.00
Min, Max	33.3, 33.3	-66.7, 0.0	-33.3, 33.3	-66.7, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Appetite Loss	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Baseline				
n	4	15	6	25
Mean (StdDev)	25.00 (31.914)	51.11 (30.516)	50.00 (34.960)	46.67 (31.914)
Median	16.67	66.67	50.00	33.33
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 2 Day 1				
n	3	13	5	21
Mean (StdDev)	11.11 (50.918)	-20.51 (39.764)	-6.67 (36.515)	-12.70 (40.106)
Median	0.00	-33.33	0.00	0.00
Min, Max	-33.3, 66.7	-100.0, 66.7	-66.7, 33.3	-100.0, 66.7
Change from Baseline to Cycle 3 Day 1				
n	3	13	5	21
Mean (StdDev)	0.00 (33.333)	-30.77 (28.744)	-6.67 (43.461)	-20.63 (34.118)
Median	0.00	-33.33	0.00	-33.33
Min, Max	-33.3, 33.3	-100.0, 0.0	-66.7, 33.3	-100.0, 33.3
Change from Baseline to Cycle 4 Day 1				
n	2	12	6	20
Mean (StdDev)	-16.67 (23.570)	-22.22 (32.824)	-22.22 (34.427)	-21.67 (31.110)
Median	-16.67	-16.67	-33.33	-33.33
Min, Max	-33.3, 0.0	-66.7, 33.3	-66.7, 33.3	-66.7, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Appetite Loss	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Change from Baseline to Cycle 5 Day 1				
n	3	10	6	19
Mean (StdDev)	11.11 (50.918)	-16.67 (36.004)	-22.22 (27.217)	-14.04 (35.687)
Median	0.00	-16.67	-16.67	0.00
Min, Max	-33.3, 66.7	-66.7, 33.3	-66.7, 0.0	-66.7, 66.7
Change from Baseline to Cycle 6 Day 1				
n	3	10	5	18
Mean (StdDev)	0.00 (57.735)	-33.33 (44.444)	-26.67 (36.515)	-25.93 (43.620)
Median	-33.33	-33.33	0.00	-33.33
Min, Max	-33.3, 66.7	-100.0, 33.3	-66.7, 0.0	-100.0, 66.7
Change from Baseline to Cycle 7 Day 1				
n	3	8	5	16
Mean (StdDev)	0.00 (57.735)	-37.50 (60.257)	-33.33 (33.333)	-29.17 (51.460)
Median	-33.33	-50.00	-33.33	-33.33
Min, Max	-33.3, 66.7	-100.0, 66.7	-66.7, 0.0	-100.0, 66.7
Change from Baseline to Cycle 8 Day 1				
n	2	9	4	15
Mean (StdDev)	0.00 (47.140)	-44.44 (40.825)	-33.33 (27.217)	-35.56 (38.764)
Median	0.00	-33.33	-33.33	-33.33
Min, Max	-33.3, 33.3	-100.0, 0.0	-66.7, 0.0	-100.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Appetite Loss	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Change from Baseline to Cycle 9 Day 1				
n	3	7	4	14
Mean (StdDev)	0.00 (33.333)	-57.14 (37.090)	-8.33 (16.667)	-30.95 (40.222)
Median	0.00	-66.67	0.00	-33.33
Min, Max	-33.3, 33.3	-100.0, 0.0	-33.3, 0.0	-100.0, 33.3
Change from Baseline to Cycle 10 Day 1				
n	3	8	3	14
Mean (StdDev)	-11.11 (50.918)	-33.33 (35.635)	0.00 (33.333)	-21.43 (38.358)
Median	0.00	-33.33	0.00	-16.67
Min, Max	-66.7, 33.3	-100.0, 0.0	-33.3, 33.3	-100.0, 33.3
Change from Baseline to Cycle 11 Day 1				
n	3	9	3	15
Mean (StdDev)	-11.11 (38.490)	-37.04 (35.136)	0.00 (33.333)	-24.44 (36.659)
Median	-33.33	-33.33	0.00	-33.33
Min, Max	-33.3, 33.3	-100.0, 0.0	-33.3, 33.3	-100.0, 33.3
Change from Baseline to Cycle 12 Day 1				
n	2	5	3	10
Mean (StdDev)	50.00 (23.570)	-40.00 (27.889)	-11.11 (50.918)	-13.33 (47.661)
Median	50.00	-33.33	0.00	-16.67
Min, Max	33.3, 66.7	-66.7, 0.0	-66.7, 33.3	-66.7, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Constipation	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Baseline				
n	4	15	6	25
Mean (StdDev)	16.67 (19.245)	26.67 (31.371)	16.67 (27.889)	22.67 (28.415)
Median	16.67	33.33	0.00	0.00
Min, Max	0.0, 33.3	0.0, 100.0	0.0, 66.7	0.0, 100.0
Change from Baseline to Cycle 2 Day 1				
n	3	13	5	21
Mean (StdDev)	44.44 (38.490)	-2.56 (25.318)	-6.67 (36.515)	3.17 (33.174)
Median	66.67	0.00	0.00	0.00
Min, Max	0.0, 66.7	-66.7, 33.3	-66.7, 33.3	-66.7, 66.7
Change from Baseline to Cycle 3 Day 1				
n	3	13	5	21
Mean (StdDev)	22.22 (38.490)	-7.69 (19.971)	0.00 (40.825)	-1.59 (28.822)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 66.7	-66.7, 0.0	-66.7, 33.3	-66.7, 66.7
Change from Baseline to Cycle 4 Day 1				
n	2	12	6	20
Mean (StdDev)	0.00 (0.000)	-13.89 (22.285)	-11.11 (27.217)	-11.67 (22.361)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 0.0	-66.7, 0.0	-66.7, 0.0	-66.7, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Constipation	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Change from Baseline to Cycle 5 Day 1				
n	3	10	6	19
Mean (StdDev)	22.22 (38.490)	-6.67 (14.055)	-5.56 (32.773)	-1.75 (25.995)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 66.7	-33.3, 0.0	-66.7, 33.3	-66.7, 66.7
Change from Baseline to Cycle 6 Day 1				
n	3	10	5	18
Mean (StdDev)	11.11 (19.245)	-23.33 (27.442)	-6.67 (14.907)	-12.96 (25.918)
Median	0.00	-16.67	0.00	0.00
Min, Max	0.0, 33.3	-66.7, 0.0	-33.3, 0.0	-66.7, 33.3
Change from Baseline to Cycle 7 Day 1				
n	3	8	5	16
Mean (StdDev)	33.33 (33.333)	-12.50 (43.416)	6.67 (49.441)	2.08 (44.670)
Median	33.33	0.00	0.00	0.00
Min, Max	0.0, 66.7	-66.7, 66.7	-66.7, 66.7	-66.7, 66.7
Change from Baseline to Cycle 8 Day 1				
n	2	9	4	15
Mean (StdDev)	0.00 (0.000)	-25.93 (22.222)	0.00 (0.000)	-15.56 (21.331)
Median	0.00	-33.33	0.00	0.00
Min, Max	0.0, 0.0	-66.7, 0.0	0.0, 0.0	-66.7, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Constipation	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Change from Baseline to Cycle 9 Day 1				
n	3	7	4	14
Mean (StdDev)	11.11 (19.245)	-33.33 (27.217)	0.00 (0.000)	-14.29 (28.388)
Median	0.00	-33.33	0.00	0.00
Min, Max	0.0, 33.3	-66.7, 0.0	0.0, 0.0	-66.7, 33.3
Change from Baseline to Cycle 10 Day 1				
n	3	8	3	14
Mean (StdDev)	22.22 (38.490)	-12.50 (24.801)	-11.11 (19.245)	-4.76 (28.815)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 66.7	-66.7, 0.0	-33.3, 0.0	-66.7, 66.7
Change from Baseline to Cycle 11 Day 1				
n	3	9	3	15
Mean (StdDev)	0.00 (0.000)	-22.22 (23.570)	0.00 (0.000)	-13.33 (21.082)
Median	0.00	-33.33	0.00	0.00
Min, Max	0.0, 0.0	-66.7, 0.0	0.0, 0.0	-66.7, 0.0
Change from Baseline to Cycle 12 Day 1				
n	2	5	3	10
Mean (StdDev)	33.33 (0.000)	-13.33 (18.257)	-11.11 (19.245)	-3.33 (24.595)
Median	33.33	0.00	0.00	0.00
Min, Max	33.3, 33.3	-33.3, 0.0	-33.3, 0.0	-33.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Diarrhea	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Baseline				
n	4	15	6	25
Mean (StdDev)	75.00 (31.914)	33.33 (30.861)	44.44 (40.369)	42.67 (35.382)
Median	83.33	33.33	50.00	33.33
Min, Max	33.3, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 2 Day 1				
n	3	13	5	21
Mean (StdDev)	-11.11 (19.245)	2.56 (41.859)	0.00 (33.333)	0.00 (36.515)
Median	0.00	0.00	0.00	0.00
Min, Max	-33.3, 0.0	-100.0, 66.7	-33.3, 33.3	-100.0, 66.7
Change from Baseline to Cycle 3 Day 1				
n	3	13	5	21
Mean (StdDev)	0.00 (33.333)	-2.56 (44.015)	6.67 (36.515)	0.00 (39.441)
Median	0.00	0.00	0.00	0.00
Min, Max	-33.3, 33.3	-100.0, 66.7	-33.3, 66.7	-100.0, 66.7
Change from Baseline to Cycle 4 Day 1				
n	2	12	6	20
Mean (StdDev)	-33.33 (47.140)	2.78 (41.337)	-27.78 (49.065)	-10.00 (44.721)
Median	-33.33	0.00	-16.67	0.00
Min, Max	-66.7, 0.0	-66.7, 66.7	-100.0, 33.3	-100.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Diarrhea	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Change from Baseline to Cycle 5 Day 1				
n	3	10	6	19
Mean (StdDev)	-11.11 (19.245)	10.00 (31.623)	-5.56 (44.305)	1.75 (34.199)
Median	0.00	0.00	0.00	0.00
Min, Max	-33.3, 0.0	-33.3, 66.7	-66.7, 66.7	-66.7, 66.7
Change from Baseline to Cycle 6 Day 1				
n	3	10	5	18
Mean (StdDev)	-11.11 (19.245)	-13.33 (54.885)	-26.67 (49.441)	-16.67 (47.486)
Median	0.00	-16.67	-33.33	-16.67
Min, Max	-33.3, 0.0	-100.0, 100.0	-100.0, 33.3	-100.0, 100.0
Change from Baseline to Cycle 7 Day 1				
n	3	8	5	16
Mean (StdDev)	-11.11 (19.245)	-16.67 (43.644)	-20.00 (50.553)	-16.67 (40.369)
Median	0.00	-16.67	0.00	0.00
Min, Max	-33.3, 0.0	-66.7, 66.7	-100.0, 33.3	-100.0, 66.7
Change from Baseline to Cycle 8 Day 1				
n	2	9	4	15
Mean (StdDev)	-16.67 (23.570)	-14.81 (29.397)	-41.67 (41.944)	-22.22 (32.530)
Median	-16.67	0.00	-33.33	-33.33
Min, Max	-33.3, 0.0	-66.7, 33.3	-100.0, 0.0	-100.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Diarrhea	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Change from Baseline to Cycle 9 Day 1				
n	3	7	4	14
Mean (StdDev)	-22.22 (19.245)	-28.57 (35.635)	-8.33 (16.667)	-21.43 (28.063)
Median	-33.33	-33.33	0.00	-16.67
Min, Max	-33.3, 0.0	-100.0, 0.0	-33.3, 0.0	-100.0, 0.0
Change from Baseline to Cycle 10 Day 1				
n	3	8	3	14
Mean (StdDev)	-55.56 (19.245)	-4.17 (27.817)	0.00 (0.000)	-14.29 (31.254)
Median	-66.67	0.00	0.00	0.00
Min, Max	-66.7, -33.3	-66.7, 33.3	0.0, 0.0	-66.7, 33.3
Change from Baseline to Cycle 11 Day 1				
n	3	9	3	15
Mean (StdDev)	-33.33 (33.333)	-7.41 (36.430)	-22.22 (19.245)	-15.56 (33.014)
Median	-33.33	0.00	-33.33	0.00
Min, Max	-66.7, 0.0	-66.7, 66.7	-33.3, 0.0	-66.7, 66.7
Change from Baseline to Cycle 12 Day 1				
n	2	5	3	10
Mean (StdDev)	-16.67 (23.570)	-13.33 (18.257)	-22.22 (19.245)	-16.67 (17.568)
Median	-16.67	0.00	-33.33	-16.67
Min, Max	-33.3, 0.0	-33.3, 0.0	-33.3, 0.0	-33.3, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Financial Difficulties	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Baseline				
n	4	15	6	25
Mean (StdDev)	66.67 (47.140)	37.78 (37.515)	61.11 (38.968)	48.00 (39.768)
Median	83.33	33.33	66.67	33.33
Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 2 Day 1				
n	3	13	5	21
Mean (StdDev)	11.11 (19.245)	0.00 (19.245)	-6.67 (36.515)	0.00 (23.570)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 33.3	-33.3, 33.3	-66.7, 33.3	-66.7, 33.3
Change from Baseline to Cycle 3 Day 1				
n	3	13	5	21
Mean (StdDev)	11.11 (50.918)	0.00 (19.245)	-20.00 (18.257)	-3.17 (25.614)
Median	0.00	0.00	-33.33	0.00
Min, Max	-33.3, 66.7	-33.3, 33.3	-33.3, 0.0	-33.3, 66.7
Change from Baseline to Cycle 4 Day 1				
n	2	12	6	20
Mean (StdDev)	16.67 (23.570)	-5.56 (12.975)	-11.11 (17.213)	-5.00 (16.312)
Median	16.67	0.00	0.00	0.00
Min, Max	0.0, 33.3	-33.3, 0.0	-33.3, 0.0	-33.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Financial Difficulties	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Change from Baseline to Cycle 5 Day 1				
n	3	10	6	19
Mean (StdDev)	11.11 (19.245)	0.00 (15.713)	-16.67 (27.889)	-3.51 (21.928)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 33.3	-33.3, 33.3	-66.7, 0.0	-66.7, 33.3
Change from Baseline to Cycle 6 Day 1				
n	3	10	5	18
Mean (StdDev)	-22.22 (50.918)	-10.00 (22.498)	-13.33 (29.814)	-12.96 (28.328)
Median	-33.33	0.00	-33.33	-16.67
Min, Max	-66.7, 33.3	-33.3, 33.3	-33.3, 33.3	-66.7, 33.3
Change from Baseline to Cycle 7 Day 1				
n	3	8	5	16
Mean (StdDev)	-11.11 (50.918)	-4.17 (21.362)	-26.67 (27.889)	-12.50 (29.502)
Median	0.00	0.00	-33.33	0.00
Min, Max	-66.7, 33.3	-33.3, 33.3	-66.7, 0.0	-66.7, 33.3
Change from Baseline to Cycle 8 Day 1				
n	2	9	4	15
Mean (StdDev)	0.00 (47.140)	-7.41 (14.699)	-8.33 (56.928)	-6.67 (31.371)
Median	0.00	0.00	-16.67	0.00
Min, Max	-33.3, 33.3	-33.3, 0.0	-66.7, 66.7	-66.7, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

Financial Difficulties	ASM (N=4)	SM-AHN (N=17)	MCL (N=6)	All AdvSM (N=27)
Change from Baseline to Cycle 9 Day 1				
n	3	7	4	14
Mean (StdDev)	-11.11 (38.490)	-4.76 (35.635)	-8.33 (56.928)	-7.14 (39.610)
Median	-33.33	0.00	-16.67	0.00
Min, Max	-33.3, 33.3	-66.7, 33.3	-66.7, 66.7	-66.7, 66.7
Change from Baseline to Cycle 10 Day 1				
n	3	8	3	14
Mean (StdDev)	-11.11 (38.490)	-4.17 (11.785)	0.00 (66.667)	-4.76 (31.642)
Median	-33.33	0.00	0.00	0.00
Min, Max	-33.3, 33.3	-33.3, 0.0	-66.7, 66.7	-66.7, 66.7
Change from Baseline to Cycle 11 Day 1				
n	3	9	3	15
Mean (StdDev)	-11.11 (38.490)	0.00 (16.667)	0.00 (66.667)	-2.22 (32.038)
Median	-33.33	0.00	0.00	0.00
Min, Max	-33.3, 33.3	-33.3, 33.3	-66.7, 66.7	-66.7, 66.7
Change from Baseline to Cycle 12 Day 1				
n	2	5	3	10
Mean (StdDev)	-50.00 (23.570)	0.00 (23.570)	-11.11 (50.918)	-13.33 (35.832)
Median	-50.00	0.00	0.00	0.00
Min, Max	-66.7, -33.3	-33.3, 33.3	-66.7, 33.3	-66.7, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Global Health Status/QoL	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	33.33 (-)	51.67 (34.561)	37.50 (19.837)	44.17 (26.946)
Median	33.33	50.00	37.50	45.83
Min, Max	33.3, 33.3	0.0, 83.3	16.7, 58.3	0.0, 83.3
Change from Baseline to Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		18.33 (34.055)	25.00 (30.046)	20.83 (30.538)
Median		0.00	16.67	8.33
Min, Max		-8.3, 66.7	0.0, 58.3	-8.3, 66.7
Change from Baseline to Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		20.83 (39.965)	22.22 (26.788)	21.43 (32.224)
Median		16.67	33.33	33.33
Min, Max		-16.7, 66.7	-8.3, 41.7	-16.7, 66.7
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		18.75 (51.088)	18.75 (31.458)	18.75 (39.277)
Median		20.83	29.17	29.17
Min, Max		-33.3, 66.7	-25.0, 41.7	-33.3, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Global Health Status/QoL	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		20.83 (53.033)	27.08 (18.478)	25.00 (27.889)
Median		20.83	33.33	33.33
Min, Max		-16.7, 58.3	0.0, 41.7	-16.7, 58.3
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		33.33 (50.690)	22.92 (23.936)	27.38 (34.263)
Median		58.33	29.17	41.67
Min, Max		-25.0, 66.7	-8.3, 41.7	-25.0, 66.7
Change from Baseline to Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		33.33 (50.690)	11.11 (26.788)	22.22 (38.249)
Median		58.33	0.00	20.83
Min, Max		-25.0, 66.7	-8.3, 41.7	-25.0, 66.7
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		62.50 (5.893)	0.00 (23.570)	31.25 (38.715)
Median		62.50	0.00	37.50
Min, Max		58.3, 66.7	-16.7, 16.7	-16.7, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Global Health Status/QoL	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		62.50 (5.893)	-8.33 (11.785)	27.08 (41.597)
Median		62.50	-8.33	29.17
Min, Max		58.3, 66.7	-16.7, 0.0	-16.7, 66.7
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		58.33 (-)	0.00 (23.570)	19.44 (37.577)
Median		58.33	0.00	16.67
Min, Max		58.3, 58.3	-16.7, 16.7	-16.7, 58.3
Change from Baseline to Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		54.17 (5.893)	-8.33 (11.785)	22.92 (36.878)
Median		54.17	-8.33	25.00
Min, Max		50.0, 58.3	-16.7, 0.0	-16.7, 58.3
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		58.33 (-)	8.33 (35.355)	25.00 (38.188)
Median		58.33	8.33	33.33
Min, Max		58.3, 58.3	-16.7, 33.3	-16.7, 58.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Physical Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	86.67 (-)	46.67 (29.059)	70.00 (24.646)	60.00 (28.284)
Median	86.67	53.33	80.00	66.67
Min, Max	86.7, 86.7	0.0, 80.0	33.3, 86.7	0.0, 86.7
Change from Baseline to Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		24.00 (28.906)	4.44 (10.184)	16.67 (24.689)
Median		6.67	6.67	6.67
Min, Max		6.7, 73.3	-6.7, 13.3	-6.7, 73.3
Change from Baseline to Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		23.33 (20.728)	13.33 (6.667)	19.05 (16.069)
Median		16.67	13.33	13.33
Min, Max		6.7, 53.3	6.7, 20.0	6.7, 53.3
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		25.00 (27.420)	16.67 (22.771)	20.83 (23.755)
Median		20.00	13.33	13.33
Min, Max		0.0, 60.0	-6.7, 46.7	-6.7, 60.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Physical Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		13.33 (28.284)	8.33 (14.782)	10.00 (17.256)
Median		13.33	13.33	13.33
Min, Max		-6.7, 33.3	-13.3, 20.0	-13.3, 33.3
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		20.00 (29.059)	1.67 (15.753)	9.52 (22.396)
Median		33.33	6.67	13.33
Min, Max		-13.3, 40.0	-20.0, 13.3	-20.0, 40.0
Change from Baseline to Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		13.33 (29.059)	-4.44 (16.777)	4.44 (23.349)
Median		26.67	-6.67	3.33
Min, Max		-20.0, 33.3	-20.0, 13.3	-20.0, 33.3
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		43.33 (14.142)	0.00 (18.856)	21.67 (28.480)
Median		43.33	0.00	23.33
Min, Max		33.3, 53.3	-13.3, 13.3	-13.3, 53.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Physical Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		46.67 (0.000)	0.00 (18.856)	23.33 (29.059)
Median		46.67	0.00	30.00
Min, Max		46.7, 46.7	-13.3, 13.3	-13.3, 46.7
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		46.67 (-)	0.00 (18.856)	15.56 (30.062)
Median		46.67	0.00	13.33
Min, Max		46.7, 46.7	-13.3, 13.3	-13.3, 46.7
Change from Baseline to Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		53.33 (9.428)	-3.33 (23.570)	25.00 (35.849)
Median		53.33	-3.33	30.00
Min, Max		46.7, 60.0	-20.0, 13.3	-20.0, 60.0
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		46.67 (-)	-3.33 (23.570)	13.33 (33.333)
Median		46.67	-3.33	13.33
Min, Max		46.7, 46.7	-20.0, 13.3	-20.0, 46.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Role Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	33.33 (-)	56.67 (22.361)	33.33 (38.490)	45.00 (29.450)
Median	33.33	66.67	33.33	50.00
Min, Max	33.3, 33.3	33.3, 83.3	0.0, 66.7	0.0, 83.3
Change from Baseline to Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		20.00 (13.944)	38.89 (41.944)	27.08 (26.633)
Median		16.67	33.33	25.00
Min, Max		0.0, 33.3	0.0, 83.3	0.0, 83.3
Change from Baseline to Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		0.00 (13.608)	33.33 (33.333)	14.29 (27.936)
Median		0.00	33.33	0.00
Min, Max		-16.7, 16.7	0.0, 66.7	-16.7, 66.7
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		0.00 (30.429)	41.67 (56.928)	20.83 (47.768)
Median		0.00	50.00	25.00
Min, Max		-33.3, 33.3	-33.3, 100.0	-33.3, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Role Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		-16.67 (23.570)	20.83 (25.000)	8.33 (29.345)
Median		-16.67	16.67	0.00
Min, Max		-33.3, 0.0	0.0, 50.0	-33.3, 50.0
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		-5.56 (25.459)	25.00 (31.914)	11.90 (31.497)
Median		0.00	16.67	0.00
Min, Max		-33.3, 16.7	0.0, 66.7	-33.3, 66.7
Change from Baseline to Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		0.00 (28.868)	16.67 (16.667)	8.33 (22.973)
Median		16.67	16.67	16.67
Min, Max		-33.3, 16.7	0.0, 33.3	-33.3, 33.3
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		25.00 (11.785)	16.67 (23.570)	20.83 (15.957)
Median		25.00	16.67	25.00
Min, Max		16.7, 33.3	0.0, 33.3	0.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Role Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		25.00 (11.785)	16.67 (23.570)	20.83 (15.957)
Median		25.00	16.67	25.00
Min, Max		16.7, 33.3	0.0, 33.3	0.0, 33.3
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		16.67 (-)	16.67 (23.570)	16.67 (16.667)
Median		16.67	16.67	16.67
Min, Max		16.7, 16.7	0.0, 33.3	0.0, 33.3
Change from Baseline to Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		16.67 (0.000)	16.67 (23.570)	16.67 (13.608)
Median		16.67	16.67	16.67
Min, Max		16.7, 16.7	0.0, 33.3	0.0, 33.3
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		16.67 (-)	16.67 (23.570)	16.67 (16.667)
Median		16.67	16.67	16.67
Min, Max		16.7, 16.7	0.0, 33.3	0.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Emotional Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	100.00 (-)	66.67 (29.463)	70.83 (20.972)	71.67 (25.215)
Median	100.00	75.00	75.00	75.00
Min, Max	100.0, 100.0	25.0, 100.0	41.7, 91.7	25.0, 100.0
Change from Baseline to Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		11.67 (30.391)	13.89 (19.245)	12.50 (25.198)
Median		0.00	25.00	12.50
Min, Max		-16.7, 58.3	-8.3, 25.0	-16.7, 58.3
Change from Baseline to Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		21.53 (23.282)	11.11 (20.972)	17.06 (21.181)
Median		16.67	8.33	8.33
Min, Max		0.0, 52.8	-8.3, 33.3	-8.3, 52.8
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		25.00 (24.533)	8.33 (20.412)	16.67 (22.713)
Median		20.83	8.33	12.50
Min, Max		0.0, 58.3	-16.7, 33.3	-16.7, 58.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Emotional Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		-4.17 (41.248)	4.17 (17.347)	1.39 (23.224)
Median		-4.17	4.17	4.17
Min, Max		-33.3, 25.0	-16.7, 25.0	-33.3, 25.0
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		25.00 (50.000)	-2.08 (24.884)	9.52 (36.777)
Median		25.00	0.00	8.33
Min, Max		-25.0, 75.0	-33.3, 25.0	-33.3, 75.0
Change from Baseline to Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		22.22 (45.896)	-25.00 (36.324)	-1.39 (45.159)
Median		25.00	-8.33	-4.17
Min, Max		-25.0, 66.7	-66.7, 0.0	-66.7, 66.7
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		37.50 (17.678)	-37.50 (17.678)	0.00 (45.644)
Median		37.50	-37.50	0.00
Min, Max		25.0, 50.0	-50.0, -25.0	-50.0, 50.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Emotional Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		37.50 (17.678)	-45.83 (5.893)	-4.17 (49.301)
Median		37.50	-45.83	-8.33
Min, Max		25.0, 50.0	-50.0, -41.7	-50.0, 50.0
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		66.67 (-)	-45.83 (5.893)	-8.33 (65.085)
Median		66.67	-45.83	-41.67
Min, Max		66.7, 66.7	-50.0, -41.7	-50.0, 66.7
Change from Baseline to Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		45.83 (29.463)	-37.50 (5.893)	4.17 (51.144)
Median		45.83	-37.50	-4.17
Min, Max		25.0, 66.7	-41.7, -33.3	-41.7, 66.7
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		25.00 (-)	-54.17 (41.248)	-27.78 (54.220)
Median		25.00	-54.17	-25.00
Min, Max		25.0, 25.0	-83.3, -25.0	-83.3, 25.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Cognitive Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	66.67 (-)	76.67 (19.003)	70.83 (15.957)	73.33 (16.102)
Median	66.67	83.33	75.00	75.00
Min, Max	66.7, 66.7	50.0, 100.0	50.0, 83.3	50.0, 100.0
Change from Baseline to Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		6.67 (27.889)	16.67 (16.667)	10.42 (23.465)
Median		0.00	16.67	8.33
Min, Max		-16.7, 50.0	0.0, 33.3	-16.7, 50.0
Change from Baseline to Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		12.50 (25.000)	11.11 (9.623)	11.90 (18.545)
Median		0.00	16.67	0.00
Min, Max		0.0, 50.0	0.0, 16.7	0.0, 50.0
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		8.33 (28.868)	8.33 (9.623)	8.33 (19.920)
Median		0.00	8.33	0.00
Min, Max		-16.7, 50.0	0.0, 16.7	-16.7, 50.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Cognitive Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		-8.33 (11.785)	0.00 (23.570)	-2.78 (19.484)
Median		-8.33	8.33	0.00
Min, Max		-16.7, 0.0	-33.3, 16.7	-33.3, 16.7
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		16.67 (28.868)	12.50 (8.333)	14.29 (17.817)
Median		0.00	16.67	16.67
Min, Max		0.0, 50.0	0.0, 16.7	0.0, 50.0
Change from Baseline to Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		11.11 (34.694)	-16.67 (16.667)	-2.78 (28.707)
Median		0.00	-16.67	-8.33
Min, Max		-16.7, 50.0	-33.3, 0.0	-33.3, 50.0
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		25.00 (35.355)	-8.33 (11.785)	8.33 (28.868)
Median		25.00	-8.33	0.00
Min, Max		0.0, 50.0	-16.7, 0.0	-16.7, 50.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Cognitive Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		16.67 (47.140)	-8.33 (11.785)	4.17 (31.549)
Median		16.67	-8.33	-8.33
Min, Max		-16.7, 50.0	-16.7, 0.0	-16.7, 50.0
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		50.00 (-)	-25.00 (35.355)	0.00 (50.000)
Median		50.00	-25.00	0.00
Min, Max		50.0, 50.0	-50.0, 0.0	-50.0, 50.0
Change from Baseline to Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		16.67 (23.570)	-16.67 (23.570)	0.00 (27.217)
Median		16.67	-16.67	0.00
Min, Max		0.0, 33.3	-33.3, 0.0	-33.3, 33.3
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	-33.33 (47.140)	-22.22 (38.490)
Median		0.00	-33.33	0.00
Min, Max		0.0, 0.0	-66.7, 0.0	-66.7, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Social Function	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	33.33 (-)	60.00 (30.277)	58.33 (41.944)	56.67 (32.584)
Median	33.33	66.67	66.67	66.67
Min, Max	33.3, 33.3	16.7, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		20.00 (36.132)	11.11 (38.490)	16.67 (34.503)
Median		33.33	33.33	33.33
Min, Max		-16.7, 66.7	-33.3, 33.3	-33.3, 66.7
Change from Baseline to Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		12.50 (25.000)	16.67 (16.667)	14.29 (20.250)
Median		16.67	16.67	16.67
Min, Max		-16.7, 33.3	0.0, 33.3	-16.7, 33.3
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		16.67 (30.429)	8.33 (16.667)	12.50 (23.146)
Median		16.67	0.00	0.00
Min, Max		-16.7, 50.0	0.0, 33.3	-16.7, 50.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Social Function	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		16.67 (23.570)	4.17 (20.972)	8.33 (20.412)
Median		16.67	0.00	0.00
Min, Max		0.0, 33.3	-16.7, 33.3	-16.7, 33.3
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		22.22 (50.918)	0.00 (49.065)	9.52 (47.000)
Median		33.33	-8.33	0.00
Min, Max		-33.3, 66.7	-50.0, 66.7	-50.0, 66.7
Change from Baseline to Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		22.22 (50.918)	-5.56 (9.623)	8.33 (36.132)
Median		33.33	0.00	0.00
Min, Max		-33.3, 66.7	-16.7, 0.0	-33.3, 66.7
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		41.67 (11.785)	-33.33 (47.140)	4.17 (51.595)
Median		41.67	-33.33	16.67
Min, Max		33.3, 50.0	-66.7, 0.0	-66.7, 50.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Social Function	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		50.00 (23.570)	-25.00 (58.926)	12.50 (56.724)
Median		50.00	-25.00	25.00
Min, Max		33.3, 66.7	-66.7, 16.7	-66.7, 66.7
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		66.67 (-)	-50.00 (70.711)	-11.11 (83.887)
Median		66.67	-50.00	0.00
Min, Max		66.7, 66.7	-100.0, 0.0	-100.0, 66.7
Change from Baseline to Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		33.33 (0.000)	-33.33 (70.711)	0.00 (56.108)
Median		33.33	-33.33	25.00
Min, Max		33.3, 33.3	-83.3, 16.7	-83.3, 33.3
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		33.33 (-)	-41.67 (58.926)	-16.67 (60.093)
Median		33.33	-41.67	0.00
Min, Max		33.3, 33.3	-83.3, 0.0	-83.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Fatigue	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	100.00 (-)	55.56 (32.394)	69.44 (30.598)	65.56 (31.186)
Median	100.00	55.56	72.22	61.11
Min, Max	100.0, 100.0	11.1, 100.0	33.3, 100.0	11.1, 100.0
Change from Baseline to Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		-20.00 (29.814)	-22.22 (38.490)	-20.83 (30.538)
Median		0.00	0.00	0.00
Min, Max		-66.7, 0.0	-66.7, 0.0	-66.7, 0.0
Change from Baseline to Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		-16.67 (26.450)	-25.93 (27.962)	-20.63 (25.198)
Median		-16.67	-22.22	-22.22
Min, Max		-44.4, 11.1	-55.6, 0.0	-55.6, 11.1
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		-2.78 (29.222)	-30.56 (43.862)	-16.67 (37.562)
Median		0.00	-38.89	-16.67
Min, Max		-33.3, 22.2	-66.7, 22.2	-66.7, 22.2

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Fatigue	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		11.11 (62.854)	-27.78 (29.397)	-14.81 (41.376)
Median		11.11	-22.22	-22.22
Min, Max		-33.3, 55.6	-66.7, 0.0	-66.7, 55.6
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		-11.11 (48.432)	-13.89 (29.222)	-12.70 (34.800)
Median		-33.33	-5.56	-11.11
Min, Max		-44.4, 44.4	-55.6, 11.1	-55.6, 44.4
Change from Baseline to Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		-25.93 (42.066)	0.00 (11.111)	-12.96 (30.965)
Median		-44.44	0.00	-5.56
Min, Max		-55.6, 22.2	-11.1, 11.1	-55.6, 22.2
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		-50.00 (7.857)	0.00 (0.000)	-25.00 (29.222)
Median		-50.00	0.00	-22.22
Min, Max		-55.6, -44.4	0.0, 0.0	-55.6, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Fatigue	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		-72.22 (7.857)	-11.11 (15.713)	-41.67 (36.712)
Median		-72.22	-11.11	-44.44
Min, Max		-77.8, -66.7	-22.2, 0.0	-77.8, 0.0
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		-55.56 (-)	-5.56 (7.857)	-22.22 (29.397)
Median		-55.56	-5.56	-11.11
Min, Max		-55.6, -55.6	-11.1, 0.0	-55.6, 0.0
Change from Baseline to Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		-55.56 (15.713)	0.00 (0.000)	-27.78 (33.333)
Median		-55.56	0.00	-22.22
Min, Max		-66.7, -44.4	0.0, 0.0	-66.7, 0.0
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		-66.67 (-)	-5.56 (7.857)	-25.93 (35.717)
Median		-66.67	-5.56	-11.11
Min, Max		-66.7, -66.7	-11.1, 0.0	-66.7, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Nausea and Vomiting	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	66.67 (-)	10.00 (22.361)	8.33 (9.623)	15.00 (24.152)
Median	66.67	0.00	8.33	0.00
Min, Max	66.7, 66.7	0.0, 50.0	0.0, 16.7	0.0, 66.7
Change from Baseline to Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		3.33 (24.721)	5.56 (9.623)	4.17 (19.416)
Median		0.00	0.00	0.00
Min, Max		-33.3, 33.3	0.0, 16.7	-33.3, 33.3
Change from Baseline to Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		8.33 (44.096)	5.56 (9.623)	7.14 (31.706)
Median		16.67	0.00	0.00
Min, Max		-50.0, 50.0	0.0, 16.7	-50.0, 50.0
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		8.33 (31.914)	-4.17 (15.957)	2.08 (24.296)
Median		16.67	-8.33	0.00
Min, Max		-33.3, 33.3	-16.7, 16.7	-33.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Nausea and Vomiting	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		16.67 (23.570)	0.00 (13.608)	5.56 (17.213)
Median		16.67	0.00	0.00
Min, Max		0.0, 33.3	-16.7, 16.7	-16.7, 33.3
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		-11.11 (34.694)	-4.17 (15.957)	-7.14 (23.288)
Median		0.00	-8.33	0.00
Min, Max		-50.0, 16.7	-16.7, 16.7	-50.0, 16.7
Change from Baseline to Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		-11.11 (19.245)	0.00 (16.667)	-5.56 (17.213)
Median		0.00	0.00	0.00
Min, Max		-33.3, 0.0	-16.7, 16.7	-33.3, 16.7
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		-16.67 (23.570)	-8.33 (11.785)	-12.50 (15.957)
Median		-16.67	-8.33	-8.33
Min, Max		-33.3, 0.0	-16.7, 0.0	-33.3, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Nausea and Vomiting	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		-16.67 (23.570)	-8.33 (11.785)	-12.50 (15.957)
Median		-16.67	-8.33	-8.33
Min, Max		-33.3, 0.0	-16.7, 0.0	-33.3, 0.0
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		-33.33 (-)	-8.33 (11.785)	-16.67 (16.667)
Median		-33.33	-8.33	-16.67
Min, Max		-33.3, -33.3	-16.7, 0.0	-33.3, 0.0
Change from Baseline to Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		-25.00 (35.355)	-16.67 (0.000)	-20.83 (20.972)
Median		-25.00	-16.67	-16.67
Min, Max		-50.0, 0.0	-16.7, -16.7	-50.0, 0.0
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	-8.33 (11.785)	-5.56 (9.623)
Median		0.00	-8.33	0.00
Min, Max		0.0, 0.0	-16.7, 0.0	-16.7, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Pain	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	83.33 (-)	26.67 (19.003)	50.00 (43.033)	41.67 (33.564)
Median	83.33	33.33	50.00	33.33
Min, Max	83.3, 83.3	0.0, 50.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		-10.00 (14.907)	-33.33 (44.096)	-18.75 (28.781)
Median		0.00	-16.67	-8.33
Min, Max		-33.3, 0.0	-83.3, 0.0	-83.3, 0.0
Change from Baseline to Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		4.17 (20.972)	-27.78 (34.694)	-9.52 (30.211)
Median		0.00	-16.67	0.00
Min, Max		-16.7, 33.3	-66.7, 0.0	-66.7, 33.3
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		-12.50 (15.957)	-25.00 (56.928)	-18.75 (39.277)
Median		-8.33	-33.33	-16.67
Min, Max		-33.3, 0.0	-83.3, 50.0	-83.3, 50.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Pain	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		-8.33 (11.785)	-37.50 (43.833)	-27.78 (37.515)
Median		-8.33	-25.00	-16.67
Min, Max		-16.7, 0.0	-100.0, 0.0	-100.0, 0.0
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		-22.22 (19.245)	-20.83 (41.667)	-21.43 (31.497)
Median		-33.33	0.00	0.00
Min, Max		-33.3, 0.0	-83.3, 0.0	-83.3, 0.0
Change from Baseline to Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		-11.11 (25.459)	-5.56 (9.623)	-8.33 (17.480)
Median		-16.67	0.00	-8.33
Min, Max		-33.3, 16.7	-16.7, 0.0	-33.3, 16.7
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		-25.00 (11.785)	8.33 (35.355)	-8.33 (28.868)
Median		-25.00	8.33	-16.67
Min, Max		-33.3, -16.7	-16.7, 33.3	-33.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Pain	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		-33.33 (0.000)	8.33 (35.355)	-12.50 (31.549)
Median		-33.33	8.33	-25.00
Min, Max		-33.3, -33.3	-16.7, 33.3	-33.3, 33.3
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		-16.67 (-)	8.33 (35.355)	0.00 (28.868)
Median		-16.67	8.33	-16.67
Min, Max		-16.7, -16.7	-16.7, 33.3	-16.7, 33.3
Change from Baseline to Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		-25.00 (11.785)	8.33 (35.355)	-8.33 (28.868)
Median		-25.00	8.33	-16.67
Min, Max		-33.3, -16.7	-16.7, 33.3	-33.3, 33.3
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		-33.33 (-)	0.00 (47.140)	-11.11 (38.490)
Median		-33.33	0.00	-33.33
Min, Max		-33.3, -33.3	-33.3, 33.3	-33.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Dyspnea	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	33.33 (-)	40.00 (36.515)	50.00 (43.033)	43.33 (35.312)
Median	33.33	33.33	50.00	33.33
Min, Max	33.3, 33.3	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		-26.67 (49.441)	-11.11 (19.245)	-20.83 (39.591)
Median		-33.33	0.00	-16.67
Min, Max		-100.0, 33.3	-33.3, 0.0	-100.0, 33.3
Change from Baseline to Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		-16.67 (43.033)	-33.33 (33.333)	-23.81 (37.090)
Median		-16.67	-33.33	-33.33
Min, Max		-66.7, 33.3	-66.7, 0.0	-66.7, 33.3
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		-25.00 (31.914)	-25.00 (31.914)	-25.00 (29.547)
Median		-16.67	-16.67	-16.67
Min, Max		-66.7, 0.0	-66.7, 0.0	-66.7, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Dyspnea	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		0.00 (47.140)	-16.67 (33.333)	-11.11 (34.427)
Median		0.00	0.00	0.00
Min, Max		-33.3, 33.3	-66.7, 0.0	-66.7, 33.3
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		-33.33 (33.333)	-8.33 (41.944)	-19.05 (37.796)
Median		-33.33	0.00	0.00
Min, Max		-66.7, 0.0	-66.7, 33.3	-66.7, 33.3
Change from Baseline to Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		-33.33 (66.667)	-11.11 (50.918)	-22.22 (54.433)
Median		-33.33	0.00	-16.67
Min, Max		-100.0, 33.3	-66.7, 33.3	-100.0, 33.3
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		-66.67 (47.140)	-33.33 (47.140)	-50.00 (43.033)
Median		-66.67	-33.33	-50.00
Min, Max		-100.0, -33.3	-66.7, 0.0	-100.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Dyspnea	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		-66.67 (47.140)	-33.33 (47.140)	-50.00 (43.033)
Median		-66.67	-33.33	-50.00
Min, Max		-100.0, -33.3	-66.7, 0.0	-100.0, 0.0
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		-100.00 (-)	-33.33 (47.140)	-55.56 (50.918)
Median		-100.00	-33.33	-66.67
Min, Max		-100.0, -100.0	-66.7, 0.0	-100.0, 0.0
Change from Baseline to Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		-66.67 (47.140)	-33.33 (47.140)	-50.00 (43.033)
Median		-66.67	-33.33	-50.00
Min, Max		-100.0, -33.3	-66.7, 0.0	-100.0, 0.0
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		-33.33 (-)	-33.33 (47.140)	-33.33 (33.333)
Median		-33.33	-33.33	-33.33
Min, Max		-33.3, -33.3	-66.7, 0.0	-66.7, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Insomnia	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	100.00 (-)	26.67 (27.889)	58.33 (50.000)	46.67 (42.164)
Median	100.00	33.33	66.67	33.33
Min, Max	100.0, 100.0	0.0, 66.7	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		-6.67 (14.907)	-22.22 (83.887)	-12.50 (46.930)
Median		0.00	-33.33	0.00
Min, Max		-33.3, 0.0	-100.0, 66.7	-100.0, 66.7
Change from Baseline to Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		8.33 (56.928)	-11.11 (69.389)	0.00 (57.735)
Median		16.67	-33.33	0.00
Min, Max		-66.7, 66.7	-66.7, 66.7	-66.7, 66.7
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		0.00 (47.140)	-16.67 (43.033)	-8.33 (42.725)
Median		16.67	-16.67	0.00
Min, Max		-66.7, 33.3	-66.7, 33.3	-66.7, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Insomnia	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		16.67 (70.711)	-25.00 (31.914)	-11.11 (45.542)
Median		16.67	-16.67	-16.67
Min, Max		-33.3, 66.7	-66.7, 0.0	-66.7, 66.7
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		11.11 (50.918)	-16.67 (43.033)	-4.76 (44.840)
Median		0.00	-16.67	0.00
Min, Max		-33.3, 66.7	-66.7, 33.3	-66.7, 66.7
Change from Baseline to Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		22.22 (50.918)	11.11 (19.245)	16.67 (34.960)
Median		33.33	0.00	16.67
Min, Max		-33.3, 66.7	0.0, 33.3	-33.3, 66.7
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		-33.33 (47.140)	0.00 (0.000)	-16.67 (33.333)
Median		-33.33	0.00	0.00
Min, Max		-66.7, 0.0	0.0, 0.0	-66.7, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Insomnia	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		-33.33 (47.140)	0.00 (0.000)	-16.67 (33.333)
Median		-33.33	0.00	0.00
Min, Max		-66.7, 0.0	0.0, 0.0	-66.7, 0.0
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	0.00 (0.000)	0.00 (0.000)
Median		0.00	0.00	0.00
Min, Max		0.0, 0.0	0.0, 0.0	0.0, 0.0
Change from Baseline to Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		-33.33 (47.140)	16.67 (23.570)	-8.33 (41.944)
Median		-33.33	16.67	0.00
Min, Max		-66.7, 0.0	0.0, 33.3	-66.7, 33.3
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		-66.67 (-)	16.67 (23.570)	-11.11 (50.918)
Median		-66.67	16.67	0.00
Min, Max		-66.7, -66.7	0.0, 33.3	-66.7, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Appetite Loss	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	0.00 (-)	40.00 (43.461)	41.67 (41.944)	36.67 (39.907)
Median	0.00	33.33	33.33	33.33
Min, Max	0.0, 0.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		-20.00 (64.979)	11.11 (19.245)	-8.33 (52.705)
Median		0.00	0.00	0.00
Min, Max		-100.0, 66.7	0.0, 33.3	-100.0, 66.7
Change from Baseline to Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		-50.00 (43.033)	22.22 (19.245)	-19.05 (50.395)
Median		-50.00	33.33	0.00
Min, Max		-100.0, 0.0	0.0, 33.3	-100.0, 33.3
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		-25.00 (50.000)	-8.33 (31.914)	-16.67 (39.841)
Median		-33.33	-16.67	-16.67
Min, Max		-66.7, 33.3	-33.3, 33.3	-66.7, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Appetite Loss	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		-16.67 (70.711)	-8.33 (16.667)	-11.11 (34.427)
Median		-16.67	0.00	0.00
Min, Max		-66.7, 33.3	-33.3, 0.0	-66.7, 33.3
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		-44.44 (69.389)	-16.67 (33.333)	-28.57 (48.795)
Median		-66.67	0.00	0.00
Min, Max		-100.0, 33.3	-66.7, 0.0	-100.0, 33.3
Change from Baseline to Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		-33.33 (88.192)	-11.11 (19.245)	-22.22 (58.373)
Median		-66.67	0.00	-16.67
Min, Max		-100.0, 66.7	-33.3, 0.0	-100.0, 66.7
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		-83.33 (23.570)	-16.67 (23.570)	-50.00 (43.033)
Median		-83.33	-16.67	-50.00
Min, Max		-100.0, -66.7	-33.3, 0.0	-100.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Appetite Loss	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		-83.33 (23.570)	0.00 (0.000)	-41.67 (50.000)
Median		-83.33	0.00	-33.33
Min, Max		-100.0, -66.7	0.0, 0.0	-100.0, 0.0
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		-100.00 (-)	16.67 (23.570)	-22.22 (69.389)
Median		-100.00	16.67	0.00
Min, Max		-100.0, -100.0	0.0, 33.3	-100.0, 33.3
Change from Baseline to Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		-83.33 (23.570)	16.67 (23.570)	-33.33 (60.858)
Median		-83.33	16.67	-33.33
Min, Max		-100.0, -66.7	0.0, 33.3	-100.0, 33.3
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		-66.67 (-)	16.67 (23.570)	-11.11 (50.918)
Median		-66.67	16.67	0.00
Min, Max		-66.7, -66.7	0.0, 33.3	-66.7, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Constipation	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	0.00 (-)	20.00 (29.814)	16.67 (33.333)	16.67 (28.328)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 0.0	0.0, 66.7	0.0, 66.7	0.0, 66.7
Change from Baseline to Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		-6.67 (36.515)	-22.22 (38.490)	-12.50 (35.355)
Median		0.00	0.00	0.00
Min, Max		-66.7, 33.3	-66.7, 0.0	-66.7, 33.3
Change from Baseline to Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		-16.67 (33.333)	-11.11 (50.918)	-14.29 (37.796)
Median		0.00	0.00	0.00
Min, Max		-66.7, 0.0	-66.7, 33.3	-66.7, 33.3
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		-16.67 (33.333)	-16.67 (33.333)	-16.67 (30.861)
Median		0.00	0.00	0.00
Min, Max		-66.7, 0.0	-66.7, 0.0	-66.7, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Constipation	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		0.00 (0.000)	-16.67 (33.333)	-11.11 (27.217)
Median		0.00	0.00	0.00
Min, Max		0.0, 0.0	-66.7, 0.0	-66.7, 0.0
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		-33.33 (33.333)	-8.33 (16.667)	-19.05 (26.227)
Median		-33.33	0.00	0.00
Min, Max		-66.7, 0.0	-33.3, 0.0	-66.7, 0.0
Change from Baseline to Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		-22.22 (38.490)	-22.22 (38.490)	-22.22 (34.427)
Median		0.00	0.00	0.00
Min, Max		-66.7, 0.0	-66.7, 0.0	-66.7, 0.0
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		-50.00 (23.570)	0.00 (0.000)	-25.00 (31.914)
Median		-50.00	0.00	-16.67
Min, Max		-66.7, -33.3	0.0, 0.0	-66.7, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Constipation	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		-50.00 (23.570)	0.00 (0.000)	-25.00 (31.914)
Median		-50.00	0.00	-16.67
Min, Max		-66.7, -33.3	0.0, 0.0	-66.7, 0.0
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		-66.67 (-)	0.00 (0.000)	-22.22 (38.490)
Median		-66.67	0.00	0.00
Min, Max		-66.7, -66.7	0.0, 0.0	-66.7, 0.0
Change from Baseline to Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		-50.00 (23.570)	0.00 (0.000)	-25.00 (31.914)
Median		-50.00	0.00	-16.67
Min, Max		-66.7, -33.3	0.0, 0.0	-66.7, 0.0
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		-33.33 (-)	0.00 (0.000)	-11.11 (19.245)
Median		-33.33	0.00	0.00
Min, Max		-33.3, -33.3	0.0, 0.0	-33.3, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Diarrhea	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	100.00 (-)	33.33 (47.140)	58.33 (41.944)	50.00 (45.134)
Median	100.00	0.00	66.67	66.67
Min, Max	100.0, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		-6.67 (64.118)	0.00 (33.333)	-4.17 (51.755)
Median		0.00	0.00	0.00
Min, Max		-100.0, 66.7	-33.3, 33.3	-100.0, 66.7
Change from Baseline to Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		-16.67 (63.828)	22.22 (38.490)	0.00 (54.433)
Median		0.00	0.00	0.00
Min, Max		-100.0, 33.3	0.0, 66.7	-100.0, 66.7
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		0.00 (60.858)	-33.33 (60.858)	-16.67 (59.094)
Median		0.00	-33.33	-16.67
Min, Max		-66.7, 66.7	-100.0, 33.3	-100.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Diarrhea	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		16.67 (70.711)	-8.33 (56.928)	0.00 (55.777)
Median		16.67	-16.67	-16.67
Min, Max		-33.3, 66.7	-66.7, 66.7	-66.7, 66.7
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		-11.11 (101.835)	-25.00 (56.928)	-19.05 (71.640)
Median		-33.33	-16.67	-33.33
Min, Max		-100.0, 100.0	-100.0, 33.3	-100.0, 100.0
Change from Baseline to Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		-11.11 (69.389)	-33.33 (66.667)	-22.22 (62.063)
Median		-33.33	-33.33	-33.33
Min, Max		-66.7, 66.7	-100.0, 33.3	-100.0, 66.7
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		-50.00 (23.570)	-66.67 (47.140)	-58.33 (31.914)
Median		-50.00	-66.67	-50.00
Min, Max		-66.7, -33.3	-100.0, -33.3	-100.0, -33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Diarrhea	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		-66.67 (47.140)	-16.67 (23.570)	-41.67 (41.944)
Median		-66.67	-16.67	-33.33
Min, Max		-100.0, -33.3	-33.3, 0.0	-100.0, 0.0
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		-66.67 (-)	0.00 (0.000)	-22.22 (38.490)
Median		-66.67	0.00	0.00
Min, Max		-66.7, -66.7	0.0, 0.0	-66.7, 0.0
Change from Baseline to Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		-50.00 (23.570)	-33.33 (0.000)	-41.67 (16.667)
Median		-50.00	-33.33	-33.33
Min, Max		-66.7, -33.3	-33.3, -33.3	-66.7, -33.3
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		-33.33 (-)	-33.33 (0.000)	-33.33 (0.000)
Median		-33.33	-33.33	-33.33
Min, Max		-33.3, -33.3	-33.3, -33.3	-33.3, -33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Financial Difficulties	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	66.67 (-)	26.67 (43.461)	58.33 (41.944)	43.33 (41.722)
Median	66.67	0.00	66.67	50.00
Min, Max	66.7, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		6.67 (27.889)	-22.22 (38.490)	-4.17 (33.034)
Median		0.00	0.00	0.00
Min, Max		-33.3, 33.3	-66.7, 0.0	-66.7, 33.3
Change from Baseline to Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		8.33 (31.914)	-11.11 (19.245)	0.00 (27.217)
Median		16.67	0.00	0.00
Min, Max		-33.3, 33.3	-33.3, 0.0	-33.3, 33.3
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		-8.33 (16.667)	-8.33 (16.667)	-8.33 (15.430)
Median		0.00	0.00	0.00
Min, Max		-33.3, 0.0	-33.3, 0.0	-33.3, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Financial Difficulties	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
Median		0.00	0.00	0.00
Min, Max		0.0, 0.0	0.0, 0.0	0.0, 0.0
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		-11.11 (19.245)	-8.33 (31.914)	-9.52 (25.198)
Median		0.00	-16.67	0.00
Min, Max		-33.3, 0.0	-33.3, 33.3	-33.3, 33.3
Change from Baseline to Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		-11.11 (19.245)	-11.11 (19.245)	-11.11 (17.213)
Median		0.00	0.00	0.00
Min, Max		-33.3, 0.0	-33.3, 0.0	-33.3, 0.0
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	33.33 (47.140)	16.67 (33.333)
Median		0.00	33.33	0.00
Min, Max		0.0, 0.0	0.0, 66.7	0.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

Financial Difficulties	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		-16.67 (23.570)	33.33 (47.140)	8.33 (41.944)
Median		-16.67	33.33	0.00
Min, Max		-33.3, 0.0	0.0, 66.7	-33.3, 66.7
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		-33.33 (-)	33.33 (47.140)	11.11 (50.918)
Median		-33.33	33.33	0.00
Min, Max		-33.3, -33.3	0.0, 66.7	-33.3, 66.7
Change from Baseline to Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		-16.67 (23.570)	33.33 (47.140)	8.33 (41.944)
Median		-16.67	33.33	0.00
Min, Max		-33.3, 0.0	0.0, 66.7	-33.3, 66.7
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	16.67 (23.570)	11.11 (19.245)
Median		0.00	16.67	0.00
Min, Max		0.0, 0.0	0.0, 33.3	0.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Global Health Status/QoL	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	33.33 (-)	51.67 (34.561)	37.50 (19.837)	44.17 (26.946)
Median	33.33	50.00	37.50	45.83
Min, Max	33.3, 33.3	0.0, 83.3	16.7, 58.3	0.0, 83.3
Change from Baseline to Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		18.33 (34.055)	25.00 (30.046)	20.83 (30.538)
Median		0.00	16.67	8.33
Min, Max		-8.3, 66.7	0.0, 58.3	-8.3, 66.7
Change from Baseline to Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		20.83 (39.965)	22.22 (26.788)	21.43 (32.224)
Median		16.67	33.33	33.33
Min, Max		-16.7, 66.7	-8.3, 41.7	-16.7, 66.7
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		18.75 (51.088)	18.75 (31.458)	18.75 (39.277)
Median		20.83	29.17	29.17
Min, Max		-33.3, 66.7	-25.0, 41.7	-33.3, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Global Health Status/QoL	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		20.83 (53.033)	27.08 (18.478)	25.00 (27.889)
Median		20.83	33.33	33.33
Min, Max		-16.7, 58.3	0.0, 41.7	-16.7, 58.3
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		33.33 (50.690)	22.92 (23.936)	27.38 (34.263)
Median		58.33	29.17	41.67
Min, Max		-25.0, 66.7	-8.3, 41.7	-25.0, 66.7
Change from Baseline to Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		33.33 (50.690)	11.11 (26.788)	22.22 (38.249)
Median		58.33	0.00	20.83
Min, Max		-25.0, 66.7	-8.3, 41.7	-25.0, 66.7
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		62.50 (5.893)	0.00 (23.570)	31.25 (38.715)
Median		62.50	0.00	37.50
Min, Max		58.3, 66.7	-16.7, 16.7	-16.7, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Global Health Status/QoL	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		62.50 (5.893)	-8.33 (11.785)	27.08 (41.597)
Median		62.50	-8.33	29.17
Min, Max		58.3, 66.7	-16.7, 0.0	-16.7, 66.7
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		58.33 (-)	0.00 (23.570)	19.44 (37.577)
Median		58.33	0.00	16.67
Min, Max		58.3, 58.3	-16.7, 16.7	-16.7, 58.3
Change from Baseline to Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		54.17 (5.893)	-8.33 (11.785)	22.92 (36.878)
Median		54.17	-8.33	25.00
Min, Max		50.0, 58.3	-16.7, 0.0	-16.7, 58.3
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		58.33 (-)	8.33 (35.355)	25.00 (38.188)
Median		58.33	8.33	33.33
Min, Max		58.3, 58.3	-16.7, 33.3	-16.7, 58.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Physical Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	86.67 (-)	46.67 (29.059)	70.00 (24.646)	60.00 (28.284)
Median	86.67	53.33	80.00	66.67
Min, Max	86.7, 86.7	0.0, 80.0	33.3, 86.7	0.0, 86.7
Change from Baseline to Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		24.00 (28.906)	4.44 (10.184)	16.67 (24.689)
Median		6.67	6.67	6.67
Min, Max		6.7, 73.3	-6.7, 13.3	-6.7, 73.3
Change from Baseline to Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		23.33 (20.728)	13.33 (6.667)	19.05 (16.069)
Median		16.67	13.33	13.33
Min, Max		6.7, 53.3	6.7, 20.0	6.7, 53.3
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		25.00 (27.420)	16.67 (22.771)	20.83 (23.755)
Median		20.00	13.33	13.33
Min, Max		0.0, 60.0	-6.7, 46.7	-6.7, 60.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Physical Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		13.33 (28.284)	8.33 (14.782)	10.00 (17.256)
Median		13.33	13.33	13.33
Min, Max		-6.7, 33.3	-13.3, 20.0	-13.3, 33.3
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		20.00 (29.059)	1.67 (15.753)	9.52 (22.396)
Median		33.33	6.67	13.33
Min, Max		-13.3, 40.0	-20.0, 13.3	-20.0, 40.0
Change from Baseline to Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		13.33 (29.059)	-4.44 (16.777)	4.44 (23.349)
Median		26.67	-6.67	3.33
Min, Max		-20.0, 33.3	-20.0, 13.3	-20.0, 33.3
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		43.33 (14.142)	0.00 (18.856)	21.67 (28.480)
Median		43.33	0.00	23.33
Min, Max		33.3, 53.3	-13.3, 13.3	-13.3, 53.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Physical Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		46.67 (0.000)	0.00 (18.856)	23.33 (29.059)
Median		46.67	0.00	30.00
Min, Max		46.7, 46.7	-13.3, 13.3	-13.3, 46.7
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		46.67 (-)	0.00 (18.856)	15.56 (30.062)
Median		46.67	0.00	13.33
Min, Max		46.7, 46.7	-13.3, 13.3	-13.3, 46.7
Change from Baseline to Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		53.33 (9.428)	-3.33 (23.570)	25.00 (35.849)
Median		53.33	-3.33	30.00
Min, Max		46.7, 60.0	-20.0, 13.3	-20.0, 60.0
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		46.67 (-)	-3.33 (23.570)	13.33 (33.333)
Median		46.67	-3.33	13.33
Min, Max		46.7, 46.7	-20.0, 13.3	-20.0, 46.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Role Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	33.33 (-)	56.67 (22.361)	33.33 (38.490)	45.00 (29.450)
Median	33.33	66.67	33.33	50.00
Min, Max	33.3, 33.3	33.3, 83.3	0.0, 66.7	0.0, 83.3
Change from Baseline to Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		20.00 (13.944)	38.89 (41.944)	27.08 (26.633)
Median		16.67	33.33	25.00
Min, Max		0.0, 33.3	0.0, 83.3	0.0, 83.3
Change from Baseline to Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		0.00 (13.608)	33.33 (33.333)	14.29 (27.936)
Median		0.00	33.33	0.00
Min, Max		-16.7, 16.7	0.0, 66.7	-16.7, 66.7
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		0.00 (30.429)	41.67 (56.928)	20.83 (47.768)
Median		0.00	50.00	25.00
Min, Max		-33.3, 33.3	-33.3, 100.0	-33.3, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Role Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		-16.67 (23.570)	20.83 (25.000)	8.33 (29.345)
Median		-16.67	16.67	0.00
Min, Max		-33.3, 0.0	0.0, 50.0	-33.3, 50.0
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		-5.56 (25.459)	25.00 (31.914)	11.90 (31.497)
Median		0.00	16.67	0.00
Min, Max		-33.3, 16.7	0.0, 66.7	-33.3, 66.7
Change from Baseline to Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		0.00 (28.868)	16.67 (16.667)	8.33 (22.973)
Median		16.67	16.67	16.67
Min, Max		-33.3, 16.7	0.0, 33.3	-33.3, 33.3
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		25.00 (11.785)	16.67 (23.570)	20.83 (15.957)
Median		25.00	16.67	25.00
Min, Max		16.7, 33.3	0.0, 33.3	0.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Role Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		25.00 (11.785)	16.67 (23.570)	20.83 (15.957)
Median		25.00	16.67	25.00
Min, Max		16.7, 33.3	0.0, 33.3	0.0, 33.3
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		16.67 (-)	16.67 (23.570)	16.67 (16.667)
Median		16.67	16.67	16.67
Min, Max		16.7, 16.7	0.0, 33.3	0.0, 33.3
Change from Baseline to Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		16.67 (0.000)	16.67 (23.570)	16.67 (13.608)
Median		16.67	16.67	16.67
Min, Max		16.7, 16.7	0.0, 33.3	0.0, 33.3
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		16.67 (-)	16.67 (23.570)	16.67 (16.667)
Median		16.67	16.67	16.67
Min, Max		16.7, 16.7	0.0, 33.3	0.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Emotional Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	100.00 (-)	66.67 (29.463)	70.83 (20.972)	71.67 (25.215)
Median	100.00	75.00	75.00	75.00
Min, Max	100.0, 100.0	25.0, 100.0	41.7, 91.7	25.0, 100.0
Change from Baseline to Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		11.67 (30.391)	13.89 (19.245)	12.50 (25.198)
Median		0.00	25.00	12.50
Min, Max		-16.7, 58.3	-8.3, 25.0	-16.7, 58.3
Change from Baseline to Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		21.53 (23.282)	11.11 (20.972)	17.06 (21.181)
Median		16.67	8.33	8.33
Min, Max		0.0, 52.8	-8.3, 33.3	-8.3, 52.8
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		25.00 (24.533)	8.33 (20.412)	16.67 (22.713)
Median		20.83	8.33	12.50
Min, Max		0.0, 58.3	-16.7, 33.3	-16.7, 58.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Emotional Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		-4.17 (41.248)	4.17 (17.347)	1.39 (23.224)
Median		-4.17	4.17	4.17
Min, Max		-33.3, 25.0	-16.7, 25.0	-33.3, 25.0
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		25.00 (50.000)	-2.08 (24.884)	9.52 (36.777)
Median		25.00	0.00	8.33
Min, Max		-25.0, 75.0	-33.3, 25.0	-33.3, 75.0
Change from Baseline to Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		22.22 (45.896)	-25.00 (36.324)	-1.39 (45.159)
Median		25.00	-8.33	-4.17
Min, Max		-25.0, 66.7	-66.7, 0.0	-66.7, 66.7
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		37.50 (17.678)	-37.50 (17.678)	0.00 (45.644)
Median		37.50	-37.50	0.00
Min, Max		25.0, 50.0	-50.0, -25.0	-50.0, 50.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Emotional Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		37.50 (17.678)	-45.83 (5.893)	-4.17 (49.301)
Median		37.50	-45.83	-8.33
Min, Max		25.0, 50.0	-50.0, -41.7	-50.0, 50.0
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		66.67 (-)	-45.83 (5.893)	-8.33 (65.085)
Median		66.67	-45.83	-41.67
Min, Max		66.7, 66.7	-50.0, -41.7	-50.0, 66.7
Change from Baseline to Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		45.83 (29.463)	-37.50 (5.893)	4.17 (51.144)
Median		45.83	-37.50	-4.17
Min, Max		25.0, 66.7	-41.7, -33.3	-41.7, 66.7
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		25.00 (-)	-54.17 (41.248)	-27.78 (54.220)
Median		25.00	-54.17	-25.00
Min, Max		25.0, 25.0	-83.3, -25.0	-83.3, 25.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Cognitive Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	66.67 (-)	76.67 (19.003)	70.83 (15.957)	73.33 (16.102)
Median	66.67	83.33	75.00	75.00
Min, Max	66.7, 66.7	50.0, 100.0	50.0, 83.3	50.0, 100.0
Change from Baseline to Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		6.67 (27.889)	16.67 (16.667)	10.42 (23.465)
Median		0.00	16.67	8.33
Min, Max		-16.7, 50.0	0.0, 33.3	-16.7, 50.0
Change from Baseline to Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		12.50 (25.000)	11.11 (9.623)	11.90 (18.545)
Median		0.00	16.67	0.00
Min, Max		0.0, 50.0	0.0, 16.7	0.0, 50.0
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		8.33 (28.868)	8.33 (9.623)	8.33 (19.920)
Median		0.00	8.33	0.00
Min, Max		-16.7, 50.0	0.0, 16.7	-16.7, 50.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Cognitive Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		-8.33 (11.785)	0.00 (23.570)	-2.78 (19.484)
Median		-8.33	8.33	0.00
Min, Max		-16.7, 0.0	-33.3, 16.7	-33.3, 16.7
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		16.67 (28.868)	12.50 (8.333)	14.29 (17.817)
Median		0.00	16.67	16.67
Min, Max		0.0, 50.0	0.0, 16.7	0.0, 50.0
Change from Baseline to Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		11.11 (34.694)	-16.67 (16.667)	-2.78 (28.707)
Median		0.00	-16.67	-8.33
Min, Max		-16.7, 50.0	-33.3, 0.0	-33.3, 50.0
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		25.00 (35.355)	-8.33 (11.785)	8.33 (28.868)
Median		25.00	-8.33	0.00
Min, Max		0.0, 50.0	-16.7, 0.0	-16.7, 50.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Cognitive Functioning	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		16.67 (47.140)	-8.33 (11.785)	4.17 (31.549)
Median		16.67	-8.33	-8.33
Min, Max		-16.7, 50.0	-16.7, 0.0	-16.7, 50.0
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		50.00 (-)	-25.00 (35.355)	0.00 (50.000)
Median		50.00	-25.00	0.00
Min, Max		50.0, 50.0	-50.0, 0.0	-50.0, 50.0
Change from Baseline to Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		16.67 (23.570)	-16.67 (23.570)	0.00 (27.217)
Median		16.67	-16.67	0.00
Min, Max		0.0, 33.3	-33.3, 0.0	-33.3, 33.3
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	-33.33 (47.140)	-22.22 (38.490)
Median		0.00	-33.33	0.00
Min, Max		0.0, 0.0	-66.7, 0.0	-66.7, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Social Function	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	33.33 (-)	60.00 (30.277)	58.33 (41.944)	56.67 (32.584)
Median	33.33	66.67	66.67	66.67
Min, Max	33.3, 33.3	16.7, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		20.00 (36.132)	11.11 (38.490)	16.67 (34.503)
Median		33.33	33.33	33.33
Min, Max		-16.7, 66.7	-33.3, 33.3	-33.3, 66.7
Change from Baseline to Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		12.50 (25.000)	16.67 (16.667)	14.29 (20.250)
Median		16.67	16.67	16.67
Min, Max		-16.7, 33.3	0.0, 33.3	-16.7, 33.3
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		16.67 (30.429)	8.33 (16.667)	12.50 (23.146)
Median		16.67	0.00	0.00
Min, Max		-16.7, 50.0	0.0, 33.3	-16.7, 50.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Social Function	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		16.67 (23.570)	4.17 (20.972)	8.33 (20.412)
Median		16.67	0.00	0.00
Min, Max		0.0, 33.3	-16.7, 33.3	-16.7, 33.3
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		22.22 (50.918)	0.00 (49.065)	9.52 (47.000)
Median		33.33	-8.33	0.00
Min, Max		-33.3, 66.7	-50.0, 66.7	-50.0, 66.7
Change from Baseline to Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		22.22 (50.918)	-5.56 (9.623)	8.33 (36.132)
Median		33.33	0.00	0.00
Min, Max		-33.3, 66.7	-16.7, 0.0	-33.3, 66.7
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		41.67 (11.785)	-33.33 (47.140)	4.17 (51.595)
Median		41.67	-33.33	16.67
Min, Max		33.3, 50.0	-66.7, 0.0	-66.7, 50.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Social Function	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		50.00 (23.570)	-25.00 (58.926)	12.50 (56.724)
Median		50.00	-25.00	25.00
Min, Max		33.3, 66.7	-66.7, 16.7	-66.7, 66.7
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		66.67 (-)	-50.00 (70.711)	-11.11 (83.887)
Median		66.67	-50.00	0.00
Min, Max		66.7, 66.7	-100.0, 0.0	-100.0, 66.7
Change from Baseline to Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		33.33 (0.000)	-33.33 (70.711)	0.00 (56.108)
Median		33.33	-33.33	25.00
Min, Max		33.3, 33.3	-83.3, 16.7	-83.3, 33.3
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		33.33 (-)	-41.67 (58.926)	-16.67 (60.093)
Median		33.33	-41.67	0.00
Min, Max		33.3, 33.3	-83.3, 0.0	-83.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Fatigue	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	100.00 (-)	55.56 (32.394)	69.44 (30.598)	65.56 (31.186)
Median	100.00	55.56	72.22	61.11
Min, Max	100.0, 100.0	11.1, 100.0	33.3, 100.0	11.1, 100.0
Change from Baseline to Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		-20.00 (29.814)	-22.22 (38.490)	-20.83 (30.538)
Median		0.00	0.00	0.00
Min, Max		-66.7, 0.0	-66.7, 0.0	-66.7, 0.0
Change from Baseline to Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		-16.67 (26.450)	-25.93 (27.962)	-20.63 (25.198)
Median		-16.67	-22.22	-22.22
Min, Max		-44.4, 11.1	-55.6, 0.0	-55.6, 11.1
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		-2.78 (29.222)	-30.56 (43.862)	-16.67 (37.562)
Median		0.00	-38.89	-16.67
Min, Max		-33.3, 22.2	-66.7, 22.2	-66.7, 22.2

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Fatigue	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		11.11 (62.854)	-27.78 (29.397)	-14.81 (41.376)
Median		11.11	-22.22	-22.22
Min, Max		-33.3, 55.6	-66.7, 0.0	-66.7, 55.6
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		-11.11 (48.432)	-13.89 (29.222)	-12.70 (34.800)
Median		-33.33	-5.56	-11.11
Min, Max		-44.4, 44.4	-55.6, 11.1	-55.6, 44.4
Change from Baseline to Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		-25.93 (42.066)	0.00 (11.111)	-12.96 (30.965)
Median		-44.44	0.00	-5.56
Min, Max		-55.6, 22.2	-11.1, 11.1	-55.6, 22.2
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		-50.00 (7.857)	0.00 (0.000)	-25.00 (29.222)
Median		-50.00	0.00	-22.22
Min, Max		-55.6, -44.4	0.0, 0.0	-55.6, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Fatigue	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		-72.22 (7.857)	-11.11 (15.713)	-41.67 (36.712)
Median		-72.22	-11.11	-44.44
Min, Max		-77.8, -66.7	-22.2, 0.0	-77.8, 0.0
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		-55.56 (-)	-5.56 (7.857)	-22.22 (29.397)
Median		-55.56	-5.56	-11.11
Min, Max		-55.6, -55.6	-11.1, 0.0	-55.6, 0.0
Change from Baseline to Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		-55.56 (15.713)	0.00 (0.000)	-27.78 (33.333)
Median		-55.56	0.00	-22.22
Min, Max		-66.7, -44.4	0.0, 0.0	-66.7, 0.0
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		-66.67 (-)	-5.56 (7.857)	-25.93 (35.717)
Median		-66.67	-5.56	-11.11
Min, Max		-66.7, -66.7	-11.1, 0.0	-66.7, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Nausea and Vomiting	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	66.67 (-)	10.00 (22.361)	8.33 (9.623)	15.00 (24.152)
Median	66.67	0.00	8.33	0.00
Min, Max	66.7, 66.7	0.0, 50.0	0.0, 16.7	0.0, 66.7
Change from Baseline to Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		3.33 (24.721)	5.56 (9.623)	4.17 (19.416)
Median		0.00	0.00	0.00
Min, Max		-33.3, 33.3	0.0, 16.7	-33.3, 33.3
Change from Baseline to Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		8.33 (44.096)	5.56 (9.623)	7.14 (31.706)
Median		16.67	0.00	0.00
Min, Max		-50.0, 50.0	0.0, 16.7	-50.0, 50.0
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		8.33 (31.914)	-4.17 (15.957)	2.08 (24.296)
Median		16.67	-8.33	0.00
Min, Max		-33.3, 33.3	-16.7, 16.7	-33.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Nausea and Vomiting	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		16.67 (23.570)	0.00 (13.608)	5.56 (17.213)
Median		16.67	0.00	0.00
Min, Max		0.0, 33.3	-16.7, 16.7	-16.7, 33.3
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		-11.11 (34.694)	-4.17 (15.957)	-7.14 (23.288)
Median		0.00	-8.33	0.00
Min, Max		-50.0, 16.7	-16.7, 16.7	-50.0, 16.7
Change from Baseline to Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		-11.11 (19.245)	0.00 (16.667)	-5.56 (17.213)
Median		0.00	0.00	0.00
Min, Max		-33.3, 0.0	-16.7, 16.7	-33.3, 16.7
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		-16.67 (23.570)	-8.33 (11.785)	-12.50 (15.957)
Median		-16.67	-8.33	-8.33
Min, Max		-33.3, 0.0	-16.7, 0.0	-33.3, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Nausea and Vomiting	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		-16.67 (23.570)	-8.33 (11.785)	-12.50 (15.957)
Median		-16.67	-8.33	-8.33
Min, Max		-33.3, 0.0	-16.7, 0.0	-33.3, 0.0
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		-33.33 (-)	-8.33 (11.785)	-16.67 (16.667)
Median		-33.33	-8.33	-16.67
Min, Max		-33.3, -33.3	-16.7, 0.0	-33.3, 0.0
Change from Baseline to Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		-25.00 (35.355)	-16.67 (0.000)	-20.83 (20.972)
Median		-25.00	-16.67	-16.67
Min, Max		-50.0, 0.0	-16.7, -16.7	-50.0, 0.0
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	-8.33 (11.785)	-5.56 (9.623)
Median		0.00	-8.33	0.00
Min, Max		0.0, 0.0	-16.7, 0.0	-16.7, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Pain	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	83.33 (-)	26.67 (19.003)	50.00 (43.033)	41.67 (33.564)
Median	83.33	33.33	50.00	33.33
Min, Max	83.3, 83.3	0.0, 50.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		-10.00 (14.907)	-33.33 (44.096)	-18.75 (28.781)
Median		0.00	-16.67	-8.33
Min, Max		-33.3, 0.0	-83.3, 0.0	-83.3, 0.0
Change from Baseline to Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		4.17 (20.972)	-27.78 (34.694)	-9.52 (30.211)
Median		0.00	-16.67	0.00
Min, Max		-16.7, 33.3	-66.7, 0.0	-66.7, 33.3
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		-12.50 (15.957)	-25.00 (56.928)	-18.75 (39.277)
Median		-8.33	-33.33	-16.67
Min, Max		-33.3, 0.0	-83.3, 50.0	-83.3, 50.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Pain	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		-8.33 (11.785)	-37.50 (43.833)	-27.78 (37.515)
Median		-8.33	-25.00	-16.67
Min, Max		-16.7, 0.0	-100.0, 0.0	-100.0, 0.0
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		-22.22 (19.245)	-20.83 (41.667)	-21.43 (31.497)
Median		-33.33	0.00	0.00
Min, Max		-33.3, 0.0	-83.3, 0.0	-83.3, 0.0
Change from Baseline to Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		-11.11 (25.459)	-5.56 (9.623)	-8.33 (17.480)
Median		-16.67	0.00	-8.33
Min, Max		-33.3, 16.7	-16.7, 0.0	-33.3, 16.7
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		-25.00 (11.785)	8.33 (35.355)	-8.33 (28.868)
Median		-25.00	8.33	-16.67
Min, Max		-33.3, -16.7	-16.7, 33.3	-33.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Pain	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		-33.33 (0.000)	8.33 (35.355)	-12.50 (31.549)
Median		-33.33	8.33	-25.00
Min, Max		-33.3, -33.3	-16.7, 33.3	-33.3, 33.3
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		-16.67 (-)	8.33 (35.355)	0.00 (28.868)
Median		-16.67	8.33	-16.67
Min, Max		-16.7, -16.7	-16.7, 33.3	-16.7, 33.3
Change from Baseline to Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		-25.00 (11.785)	8.33 (35.355)	-8.33 (28.868)
Median		-25.00	8.33	-16.67
Min, Max		-33.3, -16.7	-16.7, 33.3	-33.3, 33.3
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		-33.33 (-)	0.00 (47.140)	-11.11 (38.490)
Median		-33.33	0.00	-33.33
Min, Max		-33.3, -33.3	-33.3, 33.3	-33.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Dyspnea	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	33.33 (-)	40.00 (36.515)	50.00 (43.033)	43.33 (35.312)
Median	33.33	33.33	50.00	33.33
Min, Max	33.3, 33.3	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		-26.67 (49.441)	-11.11 (19.245)	-20.83 (39.591)
Median		-33.33	0.00	-16.67
Min, Max		-100.0, 33.3	-33.3, 0.0	-100.0, 33.3
Change from Baseline to Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		-16.67 (43.033)	-33.33 (33.333)	-23.81 (37.090)
Median		-16.67	-33.33	-33.33
Min, Max		-66.7, 33.3	-66.7, 0.0	-66.7, 33.3
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		-25.00 (31.914)	-25.00 (31.914)	-25.00 (29.547)
Median		-16.67	-16.67	-16.67
Min, Max		-66.7, 0.0	-66.7, 0.0	-66.7, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Dyspnea	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		0.00 (47.140)	-16.67 (33.333)	-11.11 (34.427)
Median		0.00	0.00	0.00
Min, Max		-33.3, 33.3	-66.7, 0.0	-66.7, 33.3
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		-33.33 (33.333)	-8.33 (41.944)	-19.05 (37.796)
Median		-33.33	0.00	0.00
Min, Max		-66.7, 0.0	-66.7, 33.3	-66.7, 33.3
Change from Baseline to Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		-33.33 (66.667)	-11.11 (50.918)	-22.22 (54.433)
Median		-33.33	0.00	-16.67
Min, Max		-100.0, 33.3	-66.7, 33.3	-100.0, 33.3
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		-66.67 (47.140)	-33.33 (47.140)	-50.00 (43.033)
Median		-66.67	-33.33	-50.00
Min, Max		-100.0, -33.3	-66.7, 0.0	-100.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Dyspnea	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		-66.67 (47.140)	-33.33 (47.140)	-50.00 (43.033)
Median		-66.67	-33.33	-50.00
Min, Max		-100.0, -33.3	-66.7, 0.0	-100.0, 0.0
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		-100.00 (-)	-33.33 (47.140)	-55.56 (50.918)
Median		-100.00	-33.33	-66.67
Min, Max		-100.0, -100.0	-66.7, 0.0	-100.0, 0.0
Change from Baseline to Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		-66.67 (47.140)	-33.33 (47.140)	-50.00 (43.033)
Median		-66.67	-33.33	-50.00
Min, Max		-100.0, -33.3	-66.7, 0.0	-100.0, 0.0
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		-33.33 (-)	-33.33 (47.140)	-33.33 (33.333)
Median		-33.33	-33.33	-33.33
Min, Max		-33.3, -33.3	-66.7, 0.0	-66.7, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Insomnia	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	100.00 (-)	26.67 (27.889)	58.33 (50.000)	46.67 (42.164)
Median	100.00	33.33	66.67	33.33
Min, Max	100.0, 100.0	0.0, 66.7	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		-6.67 (14.907)	-22.22 (83.887)	-12.50 (46.930)
Median		0.00	-33.33	0.00
Min, Max		-33.3, 0.0	-100.0, 66.7	-100.0, 66.7
Change from Baseline to Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		8.33 (56.928)	-11.11 (69.389)	0.00 (57.735)
Median		16.67	-33.33	0.00
Min, Max		-66.7, 66.7	-66.7, 66.7	-66.7, 66.7
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		0.00 (47.140)	-16.67 (43.033)	-8.33 (42.725)
Median		16.67	-16.67	0.00
Min, Max		-66.7, 33.3	-66.7, 33.3	-66.7, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Insomnia	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		16.67 (70.711)	-25.00 (31.914)	-11.11 (45.542)
Median		16.67	-16.67	-16.67
Min, Max		-33.3, 66.7	-66.7, 0.0	-66.7, 66.7
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		11.11 (50.918)	-16.67 (43.033)	-4.76 (44.840)
Median		0.00	-16.67	0.00
Min, Max		-33.3, 66.7	-66.7, 33.3	-66.7, 66.7
Change from Baseline to Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		22.22 (50.918)	11.11 (19.245)	16.67 (34.960)
Median		33.33	0.00	16.67
Min, Max		-33.3, 66.7	0.0, 33.3	-33.3, 66.7
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		-33.33 (47.140)	0.00 (0.000)	-16.67 (33.333)
Median		-33.33	0.00	0.00
Min, Max		-66.7, 0.0	0.0, 0.0	-66.7, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Insomnia	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		-33.33 (47.140)	0.00 (0.000)	-16.67 (33.333)
Median		-33.33	0.00	0.00
Min, Max		-66.7, 0.0	0.0, 0.0	-66.7, 0.0
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	0.00 (0.000)	0.00 (0.000)
Median		0.00	0.00	0.00
Min, Max		0.0, 0.0	0.0, 0.0	0.0, 0.0
Change from Baseline to Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		-33.33 (47.140)	16.67 (23.570)	-8.33 (41.944)
Median		-33.33	16.67	0.00
Min, Max		-66.7, 0.0	0.0, 33.3	-66.7, 33.3
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		-66.67 (-)	16.67 (23.570)	-11.11 (50.918)
Median		-66.67	16.67	0.00
Min, Max		-66.7, -66.7	0.0, 33.3	-66.7, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Appetite Loss	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	0.00 (-)	40.00 (43.461)	41.67 (41.944)	36.67 (39.907)
Median	0.00	33.33	33.33	33.33
Min, Max	0.0, 0.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		-20.00 (64.979)	11.11 (19.245)	-8.33 (52.705)
Median		0.00	0.00	0.00
Min, Max		-100.0, 66.7	0.0, 33.3	-100.0, 66.7
Change from Baseline to Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		-50.00 (43.033)	22.22 (19.245)	-19.05 (50.395)
Median		-50.00	33.33	0.00
Min, Max		-100.0, 0.0	0.0, 33.3	-100.0, 33.3
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		-25.00 (50.000)	-8.33 (31.914)	-16.67 (39.841)
Median		-33.33	-16.67	-16.67
Min, Max		-66.7, 33.3	-33.3, 33.3	-66.7, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Appetite Loss	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		-16.67 (70.711)	-8.33 (16.667)	-11.11 (34.427)
Median		-16.67	0.00	0.00
Min, Max		-66.7, 33.3	-33.3, 0.0	-66.7, 33.3
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		-44.44 (69.389)	-16.67 (33.333)	-28.57 (48.795)
Median		-66.67	0.00	0.00
Min, Max		-100.0, 33.3	-66.7, 0.0	-100.0, 33.3
Change from Baseline to Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		-33.33 (88.192)	-11.11 (19.245)	-22.22 (58.373)
Median		-66.67	0.00	-16.67
Min, Max		-100.0, 66.7	-33.3, 0.0	-100.0, 66.7
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		-83.33 (23.570)	-16.67 (23.570)	-50.00 (43.033)
Median		-83.33	-16.67	-50.00
Min, Max		-100.0, -66.7	-33.3, 0.0	-100.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Appetite Loss	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		-83.33 (23.570)	0.00 (0.000)	-41.67 (50.000)
Median		-83.33	0.00	-33.33
Min, Max		-100.0, -66.7	0.0, 0.0	-100.0, 0.0
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		-100.00 (-)	16.67 (23.570)	-22.22 (69.389)
Median		-100.00	16.67	0.00
Min, Max		-100.0, -100.0	0.0, 33.3	-100.0, 33.3
Change from Baseline to Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		-83.33 (23.570)	16.67 (23.570)	-33.33 (60.858)
Median		-83.33	16.67	-33.33
Min, Max		-100.0, -66.7	0.0, 33.3	-100.0, 33.3
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		-66.67 (-)	16.67 (23.570)	-11.11 (50.918)
Median		-66.67	16.67	0.00
Min, Max		-66.7, -66.7	0.0, 33.3	-66.7, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Constipation	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	0.00 (-)	20.00 (29.814)	16.67 (33.333)	16.67 (28.328)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 0.0	0.0, 66.7	0.0, 66.7	0.0, 66.7
Change from Baseline to Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		-6.67 (36.515)	-22.22 (38.490)	-12.50 (35.355)
Median		0.00	0.00	0.00
Min, Max		-66.7, 33.3	-66.7, 0.0	-66.7, 33.3
Change from Baseline to Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		-16.67 (33.333)	-11.11 (50.918)	-14.29 (37.796)
Median		0.00	0.00	0.00
Min, Max		-66.7, 0.0	-66.7, 33.3	-66.7, 33.3
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		-16.67 (33.333)	-16.67 (33.333)	-16.67 (30.861)
Median		0.00	0.00	0.00
Min, Max		-66.7, 0.0	-66.7, 0.0	-66.7, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Constipation	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		0.00 (0.000)	-16.67 (33.333)	-11.11 (27.217)
Median		0.00	0.00	0.00
Min, Max		0.0, 0.0	-66.7, 0.0	-66.7, 0.0
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		-33.33 (33.333)	-8.33 (16.667)	-19.05 (26.227)
Median		-33.33	0.00	0.00
Min, Max		-66.7, 0.0	-33.3, 0.0	-66.7, 0.0
Change from Baseline to Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		-22.22 (38.490)	-22.22 (38.490)	-22.22 (34.427)
Median		0.00	0.00	0.00
Min, Max		-66.7, 0.0	-66.7, 0.0	-66.7, 0.0
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		-50.00 (23.570)	0.00 (0.000)	-25.00 (31.914)
Median		-50.00	0.00	-16.67
Min, Max		-66.7, -33.3	0.0, 0.0	-66.7, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Constipation	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		-50.00 (23.570)	0.00 (0.000)	-25.00 (31.914)
Median		-50.00	0.00	-16.67
Min, Max		-66.7, -33.3	0.0, 0.0	-66.7, 0.0
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		-66.67 (-)	0.00 (0.000)	-22.22 (38.490)
Median		-66.67	0.00	0.00
Min, Max		-66.7, -66.7	0.0, 0.0	-66.7, 0.0
Change from Baseline to Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		-50.00 (23.570)	0.00 (0.000)	-25.00 (31.914)
Median		-50.00	0.00	-16.67
Min, Max		-66.7, -33.3	0.0, 0.0	-66.7, 0.0
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		-33.33 (-)	0.00 (0.000)	-11.11 (19.245)
Median		-33.33	0.00	0.00
Min, Max		-33.3, -33.3	0.0, 0.0	-33.3, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Diarrhea	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	100.00 (-)	33.33 (47.140)	58.33 (41.944)	50.00 (45.134)
Median	100.00	0.00	66.67	66.67
Min, Max	100.0, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		-6.67 (64.118)	0.00 (33.333)	-4.17 (51.755)
Median		0.00	0.00	0.00
Min, Max		-100.0, 66.7	-33.3, 33.3	-100.0, 66.7
Change from Baseline to Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		-16.67 (63.828)	22.22 (38.490)	0.00 (54.433)
Median		0.00	0.00	0.00
Min, Max		-100.0, 33.3	0.0, 66.7	-100.0, 66.7
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		0.00 (60.858)	-33.33 (60.858)	-16.67 (59.094)
Median		0.00	-33.33	-16.67
Min, Max		-66.7, 66.7	-100.0, 33.3	-100.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Diarrhea	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		16.67 (70.711)	-8.33 (56.928)	0.00 (55.777)
Median		16.67	-16.67	-16.67
Min, Max		-33.3, 66.7	-66.7, 66.7	-66.7, 66.7
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		-11.11 (101.835)	-25.00 (56.928)	-19.05 (71.640)
Median		-33.33	-16.67	-33.33
Min, Max		-100.0, 100.0	-100.0, 33.3	-100.0, 100.0
Change from Baseline to Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		-11.11 (69.389)	-33.33 (66.667)	-22.22 (62.063)
Median		-33.33	-33.33	-33.33
Min, Max		-66.7, 66.7	-100.0, 33.3	-100.0, 66.7
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		-50.00 (23.570)	-66.67 (47.140)	-58.33 (31.914)
Median		-50.00	-66.67	-50.00
Min, Max		-66.7, -33.3	-100.0, -33.3	-100.0, -33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Diarrhea	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		-66.67 (47.140)	-16.67 (23.570)	-41.67 (41.944)
Median		-66.67	-16.67	-33.33
Min, Max		-100.0, -33.3	-33.3, 0.0	-100.0, 0.0
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		-66.67 (-)	0.00 (0.000)	-22.22 (38.490)
Median		-66.67	0.00	0.00
Min, Max		-66.7, -66.7	0.0, 0.0	-66.7, 0.0
Change from Baseline to Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		-50.00 (23.570)	-33.33 (0.000)	-41.67 (16.667)
Median		-50.00	-33.33	-33.33
Min, Max		-66.7, -33.3	-33.3, -33.3	-66.7, -33.3
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		-33.33 (-)	-33.33 (0.000)	-33.33 (0.000)
Median		-33.33	-33.33	-33.33
Min, Max		-33.3, -33.3	-33.3, -33.3	-33.3, -33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Financial Difficulties	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Baseline				
n	1	5	4	10
Mean (StdDev)	66.67 (-)	26.67 (43.461)	58.33 (41.944)	43.33 (41.722)
Median	66.67	0.00	66.67	50.00
Min, Max	66.7, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 2 Day 1				
n	0	5	3	8
Mean (StdDev)		6.67 (27.889)	-22.22 (38.490)	-4.17 (33.034)
Median		0.00	0.00	0.00
Min, Max		-33.3, 33.3	-66.7, 0.0	-66.7, 33.3
Change from Baseline to Cycle 3 Day 1				
n	0	4	3	7
Mean (StdDev)		8.33 (31.914)	-11.11 (19.245)	0.00 (27.217)
Median		16.67	0.00	0.00
Min, Max		-33.3, 33.3	-33.3, 0.0	-33.3, 33.3
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		-8.33 (16.667)	-8.33 (16.667)	-8.33 (15.430)
Median		0.00	0.00	0.00
Min, Max		-33.3, 0.0	-33.3, 0.0	-33.3, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg				
Financial Difficulties	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 5 Day 1				
n	0	2	4	6
Mean (StdDev)		0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
Median		0.00	0.00	0.00
Min, Max		0.0, 0.0	0.0, 0.0	0.0, 0.0
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		-11.11 (19.245)	-8.33 (31.914)	-9.52 (25.198)
Median		0.00	-16.67	0.00
Min, Max		-33.3, 0.0	-33.3, 33.3	-33.3, 33.3
Change from Baseline to Cycle 7 Day 1				
n	0	3	3	6
Mean (StdDev)		-11.11 (19.245)	-11.11 (19.245)	-11.11 (17.213)
Median		0.00	0.00	0.00
Min, Max		-33.3, 0.0	-33.3, 0.0	-33.3, 0.0
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	33.33 (47.140)	16.67 (33.333)
Median		0.00	33.33	0.00
Min, Max		0.0, 0.0	0.0, 66.7	0.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

Financial Difficulties	ASM (N=1)	SM-AHN (N=5)	MCL (N=4)	All AdvSM (N=10)
Change from Baseline to Cycle 9 Day 1				
n	0	2	2	4
Mean (StdDev)		-16.67 (23.570)	33.33 (47.140)	8.33 (41.944)
Median		-16.67	33.33	0.00
Min, Max		-33.3, 0.0	0.0, 66.7	-33.3, 66.7
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		-33.33 (-)	33.33 (47.140)	11.11 (50.918)
Median		-33.33	33.33	0.00
Min, Max		-33.3, -33.3	0.0, 66.7	-33.3, 66.7
Change from Baseline to Cycle 11 Day 1				
n	0	2	2	4
Mean (StdDev)		-16.67 (23.570)	33.33 (47.140)	8.33 (41.944)
Median		-16.67	33.33	0.00
Min, Max		-33.3, 0.0	0.0, 66.7	-33.3, 66.7
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	16.67 (23.570)	11.11 (19.245)
Median		0.00	16.67	0.00
Min, Max		0.0, 0.0	0.0, 33.3	0.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Global Health Status/QoL	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Baseline				
n	3	24	8	35
Mean (StdDev)	55.56 (20.972)	31.94 (25.616)	36.46 (13.317)	35.00 (23.466)
Median	58.33	33.33	33.33	33.33
Min, Max	33.3, 75.0	0.0, 100.0	16.7, 58.3	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	2.78 (9.623)	19.58 (26.390)	11.90 (24.934)	16.11 (24.946)
Median	8.33	16.67	0.00	8.33
Min, Max	-8.3, 8.3	-25.0, 83.3	-8.3, 50.0	-25.0, 83.3
Change from Baseline to Cycle 2 Day 1				
n	2	22	8	32
Mean (StdDev)	0.00 (11.785)	23.11 (30.960)	13.54 (26.329)	19.27 (29.210)
Median	0.00	16.67	20.83	16.67
Min, Max	-8.3, 8.3	-25.0, 91.7	-33.3, 50.0	-33.3, 91.7
Change from Baseline to Cycle 3 Day 1				
n	3	22	6	31
Mean (StdDev)	5.56 (26.788)	24.62 (33.082)	5.56 (12.546)	19.09 (30.291)
Median	16.67	20.83	0.00	16.67
Min, Max	-25.0, 25.0	-66.7, 83.3	-8.3, 25.0	-66.7, 83.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Global Health Status/QoL	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Change from Baseline to Cycle 5 Day 1				
n	1	14	5	20
Mean (StdDev)	16.67 (-)	25.00 (42.992)	5.00 (18.257)	19.58 (37.588)
Median	16.67	29.17	16.67	16.67
Min, Max	16.7, 16.7	-100.0, 83.3	-25.0, 16.7	-100.0, 83.3
Change from Baseline to Cycle 7 Day 1				
n	1	14	2	17
Mean (StdDev)	-16.67 (-)	33.33 (34.746)	8.33 (11.785)	27.45 (34.456)
Median	-16.67	33.33	8.33	33.33
Min, Max	-16.7, -16.7	-33.3, 83.3	0.0, 16.7	-33.3, 83.3
Change from Baseline to Cycle 9 Day 1				
n	0	11	2	13
Mean (StdDev)		22.73 (36.910)	16.67 (0.000)	21.79 (33.771)
Median		33.33	16.67	16.67
Min, Max		-58.3, 83.3	16.7, 16.7	-58.3, 83.3
Change from Baseline to Cycle 11 Day 1				
n	0	6	1	7
Mean (StdDev)		30.56 (34.427)	25.00 (-)	29.76 (31.497)
Median		45.83	25.00	41.67
Min, Max		-33.3, 58.3	25.0, 25.0	-33.3, 58.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Global Health Status/QoL	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		30.56 (64.729)	41.67 (-)	33.33 (53.142)
Median		50.00	41.67	45.83
Min, Max		-41.7, 83.3	41.7, 41.7	-41.7, 83.3
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		-33.33 (-)		-33.33 (-)
Median		-33.33		-33.33
Min, Max		-33.3, -33.3		-33.3, -33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Physical Functioning	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Baseline				
n	3	24	8	35
Mean (StdDev)	62.22 (36.717)	51.11 (29.137)	60.00 (24.944)	54.10 (28.320)
Median	80.00	46.67	60.00	46.67
Min, Max	20.0, 86.7	0.0, 100.0	26.7, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	2.22 (3.849)	11.67 (17.951)	15.24 (22.678)	11.56 (18.189)
Median	0.00	10.00	13.33	10.00
Min, Max	0.0, 6.7	-13.3, 53.3	-20.0, 46.7	-20.0, 53.3
Change from Baseline to Cycle 2 Day 1				
n	2	22	8	32
Mean (StdDev)	0.00 (0.000)	14.85 (21.275)	11.67 (22.467)	13.13 (20.841)
Median	0.00	10.00	6.67	3.33
Min, Max	0.0, 0.0	-6.7, 66.7	-20.0, 46.7	-20.0, 66.7
Change from Baseline to Cycle 3 Day 1				
n	3	22	6	31
Mean (StdDev)	-8.89 (3.849)	16.36 (24.320)	5.56 (19.963)	11.83 (23.394)
Median	-6.67	13.33	3.33	6.67
Min, Max	-13.3, -6.7	-20.0, 73.3	-13.3, 40.0	-20.0, 73.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Physical Functioning	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Change from Baseline to Cycle 5 Day 1				
n	1	14	5	20
Mean (StdDev)	26.67 (-)	28.10 (24.832)	0.00 (25.820)	21.00 (26.778)
Median	26.67	30.00	-6.67	23.33
Min, Max	26.7, 26.7	-13.3, 73.3	-26.7, 33.3	-26.7, 73.3
Change from Baseline to Cycle 7 Day 1				
n	1	14	2	17
Mean (StdDev)	-40.00 (-)	23.81 (25.042)	23.33 (23.570)	20.00 (27.988)
Median	-40.00	10.00	23.33	6.67
Min, Max	-40.0, -40.0	-6.7, 66.7	6.7, 40.0	-40.0, 66.7
Change from Baseline to Cycle 9 Day 1				
n	0	11	2	13
Mean (StdDev)		24.24 (24.271)	20.00 (18.856)	23.59 (22.871)
Median		13.33	20.00	13.33
Min, Max		0.0, 66.7	6.7, 33.3	0.0, 66.7
Change from Baseline to Cycle 11 Day 1				
n	0	6	1	7
Mean (StdDev)		30.00 (22.998)	60.00 (-)	34.29 (23.860)
Median		30.00	60.00	33.33
Min, Max		-6.7, 60.0	60.0, 60.0	-6.7, 60.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Physical Functioning	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		35.56 (33.555)	60.00 (-)	41.67 (30.000)
Median		40.00	60.00	50.00
Min, Max		0.0, 66.7	60.0, 60.0	0.0, 66.7
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Role Functioning	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Baseline				
n	3	24	8	35
Mean (StdDev)	50.00 (44.096)	38.89 (37.644)	27.08 (26.633)	37.14 (35.490)
Median	66.67	33.33	25.00	33.33
Min, Max	0.0, 83.3	0.0, 100.0	0.0, 66.7	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	-5.56 (9.623)	12.50 (18.634)	23.81 (21.207)	13.33 (19.769)
Median	0.00	0.00	16.67	8.33
Min, Max	-16.7, 0.0	-16.7, 50.0	0.0, 66.7	-16.7, 66.7
Change from Baseline to Cycle 2 Day 1				
n	2	22	8	32
Mean (StdDev)	-16.67 (23.570)	16.67 (30.861)	18.75 (33.850)	15.10 (31.498)
Median	-16.67	8.33	25.00	8.33
Min, Max	-33.3, 0.0	-16.7, 100.0	-33.3, 66.7	-33.3, 100.0
Change from Baseline to Cycle 3 Day 1				
n	3	22	6	31
Mean (StdDev)	-11.11 (9.623)	18.18 (30.822)	13.89 (32.347)	14.52 (30.350)
Median	-16.67	16.67	25.00	16.67
Min, Max	-16.7, 0.0	-33.3, 66.7	-33.3, 50.0	-33.3, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Role Functioning	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Change from Baseline to Cycle 5 Day 1				
n	1	14	5	20
Mean (StdDev)	0.00 (-)	25.00 (40.165)	13.33 (21.731)	20.83 (35.407)
Median	0.00	25.00	16.67	16.67
Min, Max	0.0, 0.0	-66.7, 83.3	-16.7, 33.3	-66.7, 83.3
Change from Baseline to Cycle 7 Day 1				
n	1	14	2	17
Mean (StdDev)	-33.33 (-)	25.00 (36.835)	25.00 (11.785)	21.57 (36.212)
Median	-33.33	16.67	25.00	16.67
Min, Max	-33.3, -33.3	-33.3, 83.3	16.7, 33.3	-33.3, 83.3
Change from Baseline to Cycle 9 Day 1				
n	0	11	2	13
Mean (StdDev)		27.27 (32.722)	25.00 (11.785)	26.92 (30.076)
Median		50.00	25.00	33.33
Min, Max		-33.3, 66.7	16.7, 33.3	-33.3, 66.7
Change from Baseline to Cycle 11 Day 1				
n	0	6	1	7
Mean (StdDev)		41.67 (27.386)	100.00 (-)	50.00 (33.333)
Median		50.00	100.00	50.00
Min, Max		0.0, 66.7	100.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Role Functioning	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		44.44 (38.490)	66.67 (-)	50.00 (33.333)
Median		66.67	66.67	66.67
Min, Max		0.0, 66.7	66.7, 66.7	0.0, 66.7
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Emotional Functioning	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Baseline				
n	3	24	8	35
Mean (StdDev)	69.44 (31.549)	59.38 (27.288)	56.25 (27.728)	59.52 (27.052)
Median	83.33	54.17	54.17	58.33
Min, Max	33.3, 91.7	8.3, 100.0	8.3, 100.0	8.3, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	0.00 (8.333)	10.42 (17.703)	1.19 (16.265)	7.22 (16.914)
Median	0.00	12.50	0.00	8.33
Min, Max	-8.3, 8.3	-25.0, 58.3	-25.0, 16.7	-25.0, 58.3
Change from Baseline to Cycle 2 Day 1				
n	2	22	8	32
Mean (StdDev)	-12.50 (5.893)	15.15 (25.411)	11.46 (11.732)	12.50 (22.699)
Median	-12.50	16.67	12.50	12.50
Min, Max	-16.7, -8.3	-25.0, 58.3	0.0, 33.3	-25.0, 58.3
Change from Baseline to Cycle 3 Day 1				
n	3	22	6	31
Mean (StdDev)	-8.33 (25.000)	12.50 (24.767)	1.39 (9.742)	8.33 (23.174)
Median	-8.33	16.67	0.00	8.33
Min, Max	-33.3, 16.7	-33.3, 58.3	-8.3, 16.7	-33.3, 58.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Emotional Functioning	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Change from Baseline to Cycle 5 Day 1				
n	1	14	5	20
Mean (StdDev)	16.67 (-)	23.81 (28.280)	-5.00 (12.638)	16.25 (27.236)
Median	16.67	20.83	0.00	8.33
Min, Max	16.7, 16.7	-25.0, 66.7	-25.0, 8.3	-25.0, 66.7
Change from Baseline to Cycle 7 Day 1				
n	1	14	2	17
Mean (StdDev)	0.00 (-)	18.45 (21.970)	-4.17 (5.893)	14.71 (21.556)
Median	0.00	20.83	-4.17	16.67
Min, Max	0.0, 0.0	-16.7, 50.0	-8.3, 0.0	-16.7, 50.0
Change from Baseline to Cycle 9 Day 1				
n	0	11	2	13
Mean (StdDev)		15.91 (20.226)	-4.17 (5.893)	12.82 (20.016)
Median		16.67	-4.17	8.33
Min, Max		-16.7, 50.0	-8.3, 0.0	-16.7, 50.0
Change from Baseline to Cycle 11 Day 1				
n	0	6	1	7
Mean (StdDev)		15.28 (25.504)	25.00 (-)	16.67 (23.570)
Median		8.33	25.00	8.33
Min, Max		-16.7, 50.0	25.0, 25.0	-16.7, 50.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Emotional Functioning	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		30.56 (33.679)	25.00 (-)	29.17 (27.639)
Median		25.00	25.00	25.00
Min, Max		0.0, 66.7	25.0, 25.0	0.0, 66.7
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Cognitive Functioning	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Baseline				
n	3	24	8	35
Mean (StdDev)	83.33 (16.667)	70.83 (23.698)	62.50 (33.034)	70.00 (25.502)
Median	83.33	66.67	50.00	66.67
Min, Max	66.7, 100.0	33.3, 100.0	16.7, 100.0	16.7, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	-5.56 (9.623)	5.00 (14.408)	-4.76 (8.133)	1.67 (13.384)
Median	0.00	0.00	0.00	0.00
Min, Max	-16.7, 0.0	-16.7, 33.3	-16.7, 0.0	-16.7, 33.3
Change from Baseline to Cycle 2 Day 1				
n	2	22	8	32
Mean (StdDev)	0.00 (0.000)	5.30 (21.447)	2.08 (22.603)	4.17 (20.739)
Median	0.00	0.00	8.33	0.00
Min, Max	0.0, 0.0	-33.3, 50.0	-33.3, 33.3	-33.3, 50.0
Change from Baseline to Cycle 3 Day 1				
n	3	22	6	31
Mean (StdDev)	11.11 (9.623)	3.03 (20.339)	8.33 (25.276)	4.84 (20.273)
Median	16.67	0.00	8.33	0.00
Min, Max	0.0, 16.7	-33.3, 50.0	-33.3, 33.3	-33.3, 50.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Cognitive Functioning	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Change from Baseline to Cycle 5 Day 1				
n	1	14	5	20
Mean (StdDev)	-16.67 (-)	7.14 (23.310)	-10.00 (9.129)	1.67 (21.562)
Median	-16.67	16.67	-16.67	0.00
Min, Max	-16.7, -16.7	-50.0, 33.3	-16.7, 0.0	-50.0, 33.3
Change from Baseline to Cycle 7 Day 1				
n	1	14	2	17
Mean (StdDev)	16.67 (-)	5.95 (24.985)	8.33 (11.785)	6.86 (22.866)
Median	16.67	0.00	8.33	0.00
Min, Max	16.7, 16.7	-33.3, 50.0	0.0, 16.7	-33.3, 50.0
Change from Baseline to Cycle 9 Day 1				
n	0	11	2	13
Mean (StdDev)		0.00 (25.820)	-16.67 (0.000)	-2.56 (24.387)
Median		0.00	-16.67	-16.67
Min, Max		-33.3, 33.3	-16.7, -16.7	-33.3, 33.3
Change from Baseline to Cycle 11 Day 1				
n	0	6	1	7
Mean (StdDev)		5.56 (17.213)	16.67 (-)	7.14 (16.265)
Median		0.00	16.67	0.00
Min, Max		-16.7, 33.3	16.7, 16.7	-16.7, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Cognitive Functioning	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		5.56 (9.623)	16.67 (-)	8.33 (9.623)
Median		0.00	16.67	8.33
Min, Max		0.0, 16.7	16.7, 16.7	0.0, 16.7
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		-16.67 (-)		-16.67 (-)
Median		-16.67		-16.67
Min, Max		-16.7, -16.7		-16.7, -16.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Social Function	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Baseline				
n	3	24	8	35
Mean (StdDev)	55.56 (41.944)	47.92 (34.513)	45.83 (29.209)	48.10 (33.031)
Median	50.00	33.33	50.00	33.33
Min, Max	16.7, 100.0	0.0, 100.0	0.0, 83.3	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	0.00 (16.667)	17.50 (25.635)	19.05 (29.547)	16.11 (25.702)
Median	0.00	16.67	16.67	16.67
Min, Max	-16.7, 16.7	-16.7, 66.7	-16.7, 66.7	-16.7, 66.7
Change from Baseline to Cycle 2 Day 1				
n	2	22	8	32
Mean (StdDev)	-8.33 (11.785)	18.18 (36.337)	18.75 (35.003)	16.67 (34.909)
Median	-8.33	16.67	8.33	16.67
Min, Max	-16.7, 0.0	-33.3, 100.0	-16.7, 83.3	-33.3, 100.0
Change from Baseline to Cycle 3 Day 1				
n	3	22	6	31
Mean (StdDev)	-11.11 (25.459)	12.12 (27.305)	2.78 (35.616)	8.06 (28.826)
Median	-16.67	0.00	0.00	0.00
Min, Max	-33.3, 16.7	-16.7, 83.3	-50.0, 50.0	-50.0, 83.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Social Function	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Change from Baseline to Cycle 5 Day 1				
n	1	14	5	20
Mean (StdDev)	16.67 (-)	27.38 (33.720)	-3.33 (21.731)	19.17 (32.568)
Median	16.67	33.33	-16.67	33.33
Min, Max	16.7, 16.7	-50.0, 66.7	-16.7, 33.3	-50.0, 66.7
Change from Baseline to Cycle 7 Day 1				
n	1	14	2	17
Mean (StdDev)	33.33 (-)	30.95 (28.388)	0.00 (47.140)	27.45 (30.012)
Median	33.33	41.67	0.00	33.33
Min, Max	33.3, 33.3	-16.7, 66.7	-33.3, 33.3	-33.3, 66.7
Change from Baseline to Cycle 9 Day 1				
n	0	11	2	13
Mean (StdDev)		27.27 (29.129)	16.67 (0.000)	25.64 (26.887)
Median		33.33	16.67	33.33
Min, Max		-33.3, 66.7	16.7, 16.7	-33.3, 66.7
Change from Baseline to Cycle 11 Day 1				
n	0	6	1	7
Mean (StdDev)		33.33 (27.889)	100.00 (-)	42.86 (35.820)
Median		41.67	100.00	50.00
Min, Max		0.0, 66.7	100.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Social Function	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		44.44 (53.576)	100.00 (-)	58.33 (51.819)
Median		66.67	100.00	75.00
Min, Max		-16.7, 83.3	100.0, 100.0	-16.7, 100.0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Fatigue	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Baseline				
n	3	24	8	35
Mean (StdDev)	48.15 (16.973)	73.15 (32.422)	73.61 (29.058)	71.11 (30.867)
Median	44.44	88.89	77.78	77.78
Min, Max	33.3, 66.7	0.0, 100.0	22.2, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	3.70 (6.415)	-20.00 (22.970)	-19.05 (27.751)	-17.41 (23.648)
Median	0.00	-11.11	-22.22	-11.11
Min, Max	0.0, 11.1	-55.6, 11.1	-55.6, 22.2	-55.6, 22.2
Change from Baseline to Cycle 2 Day 1				
n	2	22	8	32
Mean (StdDev)	5.56 (7.857)	-20.71 (28.337)	-18.06 (22.954)	-18.40 (26.566)
Median	5.56	-22.22	-22.22	-22.22
Min, Max	0.0, 11.1	-77.8, 33.3	-44.4, 11.1	-77.8, 33.3
Change from Baseline to Cycle 3 Day 1				
n	3	22	6	31
Mean (StdDev)	14.81 (12.830)	-16.16 (29.041)	-7.41 (18.144)	-11.47 (27.290)
Median	22.22	-16.67	-5.56	-11.11
Min, Max	0.0, 22.2	-77.8, 44.4	-33.3, 11.1	-77.8, 44.4

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Fatigue	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Change from Baseline to Cycle 5 Day 1				
n	1	14	5	20
Mean (StdDev)	-11.11 (-)	-34.13 (36.842)	-11.11 (11.111)	-27.22 (32.738)
Median	-11.11	-33.33	-11.11	-22.22
Min, Max	-11.1, -11.1	-77.8, 66.7	-22.2, 0.0	-77.8, 66.7
Change from Baseline to Cycle 7 Day 1				
n	1	14	2	17
Mean (StdDev)	0.00 (-)	-36.51 (30.329)	-11.11 (15.713)	-31.37 (29.978)
Median	0.00	-33.33	-11.11	-33.33
Min, Max	0.0, 0.0	-88.9, 22.2	-22.2, 0.0	-88.9, 22.2
Change from Baseline to Cycle 9 Day 1				
n	0	11	2	13
Mean (StdDev)		-33.33 (22.222)	-5.56 (23.570)	-29.06 (23.804)
Median		-33.33	-5.56	-33.33
Min, Max		-66.7, 11.1	-22.2, 11.1	-66.7, 11.1
Change from Baseline to Cycle 11 Day 1				
n	0	6	1	7
Mean (StdDev)		-40.74 (38.276)	-77.78 (-)	-46.03 (37.641)
Median		-55.56	-77.78	-55.56
Min, Max		-66.7, 33.3	-77.8, -77.8	-77.8, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Fatigue	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-40.74 (57.018)	-66.67 (-)	-47.22 (48.326)
Median		-55.56	-66.67	-61.11
Min, Max		-88.9, 22.2	-66.7, -66.7	-88.9, 22.2
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		33.33 (-)		33.33 (-)
Median		33.33		33.33
Min, Max		33.3, 33.3		33.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Nausea and Vomiting	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Baseline				
n	3	24	8	35
Mean (StdDev)	22.22 (38.490)	23.61 (31.051)	16.67 (23.570)	21.90 (29.365)
Median	0.00	16.67	0.00	16.67
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 50.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	5.56 (9.623)	-13.33 (20.662)	-7.14 (23.288)	-10.00 (20.807)
Median	0.00	-16.67	0.00	0.00
Min, Max	0.0, 16.7	-66.7, 33.3	-50.0, 16.7	-66.7, 33.3
Change from Baseline to Cycle 2 Day 1				
n	2	22	8	32
Mean (StdDev)	0.00 (0.000)	-12.12 (29.628)	-8.33 (21.822)	-10.42 (26.690)
Median	0.00	-8.33	0.00	0.00
Min, Max	0.0, 0.0	-100.0, 33.3	-50.0, 16.7	-100.0, 33.3
Change from Baseline to Cycle 3 Day 1				
n	3	22	6	31
Mean (StdDev)	-5.56 (25.459)	-14.39 (31.411)	-8.33 (20.412)	-12.37 (28.534)
Median	0.00	-8.33	0.00	0.00
Min, Max	-33.3, 16.7	-100.0, 50.0	-50.0, 0.0	-100.0, 50.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Nausea and Vomiting	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Change from Baseline to Cycle 5 Day 1				
n	1	14	5	20
Mean (StdDev)	0.00 (-)	-21.43 (23.956)	-6.67 (25.276)	-16.67 (24.183)
Median	0.00	-16.67	0.00	-16.67
Min, Max	0.0, 0.0	-66.7, 16.7	-50.0, 16.7	-66.7, 16.7
Change from Baseline to Cycle 7 Day 1				
n	1	14	2	17
Mean (StdDev)	-50.00 (-)	-23.81 (26.726)	8.33 (11.785)	-21.57 (27.490)
Median	-50.00	-16.67	8.33	-16.67
Min, Max	-50.0, -50.0	-83.3, 0.0	0.0, 16.7	-83.3, 16.7
Change from Baseline to Cycle 9 Day 1				
n	0	11	2	13
Mean (StdDev)		-18.18 (25.226)	0.00 (0.000)	-15.38 (24.019)
Median		-16.67	0.00	0.00
Min, Max		-66.7, 16.7	0.0, 0.0	-66.7, 16.7
Change from Baseline to Cycle 11 Day 1				
n	0	6	1	7
Mean (StdDev)		-13.89 (24.533)	0.00 (-)	-11.90 (23.002)
Median		-8.33	0.00	0.00
Min, Max		-50.0, 16.7	0.0, 0.0	-50.0, 16.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Nausea and Vomiting	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		5.56 (25.459)	0.00 (-)	4.17 (20.972)
Median		0.00	0.00	0.00
Min, Max		-16.7, 33.3	0.0, 0.0	-16.7, 33.3
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Pain	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Baseline				
n	3	24	8	35
Mean (StdDev)	38.89 (25.459)	40.28 (37.078)	54.17 (29.209)	43.33 (34.347)
Median	33.33	33.33	50.00	33.33
Min, Max	16.7, 66.7	0.0, 100.0	16.7, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	0.00 (0.000)	-20.83 (32.388)	-19.05 (26.227)	-18.33 (29.475)
Median	0.00	0.00	-16.67	0.00
Min, Max	0.0, 0.0	-83.3, 33.3	-50.0, 16.7	-83.3, 33.3
Change from Baseline to Cycle 2 Day 1				
n	2	22	8	32
Mean (StdDev)	0.00 (0.000)	-21.21 (31.782)	-29.17 (26.352)	-21.88 (29.765)
Median	0.00	0.00	-33.33	0.00
Min, Max	0.0, 0.0	-100.0, 16.7	-66.7, 0.0	-100.0, 16.7
Change from Baseline to Cycle 3 Day 1				
n	3	22	6	31
Mean (StdDev)	0.00 (16.667)	-19.70 (35.870)	-30.56 (26.701)	-19.89 (33.172)
Median	0.00	-8.33	-33.33	-16.67
Min, Max	-16.7, 16.7	-100.0, 33.3	-66.7, 0.0	-100.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Pain	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Change from Baseline to Cycle 5 Day 1				
n	1	14	5	20
Mean (StdDev)	16.67 (-)	-13.10 (34.702)	-20.00 (44.721)	-13.33 (36.112)
Median	16.67	-8.33	0.00	0.00
Min, Max	16.7, 16.7	-83.3, 66.7	-66.7, 33.3	-83.3, 66.7
Change from Baseline to Cycle 7 Day 1				
n	1	14	2	17
Mean (StdDev)	0.00 (-)	-13.10 (42.456)	-41.67 (35.355)	-15.69 (40.599)
Median	0.00	-8.33	-41.67	-16.67
Min, Max	0.0, 0.0	-83.3, 83.3	-66.7, -16.7	-83.3, 83.3
Change from Baseline to Cycle 9 Day 1				
n	0	11	2	13
Mean (StdDev)		-9.09 (29.215)	-25.00 (58.926)	-11.54 (32.192)
Median		0.00	-25.00	0.00
Min, Max		-66.7, 33.3	-66.7, 16.7	-66.7, 33.3
Change from Baseline to Cycle 11 Day 1				
n	0	6	1	7
Mean (StdDev)		-16.67 (27.889)	-83.33 (-)	-26.19 (35.820)
Median		0.00	-83.33	0.00
Min, Max		-66.7, 0.0	-83.3, -83.3	-83.3, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Pain	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-11.11 (19.245)	-83.33 (-)	-29.17 (39.382)
Median		0.00	-83.33	-16.67
Min, Max		-33.3, 0.0	-83.3, -83.3	-83.3, 0.0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Dyspnea	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Baseline				
n	3	24	8	35
Mean (StdDev)	11.11 (19.245)	55.56 (34.983)	54.17 (35.355)	51.43 (35.556)
Median	0.00	50.00	50.00	33.33
Min, Max	0.0, 33.3	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	-11.11 (19.245)	-23.33 (36.031)	-23.81 (25.198)	-22.22 (31.964)
Median	0.00	-16.67	-33.33	-16.67
Min, Max	-33.3, 0.0	-100.0, 33.3	-66.7, 0.0	-100.0, 33.3
Change from Baseline to Cycle 2 Day 1				
n	2	22	8	32
Mean (StdDev)	0.00 (0.000)	-24.24 (31.171)	-20.83 (24.801)	-21.88 (28.848)
Median	0.00	-33.33	-16.67	-16.67
Min, Max	0.0, 0.0	-100.0, 33.3	-66.7, 0.0	-100.0, 33.3
Change from Baseline to Cycle 3 Day 1				
n	3	22	6	31
Mean (StdDev)	11.11 (19.245)	-30.30 (35.500)	-22.22 (17.213)	-24.73 (33.297)
Median	0.00	-33.33	-33.33	-33.33
Min, Max	0.0, 33.3	-100.0, 33.3	-33.3, 0.0	-100.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Dyspnea	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Change from Baseline to Cycle 5 Day 1				
n	1	14	5	20
Mean (StdDev)	-33.33 (-)	-35.71 (35.720)	-26.67 (14.907)	-33.33 (30.589)
Median	-33.33	-33.33	-33.33	-33.33
Min, Max	-33.3, -33.3	-100.0, 0.0	-33.3, 0.0	-100.0, 0.0
Change from Baseline to Cycle 7 Day 1				
n	1	14	2	17
Mean (StdDev)	33.33 (-)	-35.71 (33.242)	-33.33 (0.000)	-31.37 (34.300)
Median	33.33	-33.33	-33.33	-33.33
Min, Max	33.3, 33.3	-100.0, 0.0	-33.3, -33.3	-100.0, 33.3
Change from Baseline to Cycle 9 Day 1				
n	0	11	2	13
Mean (StdDev)		-39.39 (32.722)	-33.33 (0.000)	-38.46 (29.957)
Median		-33.33	-33.33	-33.33
Min, Max		-100.0, 0.0	-33.3, -33.3	-100.0, 0.0
Change from Baseline to Cycle 11 Day 1				
n	0	6	1	7
Mean (StdDev)		-44.44 (40.369)	-33.33 (-)	-42.86 (37.090)
Median		-50.00	-33.33	-33.33
Min, Max		-100.0, 0.0	-33.3, -33.3	-100.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Dyspnea	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-33.33 (57.735)	-33.33 (-)	-33.33 (47.140)
Median		0.00	-33.33	-16.67
Min, Max		-100.0, 0.0	-33.3, -33.3	-100.0, 0.0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Insomnia	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Baseline				
n	3	24	8	35
Mean (StdDev)	66.67 (33.333)	54.17 (36.531)	87.50 (24.801)	62.86 (35.948)
Median	66.67	66.67	100.00	66.67
Min, Max	33.3, 100.0	0.0, 100.0	33.3, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	-11.11 (19.245)	-13.33 (36.515)	-42.86 (25.198)	-20.00 (34.575)
Median	0.00	0.00	-33.33	-33.33
Min, Max	-33.3, 0.0	-66.7, 33.3	-66.7, 0.0	-66.7, 33.3
Change from Baseline to Cycle 2 Day 1				
n	2	22	8	32
Mean (StdDev)	0.00 (0.000)	-15.15 (49.041)	-66.67 (25.198)	-27.08 (48.221)
Median	0.00	0.00	-66.67	-33.33
Min, Max	0.0, 0.0	-100.0, 66.7	-100.0, -33.3	-100.0, 66.7
Change from Baseline to Cycle 3 Day 1				
n	3	22	6	31
Mean (StdDev)	0.00 (0.000)	-16.67 (44.544)	-66.67 (21.082)	-24.73 (43.858)
Median	0.00	0.00	-66.67	-33.33
Min, Max	0.0, 0.0	-100.0, 66.7	-100.0, -33.3	-100.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Insomnia	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Change from Baseline to Cycle 5 Day 1				
n	1	14	5	20
Mean (StdDev)	-33.33 (-)	-30.95 (33.242)	-33.33 (33.333)	-31.67 (31.484)
Median	-33.33	-33.33	-33.33	-33.33
Min, Max	-33.3, -33.3	-66.7, 33.3	-66.7, 0.0	-66.7, 33.3
Change from Baseline to Cycle 7 Day 1				
n	1	14	2	17
Mean (StdDev)	0.00 (-)	-26.19 (43.713)	-66.67 (0.000)	-29.41 (42.299)
Median	0.00	-16.67	-66.67	-33.33
Min, Max	0.0, 0.0	-100.0, 33.3	-66.7, -66.7	-100.0, 33.3
Change from Baseline to Cycle 9 Day 1				
n	0	11	2	13
Mean (StdDev)		-27.27 (41.682)	-66.67 (0.000)	-33.33 (40.825)
Median		0.00	-66.67	-33.33
Min, Max		-100.0, 33.3	-66.7, -66.7	-100.0, 33.3
Change from Baseline to Cycle 11 Day 1				
n	0	6	1	7
Mean (StdDev)		-38.89 (32.773)	-100.00 (-)	-47.62 (37.796)
Median		-50.00	-100.00	-66.67
Min, Max		-66.7, 0.0	-100.0, -100.0	-100.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Insomnia	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-22.22 (38.490)	-100.00 (-)	-41.67 (50.000)
Median		0.00	-100.00	-33.33
Min, Max		-66.7, 0.0	-100.0, -100.0	-100.0, 0.0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		33.33 (-)		33.33 (-)
Median		33.33		33.33
Min, Max		33.3, 33.3		33.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Appetite Loss	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Baseline				
n	3	24	8	35
Mean (StdDev)	22.22 (38.490)	48.61 (35.412)	50.00 (35.635)	46.67 (35.425)
Median	0.00	33.33	33.33	33.33
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	-11.11 (19.245)	-28.33 (32.936)	-23.81 (25.198)	-25.56 (29.921)
Median	0.00	-33.33	-33.33	-33.33
Min, Max	-33.3, 0.0	-100.0, 33.3	-66.7, 0.0	-100.0, 33.3
Change from Baseline to Cycle 2 Day 1				
n	2	22	8	32
Mean (StdDev)	-16.67 (23.570)	-25.76 (41.060)	-33.33 (35.635)	-27.08 (38.276)
Median	-16.67	-33.33	-33.33	-33.33
Min, Max	-33.3, 0.0	-100.0, 33.3	-100.0, 0.0	-100.0, 33.3
Change from Baseline to Cycle 3 Day 1				
n	3	22	6	31
Mean (StdDev)	0.00 (0.000)	-31.82 (39.141)	-50.00 (45.947)	-32.26 (39.892)
Median	0.00	-33.33	-50.00	-33.33
Min, Max	0.0, 0.0	-100.0, 33.3	-100.0, 0.0	-100.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Appetite Loss	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Change from Baseline to Cycle 5 Day 1				
n	1	14	5	20
Mean (StdDev)	0.00 (-)	-45.24 (44.544)	-13.33 (44.721)	-35.00 (45.209)
Median	0.00	-33.33	-33.33	-33.33
Min, Max	0.0, 0.0	-100.0, 66.7	-66.7, 33.3	-100.0, 66.7
Change from Baseline to Cycle 7 Day 1				
n	1	14	2	17
Mean (StdDev)	0.00 (-)	-45.24 (36.061)	-50.00 (23.570)	-43.14 (34.890)
Median	0.00	-33.33	-50.00	-33.33
Min, Max	0.0, 0.0	-100.0, 0.0	-66.7, -33.3	-100.0, 0.0
Change from Baseline to Cycle 9 Day 1				
n	0	11	2	13
Mean (StdDev)		-30.30 (34.816)	-50.00 (23.570)	-33.33 (33.333)
Median		-33.33	-50.00	-33.33
Min, Max		-100.0, 33.3	-66.7, -33.3	-100.0, 33.3
Change from Baseline to Cycle 11 Day 1				
n	0	6	1	7
Mean (StdDev)		-27.78 (44.305)	-66.67 (-)	-33.33 (43.033)
Median		-33.33	-66.67	-33.33
Min, Max		-100.0, 33.3	-66.7, -66.7	-100.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Appetite Loss	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-44.44 (50.918)	-66.67 (-)	-50.00 (43.033)
Median		-33.33	-66.67	-50.00
Min, Max		-100.0, 0.0	-66.7, -66.7	-100.0, 0.0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		33.33 (-)		33.33 (-)
Median		33.33		33.33
Min, Max		33.3, 33.3		33.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Constipation	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Baseline				
n	3	24	8	35
Mean (StdDev)	33.33 (33.333)	25.00 (32.969)	20.83 (35.355)	24.76 (32.683)
Median	33.33	0.00	0.00	0.00
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	0.00 (0.000)	-5.00 (24.839)	-9.52 (31.706)	-5.56 (24.888)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 0.0	-66.7, 66.7	-66.7, 33.3	-66.7, 66.7
Change from Baseline to Cycle 2 Day 1				
n	2	22	8	32
Mean (StdDev)	0.00 (0.000)	-13.64 (30.271)	-12.50 (30.538)	-12.50 (29.022)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 0.0	-100.0, 33.3	-66.7, 33.3	-100.0, 33.3
Change from Baseline to Cycle 3 Day 1				
n	3	22	6	31
Mean (StdDev)	-11.11 (19.245)	-7.58 (28.971)	-16.67 (45.947)	-9.68 (31.262)
Median	0.00	0.00	0.00	0.00
Min, Max	-33.3, 0.0	-100.0, 33.3	-100.0, 33.3	-100.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Constipation	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Change from Baseline to Cycle 5 Day 1				
n	1	14	5	20
Mean (StdDev)	0.00 (-)	-7.14 (26.726)	-26.67 (43.461)	-11.67 (31.110)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 0.0	-33.3, 66.7	-100.0, 0.0	-100.0, 66.7
Change from Baseline to Cycle 7 Day 1				
n	1	14	2	17
Mean (StdDev)	-33.33 (-)	-11.90 (24.832)	-66.67 (47.140)	-19.61 (31.311)
Median	-33.33	0.00	-66.67	0.00
Min, Max	-33.3, -33.3	-66.7, 33.3	-100.0, -33.3	-100.0, 33.3
Change from Baseline to Cycle 9 Day 1				
n	0	11	2	13
Mean (StdDev)		-18.18 (34.524)	-66.67 (47.140)	-25.64 (38.858)
Median		0.00	-66.67	-33.33
Min, Max		-100.0, 33.3	-100.0, -33.3	-100.0, 33.3
Change from Baseline to Cycle 11 Day 1				
n	0	6	1	7
Mean (StdDev)		-22.22 (17.213)	-100.00 (-)	-33.33 (33.333)
Median		-33.33	-100.00	-33.33
Min, Max		-33.3, 0.0	-100.0, -100.0	-100.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Constipation	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-22.22 (19.245)	-100.00 (-)	-41.67 (41.944)
Median		-33.33	-100.00	-33.33
Min, Max		-33.3, 0.0	-100.0, -100.0	-100.0, 0.0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Diarrhea	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Baseline				
n	3	24	8	35
Mean (StdDev)	0.00 (0.000)	41.67 (39.624)	45.83 (43.416)	39.05 (40.005)
Median	0.00	33.33	50.00	33.33
Min, Max	0.0, 0.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	11.11 (19.245)	-30.00 (32.264)	-14.29 (53.945)	-22.22 (38.490)
Median	0.00	-33.33	0.00	0.00
Min, Max	0.0, 33.3	-100.0, 0.0	-100.0, 33.3	-100.0, 33.3
Change from Baseline to Cycle 2 Day 1				
n	2	22	8	32
Mean (StdDev)	0.00 (0.000)	-27.27 (37.987)	-16.67 (39.841)	-22.92 (37.328)
Median	0.00	-33.33	-16.67	-16.67
Min, Max	0.0, 0.0	-100.0, 33.3	-66.7, 33.3	-100.0, 33.3
Change from Baseline to Cycle 3 Day 1				
n	3	22	6	31
Mean (StdDev)	0.00 (0.000)	-25.76 (39.750)	-22.22 (45.542)	-22.58 (38.861)
Median	0.00	-33.33	-16.67	0.00
Min, Max	0.0, 0.0	-100.0, 66.7	-100.0, 33.3	-100.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Diarrhea	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Change from Baseline to Cycle 5 Day 1				
n	1	14	5	20
Mean (StdDev)	0.00 (-)	-28.57 (38.911)	-20.00 (50.553)	-25.00 (40.284)
Median	0.00	-33.33	0.00	-33.33
Min, Max	0.0, 0.0	-100.0, 66.7	-100.0, 33.3	-100.0, 66.7
Change from Baseline to Cycle 7 Day 1				
n	1	14	2	17
Mean (StdDev)	33.33 (-)	-30.95 (33.242)	0.00 (0.000)	-23.53 (34.890)
Median	33.33	-33.33	0.00	-33.33
Min, Max	33.3, 33.3	-100.0, 33.3	0.0, 0.0	-100.0, 33.3
Change from Baseline to Cycle 9 Day 1				
n	0	11	2	13
Mean (StdDev)		-24.24 (39.696)	0.00 (0.000)	-20.51 (37.363)
Median		-33.33	0.00	-33.33
Min, Max		-66.7, 66.7	0.0, 0.0	-66.7, 66.7
Change from Baseline to Cycle 11 Day 1				
n	0	6	1	7
Mean (StdDev)		-33.33 (29.814)	0.00 (-)	-28.57 (29.991)
Median		-33.33	0.00	-33.33
Min, Max		-66.7, 0.0	0.0, 0.0	-66.7, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Diarrhea	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-11.11 (19.245)	0.00 (-)	-8.33 (16.667)
Median		0.00	0.00	0.00
Min, Max		-33.3, 0.0	0.0, 0.0	-33.3, 0.0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Financial Difficulties	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Baseline				
n	3	24	8	35
Mean (StdDev)	33.33 (33.333)	23.61 (30.263)	25.00 (34.503)	24.76 (30.618)
Median	33.33	0.00	16.67	0.00
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	0.00 (33.333)	1.67 (25.305)	-19.05 (42.414)	-3.33 (30.763)
Median	0.00	0.00	0.00	0.00
Min, Max	-33.3, 33.3	-66.7, 33.3	-100.0, 33.3	-100.0, 33.3
Change from Baseline to Cycle 2 Day 1				
n	2	22	8	32
Mean (StdDev)	0.00 (0.000)	-4.55 (23.672)	-8.33 (23.570)	-5.21 (22.575)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 0.0	-66.7, 33.3	-33.3, 33.3	-66.7, 33.3
Change from Baseline to Cycle 3 Day 1				
n	3	22	6	31
Mean (StdDev)	11.11 (19.245)	-3.03 (25.006)	5.56 (25.092)	0.00 (24.343)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 33.3	-66.7, 33.3	-33.3, 33.3	-66.7, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Financial Difficulties	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Change from Baseline to Cycle 5 Day 1				
n	1	14	5	20
Mean (StdDev)	-66.67 (-)	-9.52 (27.514)	13.33 (38.006)	-6.67 (33.508)
Median	-66.67	0.00	0.00	0.00
Min, Max	-66.7, -66.7	-66.7, 33.3	-33.3, 66.7	-66.7, 66.7
Change from Baseline to Cycle 7 Day 1				
n	1	14	2	17
Mean (StdDev)	0.00 (-)	-2.38 (27.625)	16.67 (23.570)	0.00 (26.352)
Median	0.00	0.00	16.67	0.00
Min, Max	0.0, 0.0	-66.7, 33.3	0.0, 33.3	-66.7, 33.3
Change from Baseline to Cycle 9 Day 1				
n	0	11	2	13
Mean (StdDev)		15.15 (22.918)	0.00 (0.000)	12.82 (21.681)
Median		0.00	0.00	0.00
Min, Max		0.0, 66.7	0.0, 0.0	0.0, 66.7
Change from Baseline to Cycle 11 Day 1				
n	0	6	1	7
Mean (StdDev)		22.22 (27.217)	0.00 (-)	19.05 (26.227)
Median		16.67	0.00	0.00
Min, Max		0.0, 66.7	0.0, 0.0	0.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

Financial Difficulties	ASM (N=5)	SM-AHN (N=28)	MCL (N=9)	All AdvSM (N=42)
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-11.11 (19.245)	0.00 (-)	-8.33 (16.667)
Median		0.00	0.00	0.00
Min, Max		-33.3, 0.0	0.0, 0.0	-33.3, 0.0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		-33.33 (-)		-33.33 (-)
Median		-33.33		-33.33
Min, Max		-33.3, -33.3		-33.3, -33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Global Health Status/QoL	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Baseline				
n	3	23	8	34
Mean (StdDev)	55.56 (20.972)	33.33 (25.251)	36.46 (13.317)	36.03 (23.003)
Median	58.33	33.33	33.33	33.33
Min, Max	33.3, 75.0	0.0, 100.0	16.7, 58.3	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	19	7	29
Mean (StdDev)	2.78 (9.623)	18.42 (26.582)	11.90 (24.934)	15.23 (24.907)
Median	8.33	16.67	0.00	8.33
Min, Max	-8.3, 8.3	-25.0, 83.3	-8.3, 50.0	-25.0, 83.3
Change from Baseline to Cycle 2 Day 1				
n	2	21	8	31
Mean (StdDev)	0.00 (11.785)	22.22 (31.439)	13.54 (26.329)	18.55 (29.401)
Median	0.00	16.67	20.83	16.67
Min, Max	-8.3, 8.3	-25.0, 91.7	-33.3, 50.0	-33.3, 91.7
Change from Baseline to Cycle 3 Day 1				
n	3	21	6	30
Mean (StdDev)	5.56 (26.788)	24.21 (33.840)	5.56 (12.546)	18.61 (30.692)
Median	16.67	16.67	0.00	16.67
Min, Max	-25.0, 25.0	-66.7, 83.3	-8.3, 25.0	-66.7, 83.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Global Health Status/QoL	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Change from Baseline to Cycle 5 Day 1				
n	1	13	5	19
Mean (StdDev)	16.67 (-)	23.08 (44.116)	5.00 (18.257)	17.98 (37.911)
Median	16.67	25.00	16.67	16.67
Min, Max	16.7, 16.7	-100.0, 83.3	-25.0, 16.7	-100.0, 83.3
Change from Baseline to Cycle 7 Day 1				
n	1	13	2	16
Mean (StdDev)	-16.67 (-)	32.05 (35.818)	8.33 (11.785)	26.04 (35.076)
Median	-16.67	33.33	8.33	33.33
Min, Max	-16.7, -16.7	-33.3, 83.3	0.0, 16.7	-33.3, 83.3
Change from Baseline to Cycle 9 Day 1				
n	0	10	2	12
Mean (StdDev)		20.00 (37.721)	16.67 (0.000)	19.44 (34.144)
Median		20.83	16.67	16.67
Min, Max		-58.3, 83.3	16.7, 16.7	-58.3, 83.3
Change from Baseline to Cycle 11 Day 1				
n	0	5	1	6
Mean (StdDev)		25.00 (35.355)	25.00 (-)	25.00 (31.623)
Median		41.67	25.00	33.33
Min, Max		-33.3, 50.0	25.0, 25.0	-33.3, 50.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Global Health Status/QoL	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		30.56 (64.729)	41.67 (-)	33.33 (53.142)
Median		50.00	41.67	45.83
Min, Max		-41.7, 83.3	41.7, 41.7	-41.7, 83.3
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		-33.33 (-)		-33.33 (-)
Median		-33.33		-33.33
Min, Max		-33.3, -33.3		-33.3, -33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg				
Physical Functioning	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Baseline				
n	3	23	8	34
Mean (StdDev)	62.22 (36.717)	51.88 (29.539)	60.00 (24.944)	54.71 (28.511)
Median	80.00	46.67	60.00	53.33
Min, Max	20.0, 86.7	0.0, 100.0	26.7, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	19	7	29
Mean (StdDev)	2.22 (3.849)	11.58 (18.438)	15.24 (22.678)	11.49 (18.508)
Median	0.00	6.67	13.33	6.67
Min, Max	0.0, 6.7	-13.3, 53.3	-20.0, 46.7	-20.0, 53.3
Change from Baseline to Cycle 2 Day 1				
n	2	21	8	31
Mean (StdDev)	0.00 (0.000)	14.60 (21.768)	11.67 (22.467)	12.90 (21.147)
Median	0.00	6.67	6.67	0.00
Min, Max	0.0, 0.0	-6.7, 66.7	-20.0, 46.7	-20.0, 66.7
Change from Baseline to Cycle 3 Day 1				
n	3	21	6	30
Mean (StdDev)	-8.89 (3.849)	15.24 (24.326)	5.56 (19.963)	10.89 (23.192)
Median	-6.67	13.33	3.33	3.33
Min, Max	-13.3, -6.7	-20.0, 73.3	-13.3, 40.0	-20.0, 73.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Physical Functioning	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Change from Baseline to Cycle 5 Day 1				
n	1	13	5	19
Mean (StdDev)	26.67 (-)	27.18 (25.598)	0.00 (25.820)	20.00 (27.126)
Median	26.67	26.67	-6.67	20.00
Min, Max	26.7, 26.7	-13.3, 73.3	-26.7, 33.3	-26.7, 73.3
Change from Baseline to Cycle 7 Day 1				
n	1	13	2	16
Mean (StdDev)	-40.00 (-)	23.59 (26.051)	23.33 (23.570)	19.58 (28.851)
Median	-40.00	6.67	23.33	6.67
Min, Max	-40.0, -40.0	-6.7, 66.7	6.7, 40.0	-40.0, 66.7
Change from Baseline to Cycle 9 Day 1				
n	0	10	2	12
Mean (StdDev)		22.67 (24.984)	20.00 (18.856)	22.22 (23.326)
Median		13.33	20.00	13.33
Min, Max		0.0, 66.7	6.7, 33.3	0.0, 66.7
Change from Baseline to Cycle 11 Day 1				
n	0	5	1	6
Mean (StdDev)		26.67 (24.037)	60.00 (-)	32.22 (25.444)
Median		26.67	60.00	30.00
Min, Max		-6.7, 60.0	60.0, 60.0	-6.7, 60.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Physical Functioning	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		35.56 (33.555)	60.00 (-)	41.67 (30.000)
Median		40.00	60.00	50.00
Min, Max		0.0, 66.7	60.0, 60.0	0.0, 66.7
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg				
Role Functioning	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Baseline				
n	3	23	8	34
Mean (StdDev)	50.00 (44.096)	40.58 (37.547)	27.08 (26.633)	38.24 (35.422)
Median	66.67	50.00	25.00	41.67
Min, Max	0.0, 83.3	0.0, 100.0	0.0, 66.7	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	19	7	29
Mean (StdDev)	-5.56 (9.623)	12.28 (19.118)	23.81 (21.207)	13.22 (20.108)
Median	0.00	0.00	16.67	0.00
Min, Max	-16.7, 0.0	-16.7, 50.0	0.0, 66.7	-16.7, 66.7
Change from Baseline to Cycle 2 Day 1				
n	2	21	8	31
Mean (StdDev)	-16.67 (23.570)	15.87 (31.392)	18.75 (33.850)	14.52 (31.839)
Median	-16.67	0.00	25.00	0.00
Min, Max	-33.3, 0.0	-16.7, 100.0	-33.3, 66.7	-33.3, 100.0
Change from Baseline to Cycle 3 Day 1				
n	3	21	6	30
Mean (StdDev)	-11.11 (9.623)	17.46 (31.392)	13.89 (32.347)	13.89 (30.664)
Median	-16.67	16.67	25.00	8.33
Min, Max	-16.7, 0.0	-33.3, 66.7	-33.3, 50.0	-33.3, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Role Functioning	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Change from Baseline to Cycle 5 Day 1				
n	1	13	5	19
Mean (StdDev)	0.00 (-)	23.08 (41.129)	13.33 (21.731)	19.30 (35.687)
Median	0.00	16.67	16.67	16.67
Min, Max	0.0, 0.0	-66.7, 83.3	-16.7, 33.3	-66.7, 83.3
Change from Baseline to Cycle 7 Day 1				
n	1	13	2	16
Mean (StdDev)	-33.33 (-)	25.64 (38.258)	25.00 (11.785)	21.88 (37.376)
Median	-33.33	16.67	25.00	16.67
Min, Max	-33.3, -33.3	-33.3, 83.3	16.7, 33.3	-33.3, 83.3
Change from Baseline to Cycle 9 Day 1				
n	0	10	2	12
Mean (StdDev)		25.00 (33.564)	25.00 (11.785)	25.00 (30.567)
Median		33.33	25.00	25.00
Min, Max		-33.3, 66.7	16.7, 33.3	-33.3, 66.7
Change from Baseline to Cycle 11 Day 1				
n	0	5	1	6
Mean (StdDev)		36.67 (27.386)	100.00 (-)	47.22 (35.616)
Median		50.00	100.00	50.00
Min, Max		0.0, 66.7	100.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Role Functioning	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		44.44 (38.490)	66.67 (-)	50.00 (33.333)
Median		66.67	66.67	66.67
Min, Max		0.0, 66.7	66.7, 66.7	0.0, 66.7
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Emotional Functioning	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Baseline				
n	3	23	8	34
Mean (StdDev)	69.44 (31.549)	59.78 (27.827)	56.25 (27.728)	59.80 (27.407)
Median	83.33	58.33	54.17	58.33
Min, Max	33.3, 91.7	8.3, 100.0	8.3, 100.0	8.3, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	19	7	29
Mean (StdDev)	0.00 (8.333)	10.09 (18.126)	1.19 (16.265)	6.90 (17.117)
Median	0.00	8.33	0.00	8.33
Min, Max	-8.3, 8.3	-25.0, 58.3	-25.0, 16.7	-25.0, 58.3
Change from Baseline to Cycle 2 Day 1				
n	2	21	8	31
Mean (StdDev)	-12.50 (5.893)	14.68 (25.941)	11.46 (11.732)	12.10 (22.957)
Median	-12.50	16.67	12.50	8.33
Min, Max	-16.7, -8.3	-25.0, 58.3	0.0, 33.3	-25.0, 58.3
Change from Baseline to Cycle 3 Day 1				
n	3	21	6	30
Mean (StdDev)	-8.33 (25.000)	12.30 (25.361)	1.39 (9.742)	8.06 (23.518)
Median	-8.33	16.67	0.00	4.17
Min, Max	-33.3, 16.7	-33.3, 58.3	-8.3, 16.7	-33.3, 58.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Emotional Functioning	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Change from Baseline to Cycle 5 Day 1				
n	1	13	5	19
Mean (StdDev)	16.67 (-)	25.00 (29.067)	-5.00 (12.638)	16.67 (27.916)
Median	16.67	25.00	0.00	8.33
Min, Max	16.7, 16.7	-25.0, 66.7	-25.0, 8.3	-25.0, 66.7
Change from Baseline to Cycle 7 Day 1				
n	1	13	2	16
Mean (StdDev)	0.00 (-)	18.59 (22.861)	-4.17 (5.893)	14.58 (22.257)
Median	0.00	25.00	-4.17	16.67
Min, Max	0.0, 0.0	-16.7, 50.0	-8.3, 0.0	-16.7, 50.0
Change from Baseline to Cycle 9 Day 1				
n	0	10	2	12
Mean (StdDev)		15.00 (21.082)	-4.17 (5.893)	11.81 (20.554)
Median		12.50	-4.17	8.33
Min, Max		-16.7, 50.0	-8.3, 0.0	-16.7, 50.0
Change from Baseline to Cycle 11 Day 1				
n	0	5	1	6
Mean (StdDev)		16.67 (28.260)	25.00 (-)	18.06 (25.504)
Median		8.33	25.00	16.67
Min, Max		-16.7, 50.0	25.0, 25.0	-16.7, 50.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Emotional Functioning	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		30.56 (33.679)	25.00 (-)	29.17 (27.639)
Median		25.00	25.00	25.00
Min, Max		0.0, 66.7	25.0, 25.0	0.0, 66.7
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Cognitive Functioning	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Baseline				
n	3	23	8	34
Mean (StdDev)	83.33 (16.667)	72.46 (22.813)	62.50 (33.034)	71.08 (25.062)
Median	83.33	66.67	50.00	66.67
Min, Max	66.7, 100.0	33.3, 100.0	16.7, 100.0	16.7, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	19	7	29
Mean (StdDev)	-5.56 (9.623)	3.51 (13.122)	-4.76 (8.133)	0.57 (12.185)
Median	0.00	0.00	0.00	0.00
Min, Max	-16.7, 0.0	-16.7, 33.3	-16.7, 0.0	-16.7, 33.3
Change from Baseline to Cycle 2 Day 1				
n	2	21	8	31
Mean (StdDev)	0.00 (0.000)	3.17 (19.450)	2.08 (22.603)	2.69 (19.292)
Median	0.00	0.00	8.33	0.00
Min, Max	0.0, 0.0	-33.3, 50.0	-33.3, 33.3	-33.3, 50.0
Change from Baseline to Cycle 3 Day 1				
n	3	21	6	30
Mean (StdDev)	11.11 (9.623)	3.17 (20.829)	8.33 (25.276)	5.00 (20.599)
Median	16.67	0.00	8.33	0.00
Min, Max	0.0, 16.7	-33.3, 50.0	-33.3, 33.3	-33.3, 50.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Cognitive Functioning	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Change from Baseline to Cycle 5 Day 1				
n	1	13	5	19
Mean (StdDev)	-16.67 (-)	5.13 (22.958)	-10.00 (9.129)	0.00 (20.787)
Median	-16.67	16.67	-16.67	0.00
Min, Max	-16.7, -16.7	-50.0, 33.3	-16.7, 0.0	-50.0, 33.3
Change from Baseline to Cycle 7 Day 1				
n	1	13	2	16
Mean (StdDev)	16.67 (-)	3.85 (24.677)	8.33 (11.785)	5.21 (22.541)
Median	16.67	0.00	8.33	0.00
Min, Max	16.7, 16.7	-33.3, 50.0	0.0, 16.7	-33.3, 50.0
Change from Baseline to Cycle 9 Day 1				
n	0	10	2	12
Mean (StdDev)		-3.33 (24.595)	-16.67 (0.000)	-5.56 (22.845)
Median		-8.33	-16.67	-16.67
Min, Max		-33.3, 33.3	-16.7, -16.7	-33.3, 33.3
Change from Baseline to Cycle 11 Day 1				
n	0	5	1	6
Mean (StdDev)		0.00 (11.785)	16.67 (-)	2.78 (12.546)
Median		0.00	16.67	0.00
Min, Max		-16.7, 16.7	16.7, 16.7	-16.7, 16.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Cognitive Functioning	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		5.56 (9.623)	16.67 (-)	8.33 (9.623)
Median		0.00	16.67	8.33
Min, Max		0.0, 16.7	16.7, 16.7	0.0, 16.7
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		-16.67 (-)		-16.67 (-)
Median		-16.67		-16.67
Min, Max		-16.7, -16.7		-16.7, -16.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Social Function	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Baseline				
n	3	23	8	34
Mean (StdDev)	55.56 (41.944)	49.28 (34.626)	45.83 (29.209)	49.02 (33.065)
Median	50.00	33.33	50.00	33.33
Min, Max	16.7, 100.0	0.0, 100.0	0.0, 83.3	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	19	7	29
Mean (StdDev)	0.00 (16.667)	15.79 (25.138)	19.05 (29.547)	14.94 (25.333)
Median	0.00	16.67	16.67	16.67
Min, Max	-16.7, 16.7	-16.7, 66.7	-16.7, 66.7	-16.7, 66.7
Change from Baseline to Cycle 2 Day 1				
n	2	21	8	31
Mean (StdDev)	-8.33 (11.785)	16.67 (36.515)	18.75 (35.003)	15.59 (34.943)
Median	-8.33	16.67	8.33	16.67
Min, Max	-16.7, 0.0	-33.3, 100.0	-16.7, 83.3	-33.3, 100.0
Change from Baseline to Cycle 3 Day 1				
n	3	21	6	30
Mean (StdDev)	-11.11 (25.459)	10.32 (26.602)	2.78 (35.616)	6.67 (28.230)
Median	-16.67	0.00	0.00	0.00
Min, Max	-33.3, 16.7	-16.7, 83.3	-50.0, 50.0	-50.0, 83.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Social Function	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Change from Baseline to Cycle 5 Day 1				
n	1	13	5	19
Mean (StdDev)	16.67 (-)	25.64 (34.437)	-3.33 (21.731)	17.54 (32.619)
Median	16.67	33.33	-16.67	33.33
Min, Max	16.7, 16.7	-50.0, 66.7	-16.7, 33.3	-50.0, 66.7
Change from Baseline to Cycle 7 Day 1				
n	1	13	2	16
Mean (StdDev)	33.33 (-)	29.49 (28.991)	0.00 (47.140)	26.04 (30.410)
Median	33.33	33.33	0.00	33.33
Min, Max	33.3, 33.3	-16.7, 66.7	-33.3, 33.3	-33.3, 66.7
Change from Baseline to Cycle 9 Day 1				
n	0	10	2	12
Mean (StdDev)		25.00 (29.659)	16.67 (0.000)	23.61 (27.023)
Median		33.33	16.67	25.00
Min, Max		-33.3, 66.7	16.7, 16.7	-33.3, 66.7
Change from Baseline to Cycle 11 Day 1				
n	0	5	1	6
Mean (StdDev)		30.00 (29.814)	100.00 (-)	41.67 (39.087)
Median		33.33	100.00	41.67
Min, Max		0.0, 66.7	100.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Social Function	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		44.44 (53.576)	100.00 (-)	58.33 (51.819)
Median		66.67	100.00	75.00
Min, Max		-16.7, 83.3	100.0, 100.0	-16.7, 100.0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Fatigue	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Baseline				
n	3	23	8	34
Mean (StdDev)	48.15 (16.973)	71.98 (32.631)	73.61 (29.058)	70.26 (30.913)
Median	44.44	88.89	77.78	77.78
Min, Max	33.3, 66.7	0.0, 100.0	22.2, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	19	7	29
Mean (StdDev)	3.70 (6.415)	-19.30 (23.378)	-19.05 (27.751)	-16.86 (23.871)
Median	0.00	-11.11	-22.22	-11.11
Min, Max	0.0, 11.1	-55.6, 11.1	-55.6, 22.2	-55.6, 22.2
Change from Baseline to Cycle 2 Day 1				
n	2	21	8	31
Mean (StdDev)	5.56 (7.857)	-20.11 (28.893)	-18.06 (22.954)	-17.92 (26.863)
Median	5.56	-22.22	-22.22	-22.22
Min, Max	0.0, 11.1	-77.8, 33.3	-44.4, 11.1	-77.8, 33.3
Change from Baseline to Cycle 3 Day 1				
n	3	21	6	30
Mean (StdDev)	14.81 (12.830)	-15.34 (29.497)	-7.41 (18.144)	-10.74 (27.448)
Median	22.22	-11.11	-5.56	-11.11
Min, Max	0.0, 22.2	-77.8, 44.4	-33.3, 11.1	-77.8, 44.4

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Fatigue	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Change from Baseline to Cycle 5 Day 1				
n	1	13	5	19
Mean (StdDev)	-11.11 (-)	-31.62 (37.087)	-11.11 (11.111)	-25.15 (32.255)
Median	-11.11	-33.33	-11.11	-22.22
Min, Max	-11.1, -11.1	-77.8, 66.7	-22.2, 0.0	-77.8, 66.7
Change from Baseline to Cycle 7 Day 1				
n	1	13	2	16
Mean (StdDev)	0.00 (-)	-36.75 (31.553)	-11.11 (15.713)	-31.25 (30.957)
Median	0.00	-33.33	-11.11	-27.78
Min, Max	0.0, 0.0	-88.9, 22.2	-22.2, 0.0	-88.9, 22.2
Change from Baseline to Cycle 9 Day 1				
n	0	10	2	12
Mean (StdDev)		-32.22 (23.100)	-5.56 (23.570)	-27.78 (24.389)
Median		-33.33	-5.56	-33.33
Min, Max		-66.7, 11.1	-22.2, 11.1	-66.7, 11.1
Change from Baseline to Cycle 11 Day 1				
n	0	5	1	6
Mean (StdDev)		-35.56 (40.369)	-77.78 (-)	-42.59 (40.010)
Median		-55.56	-77.78	-55.56
Min, Max		-66.7, 33.3	-77.8, -77.8	-77.8, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Fatigue	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-40.74 (57.018)	-66.67 (-)	-47.22 (48.326)
Median		-55.56	-66.67	-61.11
Min, Max		-88.9, 22.2	-66.7, -66.7	-88.9, 22.2
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		33.33 (-)		33.33 (-)
Median		33.33		33.33
Min, Max		33.3, 33.3		33.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Nausea and Vomiting	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Baseline				
n	3	23	8	34
Mean (StdDev)	22.22 (38.490)	23.19 (31.678)	16.67 (23.570)	21.57 (29.738)
Median	0.00	16.67	0.00	8.33
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 50.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	19	7	29
Mean (StdDev)	5.56 (9.623)	-12.28 (20.669)	-7.14 (23.288)	-9.20 (20.695)
Median	0.00	-16.67	0.00	0.00
Min, Max	0.0, 16.7	-66.7, 33.3	-50.0, 16.7	-66.7, 33.3
Change from Baseline to Cycle 2 Day 1				
n	2	21	8	31
Mean (StdDev)	0.00 (0.000)	-11.11 (29.969)	-8.33 (21.822)	-9.68 (26.796)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 0.0	-100.0, 33.3	-50.0, 16.7	-100.0, 33.3
Change from Baseline to Cycle 3 Day 1				
n	3	21	6	30
Mean (StdDev)	-5.56 (25.459)	-13.49 (31.894)	-8.33 (20.412)	-11.67 (28.751)
Median	0.00	0.00	0.00	0.00
Min, Max	-33.3, 16.7	-100.0, 50.0	-50.0, 0.0	-100.0, 50.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Nausea and Vomiting	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Change from Baseline to Cycle 5 Day 1				
n	1	13	5	19
Mean (StdDev)	0.00 (-)	-21.79 (24.893)	-6.67 (25.276)	-16.67 (24.845)
Median	0.00	-16.67	0.00	-16.67
Min, Max	0.0, 0.0	-66.7, 16.7	-50.0, 16.7	-66.7, 16.7
Change from Baseline to Cycle 7 Day 1				
n	1	13	2	16
Mean (StdDev)	-50.00 (-)	-24.36 (27.735)	8.33 (11.785)	-21.88 (28.362)
Median	-50.00	-16.67	8.33	-16.67
Min, Max	-50.0, -50.0	-83.3, 0.0	0.0, 16.7	-83.3, 16.7
Change from Baseline to Cycle 9 Day 1				
n	0	10	2	12
Mean (StdDev)		-16.67 (26.058)	0.00 (0.000)	-13.89 (24.447)
Median		-8.33	0.00	0.00
Min, Max		-66.7, 16.7	0.0, 0.0	-66.7, 16.7
Change from Baseline to Cycle 11 Day 1				
n	0	5	1	6
Mean (StdDev)		-10.00 (25.276)	0.00 (-)	-8.33 (22.973)
Median		0.00	0.00	0.00
Min, Max		-50.0, 16.7	0.0, 0.0	-50.0, 16.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Nausea and Vomiting	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		5.56 (25.459)	0.00 (-)	4.17 (20.972)
Median		0.00	0.00	0.00
Min, Max		-16.7, 33.3	0.0, 0.0	-16.7, 33.3
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Pain	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Baseline				
n	3	23	8	34
Mean (StdDev)	38.89 (25.459)	40.58 (37.881)	54.17 (29.209)	43.63 (34.819)
Median	33.33	33.33	50.00	33.33
Min, Max	16.7, 66.7	0.0, 100.0	16.7, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	19	7	29
Mean (StdDev)	0.00 (0.000)	-21.93 (32.892)	-19.05 (26.227)	-18.97 (29.789)
Median	0.00	0.00	-16.67	0.00
Min, Max	0.0, 0.0	-83.3, 33.3	-50.0, 16.7	-83.3, 33.3
Change from Baseline to Cycle 2 Day 1				
n	2	21	8	31
Mean (StdDev)	0.00 (0.000)	-23.02 (31.392)	-29.17 (26.352)	-23.12 (29.401)
Median	0.00	0.00	-33.33	0.00
Min, Max	0.0, 0.0	-100.0, 16.7	-66.7, 0.0	-100.0, 16.7
Change from Baseline to Cycle 3 Day 1				
n	3	21	6	30
Mean (StdDev)	0.00 (16.667)	-21.43 (35.801)	-30.56 (26.701)	-21.11 (33.025)
Median	0.00	-16.67	-33.33	-16.67
Min, Max	-16.7, 16.7	-100.0, 33.3	-66.7, 0.0	-100.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Pain	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Change from Baseline to Cycle 5 Day 1				
n	1	13	5	19
Mean (StdDev)	16.67 (-)	-14.10 (35.905)	-20.00 (44.721)	-14.04 (36.961)
Median	16.67	-16.67	0.00	0.00
Min, Max	16.7, 16.7	-83.3, 66.7	-66.7, 33.3	-83.3, 66.7
Change from Baseline to Cycle 7 Day 1				
n	1	13	2	16
Mean (StdDev)	0.00 (-)	-16.67 (41.944)	-41.67 (35.355)	-18.75 (39.849)
Median	0.00	-16.67	-41.67	-16.67
Min, Max	0.0, 0.0	-83.3, 83.3	-66.7, -16.7	-83.3, 83.3
Change from Baseline to Cycle 9 Day 1				
n	0	10	2	12
Mean (StdDev)		-10.00 (30.631)	-25.00 (58.926)	-12.50 (33.428)
Median		0.00	-25.00	0.00
Min, Max		-66.7, 33.3	-66.7, 16.7	-66.7, 33.3
Change from Baseline to Cycle 11 Day 1				
n	0	5	1	6
Mean (StdDev)		-20.00 (29.814)	-83.33 (-)	-30.56 (37.143)
Median		0.00	-83.33	-16.67
Min, Max		-66.7, 0.0	-83.3, -83.3	-83.3, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Pain	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-11.11 (19.245)	-83.33 (-)	-29.17 (39.382)
Median		0.00	-83.33	-16.67
Min, Max		-33.3, 0.0	-83.3, -83.3	-83.3, 0.0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Dyspnea	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Baseline				
n	3	23	8	34
Mean (StdDev)	11.11 (19.245)	53.62 (34.435)	54.17 (35.355)	50.00 (35.056)
Median	0.00	33.33	50.00	33.33
Min, Max	0.0, 33.3	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	19	7	29
Mean (StdDev)	-11.11 (19.245)	-24.56 (36.586)	-23.81 (25.198)	-22.99 (32.248)
Median	0.00	-33.33	-33.33	-33.33
Min, Max	-33.3, 0.0	-100.0, 33.3	-66.7, 0.0	-100.0, 33.3
Change from Baseline to Cycle 2 Day 1				
n	2	21	8	31
Mean (StdDev)	0.00 (0.000)	-23.81 (31.873)	-20.83 (24.801)	-21.51 (29.248)
Median	0.00	-33.33	-16.67	0.00
Min, Max	0.0, 0.0	-100.0, 33.3	-66.7, 0.0	-100.0, 33.3
Change from Baseline to Cycle 3 Day 1				
n	3	21	6	30
Mean (StdDev)	11.11 (19.245)	-30.16 (36.370)	-22.22 (17.213)	-24.44 (33.828)
Median	0.00	-33.33	-33.33	-33.33
Min, Max	0.0, 33.3	-100.0, 33.3	-33.3, 0.0	-100.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Dyspnea	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Change from Baseline to Cycle 5 Day 1				
n	1	13	5	19
Mean (StdDev)	-33.33 (-)	-35.90 (37.172)	-26.67 (14.907)	-33.33 (31.427)
Median	-33.33	-33.33	-33.33	-33.33
Min, Max	-33.3, -33.3	-100.0, 0.0	-33.3, 0.0	-100.0, 0.0
Change from Baseline to Cycle 7 Day 1				
n	1	13	2	16
Mean (StdDev)	33.33 (-)	-35.90 (34.592)	-33.33 (0.000)	-31.25 (35.421)
Median	33.33	-33.33	-33.33	-33.33
Min, Max	33.3, 33.3	-100.0, 0.0	-33.3, -33.3	-100.0, 33.3
Change from Baseline to Cycle 9 Day 1				
n	0	10	2	12
Mean (StdDev)		-36.67 (33.148)	-33.33 (0.000)	-36.11 (30.011)
Median		-33.33	-33.33	-33.33
Min, Max		-100.0, 0.0	-33.3, -33.3	-100.0, 0.0
Change from Baseline to Cycle 11 Day 1				
n	0	5	1	6
Mean (StdDev)		-40.00 (43.461)	-33.33 (-)	-38.89 (38.968)
Median		-33.33	-33.33	-33.33
Min, Max		-100.0, 0.0	-33.3, -33.3	-100.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Dyspnea	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-33.33 (57.735)	-33.33 (-)	-33.33 (47.140)
Median		0.00	-33.33	-16.67
Min, Max		-100.0, 0.0	-33.3, -33.3	-100.0, 0.0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg				
Insomnia	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Baseline				
n	3	23	8	34
Mean (StdDev)	66.67 (33.333)	53.62 (37.253)	87.50 (24.801)	62.75 (36.482)
Median	66.67	66.67	100.00	66.67
Min, Max	33.3, 100.0	0.0, 100.0	33.3, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	19	7	29
Mean (StdDev)	-11.11 (19.245)	-12.28 (37.202)	-42.86 (25.198)	-19.54 (35.093)
Median	0.00	0.00	-33.33	-33.33
Min, Max	-33.3, 0.0	-66.7, 33.3	-66.7, 0.0	-66.7, 33.3
Change from Baseline to Cycle 2 Day 1				
n	2	21	8	31
Mean (StdDev)	0.00 (0.000)	-12.70 (48.849)	-66.67 (25.198)	-25.81 (48.465)
Median	0.00	0.00	-66.67	-33.33
Min, Max	0.0, 0.0	-100.0, 66.7	-100.0, -33.3	-100.0, 66.7
Change from Baseline to Cycle 3 Day 1				
n	3	21	6	30
Mean (StdDev)	0.00 (0.000)	-15.87 (45.484)	-66.67 (21.082)	-24.44 (44.578)
Median	0.00	0.00	-66.67	-16.67
Min, Max	0.0, 0.0	-100.0, 66.7	-100.0, -33.3	-100.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Insomnia	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Change from Baseline to Cycle 5 Day 1				
n	1	13	5	19
Mean (StdDev)	-33.33 (-)	-28.21 (32.903)	-33.33 (33.333)	-29.82 (31.220)
Median	-33.33	-33.33	-33.33	-33.33
Min, Max	-33.3, -33.3	-66.7, 33.3	-66.7, 0.0	-66.7, 33.3
Change from Baseline to Cycle 7 Day 1				
n	1	13	2	16
Mean (StdDev)	0.00 (-)	-23.08 (43.853)	-66.67 (0.000)	-27.08 (42.546)
Median	0.00	0.00	-66.67	-16.67
Min, Max	0.0, 0.0	-100.0, 33.3	-66.7, -66.7	-100.0, 33.3
Change from Baseline to Cycle 9 Day 1				
n	0	10	2	12
Mean (StdDev)		-23.33 (41.722)	-66.67 (0.000)	-30.56 (41.337)
Median		0.00	-66.67	-16.67
Min, Max		-100.0, 33.3	-66.7, -66.7	-100.0, 33.3
Change from Baseline to Cycle 11 Day 1				
n	0	5	1	6
Mean (StdDev)		-33.33 (33.333)	-100.00 (-)	-44.44 (40.369)
Median		-33.33	-100.00	-50.00
Min, Max		-66.7, 0.0	-100.0, -100.0	-100.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Insomnia	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-22.22 (38.490)	-100.00 (-)	-41.67 (50.000)
Median		0.00	-100.00	-33.33
Min, Max		-66.7, 0.0	-100.0, -100.0	-100.0, 0.0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		33.33 (-)		33.33 (-)
Median		33.33		33.33
Min, Max		33.3, 33.3		33.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Appetite Loss	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Baseline				
n	3	23	8	34
Mean (StdDev)	22.22 (38.490)	49.28 (36.055)	50.00 (35.635)	47.06 (35.880)
Median	0.00	33.33	33.33	33.33
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	19	7	29
Mean (StdDev)	-11.11 (19.245)	-28.07 (33.817)	-23.81 (25.198)	-25.29 (30.414)
Median	0.00	-33.33	-33.33	-33.33
Min, Max	-33.3, 0.0	-100.0, 33.3	-66.7, 0.0	-100.0, 33.3
Change from Baseline to Cycle 2 Day 1				
n	2	21	8	31
Mean (StdDev)	-16.67 (23.570)	-25.40 (42.038)	-33.33 (35.635)	-26.88 (38.891)
Median	-16.67	-33.33	-33.33	-33.33
Min, Max	-33.3, 0.0	-100.0, 33.3	-100.0, 0.0	-100.0, 33.3
Change from Baseline to Cycle 3 Day 1				
n	3	21	6	30
Mean (StdDev)	0.00 (0.000)	-31.75 (40.106)	-50.00 (45.947)	-32.22 (40.574)
Median	0.00	-33.33	-50.00	-33.33
Min, Max	0.0, 0.0	-100.0, 33.3	-100.0, 0.0	-100.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Appetite Loss	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Change from Baseline to Cycle 5 Day 1				
n	1	13	5	19
Mean (StdDev)	0.00 (-)	-46.15 (46.225)	-13.33 (44.721)	-35.09 (46.446)
Median	0.00	-33.33	-33.33	-33.33
Min, Max	0.0, 0.0	-100.0, 66.7	-66.7, 33.3	-100.0, 66.7
Change from Baseline to Cycle 7 Day 1				
n	1	13	2	16
Mean (StdDev)	0.00 (-)	-46.15 (37.363)	-50.00 (23.570)	-43.75 (35.940)
Median	0.00	-33.33	-50.00	-33.33
Min, Max	0.0, 0.0	-100.0, 0.0	-66.7, -33.3	-100.0, 0.0
Change from Baseline to Cycle 9 Day 1				
n	0	10	2	12
Mean (StdDev)		-36.67 (29.187)	-50.00 (23.570)	-38.89 (27.828)
Median		-33.33	-50.00	-33.33
Min, Max		-100.0, 0.0	-66.7, -33.3	-100.0, 0.0
Change from Baseline to Cycle 11 Day 1				
n	0	5	1	6
Mean (StdDev)		-26.67 (49.441)	-66.67 (-)	-33.33 (47.140)
Median		-33.33	-66.67	-33.33
Min, Max		-100.0, 33.3	-66.7, -66.7	-100.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Appetite Loss	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-44.44 (50.918)	-66.67 (-)	-50.00 (43.033)
Median		-33.33	-66.67	-50.00
Min, Max		-100.0, 0.0	-66.7, -66.7	-100.0, 0.0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		33.33 (-)		33.33 (-)
Median		33.33		33.33
Min, Max		33.3, 33.3		33.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Constipation	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Baseline				
n	3	23	8	34
Mean (StdDev)	33.33 (33.333)	24.64 (33.661)	20.83 (35.355)	24.51 (33.140)
Median	33.33	0.00	0.00	0.00
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	19	7	29
Mean (StdDev)	0.00 (0.000)	-3.51 (24.582)	-9.52 (31.706)	-4.60 (24.759)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 0.0	-66.7, 66.7	-66.7, 33.3	-66.7, 66.7
Change from Baseline to Cycle 2 Day 1				
n	2	21	8	31
Mean (StdDev)	0.00 (0.000)	-12.70 (30.689)	-12.50 (30.538)	-11.83 (29.248)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 0.0	-100.0, 33.3	-66.7, 33.3	-100.0, 33.3
Change from Baseline to Cycle 3 Day 1				
n	3	21	6	30
Mean (StdDev)	-11.11 (19.245)	-6.35 (29.096)	-16.67 (45.947)	-8.89 (31.481)
Median	0.00	0.00	0.00	0.00
Min, Max	-33.3, 0.0	-100.0, 33.3	-100.0, 33.3	-100.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Constipation	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Change from Baseline to Cycle 5 Day 1				
n	1	13	5	19
Mean (StdDev)	0.00 (-)	-5.13 (26.688)	-26.67 (43.461)	-10.53 (31.530)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 0.0	-33.3, 66.7	-100.0, 0.0	-100.0, 66.7
Change from Baseline to Cycle 7 Day 1				
n	1	13	2	16
Mean (StdDev)	-33.33 (-)	-10.26 (25.036)	-66.67 (47.140)	-18.75 (32.131)
Median	-33.33	0.00	-66.67	0.00
Min, Max	-33.3, -33.3	-66.7, 33.3	-100.0, -33.3	-100.0, 33.3
Change from Baseline to Cycle 9 Day 1				
n	0	10	2	12
Mean (StdDev)		-16.67 (36.004)	-66.67 (47.140)	-25.00 (40.514)
Median		0.00	-66.67	-16.67
Min, Max		-100.0, 33.3	-100.0, -33.3	-100.0, 33.3
Change from Baseline to Cycle 11 Day 1				
n	0	5	1	6
Mean (StdDev)		-20.00 (18.257)	-100.00 (-)	-33.33 (36.515)
Median		-33.33	-100.00	-33.33
Min, Max		-33.3, 0.0	-100.0, -100.0	-100.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Constipation	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-22.22 (19.245)	-100.00 (-)	-41.67 (41.944)
Median		-33.33	-100.00	-33.33
Min, Max		-33.3, 0.0	-100.0, -100.0	-100.0, 0.0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Diarrhea	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Baseline				
n	3	23	8	34
Mean (StdDev)	0.00 (0.000)	40.58 (40.147)	45.83 (43.416)	38.24 (40.312)
Median	0.00	33.33	50.00	33.33
Min, Max	0.0, 0.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	19	7	29
Mean (StdDev)	11.11 (19.245)	-31.58 (32.344)	-14.29 (53.945)	-22.99 (38.938)
Median	0.00	-33.33	0.00	0.00
Min, Max	0.0, 33.3	-100.0, 0.0	-100.0, 33.3	-100.0, 33.3
Change from Baseline to Cycle 2 Day 1				
n	2	21	8	31
Mean (StdDev)	0.00 (0.000)	-25.40 (37.866)	-16.67 (39.841)	-21.51 (37.067)
Median	0.00	-33.33	-16.67	0.00
Min, Max	0.0, 0.0	-100.0, 33.3	-66.7, 33.3	-100.0, 33.3
Change from Baseline to Cycle 3 Day 1				
n	3	21	6	30
Mean (StdDev)	0.00 (0.000)	-23.81 (39.641)	-22.22 (45.542)	-21.11 (38.639)
Median	0.00	-33.33	-16.67	0.00
Min, Max	0.0, 0.0	-100.0, 66.7	-100.0, 33.3	-100.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Diarrhea	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Change from Baseline to Cycle 5 Day 1				
n	1	13	5	19
Mean (StdDev)	0.00 (-)	-28.21 (40.474)	-20.00 (50.553)	-24.56 (41.339)
Median	0.00	-33.33	0.00	-33.33
Min, Max	0.0, 0.0	-100.0, 66.7	-100.0, 33.3	-100.0, 66.7
Change from Baseline to Cycle 7 Day 1				
n	1	13	2	16
Mean (StdDev)	33.33 (-)	-30.77 (34.592)	0.00 (0.000)	-22.92 (35.940)
Median	33.33	-33.33	0.00	-33.33
Min, Max	33.3, 33.3	-100.0, 33.3	0.0, 0.0	-100.0, 33.3
Change from Baseline to Cycle 9 Day 1				
n	0	10	2	12
Mean (StdDev)		-20.00 (39.126)	0.00 (0.000)	-16.67 (36.237)
Median		-33.33	0.00	-16.67
Min, Max		-66.7, 66.7	0.0, 0.0	-66.7, 66.7
Change from Baseline to Cycle 11 Day 1				
n	0	5	1	6
Mean (StdDev)		-26.67 (27.889)	0.00 (-)	-22.22 (27.217)
Median		-33.33	0.00	-16.67
Min, Max		-66.7, 0.0	0.0, 0.0	-66.7, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Diarrhea	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-11.11 (19.245)	0.00 (-)	-8.33 (16.667)
Median		0.00	0.00	0.00
Min, Max		-33.3, 0.0	0.0, 0.0	-33.3, 0.0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Financial Difficulties	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Baseline				
n	3	23	8	34
Mean (StdDev)	33.33 (33.333)	24.64 (30.513)	25.00 (34.503)	25.49 (30.769)
Median	33.33	0.00	16.67	16.67
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	19	7	29
Mean (StdDev)	0.00 (33.333)	1.75 (25.995)	-19.05 (42.414)	-3.45 (31.301)
Median	0.00	0.00	0.00	0.00
Min, Max	-33.3, 33.3	-66.7, 33.3	-100.0, 33.3	-100.0, 33.3
Change from Baseline to Cycle 2 Day 1				
n	2	21	8	31
Mean (StdDev)	0.00 (0.000)	-4.76 (24.234)	-8.33 (23.570)	-5.38 (22.928)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 0.0	-66.7, 33.3	-33.3, 33.3	-66.7, 33.3
Change from Baseline to Cycle 3 Day 1				
n	3	21	6	30
Mean (StdDev)	11.11 (19.245)	-4.76 (24.234)	5.56 (25.092)	-1.11 (23.947)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 33.3	-66.7, 33.3	-33.3, 33.3	-66.7, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

Financial Difficulties	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Change from Baseline to Cycle 5 Day 1				
n	1	13	5	19
Mean (StdDev)	-66.67 (-)	-10.26 (28.495)	13.33 (38.006)	-7.02 (34.389)
Median	-66.67	0.00	0.00	0.00
Min, Max	-66.7, -66.7	-66.7, 33.3	-33.3, 66.7	-66.7, 66.7
Change from Baseline to Cycle 7 Day 1				
n	1	13	2	16
Mean (StdDev)	0.00 (-)	-5.13 (26.688)	16.67 (23.570)	-2.08 (25.730)
Median	0.00	0.00	16.67	0.00
Min, Max	0.0, 0.0	-66.7, 33.3	0.0, 33.3	-66.7, 33.3
Change from Baseline to Cycle 9 Day 1				
n	0	10	2	12
Mean (StdDev)		13.33 (23.307)	0.00 (0.000)	11.11 (21.711)
Median		0.00	0.00	0.00
Min, Max		0.0, 66.7	0.0, 0.0	0.0, 66.7
Change from Baseline to Cycle 11 Day 1				
n	0	5	1	6
Mean (StdDev)		20.00 (29.814)	0.00 (-)	16.67 (27.889)
Median		0.00	0.00	0.00
Min, Max		0.0, 66.7	0.0, 0.0	0.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg				
Financial Difficulties	ASM (N=4)	SM-AHN (N=27)	MCL (N=9)	All AdvSM (N=40)
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-11.11 (19.245)	0.00 (-)	-8.33 (16.667)
Median		0.00	0.00	0.00
Min, Max		-33.3, 0.0	0.0, 0.0	-33.3, 0.0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		-33.33 (-)		-33.33 (-)
Median		-33.33		-33.33
Min, Max		-33.3, -33.3		-33.3, -33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Global Health Status/QoL	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Baseline				
n	7	39	14	60
Mean (StdDev)	50.00 (14.434)	36.54 (26.186)	36.31 (15.194)	38.06 (23.084)
Median	50.00	33.33	33.33	33.33
Min, Max	33.3, 75.0	0.0, 100.0	16.7, 58.3	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	2.78 (9.623)	19.58 (26.390)	11.90 (24.934)	16.11 (24.946)
Median	8.33	16.67	0.00	8.33
Min, Max	-8.3, 8.3	-25.0, 83.3	-8.3, 50.0	-25.0, 83.3
Change from Baseline to Cycle 2 Day 1				
n	5	35	13	53
Mean (StdDev)	0.00 (21.246)	20.71 (27.518)	14.10 (28.338)	17.14 (27.465)
Median	8.33	16.67	16.67	16.67
Min, Max	-33.3, 16.7	-25.0, 91.7	-33.3, 58.3	-33.3, 91.7
Change from Baseline to Cycle 3 Day 1				
n	6	35	11	52
Mean (StdDev)	-1.39 (23.224)	21.90 (30.052)	12.88 (19.495)	17.31 (28.095)
Median	4.17	16.67	0.00	16.67
Min, Max	-33.3, 25.0	-66.7, 83.3	-8.3, 41.7	-66.7, 83.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Global Health Status/QoL	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 4 Day 1				
n	2	12	6	20
Mean (StdDev)	12.50 (29.463)	15.28 (31.549)	12.50 (30.619)	14.17 (29.506)
Median	12.50	20.83	20.83	20.83
Min, Max	-8.3, 33.3	-33.3, 66.7	-25.0, 41.7	-33.3, 66.7
Change from Baseline to Cycle 5 Day 1				
n	4	24	11	39
Mean (StdDev)	18.75 (10.486)	21.18 (37.022)	15.15 (20.006)	19.23 (30.836)
Median	16.67	25.00	16.67	16.67
Min, Max	8.3, 33.3	-100.0, 83.3	-25.0, 41.7	-100.0, 83.3
Change from Baseline to Cycle 6 Day 1				
n	3	10	5	18
Mean (StdDev)	22.22 (9.623)	27.50 (32.643)	21.67 (20.917)	25.00 (26.197)
Median	16.67	33.33	16.67	25.00
Min, Max	16.7, 33.3	-25.0, 66.7	-8.3, 41.7	-25.0, 66.7
Change from Baseline to Cycle 7 Day 1				
n	4	22	7	33
Mean (StdDev)	2.08 (17.180)	34.47 (32.048)	13.10 (20.893)	26.01 (30.672)
Median	4.17	33.33	0.00	33.33
Min, Max	-16.7, 16.7	-33.3, 83.3	-8.3, 41.7	-33.3, 83.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Global Health Status/QoL	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 8 Day 1				
n	2	9	4	15
Mean (StdDev)	16.67 (35.355)	34.26 (26.824)	12.50 (28.464)	26.11 (27.972)
Median	16.67	33.33	8.33	25.00
Min, Max	-8.3, 41.7	-16.7, 66.7	-16.7, 50.0	-16.7, 66.7
Change from Baseline to Cycle 9 Day 1				
n	3	18	6	27
Mean (StdDev)	8.33 (14.434)	32.87 (33.391)	4.17 (36.420)	23.77 (34.258)
Median	16.67	41.67	8.33	16.67
Min, Max	-8.3, 16.7	-58.3, 83.3	-50.0, 58.3	-58.3, 83.3
Change from Baseline to Cycle 10 Day 1				
n	3	8	3	14
Mean (StdDev)	19.44 (9.623)	33.33 (24.801)	22.22 (41.944)	27.98 (25.655)
Median	25.00	41.67	16.67	25.00
Min, Max	8.3, 25.0	0.0, 58.3	-16.7, 66.7	-16.7, 66.7
Change from Baseline to Cycle 11 Day 1				
n	3	15	4	22
Mean (StdDev)	0.00 (25.000)	31.67 (28.031)	12.50 (25.909)	23.86 (28.787)
Median	0.00	41.67	12.50	29.17
Min, Max	-25.0, 25.0	-33.3, 58.3	-16.7, 41.7	-33.3, 58.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Global Health Status/QoL	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 12 Day 1				
n	2	5	3	10
Mean (StdDev)	20.83 (17.678)	35.00 (16.029)	22.22 (34.694)	28.33 (21.588)
Median	20.83	33.33	33.33	33.33
Min, Max	8.3, 33.3	16.7, 58.3	-16.7, 50.0	-16.7, 58.3
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		30.56 (64.729)	41.67 (-)	33.33 (53.142)
Median		50.00	41.67	45.83
Min, Max		-41.7, 83.3	41.7, 41.7	-41.7, 83.3
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		-33.33 (-)		-33.33 (-)
Median		-33.33		-33.33
Min, Max		-33.3, -33.3		-33.3, -33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Physical Functioning	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Baseline				
n	7	39	14	60
Mean (StdDev)	71.43 (23.322)	50.94 (27.209)	60.48 (25.144)	55.56 (26.854)
Median	80.00	46.67	63.33	60.00
Min, Max	20.0, 86.7	0.0, 100.0	20.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	2.22 (3.849)	11.67 (17.951)	15.24 (22.678)	11.56 (18.189)
Median	0.00	10.00	13.33	10.00
Min, Max	0.0, 6.7	-13.3, 53.3	-20.0, 46.7	-20.0, 53.3
Change from Baseline to Cycle 2 Day 1				
n	5	35	13	53
Mean (StdDev)	-1.33 (7.303)	13.52 (21.297)	7.69 (19.022)	10.69 (20.142)
Median	0.00	6.67	6.67	6.67
Min, Max	-13.3, 6.7	-20.0, 73.3	-20.0, 46.7	-20.0, 73.3
Change from Baseline to Cycle 3 Day 1				
n	6	35	11	52
Mean (StdDev)	-7.78 (11.483)	14.10 (22.853)	7.88 (19.048)	10.26 (21.951)
Median	-6.67	13.33	6.67	6.67
Min, Max	-26.7, 6.7	-26.7, 73.3	-20.0, 40.0	-26.7, 73.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Physical Functioning	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 4 Day 1				
n	2	12	6	20
Mean (StdDev)	-20.00 (9.428)	15.00 (20.326)	16.67 (22.998)	12.00 (22.436)
Median	-20.00	10.00	13.33	6.67
Min, Max	-26.7, -13.3	-6.7, 60.0	-6.7, 46.7	-26.7, 60.0
Change from Baseline to Cycle 5 Day 1				
n	4	24	11	39
Mean (StdDev)	1.67 (19.907)	21.67 (22.778)	6.67 (24.766)	15.38 (23.947)
Median	0.00	13.33	13.33	13.33
Min, Max	-20.0, 26.7	-13.3, 73.3	-26.7, 53.3	-26.7, 73.3
Change from Baseline to Cycle 6 Day 1				
n	3	10	5	18
Mean (StdDev)	-11.11 (13.878)	16.67 (21.140)	-1.33 (15.202)	7.04 (21.140)
Median	-6.67	16.67	0.00	13.33
Min, Max	-26.7, 0.0	-20.0, 46.7	-20.0, 13.3	-26.7, 46.7
Change from Baseline to Cycle 7 Day 1				
n	4	22	7	33
Mean (StdDev)	-6.67 (23.727)	22.12 (22.853)	10.48 (27.449)	16.16 (25.168)
Median	0.00	13.33	6.67	13.33
Min, Max	-40.0, 13.3	-20.0, 66.7	-20.0, 53.3	-40.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Physical Functioning	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 8 Day 1				
n	2	9	4	15
Mean (StdDev)	0.00 (9.428)	22.96 (18.889)	11.67 (34.588)	16.89 (23.213)
Median	0.00	20.00	0.00	13.33
Min, Max	-6.7, 6.7	-13.3, 53.3	-13.3, 60.0	-13.3, 60.0
Change from Baseline to Cycle 9 Day 1				
n	3	18	6	27
Mean (StdDev)	-8.89 (23.413)	27.41 (20.944)	11.11 (29.414)	19.75 (25.452)
Median	-6.67	23.33	10.00	13.33
Min, Max	-33.3, 13.3	0.0, 66.7	-26.7, 53.3	-33.3, 66.7
Change from Baseline to Cycle 10 Day 1				
n	3	8	3	14
Mean (StdDev)	-4.44 (10.184)	20.00 (21.082)	20.00 (37.118)	14.76 (23.991)
Median	-6.67	16.67	13.33	13.33
Min, Max	-13.3, 6.7	-6.7, 46.7	-13.3, 60.0	-13.3, 60.0
Change from Baseline to Cycle 11 Day 1				
n	3	15	4	22
Mean (StdDev)	-6.67 (11.547)	28.89 (22.063)	26.67 (37.317)	23.64 (26.245)
Median	-13.33	26.67	33.33	20.00
Min, Max	-13.3, 6.7	-13.3, 60.0	-20.0, 60.0	-20.0, 60.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Physical Functioning	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 12 Day 1				
n	2	5	3	10
Mean (StdDev)	-10.00 (4.714)	30.67 (19.206)	15.56 (36.717)	18.00 (27.044)
Median	-10.00	26.67	13.33	16.67
Min, Max	-13.3, -6.7	6.7, 53.3	-20.0, 53.3	-20.0, 53.3
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		35.56 (33.555)	60.00 (-)	41.67 (30.000)
Median		40.00	60.00	50.00
Min, Max		0.0, 66.7	60.0, 60.0	0.0, 66.7
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Role Functioning	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Baseline				
n	7	39	14	60
Mean (StdDev)	54.76 (29.991)	39.74 (33.249)	29.76 (30.084)	39.17 (32.449)
Median	66.67	33.33	25.00	41.67
Min, Max	0.0, 83.3	0.0, 100.0	0.0, 66.7	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	-5.56 (9.623)	12.50 (18.634)	23.81 (21.207)	13.33 (19.769)
Median	0.00	0.00	16.67	8.33
Min, Max	-16.7, 0.0	-16.7, 50.0	0.0, 66.7	-16.7, 66.7
Change from Baseline to Cycle 2 Day 1				
n	5	35	13	53
Mean (StdDev)	-13.33 (27.386)	16.67 (26.507)	20.51 (33.440)	14.78 (29.356)
Median	0.00	16.67	16.67	16.67
Min, Max	-50.0, 16.7	-16.7, 100.0	-33.3, 83.3	-50.0, 100.0
Change from Baseline to Cycle 3 Day 1				
n	6	35	11	52
Mean (StdDev)	-11.11 (22.771)	17.14 (26.656)	18.18 (29.302)	14.10 (27.886)
Median	-8.33	16.67	16.67	16.67
Min, Max	-50.0, 16.7	-33.3, 66.7	-33.3, 66.7	-50.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Role Functioning	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 4 Day 1				
n	2	12	6	20
Mean (StdDev)	-25.00 (11.785)	13.89 (26.432)	33.33 (47.140)	15.83 (35.654)
Median	-25.00	16.67	33.33	16.67
Min, Max	-33.3, -16.7	-33.3, 66.7	-33.3, 100.0	-33.3, 100.0
Change from Baseline to Cycle 5 Day 1				
n	4	24	11	39
Mean (StdDev)	-4.17 (20.972)	20.83 (36.860)	16.67 (29.814)	17.09 (33.874)
Median	0.00	16.67	16.67	16.67
Min, Max	-33.3, 16.7	-66.7, 83.3	-33.3, 66.7	-66.7, 83.3
Change from Baseline to Cycle 6 Day 1				
n	3	10	5	18
Mean (StdDev)	5.56 (19.245)	8.33 (30.682)	20.00 (29.814)	11.11 (28.006)
Median	16.67	0.00	0.00	0.00
Min, Max	-16.7, 16.7	-33.3, 66.7	0.0, 66.7	-33.3, 66.7
Change from Baseline to Cycle 7 Day 1				
n	4	22	7	33
Mean (StdDev)	0.00 (30.429)	23.48 (34.755)	23.81 (23.288)	20.71 (32.283)
Median	0.00	16.67	16.67	16.67
Min, Max	-33.3, 33.3	-33.3, 83.3	0.0, 66.7	-33.3, 83.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Role Functioning	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 8 Day 1				
n	2	9	4	15
Mean (StdDev)	8.33 (11.785)	29.63 (24.689)	8.33 (56.928)	21.11 (34.195)
Median	8.33	33.33	16.67	33.33
Min, Max	0.0, 16.7	0.0, 83.3	-66.7, 66.7	-66.7, 83.3
Change from Baseline to Cycle 9 Day 1				
n	3	18	6	27
Mean (StdDev)	0.00 (28.868)	30.56 (27.565)	2.78 (37.143)	20.99 (31.889)
Median	16.67	33.33	8.33	16.67
Min, Max	-33.3, 16.7	-33.3, 66.7	-66.7, 33.3	-66.7, 66.7
Change from Baseline to Cycle 10 Day 1				
n	3	8	3	14
Mean (StdDev)	0.00 (16.667)	22.92 (36.664)	33.33 (33.333)	20.24 (32.803)
Median	0.00	25.00	33.33	16.67
Min, Max	-16.7, 16.7	-33.3, 83.3	0.0, 66.7	-33.3, 83.3
Change from Baseline to Cycle 11 Day 1				
n	3	15	4	22
Mean (StdDev)	0.00 (16.667)	32.22 (32.408)	50.00 (43.033)	31.06 (34.616)
Median	0.00	33.33	50.00	33.33
Min, Max	-16.7, 16.7	-33.3, 100.0	0.0, 100.0	-33.3, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Role Functioning	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 12 Day 1				
n	2	5	3	10
Mean (StdDev)	-16.67 (23.570)	46.67 (32.059)	27.78 (25.459)	28.33 (36.047)
Median	-16.67	33.33	33.33	33.33
Min, Max	-33.3, 0.0	16.7, 100.0	0.0, 50.0	-33.3, 100.0
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		44.44 (38.490)	66.67 (-)	50.00 (33.333)
Median		66.67	66.67	66.67
Min, Max		0.0, 66.7	66.7, 66.7	0.0, 66.7
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Emotional Functioning	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Baseline				
n	7	39	14	60
Mean (StdDev)	69.05 (29.152)	62.18 (26.411)	60.12 (26.388)	62.50 (26.375)
Median	83.33	66.67	66.67	66.67
Min, Max	33.3, 100.0	8.3, 100.0	8.3, 100.0	8.3, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	0.00 (8.333)	10.42 (17.703)	1.19 (16.265)	7.22 (16.914)
Median	0.00	12.50	0.00	8.33
Min, Max	-8.3, 8.3	-25.0, 58.3	-25.0, 16.7	-25.0, 58.3
Change from Baseline to Cycle 2 Day 1				
n	5	35	13	53
Mean (StdDev)	-1.67 (13.693)	10.95 (24.318)	10.90 (13.344)	9.75 (21.355)
Median	-8.33	8.33	16.67	8.33
Min, Max	-16.7, 16.7	-25.0, 58.3	-8.3, 33.3	-25.0, 58.3
Change from Baseline to Cycle 3 Day 1				
n	6	35	11	52
Mean (StdDev)	-5.56 (19.484)	11.27 (23.181)	7.58 (16.855)	8.55 (21.906)
Median	-8.33	8.33	0.00	4.17
Min, Max	-33.3, 16.7	-33.3, 58.3	-8.3, 41.7	-33.3, 58.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Emotional Functioning	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 4 Day 1				
n	2	12	6	20
Mean (StdDev)	12.50 (41.248)	9.03 (19.611)	11.11 (17.213)	10.00 (19.794)
Median	12.50	0.00	8.33	8.33
Min, Max	-16.7, 41.7	-8.3, 58.3	-16.7, 33.3	-16.7, 58.3
Change from Baseline to Cycle 5 Day 1				
n	4	24	11	39
Mean (StdDev)	10.42 (14.232)	12.85 (28.016)	1.52 (19.300)	9.40 (24.793)
Median	12.50	8.33	0.00	8.33
Min, Max	-8.3, 25.0	-33.3, 66.7	-25.0, 41.7	-33.3, 66.7
Change from Baseline to Cycle 6 Day 1				
n	3	10	5	18
Mean (StdDev)	8.33 (8.333)	10.00 (30.631)	-3.33 (21.731)	6.02 (25.534)
Median	8.33	4.17	-8.33	4.17
Min, Max	0.0, 16.7	-33.3, 75.0	-33.3, 25.0	-33.3, 75.0
Change from Baseline to Cycle 7 Day 1				
n	4	22	7	33
Mean (StdDev)	2.08 (14.232)	16.67 (23.710)	-3.57 (32.934)	10.61 (25.876)
Median	4.17	16.67	0.00	8.33
Min, Max	-16.7, 16.7	-25.0, 66.7	-66.7, 41.7	-66.7, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Emotional Functioning	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 8 Day 1				
n	2	9	4	15
Mean (StdDev)	4.17 (17.678)	13.27 (17.666)	-10.42 (38.715)	5.74 (25.164)
Median	4.17	8.33	-16.67	8.33
Min, Max	-8.3, 16.7	-8.3, 50.0	-50.0, 41.7	-50.0, 50.0
Change from Baseline to Cycle 9 Day 1				
n	3	18	6	27
Mean (StdDev)	11.11 (17.347)	16.67 (18.743)	-8.33 (32.489)	10.49 (23.750)
Median	16.67	16.67	-4.17	16.67
Min, Max	-8.3, 25.0	-16.7, 50.0	-50.0, 33.3	-50.0, 50.0
Change from Baseline to Cycle 10 Day 1				
n	3	8	3	14
Mean (StdDev)	8.33 (8.333)	13.54 (25.173)	-16.67 (50.690)	5.95 (30.034)
Median	8.33	8.33	-41.67	8.33
Min, Max	0.0, 16.7	-8.3, 66.7	-50.0, 41.7	-50.0, 66.7
Change from Baseline to Cycle 11 Day 1				
n	3	15	4	22
Mean (StdDev)	-2.78 (24.056)	16.11 (23.031)	0.00 (44.618)	10.61 (27.600)
Median	-16.67	8.33	-4.17	8.33
Min, Max	-16.7, 25.0	-16.7, 66.7	-41.7, 50.0	-41.7, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Emotional Functioning	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 12 Day 1				
n	2	5	3	10
Mean (StdDev)	8.33 (11.785)	16.67 (11.785)	-19.44 (66.840)	4.17 (36.694)
Median	8.33	25.00	-25.00	12.50
Min, Max	0.0, 16.7	0.0, 25.0	-83.3, 50.0	-83.3, 50.0
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		30.56 (33.679)	25.00 (-)	29.17 (27.639)
Median		25.00	25.00	25.00
Min, Max		0.0, 66.7	25.0, 25.0	0.0, 66.7
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Cognitive Functioning	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Baseline				
n	7	39	14	60
Mean (StdDev)	76.19 (23.288)	68.38 (26.981)	66.67 (27.735)	68.89 (26.480)
Median	83.33	66.67	58.33	66.67
Min, Max	33.3, 100.0	0.0, 100.0	16.7, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	-5.56 (9.623)	5.00 (14.408)	-4.76 (8.133)	1.67 (13.384)
Median	0.00	0.00	0.00	0.00
Min, Max	-16.7, 0.0	-16.7, 33.3	-16.7, 0.0	-16.7, 33.3
Change from Baseline to Cycle 2 Day 1				
n	5	35	13	53
Mean (StdDev)	-13.33 (43.141)	3.33 (21.693)	5.13 (20.844)	2.20 (24.028)
Median	0.00	0.00	16.67	0.00
Min, Max	-83.3, 33.3	-33.3, 50.0	-33.3, 33.3	-83.3, 50.0
Change from Baseline to Cycle 3 Day 1				
n	6	35	11	52
Mean (StdDev)	-2.78 (35.616)	2.86 (21.574)	7.58 (20.226)	3.21 (22.876)
Median	8.33	0.00	16.67	0.00
Min, Max	-66.7, 33.3	-50.0, 50.0	-33.3, 33.3	-66.7, 50.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Cognitive Functioning	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 4 Day 1				
n	2	12	6	20
Mean (StdDev)	16.67 (23.570)	2.78 (23.391)	5.56 (13.608)	5.00 (20.305)
Median	16.67	0.00	8.33	0.00
Min, Max	0.0, 33.3	-33.3, 50.0	-16.7, 16.7	-33.3, 50.0
Change from Baseline to Cycle 5 Day 1				
n	4	24	11	39
Mean (StdDev)	-12.50 (15.957)	3.47 (21.968)	-7.58 (17.262)	-1.28 (20.727)
Median	-8.33	0.00	0.00	0.00
Min, Max	-33.3, 0.0	-50.0, 33.3	-33.3, 16.7	-50.0, 33.3
Change from Baseline to Cycle 6 Day 1				
n	3	10	5	18
Mean (StdDev)	-16.67 (44.096)	16.67 (17.568)	6.67 (14.907)	8.33 (24.421)
Median	0.00	16.67	16.67	16.67
Min, Max	-66.7, 16.7	0.0, 50.0	-16.7, 16.7	-66.7, 50.0
Change from Baseline to Cycle 7 Day 1				
n	4	22	7	33
Mean (StdDev)	-12.50 (34.359)	8.33 (24.533)	-2.38 (17.817)	3.54 (24.916)
Median	-8.33	0.00	0.00	0.00
Min, Max	-50.0, 16.7	-33.3, 50.0	-33.3, 16.7	-50.0, 50.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Cognitive Functioning	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 8 Day 1				
n	2	9	4	15
Mean (StdDev)	0.00 (47.140)	14.81 (21.155)	-4.17 (15.957)	7.78 (23.458)
Median	0.00	16.67	-8.33	0.00
Min, Max	-33.3, 33.3	-16.7, 50.0	-16.7, 16.7	-33.3, 50.0
Change from Baseline to Cycle 9 Day 1				
n	3	18	6	27
Mean (StdDev)	-22.22 (34.694)	6.48 (27.499)	-5.56 (13.608)	0.62 (26.747)
Median	-33.33	0.00	-8.33	0.00
Min, Max	-50.0, 16.7	-33.3, 50.0	-16.7, 16.7	-50.0, 50.0
Change from Baseline to Cycle 10 Day 1				
n	3	8	3	14
Mean (StdDev)	-33.33 (16.667)	12.50 (23.146)	-11.11 (34.694)	-2.38 (29.855)
Median	-33.33	16.67	0.00	0.00
Min, Max	-50.0, -16.7	-16.7, 50.0	-50.0, 16.7	-50.0, 50.0
Change from Baseline to Cycle 11 Day 1				
n	3	15	4	22
Mean (StdDev)	-16.67 (28.868)	10.00 (17.593)	-4.17 (20.972)	3.79 (21.164)
Median	-33.33	0.00	0.00	0.00
Min, Max	-33.3, 16.7	-16.7, 33.3	-33.3, 16.7	-33.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Cognitive Functioning	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 12 Day 1				
n	2	5	3	10
Mean (StdDev)	-16.67 (47.140)	6.67 (19.003)	-16.67 (44.096)	-5.00 (31.476)
Median	-16.67	0.00	0.00	0.00
Min, Max	-50.0, 16.7	-16.7, 33.3	-66.7, 16.7	-66.7, 33.3
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		5.56 (9.623)	16.67 (-)	8.33 (9.623)
Median		0.00	16.67	8.33
Min, Max		0.0, 16.7	16.7, 16.7	0.0, 16.7
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		-16.67 (-)		-16.67 (-)
Median		-16.67		-16.67
Min, Max		-16.7, -16.7		-16.7, -16.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Social Function	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Baseline				
n	7	39	14	60
Mean (StdDev)	61.90 (32.934)	48.72 (32.078)	47.62 (33.242)	50.00 (32.184)
Median	50.00	33.33	66.67	50.00
Min, Max	16.7, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	0.00 (16.667)	17.50 (25.635)	19.05 (29.547)	16.11 (25.702)
Median	0.00	16.67	16.67	16.67
Min, Max	-16.7, 16.7	-16.7, 66.7	-16.7, 66.7	-16.7, 66.7
Change from Baseline to Cycle 2 Day 1				
n	5	35	13	53
Mean (StdDev)	-10.00 (25.276)	15.71 (33.073)	12.82 (32.740)	12.58 (32.671)
Median	0.00	16.67	0.00	16.67
Min, Max	-50.0, 16.7	-33.3, 100.0	-33.3, 83.3	-50.0, 100.0
Change from Baseline to Cycle 3 Day 1				
n	6	35	11	52
Mean (StdDev)	-11.11 (31.032)	11.43 (23.491)	10.61 (30.067)	8.65 (26.299)
Median	-16.67	0.00	0.00	0.00
Min, Max	-50.0, 33.3	-16.7, 83.3	-50.0, 50.0	-50.0, 83.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Social Function	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 4 Day 1				
n	2	12	6	20
Mean (StdDev)	8.33 (11.785)	15.28 (20.669)	8.33 (20.412)	12.50 (19.403)
Median	8.33	16.67	0.00	8.33
Min, Max	0.0, 16.7	-16.7, 50.0	-16.7, 33.3	-16.7, 50.0
Change from Baseline to Cycle 5 Day 1				
n	4	24	11	39
Mean (StdDev)	-16.67 (36.004)	22.22 (28.090)	6.06 (27.155)	13.68 (30.558)
Median	-8.33	33.33	0.00	16.67
Min, Max	-66.7, 16.7	-50.0, 66.7	-16.7, 66.7	-66.7, 66.7
Change from Baseline to Cycle 6 Day 1				
n	3	10	5	18
Mean (StdDev)	-11.11 (9.623)	18.33 (34.650)	0.00 (42.492)	8.33 (34.890)
Median	-16.67	25.00	0.00	0.00
Min, Max	-16.7, 0.0	-33.3, 66.7	-50.0, 66.7	-50.0, 66.7
Change from Baseline to Cycle 7 Day 1				
n	4	22	7	33
Mean (StdDev)	-4.17 (36.956)	25.00 (29.881)	11.90 (38.145)	18.69 (33.008)
Median	0.00	33.33	0.00	16.67
Min, Max	-50.0, 33.3	-33.3, 66.7	-33.3, 83.3	-50.0, 83.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Social Function	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 8 Day 1				
n	2	9	4	15
Mean (StdDev)	-8.33 (11.785)	16.67 (20.412)	-16.67 (43.033)	4.44 (29.859)
Median	-8.33	16.67	-16.67	0.00
Min, Max	-16.7, 0.0	-16.7, 50.0	-66.7, 33.3	-66.7, 50.0
Change from Baseline to Cycle 9 Day 1				
n	3	18	6	27
Mean (StdDev)	-16.67 (0.000)	25.93 (27.548)	11.11 (54.433)	17.90 (35.484)
Median	-16.67	33.33	16.67	16.67
Min, Max	-16.7, -16.7	-33.3, 66.7	-66.7, 100.0	-66.7, 100.0
Change from Baseline to Cycle 10 Day 1				
n	3	8	3	14
Mean (StdDev)	-11.11 (19.245)	22.92 (33.259)	-11.11 (83.887)	8.33 (45.173)
Median	0.00	25.00	0.00	0.00
Min, Max	-33.3, 0.0	-16.7, 66.7	-100.0, 66.7	-100.0, 66.7
Change from Baseline to Cycle 11 Day 1				
n	3	15	4	22
Mean (StdDev)	-27.78 (34.694)	28.89 (27.070)	25.00 (79.931)	20.45 (43.623)
Median	-16.67	33.33	41.67	25.00
Min, Max	-66.7, 0.0	-16.7, 66.7	-83.3, 100.0	-83.3, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Social Function	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 12 Day 1				
n	2	5	3	10
Mean (StdDev)	16.67 (47.140)	36.67 (18.257)	-5.56 (75.154)	20.00 (44.997)
Median	16.67	33.33	0.00	33.33
Min, Max	-16.7, 50.0	16.7, 66.7	-83.3, 66.7	-83.3, 66.7
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		44.44 (53.576)	100.00 (-)	58.33 (51.819)
Median		66.67	100.00	75.00
Min, Max		-16.7, 83.3	100.0, 100.0	-16.7, 100.0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Fatigue	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Baseline				
n	7	39	14	60
Mean (StdDev)	57.14 (23.508)	71.23 (29.696)	72.22 (28.160)	69.81 (28.647)
Median	55.56	77.78	77.78	66.67
Min, Max	33.3, 100.0	0.0, 100.0	22.2, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	3.70 (6.415)	-20.00 (22.970)	-19.05 (27.751)	-17.41 (23.648)
Median	0.00	-11.11	-22.22	-11.11
Min, Max	0.0, 11.1	-55.6, 11.1	-55.6, 22.2	-55.6, 22.2
Change from Baseline to Cycle 2 Day 1				
n	5	35	13	53
Mean (StdDev)	6.67 (20.184)	-18.73 (25.533)	-15.38 (25.474)	-15.51 (25.722)
Median	11.11	-11.11	0.00	-11.11
Min, Max	-22.2, 33.3	-77.8, 33.3	-66.7, 11.1	-77.8, 33.3
Change from Baseline to Cycle 3 Day 1				
n	6	35	11	52
Mean (StdDev)	9.26 (23.744)	-16.51 (25.476)	-11.11 (21.082)	-12.39 (25.342)
Median	16.67	-11.11	-11.11	-11.11
Min, Max	-33.3, 33.3	-77.8, 44.4	-55.6, 11.1	-77.8, 44.4

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Fatigue	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 4 Day 1				
n	2	12	6	20
Mean (StdDev)	0.00 (47.140)	-14.81 (21.883)	-22.22 (36.515)	-15.56 (28.017)
Median	0.00	-22.22	-11.11	-22.22
Min, Max	-33.3, 33.3	-44.4, 22.2	-66.7, 22.2	-66.7, 33.3
Change from Baseline to Cycle 5 Day 1				
n	4	24	11	39
Mean (StdDev)	-5.56 (23.130)	-27.31 (34.517)	-18.18 (22.918)	-22.51 (30.852)
Median	-5.56	-33.33	-11.11	-22.22
Min, Max	-33.3, 22.2	-77.8, 66.7	-66.7, 11.1	-77.8, 66.7
Change from Baseline to Cycle 6 Day 1				
n	3	10	5	18
Mean (StdDev)	-7.41 (12.830)	-24.44 (31.340)	-6.67 (30.021)	-16.67 (28.836)
Median	0.00	-33.33	0.00	-16.67
Min, Max	-22.2, 0.0	-55.6, 44.4	-55.6, 22.2	-55.6, 44.4
Change from Baseline to Cycle 7 Day 1				
n	4	22	7	33
Mean (StdDev)	-2.78 (5.556)	-36.11 (27.844)	-11.11 (18.144)	-26.77 (27.550)
Median	0.00	-36.11	-11.11	-33.33
Min, Max	-11.1, 0.0	-88.9, 22.2	-44.4, 11.1	-88.9, 22.2

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Fatigue	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 8 Day 1				
n	2	9	4	15
Mean (StdDev)	0.00 (15.713)	-39.51 (20.116)	-2.78 (22.906)	-24.44 (26.956)
Median	0.00	-44.44	0.00	-33.33
Min, Max	-11.1, 11.1	-66.7, 0.0	-33.3, 22.2	-66.7, 22.2
Change from Baseline to Cycle 9 Day 1				
n	3	18	6	27
Mean (StdDev)	-7.41 (6.415)	-42.59 (23.260)	-3.70 (28.689)	-30.04 (29.042)
Median	-11.11	-44.44	-11.11	-33.33
Min, Max	-11.1, 0.0	-77.8, 11.1	-33.3, 44.4	-77.8, 44.4
Change from Baseline to Cycle 10 Day 1				
n	3	8	3	14
Mean (StdDev)	14.81 (6.415)	-37.50 (22.954)	-22.22 (29.397)	-23.02 (29.707)
Median	11.11	-38.89	-11.11	-22.22
Min, Max	11.1, 22.2	-66.7, 0.0	-55.6, 0.0	-66.7, 22.2
Change from Baseline to Cycle 11 Day 1				
n	3	15	4	22
Mean (StdDev)	3.70 (6.415)	-40.74 (28.380)	-33.33 (39.545)	-33.33 (31.613)
Median	0.00	-44.44	-27.78	-38.89
Min, Max	0.0, 11.1	-77.8, 33.3	-77.8, 0.0	-77.8, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Fatigue	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 12 Day 1				
n	2	5	3	10
Mean (StdDev)	0.00 (0.000)	-53.33 (18.257)	-25.93 (35.717)	-34.44 (30.293)
Median	0.00	-44.44	-11.11	-38.89
Min, Max	0.0, 0.0	-77.8, -33.3	-66.7, 0.0	-77.8, 0.0
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-40.74 (57.018)	-66.67 (-)	-47.22 (48.326)
Median		-55.56	-66.67	-61.11
Min, Max		-88.9, 22.2	-66.7, -66.7	-88.9, 22.2
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		33.33 (-)		33.33 (-)
Median		33.33		33.33
Min, Max		33.3, 33.3		33.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Nausea and Vomiting	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Baseline				
n	7	39	14	60
Mean (StdDev)	38.10 (34.311)	21.37 (28.084)	16.67 (23.570)	22.22 (28.068)
Median	33.33	16.67	0.00	16.67
Min, Max	0.0, 83.3	0.0, 100.0	0.0, 66.7	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	5.56 (9.623)	-13.33 (20.662)	-7.14 (23.288)	-10.00 (20.807)
Median	0.00	-16.67	0.00	0.00
Min, Max	0.0, 16.7	-66.7, 33.3	-50.0, 16.7	-66.7, 33.3
Change from Baseline to Cycle 2 Day 1				
n	5	35	13	53
Mean (StdDev)	-3.33 (29.814)	-8.10 (27.822)	-3.85 (18.199)	-6.60 (25.600)
Median	0.00	0.00	0.00	0.00
Min, Max	-50.0, 33.3	-100.0, 33.3	-50.0, 16.7	-100.0, 33.3
Change from Baseline to Cycle 3 Day 1				
n	6	35	11	52
Mean (StdDev)	-5.56 (31.032)	-8.57 (29.531)	-6.06 (18.668)	-7.69 (27.309)
Median	0.00	0.00	0.00	0.00
Min, Max	-50.0, 33.3	-100.0, 50.0	-50.0, 16.7	-100.0, 50.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Nausea and Vomiting	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 4 Day 1				
n	2	12	6	20
Mean (StdDev)	-41.67 (58.926)	4.17 (20.257)	-8.33 (17.480)	-4.17 (26.422)
Median	-41.67	0.00	-8.33	0.00
Min, Max	-83.3, 0.0	-33.3, 33.3	-33.3, 16.7	-83.3, 33.3
Change from Baseline to Cycle 5 Day 1				
n	4	24	11	39
Mean (StdDev)	-8.33 (28.868)	-13.89 (24.409)	-6.06 (20.101)	-11.11 (23.363)
Median	0.00	-16.67	0.00	0.00
Min, Max	-50.0, 16.7	-66.7, 33.3	-50.0, 16.7	-66.7, 33.3
Change from Baseline to Cycle 6 Day 1				
n	3	10	5	18
Mean (StdDev)	-27.78 (48.113)	-8.33 (19.642)	-3.33 (13.944)	-10.19 (24.347)
Median	0.00	-8.33	0.00	0.00
Min, Max	-83.3, 0.0	-50.0, 16.7	-16.7, 16.7	-83.3, 16.7
Change from Baseline to Cycle 7 Day 1				
n	4	22	7	33
Mean (StdDev)	-20.83 (34.359)	-18.18 (24.618)	-4.76 (23.002)	-15.66 (25.324)
Median	-25.00	-16.67	0.00	0.00
Min, Max	-50.0, 16.7	-83.3, 16.7	-50.0, 16.7	-83.3, 16.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Nausea and Vomiting	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 8 Day 1				
n	2	9	4	15
Mean (StdDev)	-25.00 (35.355)	-16.67 (18.634)	-16.67 (23.570)	-17.78 (20.380)
Median	-25.00	-16.67	-8.33	-16.67
Min, Max	-50.0, 0.0	-50.0, 0.0	-50.0, 0.0	-50.0, 0.0
Change from Baseline to Cycle 9 Day 1				
n	3	18	6	27
Mean (StdDev)	-11.11 (34.694)	-15.74 (20.983)	-8.33 (22.973)	-13.58 (22.187)
Median	0.00	-16.67	0.00	0.00
Min, Max	-50.0, 16.7	-66.7, 16.7	-50.0, 16.7	-66.7, 16.7
Change from Baseline to Cycle 10 Day 1				
n	3	8	3	14
Mean (StdDev)	-11.11 (41.944)	-10.42 (12.400)	-22.22 (25.459)	-13.10 (21.857)
Median	-16.67	-8.33	-16.67	-16.67
Min, Max	-50.0, 33.3	-33.3, 0.0	-50.0, 0.0	-50.0, 33.3
Change from Baseline to Cycle 11 Day 1				
n	3	15	4	22
Mean (StdDev)	-22.22 (25.459)	-15.56 (20.380)	-20.83 (20.972)	-17.42 (20.235)
Median	-16.67	-16.67	-16.67	-16.67
Min, Max	-50.0, 0.0	-50.0, 16.7	-50.0, 0.0	-50.0, 16.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Nausea and Vomiting	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 12 Day 1				
n	2	5	3	10
Mean (StdDev)	-8.33 (35.355)	-6.67 (9.129)	-16.67 (16.667)	-10.00 (16.102)
Median	-8.33	0.00	-16.67	-8.33
Min, Max	-33.3, 16.7	-16.7, 0.0	-33.3, 0.0	-33.3, 16.7
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		5.56 (25.459)	0.00 (-)	4.17 (20.972)
Median		0.00	0.00	0.00
Min, Max		-16.7, 33.3	0.0, 0.0	-16.7, 33.3
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Pain	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Baseline				
n	7	39	14	60
Mean (StdDev)	50.00 (28.868)	41.45 (35.432)	52.38 (35.720)	45.00 (34.622)
Median	50.00	33.33	50.00	33.33
Min, Max	16.7, 83.3	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	0.00 (0.000)	-20.83 (32.388)	-19.05 (26.227)	-18.33 (29.475)
Median	0.00	0.00	-16.67	0.00
Min, Max	0.0, 0.0	-83.3, 33.3	-50.0, 16.7	-83.3, 33.3
Change from Baseline to Cycle 2 Day 1				
n	5	35	13	53
Mean (StdDev)	-6.67 (9.129)	-19.05 (28.624)	-24.36 (35.103)	-19.18 (29.125)
Median	0.00	0.00	-33.33	0.00
Min, Max	-16.7, 0.0	-100.0, 16.7	-83.3, 50.0	-100.0, 50.0
Change from Baseline to Cycle 3 Day 1				
n	6	35	11	52
Mean (StdDev)	-5.56 (17.213)	-18.10 (32.683)	-22.73 (34.378)	-17.63 (31.556)
Median	0.00	0.00	-33.33	-8.33
Min, Max	-33.3, 16.7	-100.0, 33.3	-66.7, 50.0	-100.0, 50.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Pain	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 4 Day 1				
n	2	12	6	20
Mean (StdDev)	0.00 (0.000)	-23.61 (27.023)	-5.56 (62.063)	-15.83 (39.171)
Median	0.00	-16.67	-16.67	-16.67
Min, Max	0.0, 0.0	-83.3, 0.0	-83.3, 83.3	-83.3, 83.3
Change from Baseline to Cycle 5 Day 1				
n	4	24	11	39
Mean (StdDev)	4.17 (15.957)	-16.67 (31.470)	-24.24 (51.296)	-16.67 (37.071)
Median	8.33	-16.67	-16.67	-16.67
Min, Max	-16.7, 16.7	-83.3, 66.7	-100.0, 66.7	-100.0, 66.7
Change from Baseline to Cycle 6 Day 1				
n	3	10	5	18
Mean (StdDev)	-11.11 (19.245)	-26.67 (17.916)	-6.67 (48.016)	-18.52 (29.087)
Median	0.00	-33.33	0.00	-16.67
Min, Max	-33.3, 0.0	-50.0, 0.0	-83.3, 50.0	-83.3, 50.0
Change from Baseline to Cycle 7 Day 1				
n	4	22	7	33
Mean (StdDev)	-8.33 (21.517)	-15.91 (35.440)	-11.90 (35.635)	-14.14 (33.365)
Median	-8.33	-16.67	-16.67	-16.67
Min, Max	-33.3, 16.7	-83.3, 83.3	-66.7, 50.0	-83.3, 83.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Pain	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 8 Day 1				
n	2	9	4	15
Mean (StdDev)	8.33 (11.785)	-31.48 (21.155)	16.67 (65.263)	-13.33 (41.404)
Median	8.33	-33.33	8.33	-16.67
Min, Max	0.0, 16.7	-66.7, 0.0	-50.0, 100.0	-66.7, 100.0
Change from Baseline to Cycle 9 Day 1				
n	3	18	6	27
Mean (StdDev)	-16.67 (16.667)	-21.30 (29.040)	5.56 (45.542)	-14.81 (33.119)
Median	-16.67	-25.00	8.33	-16.67
Min, Max	-33.3, 0.0	-66.7, 33.3	-66.7, 66.7	-66.7, 66.7
Change from Baseline to Cycle 10 Day 1				
n	3	8	3	14
Mean (StdDev)	-27.78 (19.245)	-27.08 (33.259)	-11.11 (41.944)	-23.81 (31.156)
Median	-16.67	-16.67	-16.67	-16.67
Min, Max	-50.0, -16.7	-66.7, 33.3	-50.0, 33.3	-66.7, 33.3
Change from Baseline to Cycle 11 Day 1				
n	3	15	4	22
Mean (StdDev)	-5.56 (9.623)	-28.89 (29.859)	-33.33 (52.705)	-26.52 (32.797)
Median	0.00	-16.67	-41.67	-16.67
Min, Max	-16.7, 0.0	-83.3, 0.0	-83.3, 33.3	-83.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Pain	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 12 Day 1				
n	2	5	3	10
Mean (StdDev)	-25.00 (11.785)	-46.67 (13.944)	-22.22 (50.918)	-35.00 (28.814)
Median	-25.00	-50.00	-33.33	-33.33
Min, Max	-33.3, -16.7	-66.7, -33.3	-66.7, 33.3	-66.7, 33.3
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-11.11 (19.245)	-83.33 (-)	-29.17 (39.382)
Median		0.00	-83.33	-16.67
Min, Max		-33.3, 0.0	-83.3, -83.3	-83.3, 0.0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Dyspnea	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Baseline				
n	7	39	14	60
Mean (StdDev)	28.57 (23.002)	52.99 (33.957)	50.00 (33.968)	49.44 (33.329)
Median	33.33	33.33	33.33	33.33
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	-11.11 (19.245)	-23.33 (36.031)	-23.81 (25.198)	-22.22 (31.964)
Median	0.00	-16.67	-33.33	-16.67
Min, Max	-33.3, 0.0	-100.0, 33.3	-66.7, 0.0	-100.0, 33.3
Change from Baseline to Cycle 2 Day 1				
n	5	35	13	53
Mean (StdDev)	6.67 (36.515)	-23.81 (31.902)	-15.38 (22.008)	-18.87 (31.015)
Median	0.00	-33.33	0.00	0.00
Min, Max	-33.3, 66.7	-100.0, 33.3	-66.7, 0.0	-100.0, 66.7
Change from Baseline to Cycle 3 Day 1				
n	6	35	11	52
Mean (StdDev)	16.67 (34.960)	-23.81 (37.549)	-21.21 (22.473)	-18.59 (36.403)
Median	16.67	-33.33	-33.33	-16.67
Min, Max	-33.3, 66.7	-100.0, 33.3	-66.7, 0.0	-100.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Dyspnea	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 4 Day 1				
n	2	12	6	20
Mean (StdDev)	0.00 (47.140)	-19.44 (26.432)	-11.11 (34.427)	-15.00 (29.568)
Median	0.00	0.00	0.00	0.00
Min, Max	-33.3, 33.3	-66.7, 0.0	-66.7, 33.3	-66.7, 33.3
Change from Baseline to Cycle 5 Day 1				
n	4	24	11	39
Mean (StdDev)	-8.33 (31.914)	-25.00 (39.624)	-18.18 (27.340)	-21.37 (35.448)
Median	-16.67	-16.67	-33.33	-33.33
Min, Max	-33.3, 33.3	-100.0, 33.3	-66.7, 33.3	-100.0, 33.3
Change from Baseline to Cycle 6 Day 1				
n	3	10	5	18
Mean (StdDev)	-11.11 (19.245)	-23.33 (31.623)	0.00 (40.825)	-14.81 (32.784)
Median	0.00	-33.33	0.00	0.00
Min, Max	-33.3, 0.0	-66.7, 33.3	-66.7, 33.3	-66.7, 33.3
Change from Baseline to Cycle 7 Day 1				
n	4	22	7	33
Mean (StdDev)	0.00 (27.217)	-33.33 (35.635)	-19.05 (32.530)	-26.26 (35.116)
Median	0.00	-33.33	-33.33	-33.33
Min, Max	-33.3, 33.3	-100.0, 33.3	-66.7, 33.3	-100.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Dyspnea	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 8 Day 1				
n	2	9	4	15
Mean (StdDev)	-16.67 (23.570)	-37.04 (42.310)	-16.67 (43.033)	-28.89 (39.574)
Median	-16.67	-33.33	-16.67	-33.33
Min, Max	-33.3, 0.0	-100.0, 0.0	-66.7, 33.3	-100.0, 33.3
Change from Baseline to Cycle 9 Day 1				
n	3	18	6	27
Mean (StdDev)	11.11 (19.245)	-44.44 (34.300)	-11.11 (40.369)	-30.86 (39.142)
Median	0.00	-33.33	-16.67	-33.33
Min, Max	0.0, 33.3	-100.0, 0.0	-66.7, 33.3	-100.0, 33.3
Change from Baseline to Cycle 10 Day 1				
n	3	8	3	14
Mean (StdDev)	11.11 (19.245)	-20.83 (35.355)	-22.22 (38.490)	-14.29 (33.878)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 33.3	-100.0, 0.0	-66.7, 0.0	-100.0, 33.3
Change from Baseline to Cycle 11 Day 1				
n	3	15	4	22
Mean (StdDev)	0.00 (0.000)	-35.56 (36.659)	-33.33 (27.217)	-30.30 (33.976)
Median	0.00	-33.33	-33.33	-33.33
Min, Max	0.0, 0.0	-100.0, 0.0	-66.7, 0.0	-100.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Dyspnea	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 12 Day 1				
n	2	4	3	9
Mean (StdDev)	0.00 (0.000)	-33.33 (27.217)	-33.33 (33.333)	-25.93 (27.778)
Median	0.00	-33.33	-33.33	-33.33
Min, Max	0.0, 0.0	-66.7, 0.0	-66.7, 0.0	-66.7, 0.0
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-33.33 (57.735)	-33.33 (-)	-33.33 (47.140)
Median		0.00	-33.33	-16.67
Min, Max		-100.0, 0.0	-33.3, -33.3	-100.0, 0.0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Insomnia	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Baseline				
n	7	39	14	60
Mean (StdDev)	57.14 (37.090)	51.28 (35.743)	73.81 (35.030)	57.22 (36.355)
Median	66.67	66.67	100.00	66.67
Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	-11.11 (19.245)	-13.33 (36.515)	-42.86 (25.198)	-20.00 (34.575)
Median	0.00	0.00	-33.33	-33.33
Min, Max	-33.3, 0.0	-66.7, 33.3	-66.7, 0.0	-66.7, 33.3
Change from Baseline to Cycle 2 Day 1				
n	5	35	13	53
Mean (StdDev)	13.33 (18.257)	-13.33 (40.584)	-46.15 (50.071)	-18.87 (44.582)
Median	0.00	0.00	-66.67	0.00
Min, Max	0.0, 33.3	-100.0, 66.7	-100.0, 66.7	-100.0, 66.7
Change from Baseline to Cycle 3 Day 1				
n	6	35	11	52
Mean (StdDev)	0.00 (21.082)	-13.33 (40.584)	-42.42 (44.947)	-17.95 (41.466)
Median	0.00	0.00	-66.67	0.00
Min, Max	-33.3, 33.3	-100.0, 66.7	-100.0, 66.7	-100.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Insomnia	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 4 Day 1				
n	2	12	6	20
Mean (StdDev)	16.67 (23.570)	-5.56 (27.828)	0.00 (47.140)	-1.67 (33.289)
Median	16.67	0.00	0.00	0.00
Min, Max	0.0, 33.3	-66.7, 33.3	-66.7, 66.7	-66.7, 66.7
Change from Baseline to Cycle 5 Day 1				
n	4	24	11	39
Mean (StdDev)	-8.33 (31.914)	-20.83 (36.531)	-33.33 (29.814)	-23.08 (34.331)
Median	-16.67	-33.33	-33.33	-33.33
Min, Max	-33.3, 33.3	-66.7, 66.7	-66.7, 0.0	-66.7, 66.7
Change from Baseline to Cycle 6 Day 1				
n	3	10	5	18
Mean (StdDev)	0.00 (33.333)	-16.67 (36.004)	-13.33 (38.006)	-12.96 (34.563)
Median	0.00	-33.33	0.00	-16.67
Min, Max	-33.3, 33.3	-66.7, 66.7	-66.7, 33.3	-66.7, 66.7
Change from Baseline to Cycle 7 Day 1				
n	4	22	7	33
Mean (StdDev)	8.33 (16.667)	-18.18 (42.072)	-14.29 (42.414)	-14.14 (39.992)
Median	0.00	-16.67	0.00	0.00
Min, Max	0.0, 33.3	-100.0, 66.7	-66.7, 33.3	-100.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Insomnia	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 8 Day 1				
n	2	9	4	15
Mean (StdDev)	16.67 (23.570)	-25.93 (27.778)	-8.33 (16.667)	-15.56 (27.794)
Median	16.67	-33.33	0.00	0.00
Min, Max	0.0, 33.3	-66.7, 0.0	-33.3, 0.0	-66.7, 33.3
Change from Baseline to Cycle 9 Day 1				
n	3	18	6	27
Mean (StdDev)	22.22 (38.490)	-29.63 (35.954)	-22.22 (34.427)	-22.22 (38.118)
Median	0.00	-33.33	0.00	0.00
Min, Max	0.0, 66.7	-100.0, 33.3	-66.7, 0.0	-100.0, 66.7
Change from Baseline to Cycle 10 Day 1				
n	3	8	3	14
Mean (StdDev)	11.11 (38.490)	-8.33 (23.570)	-11.11 (19.245)	-4.76 (25.678)
Median	33.33	0.00	0.00	0.00
Min, Max	-33.3, 33.3	-33.3, 33.3	-33.3, 0.0	-33.3, 33.3
Change from Baseline to Cycle 11 Day 1				
n	3	15	4	22
Mean (StdDev)	33.33 (0.000)	-26.67 (33.806)	-16.67 (57.735)	-16.67 (40.825)
Median	33.33	-33.33	0.00	0.00
Min, Max	33.3, 33.3	-66.7, 33.3	-100.0, 33.3	-100.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Insomnia	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 12 Day 1				
n	2	5	3	10
Mean (StdDev)	33.33 (0.000)	-33.33 (33.333)	0.00 (33.333)	-10.00 (38.650)
Median	33.33	-33.33	0.00	0.00
Min, Max	33.3, 33.3	-66.7, 0.0	-33.3, 33.3	-66.7, 33.3
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-22.22 (38.490)	-100.00 (-)	-41.67 (50.000)
Median		0.00	-100.00	-33.33
Min, Max		-66.7, 0.0	-100.0, -100.0	-100.0, 0.0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		33.33 (-)		33.33 (-)
Median		33.33		33.33
Min, Max		33.3, 33.3		33.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Appetite Loss	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Baseline				
n	7	39	14	60
Mean (StdDev)	23.81 (31.706)	49.57 (33.221)	50.00 (33.968)	46.67 (33.726)
Median	0.00	33.33	33.33	33.33
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	-11.11 (19.245)	-28.33 (32.936)	-23.81 (25.198)	-25.56 (29.921)
Median	0.00	-33.33	-33.33	-33.33
Min, Max	-33.3, 0.0	-100.0, 33.3	-66.7, 0.0	-100.0, 33.3
Change from Baseline to Cycle 2 Day 1				
n	5	35	13	53
Mean (StdDev)	0.00 (40.825)	-23.81 (40.075)	-23.08 (36.980)	-21.38 (39.275)
Median	0.00	-33.33	0.00	-33.33
Min, Max	-33.3, 66.7	-100.0, 66.7	-100.0, 33.3	-100.0, 66.7
Change from Baseline to Cycle 3 Day 1				
n	6	35	11	52
Mean (StdDev)	0.00 (21.082)	-31.43 (35.187)	-30.30 (48.200)	-27.56 (37.759)
Median	0.00	-33.33	-33.33	-33.33
Min, Max	-33.3, 33.3	-100.0, 33.3	-100.0, 33.3	-100.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Appetite Loss	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 4 Day 1				
n	2	12	6	20
Mean (StdDev)	-16.67 (23.570)	-22.22 (32.824)	-22.22 (34.427)	-21.67 (31.110)
Median	-16.67	-16.67	-33.33	-33.33
Min, Max	-33.3, 0.0	-66.7, 33.3	-66.7, 33.3	-66.7, 33.3
Change from Baseline to Cycle 5 Day 1				
n	4	24	11	39
Mean (StdDev)	8.33 (41.944)	-33.33 (42.846)	-18.18 (34.524)	-24.79 (41.688)
Median	0.00	-33.33	-33.33	-33.33
Min, Max	-33.3, 66.7	-100.0, 66.7	-66.7, 33.3	-100.0, 66.7
Change from Baseline to Cycle 6 Day 1				
n	3	10	5	18
Mean (StdDev)	0.00 (57.735)	-33.33 (44.444)	-26.67 (36.515)	-25.93 (43.620)
Median	-33.33	-33.33	0.00	-33.33
Min, Max	-33.3, 66.7	-100.0, 33.3	-66.7, 0.0	-100.0, 66.7
Change from Baseline to Cycle 7 Day 1				
n	4	22	7	33
Mean (StdDev)	0.00 (47.140)	-42.42 (45.054)	-38.10 (29.991)	-36.36 (43.592)
Median	-16.67	-33.33	-33.33	-33.33
Min, Max	-33.3, 66.7	-100.0, 66.7	-66.7, 0.0	-100.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Appetite Loss	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 8 Day 1				
n	2	9	4	15
Mean (StdDev)	0.00 (47.140)	-44.44 (40.825)	-33.33 (27.217)	-35.56 (38.764)
Median	0.00	-33.33	-33.33	-33.33
Min, Max	-33.3, 33.3	-100.0, 0.0	-66.7, 0.0	-100.0, 33.3
Change from Baseline to Cycle 9 Day 1				
n	3	18	6	27
Mean (StdDev)	0.00 (33.333)	-40.74 (37.146)	-22.22 (27.217)	-32.10 (36.376)
Median	0.00	-33.33	-16.67	-33.33
Min, Max	-33.3, 33.3	-100.0, 33.3	-66.7, 0.0	-100.0, 33.3
Change from Baseline to Cycle 10 Day 1				
n	3	8	3	14
Mean (StdDev)	-11.11 (50.918)	-33.33 (35.635)	0.00 (33.333)	-21.43 (38.358)
Median	0.00	-33.33	0.00	-16.67
Min, Max	-66.7, 33.3	-100.0, 0.0	-33.3, 33.3	-100.0, 33.3
Change from Baseline to Cycle 11 Day 1				
n	3	15	4	22
Mean (StdDev)	-11.11 (38.490)	-33.33 (37.796)	-16.67 (43.033)	-27.27 (37.987)
Median	-33.33	-33.33	-16.67	-33.33
Min, Max	-33.3, 33.3	-100.0, 33.3	-66.7, 33.3	-100.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Appetite Loss	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 12 Day 1				
n	2	5	3	10
Mean (StdDev)	50.00 (23.570)	-40.00 (27.889)	-11.11 (50.918)	-13.33 (47.661)
Median	50.00	-33.33	0.00	-16.67
Min, Max	33.3, 66.7	-66.7, 0.0	-66.7, 33.3	-66.7, 66.7
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-44.44 (50.918)	-66.67 (-)	-50.00 (43.033)
Median		-33.33	-66.67	-50.00
Min, Max		-100.0, 0.0	-66.7, -66.7	-100.0, 0.0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		33.33 (-)		33.33 (-)
Median		33.33		33.33
Min, Max		33.3, 33.3		33.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Constipation	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Baseline				
n	7	39	14	60
Mean (StdDev)	23.81 (25.198)	25.64 (31.955)	19.05 (31.254)	23.89 (30.742)
Median	33.33	0.00	0.00	0.00
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	0.00 (0.000)	-5.00 (24.839)	-9.52 (31.706)	-5.56 (24.888)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 0.0	-66.7, 66.7	-66.7, 33.3	-66.7, 66.7
Change from Baseline to Cycle 2 Day 1				
n	5	35	13	53
Mean (StdDev)	26.67 (36.515)	-9.52 (28.665)	-10.26 (31.578)	-6.29 (31.390)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 66.7	-100.0, 33.3	-66.7, 33.3	-100.0, 66.7
Change from Baseline to Cycle 3 Day 1				
n	6	35	11	52
Mean (StdDev)	5.56 (32.773)	-7.62 (25.675)	-9.09 (42.403)	-6.41 (30.277)
Median	0.00	0.00	0.00	0.00
Min, Max	-33.3, 66.7	-100.0, 33.3	-100.0, 33.3	-100.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Constipation	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 4 Day 1				
n	2	12	6	20
Mean (StdDev)	0.00 (0.000)	-13.89 (22.285)	-11.11 (27.217)	-11.67 (22.361)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 0.0	-66.7, 0.0	-66.7, 0.0	-66.7, 0.0
Change from Baseline to Cycle 5 Day 1				
n	4	24	11	39
Mean (StdDev)	16.67 (33.333)	-6.94 (21.934)	-15.15 (37.605)	-6.84 (28.796)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 66.7	-33.3, 66.7	-100.0, 33.3	-100.0, 66.7
Change from Baseline to Cycle 6 Day 1				
n	3	10	5	18
Mean (StdDev)	11.11 (19.245)	-23.33 (27.442)	-6.67 (14.907)	-12.96 (25.918)
Median	0.00	-16.67	0.00	0.00
Min, Max	0.0, 33.3	-66.7, 0.0	-33.3, 0.0	-66.7, 33.3
Change from Baseline to Cycle 7 Day 1				
n	4	22	7	33
Mean (StdDev)	16.67 (43.033)	-12.12 (31.782)	-14.29 (57.275)	-9.09 (39.328)
Median	16.67	0.00	0.00	0.00
Min, Max	-33.3, 66.7	-66.7, 66.7	-100.0, 66.7	-100.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Constipation	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 8 Day 1				
n	2	9	4	15
Mean (StdDev)	0.00 (0.000)	-25.93 (22.222)	0.00 (0.000)	-15.56 (21.331)
Median	0.00	-33.33	0.00	0.00
Min, Max	0.0, 0.0	-66.7, 0.0	0.0, 0.0	-66.7, 0.0
Change from Baseline to Cycle 9 Day 1				
n	3	18	6	27
Mean (StdDev)	11.11 (19.245)	-24.07 (31.943)	-22.22 (40.369)	-19.75 (33.664)
Median	0.00	-33.33	0.00	0.00
Min, Max	0.0, 33.3	-100.0, 33.3	-100.0, 0.0	-100.0, 33.3
Change from Baseline to Cycle 10 Day 1				
n	3	8	3	14
Mean (StdDev)	22.22 (38.490)	-12.50 (24.801)	-11.11 (19.245)	-4.76 (28.815)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 66.7	-66.7, 0.0	-33.3, 0.0	-66.7, 66.7
Change from Baseline to Cycle 11 Day 1				
n	3	15	4	22
Mean (StdDev)	0.00 (0.000)	-22.22 (20.574)	-25.00 (50.000)	-19.70 (26.546)
Median	0.00	-33.33	0.00	0.00
Min, Max	0.0, 0.0	-66.7, 0.0	-100.0, 0.0	-100.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Constipation	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 12 Day 1				
n	2	5	3	10
Mean (StdDev)	33.33 (0.000)	-13.33 (18.257)	-11.11 (19.245)	-3.33 (24.595)
Median	33.33	0.00	0.00	0.00
Min, Max	33.3, 33.3	-33.3, 0.0	-33.3, 0.0	-33.3, 33.3
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-22.22 (19.245)	-100.00 (-)	-41.67 (41.944)
Median		-33.33	-100.00	-33.33
Min, Max		-33.3, 0.0	-100.0, -100.0	-100.0, 0.0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Diarrhea	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Baseline				
n	7	39	14	60
Mean (StdDev)	42.86 (46.004)	38.46 (36.305)	45.24 (40.525)	40.56 (37.878)
Median	33.33	33.33	50.00	33.33
Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	11.11 (19.245)	-30.00 (32.264)	-14.29 (53.945)	-22.22 (38.490)
Median	0.00	-33.33	0.00	0.00
Min, Max	0.0, 33.3	-100.0, 0.0	-100.0, 33.3	-100.0, 33.3
Change from Baseline to Cycle 2 Day 1				
n	5	35	13	53
Mean (StdDev)	-6.67 (14.907)	-16.19 (41.517)	-10.26 (36.980)	-13.84 (38.361)
Median	0.00	0.00	0.00	0.00
Min, Max	-33.3, 0.0	-100.0, 66.7	-66.7, 33.3	-100.0, 66.7
Change from Baseline to Cycle 3 Day 1				
n	6	35	11	52
Mean (StdDev)	0.00 (21.082)	-17.14 (42.296)	-9.09 (42.403)	-13.46 (40.293)
Median	0.00	0.00	0.00	0.00
Min, Max	-33.3, 33.3	-100.0, 66.7	-100.0, 66.7	-100.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Diarrhea	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 4 Day 1				
n	2	12	6	20
Mean (StdDev)	-33.33 (47.140)	2.78 (41.337)	-27.78 (49.065)	-10.00 (44.721)
Median	-33.33	0.00	-16.67	0.00
Min, Max	-66.7, 0.0	-66.7, 66.7	-100.0, 33.3	-100.0, 66.7
Change from Baseline to Cycle 5 Day 1				
n	4	24	11	39
Mean (StdDev)	-8.33 (16.667)	-12.50 (40.304)	-12.12 (45.394)	-11.97 (39.357)
Median	0.00	-16.67	0.00	0.00
Min, Max	-33.3, 0.0	-100.0, 66.7	-100.0, 66.7	-100.0, 66.7
Change from Baseline to Cycle 6 Day 1				
n	3	10	5	18
Mean (StdDev)	-11.11 (19.245)	-13.33 (54.885)	-26.67 (49.441)	-16.67 (47.486)
Median	0.00	-16.67	-33.33	-16.67
Min, Max	-33.3, 0.0	-100.0, 100.0	-100.0, 33.3	-100.0, 100.0
Change from Baseline to Cycle 7 Day 1				
n	4	22	7	33
Mean (StdDev)	0.00 (27.217)	-25.76 (36.993)	-14.29 (42.414)	-20.20 (37.211)
Median	0.00	-33.33	0.00	-33.33
Min, Max	-33.3, 33.3	-100.0, 66.7	-100.0, 33.3	-100.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Diarrhea	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 8 Day 1				
n	2	9	4	15
Mean (StdDev)	-16.67 (23.570)	-14.81 (29.397)	-41.67 (41.944)	-22.22 (32.530)
Median	-16.67	0.00	-33.33	-33.33
Min, Max	-33.3, 0.0	-66.7, 33.3	-100.0, 0.0	-100.0, 33.3
Change from Baseline to Cycle 9 Day 1				
n	3	18	6	27
Mean (StdDev)	-22.22 (19.245)	-25.93 (37.146)	-5.56 (13.608)	-20.99 (32.223)
Median	-33.33	-33.33	0.00	-33.33
Min, Max	-33.3, 0.0	-100.0, 66.7	-33.3, 0.0	-100.0, 66.7
Change from Baseline to Cycle 10 Day 1				
n	3	8	3	14
Mean (StdDev)	-55.56 (19.245)	-4.17 (27.817)	0.00 (0.000)	-14.29 (31.254)
Median	-66.67	0.00	0.00	0.00
Min, Max	-66.7, -33.3	-66.7, 33.3	0.0, 0.0	-66.7, 33.3
Change from Baseline to Cycle 11 Day 1				
n	3	15	4	22
Mean (StdDev)	-33.33 (33.333)	-17.78 (35.337)	-16.67 (19.245)	-19.70 (31.971)
Median	-33.33	0.00	-16.67	-16.67
Min, Max	-66.7, 0.0	-66.7, 66.7	-33.3, 0.0	-66.7, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Diarrhea	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 12 Day 1				
n	2	5	3	10
Mean (StdDev)	-16.67 (23.570)	-13.33 (18.257)	-22.22 (19.245)	-16.67 (17.568)
Median	-16.67	0.00	-33.33	-16.67
Min, Max	-33.3, 0.0	-33.3, 0.0	-33.3, 0.0	-33.3, 0.0
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-11.11 (19.245)	0.00 (-)	-8.33 (16.667)
Median		0.00	0.00	0.00
Min, Max		-33.3, 0.0	0.0, 0.0	-33.3, 0.0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Financial Difficulties	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Baseline				
n	7	39	14	60
Mean (StdDev)	52.38 (42.414)	29.06 (33.490)	40.48 (39.610)	34.44 (36.291)
Median	66.67	33.33	33.33	33.33
Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	0.00 (33.333)	1.67 (25.305)	-19.05 (42.414)	-3.33 (30.763)
Median	0.00	0.00	0.00	0.00
Min, Max	-33.3, 33.3	-66.7, 33.3	-100.0, 33.3	-100.0, 33.3
Change from Baseline to Cycle 2 Day 1				
n	5	35	13	53
Mean (StdDev)	6.67 (14.907)	-2.86 (21.950)	-7.69 (27.735)	-3.14 (22.893)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 33.3	-66.7, 33.3	-66.7, 33.3	-66.7, 33.3
Change from Baseline to Cycle 3 Day 1				
n	6	35	11	52
Mean (StdDev)	11.11 (34.427)	-1.90 (22.785)	-6.06 (25.025)	-1.28 (24.665)
Median	0.00	0.00	0.00	0.00
Min, Max	-33.3, 66.7	-66.7, 33.3	-33.3, 33.3	-66.7, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Financial Difficulties	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 4 Day 1				
n	2	12	6	20
Mean (StdDev)	16.67 (23.570)	-5.56 (12.975)	-11.11 (17.213)	-5.00 (16.312)
Median	16.67	0.00	0.00	0.00
Min, Max	0.0, 33.3	-33.3, 0.0	-33.3, 0.0	-33.3, 33.3
Change from Baseline to Cycle 5 Day 1				
n	4	24	11	39
Mean (StdDev)	-8.33 (41.944)	-5.56 (23.399)	-3.03 (34.816)	-5.13 (28.138)
Median	0.00	0.00	0.00	0.00
Min, Max	-66.7, 33.3	-66.7, 33.3	-66.7, 66.7	-66.7, 66.7
Change from Baseline to Cycle 6 Day 1				
n	3	10	5	18
Mean (StdDev)	-22.22 (50.918)	-10.00 (22.498)	-13.33 (29.814)	-12.96 (28.328)
Median	-33.33	0.00	-33.33	-16.67
Min, Max	-66.7, 33.3	-33.3, 33.3	-33.3, 33.3	-66.7, 33.3
Change from Baseline to Cycle 7 Day 1				
n	4	22	7	33
Mean (StdDev)	-8.33 (41.944)	-3.03 (25.006)	-14.29 (32.530)	-6.06 (28.204)
Median	0.00	0.00	0.00	0.00
Min, Max	-66.7, 33.3	-66.7, 33.3	-66.7, 33.3	-66.7, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Financial Difficulties	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 8 Day 1				
n	2	9	4	15
Mean (StdDev)	0.00 (47.140)	-7.41 (14.699)	-8.33 (56.928)	-6.67 (31.371)
Median	0.00	0.00	-16.67	0.00
Min, Max	-33.3, 33.3	-33.3, 0.0	-66.7, 66.7	-66.7, 66.7
Change from Baseline to Cycle 9 Day 1				
n	3	18	6	27
Mean (StdDev)	-11.11 (38.490)	7.41 (29.273)	-5.56 (44.305)	2.47 (33.238)
Median	-33.33	0.00	0.00	0.00
Min, Max	-33.3, 33.3	-66.7, 66.7	-66.7, 66.7	-66.7, 66.7
Change from Baseline to Cycle 10 Day 1				
n	3	8	3	14
Mean (StdDev)	-11.11 (38.490)	-4.17 (11.785)	0.00 (66.667)	-4.76 (31.642)
Median	-33.33	0.00	0.00	0.00
Min, Max	-33.3, 33.3	-33.3, 0.0	-66.7, 66.7	-66.7, 66.7
Change from Baseline to Cycle 11 Day 1				
n	3	15	4	22
Mean (StdDev)	-11.11 (38.490)	8.89 (23.458)	0.00 (54.433)	4.55 (31.363)
Median	-33.33	0.00	0.00	0.00
Min, Max	-33.3, 33.3	-33.3, 66.7	-66.7, 66.7	-66.7, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

Financial Difficulties	ASM (N=9)	SM-AHN (N=45)	MCL (N=15)	All AdvSM (N=69)
Change from Baseline to Cycle 12 Day 1				
n	2	5	3	10
Mean (StdDev)	-50.00 (23.570)	0.00 (23.570)	-11.11 (50.918)	-13.33 (35.832)
Median	-50.00	0.00	0.00	0.00
Min, Max	-66.7, -33.3	-33.3, 33.3	-66.7, 33.3	-66.7, 33.3
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-11.11 (19.245)	0.00 (-)	-8.33 (16.667)
Median		0.00	0.00	0.00
Min, Max		-33.3, 0.0	0.0, 0.0	-33.3, 0.0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		-33.33 (-)		-33.33 (-)
Median		-33.33		-33.33
Min, Max		-33.3, -33.3		-33.3, -33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Global Health Status/QoL	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Baseline				
n	4	29	12	45
Mean (StdDev)	50.00 (20.412)	35.34 (27.697)	36.81 (14.847)	37.04 (24.267)
Median	45.83	33.33	33.33	33.33
Min, Max	33.3, 75.0	0.0, 100.0	16.7, 58.3	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	2.78 (9.623)	19.58 (26.390)	11.90 (24.934)	16.11 (24.946)
Median	8.33	16.67	0.00	8.33
Min, Max	-8.3, 8.3	-25.0, 83.3	-8.3, 50.0	-25.0, 83.3
Change from Baseline to Cycle 2 Day 1				
n	2	27	11	40
Mean (StdDev)	0.00 (11.785)	22.22 (30.922)	16.67 (26.352)	19.58 (29.086)
Median	0.00	16.67	16.67	16.67
Min, Max	-8.3, 8.3	-25.0, 91.7	-33.3, 58.3	-33.3, 91.7
Change from Baseline to Cycle 3 Day 1				
n	3	26	9	38
Mean (StdDev)	5.56 (26.788)	24.04 (33.361)	11.11 (18.634)	19.52 (30.219)
Median	16.67	20.83	0.00	16.67
Min, Max	-25.0, 25.0	-66.7, 83.3	-8.3, 41.7	-66.7, 83.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Global Health Status/QoL	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		18.75 (51.088)	18.75 (31.458)	18.75 (39.277)
Median		20.83	29.17	29.17
Min, Max		-33.3, 66.7	-25.0, 41.7	-33.3, 66.7
Change from Baseline to Cycle 5 Day 1				
n	1	16	9	26
Mean (StdDev)	16.67 (-)	24.48 (42.325)	14.81 (20.741)	20.83 (35.139)
Median	16.67	29.17	16.67	20.83
Min, Max	16.7, 16.7	-100.0, 83.3	-25.0, 41.7	-100.0, 83.3
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		33.33 (50.690)	22.92 (23.936)	27.38 (34.263)
Median		58.33	29.17	41.67
Min, Max		-25.0, 66.7	-8.3, 41.7	-25.0, 66.7
Change from Baseline to Cycle 7 Day 1				
n	1	17	5	23
Mean (StdDev)	-16.67 (-)	33.33 (36.084)	10.00 (19.896)	26.09 (34.661)
Median	-16.67	33.33	0.00	33.33
Min, Max	-16.7, -16.7	-33.3, 83.3	-8.3, 41.7	-33.3, 83.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Global Health Status/QoL	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		62.50 (5.893)	0.00 (23.570)	31.25 (38.715)
Median		62.50	0.00	37.50
Min, Max		58.3, 66.7	-16.7, 16.7	-16.7, 66.7
Change from Baseline to Cycle 9 Day 1				
n	0	13	4	17
Mean (StdDev)		28.85 (36.896)	4.17 (15.957)	23.04 (34.426)
Median		41.67	8.33	16.67
Min, Max		-58.3, 83.3	-16.7, 16.7	-58.3, 83.3
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		58.33 (-)	0.00 (23.570)	19.44 (37.577)
Median		58.33	0.00	16.67
Min, Max		58.3, 58.3	-16.7, 16.7	-16.7, 58.3
Change from Baseline to Cycle 11 Day 1				
n	0	8	3	11
Mean (StdDev)		36.46 (31.161)	2.78 (20.972)	27.27 (31.861)
Median		50.00	0.00	41.67
Min, Max		-33.3, 58.3	-16.7, 25.0	-33.3, 58.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Global Health Status/QoL	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		58.33 (-)	8.33 (35.355)	25.00 (38.188)
Median		58.33	8.33	33.33
Min, Max		58.3, 58.3	-16.7, 33.3	-16.7, 58.3
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		30.56 (64.729)	41.67 (-)	33.33 (53.142)
Median		50.00	41.67	45.83
Min, Max		-41.7, 83.3	41.7, 41.7	-41.7, 83.3
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		-33.33 (-)		-33.33 (-)
Median		-33.33		-33.33
Min, Max		-33.3, -33.3		-33.3, -33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Physical Functioning	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Baseline				
n	4	29	12	45
Mean (StdDev)	68.33 (32.375)	50.34 (28.652)	63.33 (24.205)	55.41 (28.099)
Median	83.33	46.67	63.33	53.33
Min, Max	20.0, 86.7	0.0, 100.0	26.7, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	2.22 (3.849)	11.67 (17.951)	15.24 (22.678)	11.56 (18.189)
Median	0.00	10.00	13.33	10.00
Min, Max	0.0, 6.7	-13.3, 53.3	-20.0, 46.7	-20.0, 53.3
Change from Baseline to Cycle 2 Day 1				
n	2	27	11	40
Mean (StdDev)	0.00 (0.000)	16.54 (22.522)	9.70 (19.633)	13.83 (21.371)
Median	0.00	6.67	6.67	6.67
Min, Max	0.0, 0.0	-6.7, 73.3	-20.0, 46.7	-20.0, 73.3
Change from Baseline to Cycle 3 Day 1				
n	3	26	9	38
Mean (StdDev)	-8.89 (3.849)	17.44 (23.557)	8.15 (16.592)	13.16 (22.219)
Median	-6.67	13.33	6.67	10.00
Min, Max	-13.3, -6.7	-20.0, 73.3	-13.3, 40.0	-20.0, 73.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Physical Functioning	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		25.00 (27.420)	16.67 (22.771)	20.83 (23.755)
Median		20.00	13.33	13.33
Min, Max		0.0, 60.0	-6.7, 46.7	-6.7, 60.0
Change from Baseline to Cycle 5 Day 1				
n	1	16	9	26
Mean (StdDev)	26.67 (-)	26.25 (24.762)	3.70 (20.846)	18.46 (25.037)
Median	26.67	30.00	13.33	16.67
Min, Max	26.7, 26.7	-13.3, 73.3	-26.7, 33.3	-26.7, 73.3
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		20.00 (29.059)	1.67 (15.753)	9.52 (22.396)
Median		33.33	6.67	13.33
Min, Max		-13.3, 40.0	-20.0, 13.3	-20.0, 40.0
Change from Baseline to Cycle 7 Day 1				
n	1	17	5	23
Mean (StdDev)	-40.00 (-)	21.96 (25.140)	6.67 (22.608)	15.94 (27.247)
Median	-40.00	13.33	6.67	6.67
Min, Max	-40.0, -40.0	-20.0, 66.7	-20.0, 40.0	-40.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Physical Functioning	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		43.33 (14.142)	0.00 (18.856)	21.67 (28.480)
Median		43.33	0.00	23.33
Min, Max		33.3, 53.3	-13.3, 13.3	-13.3, 53.3
Change from Baseline to Cycle 9 Day 1				
n	0	13	4	17
Mean (StdDev)		27.69 (23.703)	10.00 (19.245)	23.53 (23.466)
Median		26.67	10.00	13.33
Min, Max		0.0, 66.7	-13.3, 33.3	-13.3, 66.7
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		46.67 (-)	0.00 (18.856)	15.56 (30.062)
Median		46.67	0.00	13.33
Min, Max		46.7, 46.7	-13.3, 13.3	-13.3, 46.7
Change from Baseline to Cycle 11 Day 1				
n	0	8	3	11
Mean (StdDev)		35.83 (22.520)	17.78 (40.185)	30.91 (27.370)
Median		40.00	13.33	33.33
Min, Max		-6.7, 60.0	-20.0, 60.0	-20.0, 60.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Physical Functioning	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		46.67 (-)	-3.33 (23.570)	13.33 (33.333)
Median		46.67	-3.33	13.33
Min, Max		46.7, 46.7	-20.0, 13.3	-20.0, 46.7
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		35.56 (33.555)	60.00 (-)	41.67 (30.000)
Median		40.00	60.00	50.00
Min, Max		0.0, 66.7	60.0, 60.0	0.0, 66.7
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Role Functioning	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Baseline				
n	4	29	12	45
Mean (StdDev)	45.83 (36.956)	41.95 (35.807)	29.17 (29.409)	38.89 (34.082)
Median	50.00	50.00	25.00	33.33
Min, Max	0.0, 83.3	0.0, 100.0	0.0, 66.7	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	-5.56 (9.623)	12.50 (18.634)	23.81 (21.207)	13.33 (19.769)
Median	0.00	0.00	16.67	8.33
Min, Max	-16.7, 0.0	-16.7, 50.0	0.0, 66.7	-16.7, 66.7
Change from Baseline to Cycle 2 Day 1				
n	2	27	11	40
Mean (StdDev)	-16.67 (23.570)	17.28 (28.300)	24.24 (35.248)	17.50 (30.651)
Median	-16.67	16.67	33.33	16.67
Min, Max	-33.3, 0.0	-16.7, 100.0	-33.3, 83.3	-33.3, 100.0
Change from Baseline to Cycle 3 Day 1				
n	3	26	9	38
Mean (StdDev)	-11.11 (9.623)	15.38 (29.410)	20.37 (32.035)	14.47 (29.554)
Median	-16.67	8.33	33.33	8.33
Min, Max	-16.7, 0.0	-33.3, 66.7	-33.3, 66.7	-33.3, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Role Functioning	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		0.00 (30.429)	41.67 (56.928)	20.83 (47.768)
Median		0.00	50.00	25.00
Min, Max		-33.3, 33.3	-33.3, 100.0	-33.3, 100.0
Change from Baseline to Cycle 5 Day 1				
n	1	16	9	26
Mean (StdDev)	0.00 (-)	19.79 (40.469)	16.67 (22.048)	17.95 (33.968)
Median	0.00	16.67	16.67	16.67
Min, Max	0.0, 0.0	-66.7, 83.3	-16.7, 50.0	-66.7, 83.3
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		-5.56 (25.459)	25.00 (31.914)	11.90 (31.497)
Median		0.00	16.67	0.00
Min, Max		-33.3, 16.7	0.0, 66.7	-33.3, 66.7
Change from Baseline to Cycle 7 Day 1				
n	1	17	5	23
Mean (StdDev)	-33.33 (-)	20.59 (36.099)	20.00 (13.944)	18.12 (33.300)
Median	-33.33	16.67	16.67	16.67
Min, Max	-33.3, -33.3	-33.3, 83.3	0.0, 33.3	-33.3, 83.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Role Functioning	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		25.00 (11.785)	16.67 (23.570)	20.83 (15.957)
Median		25.00	16.67	25.00
Min, Max		16.7, 33.3	0.0, 33.3	0.0, 33.3
Change from Baseline to Cycle 9 Day 1				
n	0	13	4	17
Mean (StdDev)		26.92 (30.076)	20.83 (15.957)	25.49 (27.079)
Median		33.33	25.00	33.33
Min, Max		-33.3, 66.7	0.0, 33.3	-33.3, 66.7
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		16.67 (-)	16.67 (23.570)	16.67 (16.667)
Median		16.67	16.67	16.67
Min, Max		16.7, 16.7	0.0, 33.3	0.0, 33.3
Change from Baseline to Cycle 11 Day 1				
n	0	8	3	11
Mean (StdDev)		35.42 (25.877)	44.44 (50.918)	37.88 (31.703)
Median		33.33	33.33	33.33
Min, Max		0.0, 66.7	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Role Functioning	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		16.67 (-)	16.67 (23.570)	16.67 (16.667)
Median		16.67	16.67	16.67
Min, Max		16.7, 16.7	0.0, 33.3	0.0, 33.3
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		44.44 (38.490)	66.67 (-)	50.00 (33.333)
Median		66.67	66.67	66.67
Min, Max		0.0, 66.7	66.7, 66.7	0.0, 66.7
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Emotional Functioning	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Baseline				
n	4	29	12	45
Mean (StdDev)	77.08 (29.950)	60.63 (27.268)	61.11 (25.706)	62.22 (26.862)
Median	87.50	58.33	66.67	58.33
Min, Max	33.3, 100.0	8.3, 100.0	8.3, 100.0	8.3, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	0.00 (8.333)	10.42 (17.703)	1.19 (16.265)	7.22 (16.914)
Median	0.00	12.50	0.00	8.33
Min, Max	-8.3, 8.3	-25.0, 58.3	-25.0, 16.7	-25.0, 58.3
Change from Baseline to Cycle 2 Day 1				
n	2	27	11	40
Mean (StdDev)	-12.50 (5.893)	14.51 (25.798)	12.12 (13.104)	12.50 (22.880)
Median	-12.50	16.67	16.67	12.50
Min, Max	-16.7, -8.3	-25.0, 58.3	-8.3, 33.3	-25.0, 58.3
Change from Baseline to Cycle 3 Day 1				
n	3	26	9	38
Mean (StdDev)	-8.33 (25.000)	13.89 (24.318)	4.63 (13.889)	9.94 (22.802)
Median	-8.33	16.67	0.00	8.33
Min, Max	-33.3, 16.7	-33.3, 58.3	-8.3, 33.3	-33.3, 58.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Emotional Functioning	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		25.00 (24.533)	8.33 (20.412)	16.67 (22.713)
Median		20.83	8.33	12.50
Min, Max		0.0, 58.3	-16.7, 33.3	-16.7, 58.3
Change from Baseline to Cycle 5 Day 1				
n	1	16	9	26
Mean (StdDev)	16.67 (-)	20.31 (29.964)	-0.93 (14.699)	12.82 (26.691)
Median	16.67	20.83	0.00	8.33
Min, Max	16.7, 16.7	-33.3, 66.7	-25.0, 25.0	-33.3, 66.7
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		25.00 (50.000)	-2.08 (24.884)	9.52 (36.777)
Median		25.00	0.00	8.33
Min, Max		-25.0, 75.0	-33.3, 25.0	-33.3, 75.0
Change from Baseline to Cycle 7 Day 1				
n	1	17	5	23
Mean (StdDev)	0.00 (-)	19.12 (25.645)	-16.67 (28.260)	10.51 (29.217)
Median	0.00	25.00	-8.33	16.67
Min, Max	0.0, 0.0	-25.0, 66.7	-66.7, 0.0	-66.7, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Emotional Functioning	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		37.50 (17.678)	-37.50 (17.678)	0.00 (45.644)
Median		37.50	-37.50	0.00
Min, Max		25.0, 50.0	-50.0, -25.0	-50.0, 50.0
Change from Baseline to Cycle 9 Day 1				
n	0	13	4	17
Mean (StdDev)		19.23 (20.801)	-25.00 (24.533)	8.82 (28.485)
Median		25.00	-25.00	8.33
Min, Max		-16.7, 50.0	-50.0, 0.0	-50.0, 50.0
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		66.67 (-)	-45.83 (5.893)	-8.33 (65.085)
Median		66.67	-45.83	-41.67
Min, Max		66.7, 66.7	-50.0, -41.7	-50.0, 66.7
Change from Baseline to Cycle 11 Day 1				
n	0	8	3	11
Mean (StdDev)		22.92 (28.084)	-16.67 (36.324)	12.12 (34.027)
Median		16.67	-33.33	8.33
Min, Max		-16.7, 66.7	-41.7, 25.0	-41.7, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Emotional Functioning	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		25.00 (-)	-54.17 (41.248)	-27.78 (54.220)
Median		25.00	-54.17	-25.00
Min, Max		25.0, 25.0	-83.3, -25.0	-83.3, 25.0
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		30.56 (33.679)	25.00 (-)	29.17 (27.639)
Median		25.00	25.00	25.00
Min, Max		0.0, 66.7	25.0, 25.0	0.0, 66.7
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Cognitive Functioning	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Baseline				
n	4	29	12	45
Mean (StdDev)	79.17 (15.957)	71.84 (22.758)	65.28 (27.941)	70.74 (23.612)
Median	75.00	66.67	58.33	66.67
Min, Max	66.7, 100.0	33.3, 100.0	16.7, 100.0	16.7, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	-5.56 (9.623)	5.00 (14.408)	-4.76 (8.133)	1.67 (13.384)
Median	0.00	0.00	0.00	0.00
Min, Max	-16.7, 0.0	-16.7, 33.3	-16.7, 0.0	-16.7, 33.3
Change from Baseline to Cycle 2 Day 1				
n	2	27	11	40
Mean (StdDev)	0.00 (0.000)	5.56 (22.169)	6.06 (21.438)	5.42 (21.145)
Median	0.00	0.00	16.67	0.00
Min, Max	0.0, 0.0	-33.3, 50.0	-33.3, 33.3	-33.3, 50.0
Change from Baseline to Cycle 3 Day 1				
n	3	26	9	38
Mean (StdDev)	11.11 (9.623)	4.49 (20.847)	9.26 (20.601)	6.14 (19.918)
Median	16.67	0.00	16.67	0.00
Min, Max	0.0, 16.7	-33.3, 50.0	-33.3, 33.3	-33.3, 50.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Cognitive Functioning	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		8.33 (28.868)	8.33 (9.623)	8.33 (19.920)
Median		0.00	8.33	0.00
Min, Max		-16.7, 50.0	0.0, 16.7	-16.7, 50.0
Change from Baseline to Cycle 5 Day 1				
n	1	16	9	26
Mean (StdDev)	-16.67 (-)	5.21 (22.541)	-5.56 (16.667)	0.64 (20.806)
Median	-16.67	8.33	0.00	0.00
Min, Max	-16.7, -16.7	-50.0, 33.3	-33.3, 16.7	-50.0, 33.3
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		16.67 (28.868)	12.50 (8.333)	14.29 (17.817)
Median		0.00	16.67	16.67
Min, Max		0.0, 50.0	0.0, 16.7	0.0, 50.0
Change from Baseline to Cycle 7 Day 1				
n	1	17	5	23
Mean (StdDev)	16.67 (-)	6.86 (25.725)	-6.67 (19.003)	4.35 (24.214)
Median	16.67	0.00	0.00	0.00
Min, Max	16.7, 16.7	-33.3, 50.0	-33.3, 16.7	-33.3, 50.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Cognitive Functioning	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		25.00 (35.355)	-8.33 (11.785)	8.33 (28.868)
Median		25.00	-8.33	0.00
Min, Max		0.0, 50.0	-16.7, 0.0	-16.7, 50.0
Change from Baseline to Cycle 9 Day 1				
n	0	13	4	17
Mean (StdDev)		2.56 (27.927)	-12.50 (8.333)	-0.98 (25.325)
Median		0.00	-16.67	-16.67
Min, Max		-33.3, 50.0	-16.7, 0.0	-33.3, 50.0
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		50.00 (-)	-25.00 (35.355)	0.00 (50.000)
Median		50.00	-25.00	0.00
Min, Max		50.0, 50.0	-50.0, 0.0	-50.0, 50.0
Change from Baseline to Cycle 11 Day 1				
n	0	8	3	11
Mean (StdDev)		8.33 (17.817)	-5.56 (25.459)	4.55 (19.848)
Median		0.00	0.00	0.00
Min, Max		-16.7, 33.3	-33.3, 16.7	-33.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Cognitive Functioning	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	-33.33 (47.140)	-22.22 (38.490)
Median		0.00	-33.33	0.00
Min, Max		0.0, 0.0	-66.7, 0.0	-66.7, 0.0
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		5.56 (9.623)	16.67 (-)	8.33 (9.623)
Median		0.00	16.67	8.33
Min, Max		0.0, 16.7	16.7, 16.7	0.0, 16.7
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		-16.67 (-)		-16.67 (-)
Median		-16.67		-16.67
Min, Max		-16.7, -16.7		-16.7, -16.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Social Function	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Baseline				
n	4	29	12	45
Mean (StdDev)	50.00 (36.004)	50.00 (33.630)	50.00 (32.567)	50.00 (32.760)
Median	41.67	33.33	66.67	33.33
Min, Max	16.7, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	0.00 (16.667)	17.50 (25.635)	19.05 (29.547)	16.11 (25.702)
Median	0.00	16.67	16.67	16.67
Min, Max	-16.7, 16.7	-16.7, 66.7	-16.7, 66.7	-16.7, 66.7
Change from Baseline to Cycle 2 Day 1				
n	2	27	11	40
Mean (StdDev)	-8.33 (11.785)	18.52 (35.606)	16.67 (34.157)	16.67 (34.385)
Median	-8.33	16.67	16.67	16.67
Min, Max	-16.7, 0.0	-33.3, 100.0	-33.3, 83.3	-33.3, 100.0
Change from Baseline to Cycle 3 Day 1				
n	3	26	9	38
Mean (StdDev)	-11.11 (25.459)	12.18 (26.482)	7.41 (30.174)	9.21 (27.317)
Median	-16.67	0.00	0.00	0.00
Min, Max	-33.3, 16.7	-16.7, 83.3	-50.0, 50.0	-50.0, 83.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Social Function	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		16.67 (30.429)	8.33 (16.667)	12.50 (23.146)
Median		16.67	0.00	0.00
Min, Max		-16.7, 50.0	0.0, 33.3	-16.7, 50.0
Change from Baseline to Cycle 5 Day 1				
n	1	16	9	26
Mean (StdDev)	16.67 (-)	26.04 (32.185)	0.00 (20.412)	16.67 (30.185)
Median	16.67	33.33	0.00	25.00
Min, Max	16.7, 16.7	-50.0, 66.7	-16.7, 33.3	-50.0, 66.7
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		22.22 (50.918)	0.00 (49.065)	9.52 (47.000)
Median		33.33	-8.33	0.00
Min, Max		-33.3, 66.7	-50.0, 66.7	-50.0, 66.7
Change from Baseline to Cycle 7 Day 1				
n	1	17	5	23
Mean (StdDev)	33.33 (-)	29.41 (31.474)	-3.33 (24.721)	22.46 (32.023)
Median	33.33	33.33	0.00	33.33
Min, Max	33.3, 33.3	-33.3, 66.7	-33.3, 33.3	-33.3, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Social Function	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		41.67 (11.785)	-33.33 (47.140)	4.17 (51.595)
Median		41.67	-33.33	16.67
Min, Max		33.3, 50.0	-66.7, 0.0	-66.7, 50.0
Change from Baseline to Cycle 9 Day 1				
n	0	13	4	17
Mean (StdDev)		30.77 (28.744)	-4.17 (41.667)	22.55 (34.329)
Median		33.33	16.67	33.33
Min, Max		-33.3, 66.7	-66.7, 16.7	-66.7, 66.7
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		66.67 (-)	-50.00 (70.711)	-11.11 (83.887)
Median		66.67	-50.00	0.00
Min, Max		66.7, 66.7	-100.0, 0.0	-100.0, 66.7
Change from Baseline to Cycle 11 Day 1				
n	0	8	3	11
Mean (StdDev)		33.33 (23.570)	11.11 (91.793)	27.27 (46.710)
Median		33.33	16.67	33.33
Min, Max		0.0, 66.7	-83.3, 100.0	-83.3, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Social Function	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		33.33 (-)	-41.67 (58.926)	-16.67 (60.093)
Median		33.33	-41.67	0.00
Min, Max		33.3, 33.3	-83.3, 0.0	-83.3, 33.3
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		44.44 (53.576)	100.00 (-)	58.33 (51.819)
Median		66.67	100.00	75.00
Min, Max		-16.7, 83.3	100.0, 100.0	-16.7, 100.0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Fatigue	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Baseline				
n	4	29	12	45
Mean (StdDev)	61.11 (29.397)	70.11 (32.544)	72.22 (28.229)	69.88 (30.670)
Median	55.56	77.78	77.78	77.78
Min, Max	33.3, 100.0	0.0, 100.0	22.2, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	3.70 (6.415)	-20.00 (22.970)	-19.05 (27.751)	-17.41 (23.648)
Median	0.00	-11.11	-22.22	-11.11
Min, Max	0.0, 11.1	-55.6, 11.1	-55.6, 22.2	-55.6, 22.2
Change from Baseline to Cycle 2 Day 1				
n	2	27	11	40
Mean (StdDev)	5.56 (7.857)	-20.58 (28.025)	-19.19 (25.863)	-18.89 (27.006)
Median	5.56	-22.22	-22.22	-16.67
Min, Max	0.0, 11.1	-77.8, 33.3	-66.7, 11.1	-77.8, 33.3
Change from Baseline to Cycle 3 Day 1				
n	3	26	9	38
Mean (StdDev)	14.81 (12.830)	-16.24 (28.150)	-13.58 (22.067)	-13.16 (26.828)
Median	22.22	-16.67	-11.11	-11.11
Min, Max	0.0, 22.2	-77.8, 44.4	-55.6, 11.1	-77.8, 44.4

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Fatigue	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		-2.78 (29.222)	-30.56 (43.862)	-16.67 (37.562)
Median		0.00	-38.89	-16.67
Min, Max		-33.3, 22.2	-66.7, 22.2	-66.7, 22.2
Change from Baseline to Cycle 5 Day 1				
n	1	16	9	26
Mean (StdDev)	-11.11 (-)	-28.47 (40.969)	-18.52 (21.517)	-24.36 (34.429)
Median	-11.11	-33.33	-11.11	-22.22
Min, Max	-11.1, -11.1	-77.8, 66.7	-66.7, 0.0	-77.8, 66.7
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		-11.11 (48.432)	-13.89 (29.222)	-12.70 (34.800)
Median		-33.33	-5.56	-11.11
Min, Max		-44.4, 44.4	-55.6, 11.1	-55.6, 44.4
Change from Baseline to Cycle 7 Day 1				
n	1	17	5	23
Mean (StdDev)	0.00 (-)	-34.64 (31.398)	-4.44 (12.669)	-26.57 (30.657)
Median	0.00	-33.33	0.00	-22.22
Min, Max	0.0, 0.0	-88.9, 22.2	-22.2, 11.1	-88.9, 22.2

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Fatigue	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		-50.00 (7.857)	0.00 (0.000)	-25.00 (29.222)
Median		-50.00	0.00	-22.22
Min, Max		-55.6, -44.4	0.0, 0.0	-55.6, 0.0
Change from Baseline to Cycle 9 Day 1				
n	0	13	4	17
Mean (StdDev)		-39.32 (25.099)	-8.33 (16.667)	-32.03 (26.609)
Median		-44.44	-11.11	-33.33
Min, Max		-77.8, 11.1	-22.2, 11.1	-77.8, 11.1
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		-55.56 (-)	-5.56 (7.857)	-22.22 (29.397)
Median		-55.56	-5.56	-11.11
Min, Max		-55.6, -55.6	-11.1, 0.0	-55.6, 0.0
Change from Baseline to Cycle 11 Day 1				
n	0	8	3	11
Mean (StdDev)		-44.44 (33.597)	-25.93 (44.905)	-39.39 (35.612)
Median		-55.56	0.00	-55.56
Min, Max		-66.7, 33.3	-77.8, 0.0	-77.8, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Fatigue	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		-66.67 (-)	-5.56 (7.857)	-25.93 (35.717)
Median		-66.67	-5.56	-11.11
Min, Max		-66.7, -66.7	-11.1, 0.0	-66.7, 0.0
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-40.74 (57.018)	-66.67 (-)	-47.22 (48.326)
Median		-55.56	-66.67	-61.11
Min, Max		-88.9, 22.2	-66.7, -66.7	-88.9, 22.2
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		33.33 (-)		33.33 (-)
Median		33.33		33.33
Min, Max		33.3, 33.3		33.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Nausea and Vomiting	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Baseline				
n	4	29	12	45
Mean (StdDev)	33.33 (38.490)	21.26 (29.846)	13.89 (19.890)	20.37 (28.179)
Median	33.33	16.67	0.00	0.00
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 50.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	5.56 (9.623)	-13.33 (20.662)	-7.14 (23.288)	-10.00 (20.807)
Median	0.00	-16.67	0.00	0.00
Min, Max	0.0, 16.7	-66.7, 33.3	-50.0, 16.7	-66.7, 33.3
Change from Baseline to Cycle 2 Day 1				
n	2	27	11	40
Mean (StdDev)	0.00 (0.000)	-9.26 (28.991)	-4.55 (19.848)	-7.50 (25.861)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 0.0	-100.0, 33.3	-50.0, 16.7	-100.0, 33.3
Change from Baseline to Cycle 3 Day 1				
n	3	26	9	38
Mean (StdDev)	-5.56 (25.459)	-10.90 (33.646)	-3.70 (18.215)	-8.77 (29.697)
Median	0.00	0.00	0.00	0.00
Min, Max	-33.3, 16.7	-100.0, 50.0	-50.0, 16.7	-100.0, 50.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Nausea and Vomiting	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		8.33 (31.914)	-4.17 (15.957)	2.08 (24.296)
Median		16.67	-8.33	0.00
Min, Max		-33.3, 33.3	-16.7, 16.7	-33.3, 33.3
Change from Baseline to Cycle 5 Day 1				
n	1	16	9	26
Mean (StdDev)	0.00 (-)	-16.67 (26.527)	-3.70 (20.031)	-11.54 (24.390)
Median	0.00	-16.67	0.00	0.00
Min, Max	0.0, 0.0	-66.7, 33.3	-50.0, 16.7	-66.7, 33.3
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		-11.11 (34.694)	-4.17 (15.957)	-7.14 (23.288)
Median		0.00	-8.33	0.00
Min, Max		-50.0, 16.7	-16.7, 16.7	-50.0, 16.7
Change from Baseline to Cycle 7 Day 1				
n	1	17	5	23
Mean (StdDev)	-50.00 (-)	-21.57 (25.526)	3.33 (13.944)	-17.39 (25.858)
Median	-50.00	-16.67	0.00	-16.67
Min, Max	-50.0, -50.0	-83.3, 0.0	-16.7, 16.7	-83.3, 16.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Nausea and Vomiting	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		-16.67 (23.570)	-8.33 (11.785)	-12.50 (15.957)
Median		-16.67	-8.33	-8.33
Min, Max		-33.3, 0.0	-16.7, 0.0	-33.3, 0.0
Change from Baseline to Cycle 9 Day 1				
n	0	13	4	17
Mean (StdDev)		-17.95 (24.019)	-4.17 (8.333)	-14.71 (21.955)
Median		-16.67	0.00	0.00
Min, Max		-66.7, 16.7	-16.7, 0.0	-66.7, 16.7
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		-33.33 (-)	-8.33 (11.785)	-16.67 (16.667)
Median		-33.33	-8.33	-16.67
Min, Max		-33.3, -33.3	-16.7, 0.0	-33.3, 0.0
Change from Baseline to Cycle 11 Day 1				
n	0	8	3	11
Mean (StdDev)		-16.67 (25.198)	-11.11 (9.623)	-15.15 (21.672)
Median		-8.33	-16.67	-16.67
Min, Max		-50.0, 16.7	-16.7, 0.0	-50.0, 16.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Nausea and Vomiting	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	-8.33 (11.785)	-5.56 (9.623)
Median		0.00	-8.33	0.00
Min, Max		0.0, 0.0	-16.7, 0.0	-16.7, 0.0
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		5.56 (25.459)	0.00 (-)	4.17 (20.972)
Median		0.00	0.00	0.00
Min, Max		-16.7, 33.3	0.0, 0.0	-16.7, 33.3
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Pain	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Baseline				
n	4	29	12	45
Mean (StdDev)	50.00 (30.429)	37.93 (34.760)	52.78 (32.437)	42.96 (33.801)
Median	50.00	33.33	50.00	33.33
Min, Max	16.7, 83.3	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	0.00 (0.000)	-20.83 (32.388)	-19.05 (26.227)	-18.33 (29.475)
Median	0.00	0.00	-16.67	0.00
Min, Max	0.0, 0.0	-83.3, 33.3	-50.0, 16.7	-83.3, 33.3
Change from Baseline to Cycle 2 Day 1				
n	2	27	11	40
Mean (StdDev)	0.00 (0.000)	-19.14 (29.491)	-30.30 (29.644)	-21.25 (29.232)
Median	0.00	0.00	-33.33	0.00
Min, Max	0.0, 0.0	-100.0, 16.7	-83.3, 0.0	-100.0, 16.7
Change from Baseline to Cycle 3 Day 1				
n	3	26	9	38
Mean (StdDev)	0.00 (16.667)	-16.03 (34.795)	-29.63 (27.358)	-17.98 (32.508)
Median	0.00	0.00	-33.33	-8.33
Min, Max	-16.7, 16.7	-100.0, 33.3	-66.7, 0.0	-100.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Pain	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		-12.50 (15.957)	-25.00 (56.928)	-18.75 (39.277)
Median		-8.33	-33.33	-16.67
Min, Max		-33.3, 0.0	-83.3, 50.0	-83.3, 50.0
Change from Baseline to Cycle 5 Day 1				
n	1	16	9	26
Mean (StdDev)	16.67 (-)	-12.50 (32.489)	-27.78 (42.492)	-16.67 (36.209)
Median	16.67	-8.33	-16.67	-8.33
Min, Max	16.7, 16.7	-83.3, 66.7	-100.0, 33.3	-100.0, 66.7
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		-22.22 (19.245)	-20.83 (41.667)	-21.43 (31.497)
Median		-33.33	0.00	0.00
Min, Max		-33.3, 0.0	-83.3, 0.0	-83.3, 0.0
Change from Baseline to Cycle 7 Day 1				
n	1	17	5	23
Mean (StdDev)	0.00 (-)	-12.75 (39.321)	-20.00 (27.386)	-13.77 (35.764)
Median	0.00	-16.67	-16.67	-16.67
Min, Max	0.0, 0.0	-83.3, 83.3	-66.7, 0.0	-83.3, 83.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Pain	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		-25.00 (11.785)	8.33 (35.355)	-8.33 (28.868)
Median		-25.00	8.33	-16.67
Min, Max		-33.3, -16.7	-16.7, 33.3	-33.3, 33.3
Change from Baseline to Cycle 9 Day 1				
n	0	13	4	17
Mean (StdDev)		-12.82 (28.181)	-8.33 (44.096)	-11.76 (31.049)
Median		0.00	0.00	0.00
Min, Max		-66.7, 33.3	-66.7, 33.3	-66.7, 33.3
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		-16.67 (-)	8.33 (35.355)	0.00 (28.868)
Median		-16.67	8.33	-16.67
Min, Max		-16.7, -16.7	-16.7, 33.3	-16.7, 33.3
Change from Baseline to Cycle 11 Day 1				
n	0	8	3	11
Mean (StdDev)		-18.75 (24.296)	-22.22 (58.531)	-19.70 (33.181)
Median		-8.33	-16.67	-16.67
Min, Max		-66.7, 0.0	-83.3, 33.3	-83.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Pain	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		-33.33 (-)	0.00 (47.140)	-11.11 (38.490)
Median		-33.33	0.00	-33.33
Min, Max		-33.3, -33.3	-33.3, 33.3	-33.3, 33.3
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-11.11 (19.245)	-83.33 (-)	-29.17 (39.382)
Median		0.00	-83.33	-16.67
Min, Max		-33.3, 0.0	-83.3, -83.3	-83.3, 0.0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Dyspnea	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Baseline				
n	4	29	12	45
Mean (StdDev)	16.67 (19.245)	52.87 (35.093)	52.78 (36.121)	49.63 (35.264)
Median	16.67	33.33	50.00	33.33
Min, Max	0.0, 33.3	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	-11.11 (19.245)	-23.33 (36.031)	-23.81 (25.198)	-22.22 (31.964)
Median	0.00	-16.67	-33.33	-16.67
Min, Max	-33.3, 0.0	-100.0, 33.3	-66.7, 0.0	-100.0, 33.3
Change from Baseline to Cycle 2 Day 1				
n	2	27	11	40
Mean (StdDev)	0.00 (0.000)	-24.69 (34.085)	-18.18 (22.918)	-21.67 (30.709)
Median	0.00	-33.33	0.00	-16.67
Min, Max	0.0, 0.0	-100.0, 33.3	-66.7, 0.0	-100.0, 33.3
Change from Baseline to Cycle 3 Day 1				
n	3	26	9	38
Mean (StdDev)	11.11 (19.245)	-28.21 (36.138)	-25.93 (22.222)	-24.56 (33.499)
Median	0.00	-33.33	-33.33	-33.33
Min, Max	0.0, 33.3	-100.0, 33.3	-66.7, 0.0	-100.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Dyspnea	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		-25.00 (31.914)	-25.00 (31.914)	-25.00 (29.547)
Median		-16.67	-16.67	-16.67
Min, Max		-66.7, 0.0	-66.7, 0.0	-66.7, 0.0
Change from Baseline to Cycle 5 Day 1				
n	1	16	9	26
Mean (StdDev)	-33.33 (-)	-31.25 (37.454)	-22.22 (23.570)	-28.21 (32.238)
Median	-33.33	-33.33	-33.33	-33.33
Min, Max	-33.3, -33.3	-100.0, 33.3	-66.7, 0.0	-100.0, 33.3
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		-33.33 (33.333)	-8.33 (41.944)	-19.05 (37.796)
Median		-33.33	0.00	0.00
Min, Max		-66.7, 0.0	-66.7, 33.3	-66.7, 33.3
Change from Baseline to Cycle 7 Day 1				
n	1	17	5	23
Mean (StdDev)	33.33 (-)	-35.29 (38.135)	-20.00 (38.006)	-28.99 (39.318)
Median	33.33	-33.33	-33.33	-33.33
Min, Max	33.3, 33.3	-100.0, 33.3	-66.7, 33.3	-100.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Dyspnea	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		-66.67 (47.140)	-33.33 (47.140)	-50.00 (43.033)
Median		-66.67	-33.33	-50.00
Min, Max		-100.0, -33.3	-66.7, 0.0	-100.0, 0.0
Change from Baseline to Cycle 9 Day 1				
n	0	13	4	17
Mean (StdDev)		-43.59 (34.385)	-33.33 (27.217)	-41.18 (32.338)
Median		-33.33	-33.33	-33.33
Min, Max		-100.0, 0.0	-66.7, 0.0	-100.0, 0.0
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		-100.00 (-)	-33.33 (47.140)	-55.56 (50.918)
Median		-100.00	-33.33	-66.67
Min, Max		-100.0, -100.0	-66.7, 0.0	-100.0, 0.0
Change from Baseline to Cycle 11 Day 1				
n	0	8	3	11
Mean (StdDev)		-50.00 (39.841)	-33.33 (33.333)	-45.45 (37.335)
Median		-50.00	-33.33	-33.33
Min, Max		-100.0, 0.0	-66.7, 0.0	-100.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Dyspnea	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		-33.33 (-)	-33.33 (47.140)	-33.33 (33.333)
Median		-33.33	-33.33	-33.33
Min, Max		-33.3, -33.3	-66.7, 0.0	-66.7, 0.0
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-33.33 (57.735)	-33.33 (-)	-33.33 (47.140)
Median		0.00	-33.33	-16.67
Min, Max		-100.0, 0.0	-33.3, -33.3	-100.0, 0.0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Insomnia	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Baseline				
n	4	29	12	45
Mean (StdDev)	75.00 (31.914)	49.43 (36.319)	77.78 (35.770)	59.26 (37.530)
Median	83.33	66.67	100.00	66.67
Min, Max	33.3, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	-11.11 (19.245)	-13.33 (36.515)	-42.86 (25.198)	-20.00 (34.575)
Median	0.00	0.00	-33.33	-33.33
Min, Max	-33.3, 0.0	-66.7, 33.3	-66.7, 0.0	-66.7, 33.3
Change from Baseline to Cycle 2 Day 1				
n	2	27	11	40
Mean (StdDev)	0.00 (0.000)	-13.58 (44.587)	-54.55 (47.779)	-24.17 (47.734)
Median	0.00	0.00	-66.67	-33.33
Min, Max	0.0, 0.0	-100.0, 66.7	-100.0, 66.7	-100.0, 66.7
Change from Baseline to Cycle 3 Day 1				
n	3	26	9	38
Mean (StdDev)	0.00 (0.000)	-12.82 (46.262)	-48.15 (47.467)	-20.18 (46.846)
Median	0.00	0.00	-66.67	-16.67
Min, Max	0.0, 0.0	-100.0, 66.7	-100.0, 66.7	-100.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Insomnia	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		0.00 (47.140)	-16.67 (43.033)	-8.33 (42.725)
Median		16.67	-16.67	0.00
Min, Max		-66.7, 33.3	-66.7, 33.3	-66.7, 33.3
Change from Baseline to Cycle 5 Day 1				
n	1	16	9	26
Mean (StdDev)	-33.33 (-)	-25.00 (39.441)	-29.63 (30.932)	-26.92 (35.301)
Median	-33.33	-33.33	-33.33	-33.33
Min, Max	-33.3, -33.3	-66.7, 66.7	-66.7, 0.0	-66.7, 66.7
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		11.11 (50.918)	-16.67 (43.033)	-4.76 (44.840)
Median		0.00	-16.67	0.00
Min, Max		-33.3, 66.7	-66.7, 33.3	-66.7, 66.7
Change from Baseline to Cycle 7 Day 1				
n	1	17	5	23
Mean (StdDev)	0.00 (-)	-17.65 (47.313)	-20.00 (44.721)	-17.39 (44.800)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 0.0	-100.0, 66.7	-66.7, 33.3	-100.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Insomnia	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		-33.33 (47.140)	0.00 (0.000)	-16.67 (33.333)
Median		-33.33	0.00	0.00
Min, Max		-66.7, 0.0	0.0, 0.0	-66.7, 0.0
Change from Baseline to Cycle 9 Day 1				
n	0	13	4	17
Mean (StdDev)		-28.21 (40.474)	-33.33 (38.490)	-29.41 (38.877)
Median		0.00	-33.33	0.00
Min, Max		-100.0, 33.3	-66.7, 0.0	-100.0, 33.3
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	0.00 (0.000)	0.00 (0.000)
Median		0.00	0.00	0.00
Min, Max		0.0, 0.0	0.0, 0.0	0.0, 0.0
Change from Baseline to Cycle 11 Day 1				
n	0	8	3	11
Mean (StdDev)		-37.50 (33.034)	-22.22 (69.389)	-33.33 (42.164)
Median		-50.00	0.00	-33.33
Min, Max		-66.7, 0.0	-100.0, 33.3	-100.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Insomnia	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		-66.67 (-)	16.67 (23.570)	-11.11 (50.918)
Median		-66.67	16.67	0.00
Min, Max		-66.7, -66.7	0.0, 33.3	-66.7, 33.3
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-22.22 (38.490)	-100.00 (-)	-41.67 (50.000)
Median		0.00	-100.00	-33.33
Min, Max		-66.7, 0.0	-100.0, -100.0	-100.0, 0.0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		33.33 (-)		33.33 (-)
Median		33.33		33.33
Min, Max		33.3, 33.3		33.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Appetite Loss	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Baseline				
n	4	29	12	45
Mean (StdDev)	16.67 (33.333)	47.13 (36.206)	47.22 (36.121)	44.44 (36.237)
Median	0.00	33.33	33.33	33.33
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	-11.11 (19.245)	-28.33 (32.936)	-23.81 (25.198)	-25.56 (29.921)
Median	0.00	-33.33	-33.33	-33.33
Min, Max	-33.3, 0.0	-100.0, 33.3	-66.7, 0.0	-100.0, 33.3
Change from Baseline to Cycle 2 Day 1				
n	2	27	11	40
Mean (StdDev)	-16.67 (23.570)	-24.69 (44.905)	-21.21 (37.335)	-23.33 (41.482)
Median	-16.67	-33.33	0.00	-16.67
Min, Max	-33.3, 0.0	-100.0, 66.7	-100.0, 33.3	-100.0, 66.7
Change from Baseline to Cycle 3 Day 1				
n	3	26	9	38
Mean (StdDev)	0.00 (0.000)	-34.62 (39.419)	-25.93 (52.116)	-29.82 (41.582)
Median	0.00	-33.33	0.00	-33.33
Min, Max	0.0, 0.0	-100.0, 33.3	-100.0, 33.3	-100.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Appetite Loss	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		-25.00 (50.000)	-8.33 (31.914)	-16.67 (39.841)
Median		-33.33	-16.67	-16.67
Min, Max		-66.7, 33.3	-33.3, 33.3	-66.7, 33.3
Change from Baseline to Cycle 5 Day 1				
n	1	16	9	26
Mean (StdDev)	0.00 (-)	-41.67 (46.348)	-11.11 (33.333)	-29.49 (43.540)
Median	0.00	-33.33	0.00	-33.33
Min, Max	0.0, 0.0	-100.0, 66.7	-66.7, 33.3	-100.0, 66.7
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		-44.44 (69.389)	-16.67 (33.333)	-28.57 (48.795)
Median		-66.67	0.00	0.00
Min, Max		-100.0, 33.3	-66.7, 0.0	-100.0, 33.3
Change from Baseline to Cycle 7 Day 1				
n	1	17	5	23
Mean (StdDev)	0.00 (-)	-43.14 (45.284)	-26.67 (27.889)	-37.68 (41.808)
Median	0.00	-33.33	-33.33	-33.33
Min, Max	0.0, 0.0	-100.0, 66.7	-66.7, 0.0	-100.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Appetite Loss	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		-83.33 (23.570)	-16.67 (23.570)	-50.00 (43.033)
Median		-83.33	-16.67	-50.00
Min, Max		-100.0, -66.7	-33.3, 0.0	-100.0, 0.0
Change from Baseline to Cycle 9 Day 1				
n	0	13	4	17
Mean (StdDev)		-38.46 (38.118)	-25.00 (31.914)	-35.29 (36.268)
Median		-33.33	-16.67	-33.33
Min, Max		-100.0, 33.3	-66.7, 0.0	-100.0, 33.3
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		-100.00 (-)	16.67 (23.570)	-22.22 (69.389)
Median		-100.00	16.67	0.00
Min, Max		-100.0, -100.0	0.0, 33.3	-100.0, 33.3
Change from Baseline to Cycle 11 Day 1				
n	0	8	3	11
Mean (StdDev)		-41.67 (46.291)	-11.11 (50.918)	-33.33 (47.140)
Median		-33.33	0.00	-33.33
Min, Max		-100.0, 33.3	-66.7, 33.3	-100.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Appetite Loss	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		-66.67 (-)	16.67 (23.570)	-11.11 (50.918)
Median		-66.67	16.67	0.00
Min, Max		-66.7, -66.7	0.0, 33.3	-66.7, 33.3
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-44.44 (50.918)	-66.67 (-)	-50.00 (43.033)
Median		-33.33	-66.67	-50.00
Min, Max		-100.0, 0.0	-66.7, -66.7	-100.0, 0.0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		33.33 (-)		33.33 (-)
Median		33.33		33.33
Min, Max		33.3, 33.3		33.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Constipation	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Baseline				
n	4	29	12	45
Mean (StdDev)	25.00 (31.914)	24.14 (31.993)	19.44 (33.207)	22.96 (31.641)
Median	16.67	0.00	0.00	0.00
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	0.00 (0.000)	-5.00 (24.839)	-9.52 (31.706)	-5.56 (24.888)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 0.0	-66.7, 66.7	-66.7, 33.3	-66.7, 66.7
Change from Baseline to Cycle 2 Day 1				
n	2	27	11	40
Mean (StdDev)	0.00 (0.000)	-12.35 (30.868)	-15.15 (31.140)	-12.50 (29.898)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 0.0	-100.0, 33.3	-66.7, 33.3	-100.0, 33.3
Change from Baseline to Cycle 3 Day 1				
n	3	26	9	38
Mean (StdDev)	-11.11 (19.245)	-8.97 (29.147)	-14.81 (44.444)	-10.53 (32.052)
Median	0.00	0.00	0.00	0.00
Min, Max	-33.3, 0.0	-100.0, 33.3	-100.0, 33.3	-100.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Constipation	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		-16.67 (33.333)	-16.67 (33.333)	-16.67 (30.861)
Median		0.00	0.00	0.00
Min, Max		-66.7, 0.0	-66.7, 0.0	-66.7, 0.0
Change from Baseline to Cycle 5 Day 1				
n	1	16	9	26
Mean (StdDev)	0.00 (-)	-6.25 (25.000)	-22.22 (37.268)	-11.54 (29.728)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 0.0	-33.3, 66.7	-100.0, 0.0	-100.0, 66.7
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		-33.33 (33.333)	-8.33 (16.667)	-19.05 (26.227)
Median		-33.33	0.00	0.00
Min, Max		-66.7, 0.0	-33.3, 0.0	-66.7, 0.0
Change from Baseline to Cycle 7 Day 1				
n	1	17	5	23
Mean (StdDev)	-33.33 (-)	-13.73 (26.507)	-40.00 (43.461)	-20.29 (31.365)
Median	-33.33	0.00	-33.33	0.00
Min, Max	-33.3, -33.3	-66.7, 33.3	-100.0, 0.0	-100.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Constipation	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		-50.00 (23.570)	0.00 (0.000)	-25.00 (31.914)
Median		-50.00	0.00	-16.67
Min, Max		-66.7, -33.3	0.0, 0.0	-66.7, 0.0
Change from Baseline to Cycle 9 Day 1				
n	0	13	4	17
Mean (StdDev)		-23.08 (34.385)	-33.33 (47.140)	-25.49 (36.380)
Median		-33.33	-16.67	-33.33
Min, Max		-100.0, 33.3	-100.0, 0.0	-100.0, 33.3
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		-66.67 (-)	0.00 (0.000)	-22.22 (38.490)
Median		-66.67	0.00	0.00
Min, Max		-66.7, -66.7	0.0, 0.0	-66.7, 0.0
Change from Baseline to Cycle 11 Day 1				
n	0	8	3	11
Mean (StdDev)		-29.17 (21.362)	-33.33 (57.735)	-30.30 (31.463)
Median		-33.33	0.00	-33.33
Min, Max		-66.7, 0.0	-100.0, 0.0	-100.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Constipation	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		-33.33 (-)	0.00 (0.000)	-11.11 (19.245)
Median		-33.33	0.00	0.00
Min, Max		-33.3, -33.3	0.0, 0.0	-33.3, 0.0
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-22.22 (19.245)	-100.00 (-)	-41.67 (41.944)
Median		-33.33	-100.00	-33.33
Min, Max		-33.3, 0.0	-100.0, -100.0	-100.0, 0.0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Diarrhea	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Baseline				
n	4	29	12	45
Mean (StdDev)	25.00 (50.000)	40.23 (40.217)	50.00 (41.439)	41.48 (40.921)
Median	0.00	33.33	66.67	33.33
Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	11.11 (19.245)	-30.00 (32.264)	-14.29 (53.945)	-22.22 (38.490)
Median	0.00	-33.33	0.00	0.00
Min, Max	0.0, 33.3	-100.0, 0.0	-100.0, 33.3	-100.0, 33.3
Change from Baseline to Cycle 2 Day 1				
n	2	27	11	40
Mean (StdDev)	0.00 (0.000)	-23.46 (43.180)	-12.12 (37.335)	-19.17 (40.571)
Median	0.00	-33.33	0.00	0.00
Min, Max	0.0, 0.0	-100.0, 66.7	-66.7, 33.3	-100.0, 66.7
Change from Baseline to Cycle 3 Day 1				
n	3	26	9	38
Mean (StdDev)	0.00 (0.000)	-24.36 (42.748)	-7.41 (46.481)	-18.42 (42.233)
Median	0.00	-33.33	0.00	0.00
Min, Max	0.0, 0.0	-100.0, 66.7	-100.0, 66.7	-100.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Diarrhea	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		0.00 (60.858)	-33.33 (60.858)	-16.67 (59.094)
Median		0.00	-33.33	-16.67
Min, Max		-66.7, 66.7	-100.0, 33.3	-100.0, 66.7
Change from Baseline to Cycle 5 Day 1				
n	1	16	9	26
Mean (StdDev)	0.00 (-)	-22.92 (43.408)	-14.81 (50.308)	-19.23 (44.395)
Median	0.00	-33.33	0.00	-33.33
Min, Max	0.0, 0.0	-100.0, 66.7	-100.0, 66.7	-100.0, 66.7
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		-11.11 (101.835)	-25.00 (56.928)	-19.05 (71.640)
Median		-33.33	-16.67	-33.33
Min, Max		-100.0, 100.0	-100.0, 33.3	-100.0, 100.0
Change from Baseline to Cycle 7 Day 1				
n	1	17	5	23
Mean (StdDev)	33.33 (-)	-27.45 (39.503)	-20.00 (50.553)	-23.19 (41.965)
Median	33.33	-33.33	0.00	-33.33
Min, Max	33.3, 33.3	-100.0, 66.7	-100.0, 33.3	-100.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Diarrhea	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		-50.00 (23.570)	-66.67 (47.140)	-58.33 (31.914)
Median		-50.00	-66.67	-50.00
Min, Max		-66.7, -33.3	-100.0, -33.3	-100.0, -33.3
Change from Baseline to Cycle 9 Day 1				
n	0	13	4	17
Mean (StdDev)		-30.77 (41.859)	-8.33 (16.667)	-25.49 (38.242)
Median		-33.33	0.00	-33.33
Min, Max		-100.0, 66.7	-33.3, 0.0	-100.0, 66.7
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		-66.67 (-)	0.00 (0.000)	-22.22 (38.490)
Median		-66.67	0.00	0.00
Min, Max		-66.7, -66.7	0.0, 0.0	-66.7, 0.0
Change from Baseline to Cycle 11 Day 1				
n	0	8	3	11
Mean (StdDev)		-37.50 (27.817)	-22.22 (19.245)	-33.33 (25.820)
Median		-33.33	-33.33	-33.33
Min, Max		-66.7, 0.0	-33.3, 0.0	-66.7, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Diarrhea	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		-33.33 (-)	-33.33 (0.000)	-33.33 (0.000)
Median		-33.33	-33.33	-33.33
Min, Max		-33.3, -33.3	-33.3, -33.3	-33.3, -33.3
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-11.11 (19.245)	0.00 (-)	-8.33 (16.667)
Median		0.00	0.00	0.00
Min, Max		-33.3, 0.0	0.0, 0.0	-33.3, 0.0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Financial Difficulties	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Baseline				
n	4	29	12	45
Mean (StdDev)	41.67 (31.914)	24.14 (31.993)	36.11 (38.817)	28.89 (33.785)
Median	50.00	0.00	33.33	33.33
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	20	7	30
Mean (StdDev)	0.00 (33.333)	1.67 (25.305)	-19.05 (42.414)	-3.33 (30.763)
Median	0.00	0.00	0.00	0.00
Min, Max	-33.3, 33.3	-66.7, 33.3	-100.0, 33.3	-100.0, 33.3
Change from Baseline to Cycle 2 Day 1				
n	2	27	11	40
Mean (StdDev)	0.00 (0.000)	-2.47 (24.330)	-12.12 (26.968)	-5.00 (24.518)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 0.0	-66.7, 33.3	-66.7, 33.3	-66.7, 33.3
Change from Baseline to Cycle 3 Day 1				
n	3	26	9	38
Mean (StdDev)	11.11 (19.245)	-1.28 (25.787)	0.00 (23.570)	0.00 (24.507)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 33.3	-66.7, 33.3	-33.3, 33.3	-66.7, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Financial Difficulties	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		-8.33 (16.667)	-8.33 (16.667)	-8.33 (15.430)
Median		0.00	0.00	0.00
Min, Max		-33.3, 0.0	-33.3, 0.0	-33.3, 0.0
Change from Baseline to Cycle 5 Day 1				
n	1	16	9	26
Mean (StdDev)	-66.67 (-)	-8.33 (25.820)	7.41 (27.778)	-5.13 (29.352)
Median	-66.67	0.00	0.00	0.00
Min, Max	-66.7, -66.7	-66.7, 33.3	-33.3, 66.7	-66.7, 66.7
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		-11.11 (19.245)	-8.33 (31.914)	-9.52 (25.198)
Median		0.00	-16.67	0.00
Min, Max		-33.3, 0.0	-33.3, 33.3	-33.3, 33.3
Change from Baseline to Cycle 7 Day 1				
n	1	17	5	23
Mean (StdDev)	0.00 (-)	-3.92 (26.040)	0.00 (23.570)	-2.90 (24.439)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 0.0	-66.7, 33.3	-33.3, 33.3	-66.7, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Financial Difficulties	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	33.33 (47.140)	16.67 (33.333)
Median		0.00	33.33	0.00
Min, Max		0.0, 0.0	0.0, 66.7	0.0, 66.7
Change from Baseline to Cycle 9 Day 1				
n	0	13	4	17
Mean (StdDev)		10.26 (25.036)	16.67 (33.333)	11.76 (26.197)
Median		0.00	0.00	0.00
Min, Max		-33.3, 66.7	0.0, 66.7	-33.3, 66.7
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		-33.33 (-)	33.33 (47.140)	11.11 (50.918)
Median		-33.33	33.33	0.00
Min, Max		-33.3, -33.3	0.0, 66.7	-33.3, 66.7
Change from Baseline to Cycle 11 Day 1				
n	0	8	3	11
Mean (StdDev)		12.50 (30.538)	22.22 (38.490)	15.15 (31.140)
Median		0.00	0.00	0.00
Min, Max		-33.3, 66.7	0.0, 66.7	-33.3, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

Financial Difficulties	ASM (N=6)	SM-AHN (N=33)	MCL (N=13)	All AdvSM (N=52)
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	16.67 (23.570)	11.11 (19.245)
Median		0.00	16.67	0.00
Min, Max		0.0, 0.0	0.0, 33.3	0.0, 33.3
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-11.11 (19.245)	0.00 (-)	-8.33 (16.667)
Median		0.00	0.00	0.00
Min, Max		-33.3, 0.0	0.0, 0.0	-33.3, 0.0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		-33.33 (-)		-33.33 (-)
Median		-33.33		-33.33
Min, Max		-33.3, -33.3		-33.3, -33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Global Health Status/QoL	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Baseline				
n	4	28	12	44
Mean (StdDev)	50.00 (20.412)	36.61 (27.343)	36.81 (14.847)	37.88 (23.873)
Median	45.83	33.33	33.33	33.33
Min, Max	33.3, 75.0	0.0, 100.0	16.7, 58.3	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	19	7	29
Mean (StdDev)	2.78 (9.623)	18.42 (26.582)	11.90 (24.934)	15.23 (24.907)
Median	8.33	16.67	0.00	8.33
Min, Max	-8.3, 8.3	-25.0, 83.3	-8.3, 50.0	-25.0, 83.3
Change from Baseline to Cycle 2 Day 1				
n	2	26	11	39
Mean (StdDev)	0.00 (11.785)	21.47 (31.285)	16.67 (26.352)	19.02 (29.242)
Median	0.00	12.50	16.67	16.67
Min, Max	-8.3, 8.3	-25.0, 91.7	-33.3, 58.3	-33.3, 91.7
Change from Baseline to Cycle 3 Day 1				
n	3	25	9	37
Mean (StdDev)	5.56 (26.788)	23.67 (33.993)	11.11 (18.634)	19.14 (30.547)
Median	16.67	16.67	0.00	16.67
Min, Max	-25.0, 25.0	-66.7, 83.3	-8.3, 41.7	-66.7, 83.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Global Health Status/QoL	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		18.75 (51.088)	18.75 (31.458)	18.75 (39.277)
Median		20.83	29.17	29.17
Min, Max		-33.3, 66.7	-25.0, 41.7	-33.3, 66.7
Change from Baseline to Cycle 5 Day 1				
n	1	15	9	25
Mean (StdDev)	16.67 (-)	22.78 (43.240)	14.81 (20.741)	19.67 (35.346)
Median	16.67	25.00	16.67	16.67
Min, Max	16.7, 16.7	-100.0, 83.3	-25.0, 41.7	-100.0, 83.3
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		33.33 (50.690)	22.92 (23.936)	27.38 (34.263)
Median		58.33	29.17	41.67
Min, Max		-25.0, 66.7	-8.3, 41.7	-25.0, 66.7
Change from Baseline to Cycle 7 Day 1				
n	1	16	5	22
Mean (StdDev)	-16.67 (-)	32.29 (37.003)	10.00 (19.896)	25.00 (35.074)
Median	-16.67	33.33	0.00	33.33
Min, Max	-16.7, -16.7	-33.3, 83.3	-8.3, 41.7	-33.3, 83.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Global Health Status/QoL	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		62.50 (5.893)	0.00 (23.570)	31.25 (38.715)
Median		62.50	0.00	37.50
Min, Max		58.3, 66.7	-16.7, 16.7	-16.7, 66.7
Change from Baseline to Cycle 9 Day 1				
n	0	12	4	16
Mean (StdDev)		27.08 (37.960)	4.17 (15.957)	21.35 (34.823)
Median		37.50	8.33	16.67
Min, Max		-58.3, 83.3	-16.7, 16.7	-58.3, 83.3
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		58.33 (-)	0.00 (23.570)	19.44 (37.577)
Median		58.33	0.00	16.67
Min, Max		58.3, 58.3	-16.7, 16.7	-16.7, 58.3
Change from Baseline to Cycle 11 Day 1				
n	0	7	3	10
Mean (StdDev)		33.33 (32.275)	2.78 (20.972)	24.17 (31.781)
Median		50.00	0.00	33.33
Min, Max		-33.3, 58.3	-16.7, 25.0	-33.3, 58.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Global Health Status/QoL	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		58.33 (-)	8.33 (35.355)	25.00 (38.188)
Median		58.33	8.33	33.33
Min, Max		58.3, 58.3	-16.7, 33.3	-16.7, 58.3
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		30.56 (64.729)	41.67 (-)	33.33 (53.142)
Median		50.00	41.67	45.83
Min, Max		-41.7, 83.3	41.7, 41.7	-41.7, 83.3
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		-33.33 (-)		-33.33 (-)
Median		-33.33		-33.33
Min, Max		-33.3, -33.3		-33.3, -33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Physical Functioning	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Baseline				
n	4	28	12	44
Mean (StdDev)	68.33 (32.375)	50.95 (28.986)	63.33 (24.205)	55.91 (28.219)
Median	83.33	46.67	63.33	56.67
Min, Max	20.0, 86.7	0.0, 100.0	26.7, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	19	7	29
Mean (StdDev)	2.22 (3.849)	11.58 (18.438)	15.24 (22.678)	11.49 (18.508)
Median	0.00	6.67	13.33	6.67
Min, Max	0.0, 6.7	-13.3, 53.3	-20.0, 46.7	-20.0, 53.3
Change from Baseline to Cycle 2 Day 1				
n	2	26	11	39
Mean (StdDev)	0.00 (0.000)	16.41 (22.957)	9.70 (19.633)	13.68 (21.627)
Median	0.00	6.67	6.67	6.67
Min, Max	0.0, 0.0	-6.7, 73.3	-20.0, 46.7	-20.0, 73.3
Change from Baseline to Cycle 3 Day 1				
n	3	25	9	37
Mean (StdDev)	-8.89 (3.849)	16.53 (23.580)	8.15 (16.592)	12.43 (22.064)
Median	-6.67	13.33	6.67	6.67
Min, Max	-13.3, -6.7	-20.0, 73.3	-13.3, 40.0	-20.0, 73.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Physical Functioning	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		25.00 (27.420)	16.67 (22.771)	20.83 (23.755)
Median		20.00	13.33	13.33
Min, Max		0.0, 60.0	-6.7, 46.7	-6.7, 60.0
Change from Baseline to Cycle 5 Day 1				
n	1	15	9	25
Mean (StdDev)	26.67 (-)	25.33 (25.348)	3.70 (20.846)	17.60 (25.157)
Median	26.67	26.67	13.33	13.33
Min, Max	26.7, 26.7	-13.3, 73.3	-26.7, 33.3	-26.7, 73.3
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		20.00 (29.059)	1.67 (15.753)	9.52 (22.396)
Median		33.33	6.67	13.33
Min, Max		-13.3, 40.0	-20.0, 13.3	-20.0, 40.0
Change from Baseline to Cycle 7 Day 1				
n	1	16	5	22
Mean (StdDev)	-40.00 (-)	21.67 (25.934)	6.67 (22.608)	15.45 (27.785)
Median	-40.00	10.00	6.67	6.67
Min, Max	-40.0, -40.0	-20.0, 66.7	-20.0, 40.0	-40.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Physical Functioning	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		43.33 (14.142)	0.00 (18.856)	21.67 (28.480)
Median		43.33	0.00	23.33
Min, Max		33.3, 53.3	-13.3, 13.3	-13.3, 53.3
Change from Baseline to Cycle 9 Day 1				
n	0	12	4	16
Mean (StdDev)		26.67 (24.454)	10.00 (19.245)	22.50 (23.836)
Median		20.00	10.00	13.33
Min, Max		0.0, 66.7	-13.3, 33.3	-13.3, 66.7
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		46.67 (-)	0.00 (18.856)	15.56 (30.062)
Median		46.67	0.00	13.33
Min, Max		46.7, 46.7	-13.3, 13.3	-13.3, 46.7
Change from Baseline to Cycle 11 Day 1				
n	0	7	3	10
Mean (StdDev)		34.29 (23.860)	17.78 (40.185)	29.33 (28.319)
Median		33.33	13.33	30.00
Min, Max		-6.7, 60.0	-20.0, 60.0	-20.0, 60.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Physical Functioning	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		46.67 (-)	-3.33 (23.570)	13.33 (33.333)
Median		46.67	-3.33	13.33
Min, Max		46.7, 46.7	-20.0, 13.3	-20.0, 46.7
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		35.56 (33.555)	60.00 (-)	41.67 (30.000)
Median		40.00	60.00	50.00
Min, Max		0.0, 66.7	60.0, 60.0	0.0, 66.7
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Role Functioning	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Baseline				
n	4	28	12	44
Mean (StdDev)	45.83 (36.956)	43.45 (35.526)	29.17 (29.409)	39.77 (33.951)
Median	50.00	50.00	25.00	41.67
Min, Max	0.0, 83.3	0.0, 100.0	0.0, 66.7	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	19	7	29
Mean (StdDev)	-5.56 (9.623)	12.28 (19.118)	23.81 (21.207)	13.22 (20.108)
Median	0.00	0.00	16.67	0.00
Min, Max	-16.7, 0.0	-16.7, 50.0	0.0, 66.7	-16.7, 66.7
Change from Baseline to Cycle 2 Day 1				
n	2	26	11	39
Mean (StdDev)	-16.67 (23.570)	16.67 (28.674)	24.24 (35.248)	17.09 (30.942)
Median	-16.67	16.67	33.33	16.67
Min, Max	-33.3, 0.0	-16.7, 100.0	-33.3, 83.3	-33.3, 100.0
Change from Baseline to Cycle 3 Day 1				
n	3	25	9	37
Mean (StdDev)	-11.11 (9.623)	14.67 (29.783)	20.37 (32.035)	13.96 (29.792)
Median	-16.67	0.00	33.33	0.00
Min, Max	-16.7, 0.0	-33.3, 66.7	-33.3, 66.7	-33.3, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Role Functioning	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		0.00 (30.429)	41.67 (56.928)	20.83 (47.768)
Median		0.00	50.00	25.00
Min, Max		-33.3, 33.3	-33.3, 100.0	-33.3, 100.0
Change from Baseline to Cycle 5 Day 1				
n	1	15	9	25
Mean (StdDev)	0.00 (-)	17.78 (41.051)	16.67 (22.048)	16.67 (34.021)
Median	0.00	16.67	16.67	16.67
Min, Max	0.0, 0.0	-66.7, 83.3	-16.7, 50.0	-66.7, 83.3
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		-5.56 (25.459)	25.00 (31.914)	11.90 (31.497)
Median		0.00	16.67	0.00
Min, Max		-33.3, 16.7	0.0, 66.7	-33.3, 66.7
Change from Baseline to Cycle 7 Day 1				
n	1	16	5	22
Mean (StdDev)	-33.33 (-)	20.83 (37.268)	20.00 (13.944)	18.18 (34.082)
Median	-33.33	16.67	16.67	16.67
Min, Max	-33.3, -33.3	-33.3, 83.3	0.0, 33.3	-33.3, 83.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Role Functioning	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		25.00 (11.785)	16.67 (23.570)	20.83 (15.957)
Median		25.00	16.67	25.00
Min, Max		16.7, 33.3	0.0, 33.3	0.0, 33.3
Change from Baseline to Cycle 9 Day 1				
n	0	12	4	16
Mean (StdDev)		25.00 (30.567)	20.83 (15.957)	23.96 (27.195)
Median		25.00	25.00	25.00
Min, Max		-33.3, 66.7	0.0, 33.3	-33.3, 66.7
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		16.67 (-)	16.67 (23.570)	16.67 (16.667)
Median		16.67	16.67	16.67
Min, Max		16.7, 16.7	0.0, 33.3	0.0, 33.3
Change from Baseline to Cycle 11 Day 1				
n	0	7	3	10
Mean (StdDev)		30.95 (24.398)	44.44 (50.918)	35.00 (31.866)
Median		16.67	33.33	25.00
Min, Max		0.0, 66.7	0.0, 100.0	0.0, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Role Functioning	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		16.67 (-)	16.67 (23.570)	16.67 (16.667)
Median		16.67	16.67	16.67
Min, Max		16.7, 16.7	0.0, 33.3	0.0, 33.3
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		44.44 (38.490)	66.67 (-)	50.00 (33.333)
Median		66.67	66.67	66.67
Min, Max		0.0, 66.7	66.7, 66.7	0.0, 66.7
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Emotional Functioning	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Baseline				
n	4	28	12	44
Mean (StdDev)	77.08 (29.950)	61.01 (27.690)	61.11 (25.706)	62.50 (27.108)
Median	87.50	58.33	66.67	62.50
Min, Max	33.3, 100.0	8.3, 100.0	8.3, 100.0	8.3, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	19	7	29
Mean (StdDev)	0.00 (8.333)	10.09 (18.126)	1.19 (16.265)	6.90 (17.117)
Median	0.00	8.33	0.00	8.33
Min, Max	-8.3, 8.3	-25.0, 58.3	-25.0, 16.7	-25.0, 58.3
Change from Baseline to Cycle 2 Day 1				
n	2	26	11	39
Mean (StdDev)	-12.50 (5.893)	14.10 (26.222)	12.12 (13.104)	12.18 (23.088)
Median	-12.50	12.50	16.67	8.33
Min, Max	-16.7, -8.3	-25.0, 58.3	-8.3, 33.3	-25.0, 58.3
Change from Baseline to Cycle 3 Day 1				
n	3	25	9	37
Mean (StdDev)	-8.33 (25.000)	13.78 (24.813)	4.63 (13.889)	9.76 (23.089)
Median	-8.33	16.67	0.00	8.33
Min, Max	-33.3, 16.7	-33.3, 58.3	-8.3, 33.3	-33.3, 58.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Emotional Functioning	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		25.00 (24.533)	8.33 (20.412)	16.67 (22.713)
Median		20.83	8.33	12.50
Min, Max		0.0, 58.3	-16.7, 33.3	-16.7, 58.3
Change from Baseline to Cycle 5 Day 1				
n	1	15	9	25
Mean (StdDev)	16.67 (-)	21.11 (30.839)	-0.93 (14.699)	13.00 (27.225)
Median	16.67	25.00	0.00	8.33
Min, Max	16.7, 16.7	-33.3, 66.7	-25.0, 25.0	-33.3, 66.7
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		25.00 (50.000)	-2.08 (24.884)	9.52 (36.777)
Median		25.00	0.00	8.33
Min, Max		-25.0, 75.0	-33.3, 25.0	-33.3, 75.0
Change from Baseline to Cycle 7 Day 1				
n	1	16	5	22
Mean (StdDev)	0.00 (-)	19.27 (26.478)	-16.67 (28.260)	10.23 (29.873)
Median	0.00	25.00	-8.33	8.33
Min, Max	0.0, 0.0	-25.0, 66.7	-66.7, 0.0	-66.7, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Emotional Functioning	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		37.50 (17.678)	-37.50 (17.678)	0.00 (45.644)
Median		37.50	-37.50	0.00
Min, Max		25.0, 50.0	-50.0, -25.0	-50.0, 50.0
Change from Baseline to Cycle 9 Day 1				
n	0	12	4	16
Mean (StdDev)		18.75 (21.651)	-25.00 (24.533)	7.81 (29.102)
Median		20.83	-25.00	8.33
Min, Max		-16.7, 50.0	-50.0, 0.0	-50.0, 50.0
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		66.67 (-)	-45.83 (5.893)	-8.33 (65.085)
Median		66.67	-45.83	-41.67
Min, Max		66.7, 66.7	-50.0, -41.7	-50.0, 66.7
Change from Baseline to Cycle 11 Day 1				
n	0	7	3	10
Mean (StdDev)		25.00 (29.659)	-16.67 (36.324)	12.50 (35.843)
Median		25.00	-33.33	16.67
Min, Max		-16.7, 66.7	-41.7, 25.0	-41.7, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Emotional Functioning	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		25.00 (-)	-54.17 (41.248)	-27.78 (54.220)
Median		25.00	-54.17	-25.00
Min, Max		25.0, 25.0	-83.3, -25.0	-83.3, 25.0
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		30.56 (33.679)	25.00 (-)	29.17 (27.639)
Median		25.00	25.00	25.00
Min, Max		0.0, 66.7	25.0, 25.0	0.0, 66.7
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Cognitive Functioning	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Baseline				
n	4	28	12	44
Mean (StdDev)	79.17 (15.957)	73.21 (21.914)	65.28 (27.941)	71.59 (23.178)
Median	75.00	75.00	58.33	66.67
Min, Max	66.7, 100.0	33.3, 100.0	16.7, 100.0	16.7, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	19	7	29
Mean (StdDev)	-5.56 (9.623)	3.51 (13.122)	-4.76 (8.133)	0.57 (12.185)
Median	0.00	0.00	0.00	0.00
Min, Max	-16.7, 0.0	-16.7, 33.3	-16.7, 0.0	-16.7, 33.3
Change from Baseline to Cycle 2 Day 1				
n	2	26	11	39
Mean (StdDev)	0.00 (0.000)	3.85 (20.714)	6.06 (21.438)	4.27 (20.130)
Median	0.00	0.00	16.67	0.00
Min, Max	0.0, 0.0	-33.3, 50.0	-33.3, 33.3	-33.3, 50.0
Change from Baseline to Cycle 3 Day 1				
n	3	25	9	37
Mean (StdDev)	11.11 (9.623)	4.67 (21.257)	9.26 (20.601)	6.31 (20.166)
Median	16.67	0.00	16.67	0.00
Min, Max	0.0, 16.7	-33.3, 50.0	-33.3, 33.3	-33.3, 50.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Cognitive Functioning	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		8.33 (28.868)	8.33 (9.623)	8.33 (19.920)
Median		0.00	8.33	0.00
Min, Max		-16.7, 50.0	0.0, 16.7	-16.7, 50.0
Change from Baseline to Cycle 5 Day 1				
n	1	15	9	25
Mean (StdDev)	-16.67 (-)	3.33 (22.003)	-5.56 (16.667)	-0.67 (20.115)
Median	-16.67	0.00	0.00	0.00
Min, Max	-16.7, -16.7	-50.0, 33.3	-33.3, 16.7	-50.0, 33.3
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		16.67 (28.868)	12.50 (8.333)	14.29 (17.817)
Median		0.00	16.67	16.67
Min, Max		0.0, 50.0	0.0, 16.7	0.0, 50.0
Change from Baseline to Cycle 7 Day 1				
n	1	16	5	22
Mean (StdDev)	16.67 (-)	5.21 (25.617)	-6.67 (19.003)	3.03 (23.925)
Median	16.67	0.00	0.00	0.00
Min, Max	16.7, 16.7	-33.3, 50.0	-33.3, 16.7	-33.3, 50.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Cognitive Functioning	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		25.00 (35.355)	-8.33 (11.785)	8.33 (28.868)
Median		25.00	-8.33	0.00
Min, Max		0.0, 50.0	-16.7, 0.0	-16.7, 50.0
Change from Baseline to Cycle 9 Day 1				
n	0	12	4	16
Mean (StdDev)		0.00 (27.524)	-12.50 (8.333)	-3.13 (24.509)
Median		-8.33	-16.67	-16.67
Min, Max		-33.3, 50.0	-16.7, 0.0	-33.3, 50.0
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		50.00 (-)	-25.00 (35.355)	0.00 (50.000)
Median		50.00	-25.00	0.00
Min, Max		50.0, 50.0	-50.0, 0.0	-50.0, 50.0
Change from Baseline to Cycle 11 Day 1				
n	0	7	3	10
Mean (StdDev)		4.76 (15.853)	-5.56 (25.459)	1.67 (18.342)
Median		0.00	0.00	0.00
Min, Max		-16.7, 33.3	-33.3, 16.7	-33.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Cognitive Functioning	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	-33.33 (47.140)	-22.22 (38.490)
Median		0.00	-33.33	0.00
Min, Max		0.0, 0.0	-66.7, 0.0	-66.7, 0.0
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		5.56 (9.623)	16.67 (-)	8.33 (9.623)
Median		0.00	16.67	8.33
Min, Max		0.0, 16.7	16.7, 16.7	0.0, 16.7
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		-16.67 (-)		-16.67 (-)
Median		-16.67		-16.67
Min, Max		-16.7, -16.7		-16.7, -16.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Social Function	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Baseline				
n	4	28	12	44
Mean (StdDev)	50.00 (36.004)	51.19 (33.619)	50.00 (32.567)	50.76 (32.738)
Median	41.67	33.33	66.67	41.67
Min, Max	16.7, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	19	7	29
Mean (StdDev)	0.00 (16.667)	15.79 (25.138)	19.05 (29.547)	14.94 (25.333)
Median	0.00	16.67	16.67	16.67
Min, Max	-16.7, 16.7	-16.7, 66.7	-16.7, 66.7	-16.7, 66.7
Change from Baseline to Cycle 2 Day 1				
n	2	26	11	39
Mean (StdDev)	-8.33 (11.785)	17.31 (35.740)	16.67 (34.157)	15.81 (34.401)
Median	-8.33	16.67	16.67	16.67
Min, Max	-16.7, 0.0	-33.3, 100.0	-33.3, 83.3	-33.3, 100.0
Change from Baseline to Cycle 3 Day 1				
n	3	25	9	37
Mean (StdDev)	-11.11 (25.459)	10.67 (25.856)	7.41 (30.174)	8.11 (26.823)
Median	-16.67	0.00	0.00	0.00
Min, Max	-33.3, 16.7	-16.7, 83.3	-50.0, 50.0	-50.0, 83.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Social Function	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		16.67 (30.429)	8.33 (16.667)	12.50 (23.146)
Median		16.67	0.00	0.00
Min, Max		-16.7, 50.0	0.0, 33.3	-16.7, 50.0
Change from Baseline to Cycle 5 Day 1				
n	1	15	9	25
Mean (StdDev)	16.67 (-)	24.44 (32.652)	0.00 (20.412)	15.33 (30.015)
Median	16.67	33.33	0.00	16.67
Min, Max	16.7, 16.7	-50.0, 66.7	-16.7, 33.3	-50.0, 66.7
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		22.22 (50.918)	0.00 (49.065)	9.52 (47.000)
Median		33.33	-8.33	0.00
Min, Max		-33.3, 66.7	-50.0, 66.7	-50.0, 66.7
Change from Baseline to Cycle 7 Day 1				
n	1	16	5	22
Mean (StdDev)	33.33 (-)	28.13 (32.041)	-3.33 (24.721)	21.21 (32.196)
Median	33.33	33.33	0.00	33.33
Min, Max	33.3, 33.3	-33.3, 66.7	-33.3, 33.3	-33.3, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Social Function	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		41.67 (11.785)	-33.33 (47.140)	4.17 (51.595)
Median		41.67	-33.33	16.67
Min, Max		33.3, 50.0	-66.7, 0.0	-66.7, 50.0
Change from Baseline to Cycle 9 Day 1				
n	0	12	4	16
Mean (StdDev)		29.17 (29.409)	-4.17 (41.667)	20.83 (34.694)
Median		33.33	16.67	25.00
Min, Max		-33.3, 66.7	-66.7, 16.7	-66.7, 66.7
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		66.67 (-)	-50.00 (70.711)	-11.11 (83.887)
Median		66.67	-50.00	0.00
Min, Max		66.7, 66.7	-100.0, 0.0	-100.0, 66.7
Change from Baseline to Cycle 11 Day 1				
n	0	7	3	10
Mean (StdDev)		30.95 (24.398)	11.11 (91.793)	25.00 (48.591)
Median		33.33	16.67	33.33
Min, Max		0.0, 66.7	-83.3, 100.0	-83.3, 100.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Social Function	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		33.33 (-)	-41.67 (58.926)	-16.67 (60.093)
Median		33.33	-41.67	0.00
Min, Max		33.3, 33.3	-83.3, 0.0	-83.3, 33.3
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		44.44 (53.576)	100.00 (-)	58.33 (51.819)
Median		66.67	100.00	75.00
Min, Max		-16.7, 83.3	100.0, 100.0	-16.7, 100.0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg				
Fatigue	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Baseline				
n	4	28	12	44
Mean (StdDev)	61.11 (29.397)	69.05 (32.620)	72.22 (28.229)	69.19 (30.675)
Median	55.56	77.78	77.78	72.22
Min, Max	33.3, 100.0	0.0, 100.0	22.2, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	19	7	29
Mean (StdDev)	3.70 (6.415)	-19.30 (23.378)	-19.05 (27.751)	-16.86 (23.871)
Median	0.00	-11.11	-22.22	-11.11
Min, Max	0.0, 11.1	-55.6, 11.1	-55.6, 22.2	-55.6, 22.2
Change from Baseline to Cycle 2 Day 1				
n	2	26	11	39
Mean (StdDev)	5.56 (7.857)	-20.09 (28.462)	-19.19 (25.863)	-18.52 (27.256)
Median	5.56	-16.67	-22.22	-11.11
Min, Max	0.0, 11.1	-77.8, 33.3	-66.7, 11.1	-77.8, 33.3
Change from Baseline to Cycle 3 Day 1				
n	3	25	9	37
Mean (StdDev)	14.81 (12.830)	-15.56 (28.509)	-13.58 (22.067)	-12.61 (26.984)
Median	22.22	-11.11	-11.11	-11.11
Min, Max	0.0, 22.2	-77.8, 44.4	-55.6, 11.1	-77.8, 44.4

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Fatigue	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		-2.78 (29.222)	-30.56 (43.862)	-16.67 (37.562)
Median		0.00	-38.89	-16.67
Min, Max		-33.3, 22.2	-66.7, 22.2	-66.7, 22.2
Change from Baseline to Cycle 5 Day 1				
n	1	15	9	25
Mean (StdDev)	-11.11 (-)	-25.93 (41.076)	-18.52 (21.517)	-22.67 (34.018)
Median	-11.11	-33.33	-11.11	-22.22
Min, Max	-11.1, -11.1	-77.8, 66.7	-66.7, 0.0	-77.8, 66.7
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		-11.11 (48.432)	-13.89 (29.222)	-12.70 (34.800)
Median		-33.33	-5.56	-11.11
Min, Max		-44.4, 44.4	-55.6, 11.1	-55.6, 44.4
Change from Baseline to Cycle 7 Day 1				
n	1	16	5	22
Mean (StdDev)	0.00 (-)	-34.72 (32.426)	-4.44 (12.669)	-26.26 (31.342)
Median	0.00	-38.89	0.00	-16.67
Min, Max	0.0, 0.0	-88.9, 22.2	-22.2, 11.1	-88.9, 22.2

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Fatigue	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		-50.00 (7.857)	0.00 (0.000)	-25.00 (29.222)
Median		-50.00	0.00	-22.22
Min, Max		-55.6, -44.4	0.0, 0.0	-55.6, 0.0
Change from Baseline to Cycle 9 Day 1				
n	0	12	4	16
Mean (StdDev)		-38.89 (26.165)	-8.33 (16.667)	-31.25 (27.283)
Median		-38.89	-11.11	-33.33
Min, Max		-77.8, 11.1	-22.2, 11.1	-77.8, 11.1
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		-55.56 (-)	-5.56 (7.857)	-22.22 (29.397)
Median		-55.56	-5.56	-11.11
Min, Max		-55.6, -55.6	-11.1, 0.0	-55.6, 0.0
Change from Baseline to Cycle 11 Day 1				
n	0	7	3	10
Mean (StdDev)		-41.27 (34.969)	-25.93 (44.905)	-36.67 (36.308)
Median		-55.56	0.00	-50.00
Min, Max		-66.7, 33.3	-77.8, 0.0	-77.8, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Fatigue	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		-66.67 (-)	-5.56 (7.857)	-25.93 (35.717)
Median		-66.67	-5.56	-11.11
Min, Max		-66.7, -66.7	-11.1, 0.0	-66.7, 0.0
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-40.74 (57.018)	-66.67 (-)	-47.22 (48.326)
Median		-55.56	-66.67	-61.11
Min, Max		-88.9, 22.2	-66.7, -66.7	-88.9, 22.2
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		33.33 (-)		33.33 (-)
Median		33.33		33.33
Min, Max		33.3, 33.3		33.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Nausea and Vomiting	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Baseline				
n	4	28	12	44
Mean (StdDev)	33.33 (38.490)	20.83 (30.302)	13.89 (19.890)	20.08 (28.435)
Median	33.33	8.33	0.00	0.00
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 50.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	19	7	29
Mean (StdDev)	5.56 (9.623)	-12.28 (20.669)	-7.14 (23.288)	-9.20 (20.695)
Median	0.00	-16.67	0.00	0.00
Min, Max	0.0, 16.7	-66.7, 33.3	-50.0, 16.7	-66.7, 33.3
Change from Baseline to Cycle 2 Day 1				
n	2	26	11	39
Mean (StdDev)	0.00 (0.000)	-8.33 (29.155)	-4.55 (19.848)	-6.84 (25.853)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 0.0	-100.0, 33.3	-50.0, 16.7	-100.0, 33.3
Change from Baseline to Cycle 3 Day 1				
n	3	25	9	37
Mean (StdDev)	-5.56 (25.459)	-10.00 (34.021)	-3.70 (18.215)	-8.11 (29.820)
Median	0.00	0.00	0.00	0.00
Min, Max	-33.3, 16.7	-100.0, 50.0	-50.0, 16.7	-100.0, 50.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Nausea and Vomiting	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		8.33 (31.914)	-4.17 (15.957)	2.08 (24.296)
Median		16.67	-8.33	0.00
Min, Max		-33.3, 33.3	-16.7, 16.7	-33.3, 33.3
Change from Baseline to Cycle 5 Day 1				
n	1	15	9	25
Mean (StdDev)	0.00 (-)	-16.67 (27.458)	-3.70 (20.031)	-11.33 (24.870)
Median	0.00	-16.67	0.00	0.00
Min, Max	0.0, 0.0	-66.7, 33.3	-50.0, 16.7	-66.7, 33.3
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		-11.11 (34.694)	-4.17 (15.957)	-7.14 (23.288)
Median		0.00	-8.33	0.00
Min, Max		-50.0, 16.7	-16.7, 16.7	-50.0, 16.7
Change from Baseline to Cycle 7 Day 1				
n	1	16	5	22
Mean (StdDev)	-50.00 (-)	-21.88 (26.330)	3.33 (13.944)	-17.42 (26.466)
Median	-50.00	-16.67	0.00	-8.33
Min, Max	-50.0, -50.0	-83.3, 0.0	-16.7, 16.7	-83.3, 16.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Nausea and Vomiting	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		-16.67 (23.570)	-8.33 (11.785)	-12.50 (15.957)
Median		-16.67	-8.33	-8.33
Min, Max		-33.3, 0.0	-16.7, 0.0	-33.3, 0.0
Change from Baseline to Cycle 9 Day 1				
n	0	12	4	16
Mean (StdDev)		-16.67 (24.618)	-4.17 (8.333)	-13.54 (22.127)
Median		-8.33	0.00	0.00
Min, Max		-66.7, 16.7	-16.7, 0.0	-66.7, 16.7
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		-33.33 (-)	-8.33 (11.785)	-16.67 (16.667)
Median		-33.33	-8.33	-16.67
Min, Max		-33.3, -33.3	-16.7, 0.0	-33.3, 0.0
Change from Baseline to Cycle 11 Day 1				
n	0	7	3	10
Mean (StdDev)		-14.29 (26.227)	-11.11 (9.623)	-13.33 (21.943)
Median		0.00	-16.67	-8.33
Min, Max		-50.0, 16.7	-16.7, 0.0	-50.0, 16.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Nausea and Vomiting	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	-8.33 (11.785)	-5.56 (9.623)
Median		0.00	-8.33	0.00
Min, Max		0.0, 0.0	-16.7, 0.0	-16.7, 0.0
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		5.56 (25.459)	0.00 (-)	4.17 (20.972)
Median		0.00	0.00	0.00
Min, Max		-16.7, 33.3	0.0, 0.0	-16.7, 33.3
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Pain	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Baseline				
n	4	28	12	44
Mean (StdDev)	50.00 (30.429)	38.10 (35.387)	52.78 (32.437)	43.18 (34.160)
Median	50.00	33.33	50.00	33.33
Min, Max	16.7, 83.3	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	19	7	29
Mean (StdDev)	0.00 (0.000)	-21.93 (32.892)	-19.05 (26.227)	-18.97 (29.789)
Median	0.00	0.00	-16.67	0.00
Min, Max	0.0, 0.0	-83.3, 33.3	-50.0, 16.7	-83.3, 33.3
Change from Baseline to Cycle 2 Day 1				
n	2	26	11	39
Mean (StdDev)	0.00 (0.000)	-20.51 (29.177)	-30.30 (29.644)	-22.22 (28.952)
Median	0.00	0.00	-33.33	0.00
Min, Max	0.0, 0.0	-100.0, 16.7	-83.3, 0.0	-100.0, 16.7
Change from Baseline to Cycle 3 Day 1				
n	3	25	9	37
Mean (StdDev)	0.00 (16.667)	-17.33 (34.854)	-29.63 (27.358)	-18.92 (32.433)
Median	0.00	0.00	-33.33	-16.67
Min, Max	-16.7, 16.7	-100.0, 33.3	-66.7, 0.0	-100.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Pain	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		-12.50 (15.957)	-25.00 (56.928)	-18.75 (39.277)
Median		-8.33	-33.33	-16.67
Min, Max		-33.3, 0.0	-83.3, 50.0	-83.3, 50.0
Change from Baseline to Cycle 5 Day 1				
n	1	15	9	25
Mean (StdDev)	16.67 (-)	-13.33 (33.452)	-27.78 (42.492)	-17.33 (36.793)
Median	16.67	-16.67	-16.67	-16.67
Min, Max	16.7, 16.7	-83.3, 66.7	-100.0, 33.3	-100.0, 66.7
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		-22.22 (19.245)	-20.83 (41.667)	-21.43 (31.497)
Median		-33.33	0.00	0.00
Min, Max		-33.3, 0.0	-83.3, 0.0	-83.3, 0.0
Change from Baseline to Cycle 7 Day 1				
n	1	16	5	22
Mean (StdDev)	0.00 (-)	-15.63 (38.715)	-20.00 (27.386)	-15.91 (35.065)
Median	0.00	-16.67	-16.67	-16.67
Min, Max	0.0, 0.0	-83.3, 83.3	-66.7, 0.0	-83.3, 83.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Pain	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		-25.00 (11.785)	8.33 (35.355)	-8.33 (28.868)
Median		-25.00	8.33	-16.67
Min, Max		-33.3, -16.7	-16.7, 33.3	-33.3, 33.3
Change from Baseline to Cycle 9 Day 1				
n	0	12	4	16
Mean (StdDev)		-13.89 (29.158)	-8.33 (44.096)	-12.50 (31.914)
Median		0.00	0.00	0.00
Min, Max		-66.7, 33.3	-66.7, 33.3	-66.7, 33.3
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		-16.67 (-)	8.33 (35.355)	0.00 (28.868)
Median		-16.67	8.33	-16.67
Min, Max		-16.7, -16.7	-16.7, 33.3	-16.7, 33.3
Change from Baseline to Cycle 11 Day 1				
n	0	7	3	10
Mean (StdDev)		-21.43 (24.934)	-22.22 (58.531)	-21.67 (34.292)
Median		-16.67	-16.67	-16.67
Min, Max		-66.7, 0.0	-83.3, 33.3	-83.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Pain	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		-33.33 (-)	0.00 (47.140)	-11.11 (38.490)
Median		-33.33	0.00	-33.33
Min, Max		-33.3, -33.3	-33.3, 33.3	-33.3, 33.3
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-11.11 (19.245)	-83.33 (-)	-29.17 (39.382)
Median		0.00	-83.33	-16.67
Min, Max		-33.3, 0.0	-83.3, -83.3	-83.3, 0.0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Dyspnea	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Baseline				
n	4	28	12	44
Mean (StdDev)	16.67 (19.245)	51.19 (34.525)	52.78 (36.121)	48.48 (34.816)
Median	16.67	33.33	50.00	33.33
Min, Max	0.0, 33.3	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	19	7	29
Mean (StdDev)	-11.11 (19.245)	-24.56 (36.586)	-23.81 (25.198)	-22.99 (32.248)
Median	0.00	-33.33	-33.33	-33.33
Min, Max	-33.3, 0.0	-100.0, 33.3	-66.7, 0.0	-100.0, 33.3
Change from Baseline to Cycle 2 Day 1				
n	2	26	11	39
Mean (StdDev)	0.00 (0.000)	-24.36 (34.715)	-18.18 (22.918)	-21.37 (31.051)
Median	0.00	-33.33	0.00	0.00
Min, Max	0.0, 0.0	-100.0, 33.3	-66.7, 0.0	-100.0, 33.3
Change from Baseline to Cycle 3 Day 1				
n	3	25	9	37
Mean (StdDev)	11.11 (19.245)	-28.00 (36.868)	-25.93 (22.222)	-24.32 (33.929)
Median	0.00	-33.33	-33.33	-33.33
Min, Max	0.0, 33.3	-100.0, 33.3	-66.7, 0.0	-100.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Dyspnea	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		-25.00 (31.914)	-25.00 (31.914)	-25.00 (29.547)
Median		-16.67	-16.67	-16.67
Min, Max		-66.7, 0.0	-66.7, 0.0	-66.7, 0.0
Change from Baseline to Cycle 5 Day 1				
n	1	15	9	25
Mean (StdDev)	-33.33 (-)	-31.11 (38.764)	-22.22 (23.570)	-28.00 (32.886)
Median	-33.33	-33.33	-33.33	-33.33
Min, Max	-33.3, -33.3	-100.0, 33.3	-66.7, 0.0	-100.0, 33.3
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		-33.33 (33.333)	-8.33 (41.944)	-19.05 (37.796)
Median		-33.33	0.00	0.00
Min, Max		-66.7, 0.0	-66.7, 33.3	-66.7, 33.3
Change from Baseline to Cycle 7 Day 1				
n	1	16	5	22
Mean (StdDev)	33.33 (-)	-35.42 (39.382)	-20.00 (38.006)	-28.79 (40.231)
Median	33.33	-33.33	-33.33	-33.33
Min, Max	33.3, 33.3	-100.0, 33.3	-66.7, 33.3	-100.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Dyspnea	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		-66.67 (47.140)	-33.33 (47.140)	-50.00 (43.033)
Median		-66.67	-33.33	-50.00
Min, Max		-100.0, -33.3	-66.7, 0.0	-100.0, 0.0
Change from Baseline to Cycle 9 Day 1				
n	0	12	4	16
Mean (StdDev)		-41.67 (35.176)	-33.33 (27.217)	-39.58 (32.702)
Median		-33.33	-33.33	-33.33
Min, Max		-100.0, 0.0	-66.7, 0.0	-100.0, 0.0
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		-100.00 (-)	-33.33 (47.140)	-55.56 (50.918)
Median		-100.00	-33.33	-66.67
Min, Max		-100.0, -100.0	-66.7, 0.0	-100.0, 0.0
Change from Baseline to Cycle 11 Day 1				
n	0	7	3	10
Mean (StdDev)		-47.62 (42.414)	-33.33 (33.333)	-43.33 (38.650)
Median		-33.33	-33.33	-33.33
Min, Max		-100.0, 0.0	-66.7, 0.0	-100.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Dyspnea	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		-33.33 (-)	-33.33 (47.140)	-33.33 (33.333)
Median		-33.33	-33.33	-33.33
Min, Max		-33.3, -33.3	-66.7, 0.0	-66.7, 0.0
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-33.33 (57.735)	-33.33 (-)	-33.33 (47.140)
Median		0.00	-33.33	-16.67
Min, Max		-100.0, 0.0	-33.3, -33.3	-100.0, 0.0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Insomnia	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Baseline				
n	4	28	12	44
Mean (StdDev)	75.00 (31.914)	48.81 (36.831)	77.78 (35.770)	59.09 (37.947)
Median	83.33	50.00	100.00	66.67
Min, Max	33.3, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	19	7	29
Mean (StdDev)	-11.11 (19.245)	-12.28 (37.202)	-42.86 (25.198)	-19.54 (35.093)
Median	0.00	0.00	-33.33	-33.33
Min, Max	-33.3, 0.0	-66.7, 33.3	-66.7, 0.0	-66.7, 33.3
Change from Baseline to Cycle 2 Day 1				
n	2	26	11	39
Mean (StdDev)	0.00 (0.000)	-11.54 (44.164)	-54.55 (47.779)	-23.08 (47.851)
Median	0.00	0.00	-66.67	-33.33
Min, Max	0.0, 0.0	-100.0, 66.7	-100.0, 66.7	-100.0, 66.7
Change from Baseline to Cycle 3 Day 1				
n	3	25	9	37
Mean (StdDev)	0.00 (0.000)	-12.00 (47.022)	-48.15 (47.467)	-19.82 (47.440)
Median	0.00	0.00	-66.67	0.00
Min, Max	0.0, 0.0	-100.0, 66.7	-100.0, 66.7	-100.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Insomnia	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		0.00 (47.140)	-16.67 (43.033)	-8.33 (42.725)
Median		16.67	-16.67	0.00
Min, Max		-66.7, 33.3	-66.7, 33.3	-66.7, 33.3
Change from Baseline to Cycle 5 Day 1				
n	1	15	9	25
Mean (StdDev)	-33.33 (-)	-22.22 (39.171)	-29.63 (30.932)	-25.33 (35.066)
Median	-33.33	-33.33	-33.33	-33.33
Min, Max	-33.3, -33.3	-66.7, 66.7	-66.7, 0.0	-66.7, 66.7
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		11.11 (50.918)	-16.67 (43.033)	-4.76 (44.840)
Median		0.00	-16.67	0.00
Min, Max		-33.3, 66.7	-66.7, 33.3	-66.7, 66.7
Change from Baseline to Cycle 7 Day 1				
n	1	16	5	22
Mean (StdDev)	0.00 (-)	-14.58 (47.091)	-20.00 (44.721)	-15.15 (44.517)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 0.0	-100.0, 66.7	-66.7, 33.3	-100.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Insomnia	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		-33.33 (47.140)	0.00 (0.000)	-16.67 (33.333)
Median		-33.33	0.00	0.00
Min, Max		-66.7, 0.0	0.0, 0.0	-66.7, 0.0
Change from Baseline to Cycle 9 Day 1				
n	0	12	4	16
Mean (StdDev)		-25.00 (40.514)	-33.33 (38.490)	-27.08 (38.909)
Median		0.00	-33.33	0.00
Min, Max		-100.0, 33.3	-66.7, 0.0	-100.0, 33.3
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	0.00 (0.000)	0.00 (0.000)
Median		0.00	0.00	0.00
Min, Max		0.0, 0.0	0.0, 0.0	0.0, 0.0
Change from Baseline to Cycle 11 Day 1				
n	0	7	3	10
Mean (StdDev)		-33.33 (33.333)	-22.22 (69.389)	-30.00 (42.889)
Median		-33.33	0.00	-16.67
Min, Max		-66.7, 0.0	-100.0, 33.3	-100.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Insomnia	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		-66.67 (-)	16.67 (23.570)	-11.11 (50.918)
Median		-66.67	16.67	0.00
Min, Max		-66.7, -66.7	0.0, 33.3	-66.7, 33.3
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-22.22 (38.490)	-100.00 (-)	-41.67 (50.000)
Median		0.00	-100.00	-33.33
Min, Max		-66.7, 0.0	-100.0, -100.0	-100.0, 0.0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		33.33 (-)		33.33 (-)
Median		33.33		33.33
Min, Max		33.3, 33.3		33.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Appetite Loss	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Baseline				
n	4	28	12	44
Mean (StdDev)	16.67 (33.333)	47.62 (36.772)	47.22 (36.121)	44.70 (36.616)
Median	0.00	33.33	33.33	33.33
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	19	7	29
Mean (StdDev)	-11.11 (19.245)	-28.07 (33.817)	-23.81 (25.198)	-25.29 (30.414)
Median	0.00	-33.33	-33.33	-33.33
Min, Max	-33.3, 0.0	-100.0, 33.3	-66.7, 0.0	-100.0, 33.3
Change from Baseline to Cycle 2 Day 1				
n	2	26	11	39
Mean (StdDev)	-16.67 (23.570)	-24.36 (45.760)	-21.21 (37.335)	-23.08 (41.993)
Median	-16.67	-16.67	0.00	0.00
Min, Max	-33.3, 0.0	-100.0, 66.7	-100.0, 33.3	-100.0, 66.7
Change from Baseline to Cycle 3 Day 1				
n	3	25	9	37
Mean (StdDev)	0.00 (0.000)	-34.67 (40.231)	-25.93 (52.116)	-29.73 (42.152)
Median	0.00	-33.33	0.00	-33.33
Min, Max	0.0, 0.0	-100.0, 33.3	-100.0, 33.3	-100.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Appetite Loss	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		-25.00 (50.000)	-8.33 (31.914)	-16.67 (39.841)
Median		-33.33	-16.67	-16.67
Min, Max		-66.7, 33.3	-33.3, 33.3	-66.7, 33.3
Change from Baseline to Cycle 5 Day 1				
n	1	15	9	25
Mean (StdDev)	0.00 (-)	-42.22 (47.920)	-11.11 (33.333)	-29.33 (44.431)
Median	0.00	-33.33	0.00	-33.33
Min, Max	0.0, 0.0	-100.0, 66.7	-66.7, 33.3	-100.0, 66.7
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		-44.44 (69.389)	-16.67 (33.333)	-28.57 (48.795)
Median		-66.67	0.00	0.00
Min, Max		-100.0, 33.3	-66.7, 0.0	-100.0, 33.3
Change from Baseline to Cycle 7 Day 1				
n	1	16	5	22
Mean (StdDev)	0.00 (-)	-43.75 (46.696)	-26.67 (27.889)	-37.88 (42.781)
Median	0.00	-33.33	-33.33	-33.33
Min, Max	0.0, 0.0	-100.0, 66.7	-66.7, 0.0	-100.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Appetite Loss	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		-83.33 (23.570)	-16.67 (23.570)	-50.00 (43.033)
Median		-83.33	-16.67	-50.00
Min, Max		-100.0, -66.7	-33.3, 0.0	-100.0, 0.0
Change from Baseline to Cycle 9 Day 1				
n	0	12	4	16
Mean (StdDev)		-44.44 (32.824)	-25.00 (31.914)	-39.58 (32.702)
Median		-33.33	-16.67	-33.33
Min, Max		-100.0, 0.0	-66.7, 0.0	-100.0, 0.0
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		-100.00 (-)	16.67 (23.570)	-22.22 (69.389)
Median		-100.00	16.67	0.00
Min, Max		-100.0, -100.0	0.0, 33.3	-100.0, 33.3
Change from Baseline to Cycle 11 Day 1				
n	0	7	3	10
Mean (StdDev)		-42.86 (49.868)	-11.11 (50.918)	-33.33 (49.690)
Median		-33.33	0.00	-33.33
Min, Max		-100.0, 33.3	-66.7, 33.3	-100.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Appetite Loss	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		-66.67 (-)	16.67 (23.570)	-11.11 (50.918)
Median		-66.67	16.67	0.00
Min, Max		-66.7, -66.7	0.0, 33.3	-66.7, 33.3
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-44.44 (50.918)	-66.67 (-)	-50.00 (43.033)
Median		-33.33	-66.67	-50.00
Min, Max		-100.0, 0.0	-66.7, -66.7	-100.0, 0.0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		33.33 (-)		33.33 (-)
Median		33.33		33.33
Min, Max		33.3, 33.3		33.3, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Constipation	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Baseline				
n	4	28	12	44
Mean (StdDev)	25.00 (31.914)	23.81 (32.530)	19.44 (33.207)	22.73 (31.966)
Median	16.67	0.00	0.00	0.00
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	19	7	29
Mean (StdDev)	0.00 (0.000)	-3.51 (24.582)	-9.52 (31.706)	-4.60 (24.759)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 0.0	-66.7, 66.7	-66.7, 33.3	-66.7, 66.7
Change from Baseline to Cycle 2 Day 1				
n	2	26	11	39
Mean (StdDev)	0.00 (0.000)	-11.54 (31.187)	-15.15 (31.140)	-11.97 (30.095)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 0.0	-100.0, 33.3	-66.7, 33.3	-100.0, 33.3
Change from Baseline to Cycle 3 Day 1				
n	3	25	9	37
Mean (StdDev)	-11.11 (19.245)	-8.00 (29.313)	-14.81 (44.444)	-9.91 (32.265)
Median	0.00	0.00	0.00	0.00
Min, Max	-33.3, 0.0	-100.0, 33.3	-100.0, 33.3	-100.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Constipation	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		-16.67 (33.333)	-16.67 (33.333)	-16.67 (30.861)
Median		0.00	0.00	0.00
Min, Max		-66.7, 0.0	-66.7, 0.0	-66.7, 0.0
Change from Baseline to Cycle 5 Day 1				
n	1	15	9	25
Mean (StdDev)	0.00 (-)	-4.44 (24.774)	-22.22 (37.268)	-10.67 (30.000)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 0.0	-33.3, 66.7	-100.0, 0.0	-100.0, 66.7
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		-33.33 (33.333)	-8.33 (16.667)	-19.05 (26.227)
Median		-33.33	0.00	0.00
Min, Max		-66.7, 0.0	-33.3, 0.0	-66.7, 0.0
Change from Baseline to Cycle 7 Day 1				
n	1	16	5	22
Mean (StdDev)	-33.33 (-)	-12.50 (26.874)	-40.00 (43.461)	-19.70 (31.971)
Median	-33.33	0.00	-33.33	0.00
Min, Max	-33.3, -33.3	-66.7, 33.3	-100.0, 0.0	-100.0, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Constipation	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		-50.00 (23.570)	0.00 (0.000)	-25.00 (31.914)
Median		-50.00	0.00	-16.67
Min, Max		-66.7, -33.3	0.0, 0.0	-66.7, 0.0
Change from Baseline to Cycle 9 Day 1				
n	0	12	4	16
Mean (StdDev)		-22.22 (35.770)	-33.33 (47.140)	-25.00 (37.515)
Median		-16.67	-16.67	-16.67
Min, Max		-100.0, 33.3	-100.0, 0.0	-100.0, 33.3
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		-66.67 (-)	0.00 (0.000)	-22.22 (38.490)
Median		-66.67	0.00	0.00
Min, Max		-66.7, -66.7	0.0, 0.0	-66.7, 0.0
Change from Baseline to Cycle 11 Day 1				
n	0	7	3	10
Mean (StdDev)		-28.57 (23.002)	-33.33 (57.735)	-30.00 (33.148)
Median		-33.33	0.00	-33.33
Min, Max		-66.7, 0.0	-100.0, 0.0	-100.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Constipation	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		-33.33 (-)	0.00 (0.000)	-11.11 (19.245)
Median		-33.33	0.00	0.00
Min, Max		-33.3, -33.3	0.0, 0.0	-33.3, 0.0
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-22.22 (19.245)	-100.00 (-)	-41.67 (41.944)
Median		-33.33	-100.00	-33.33
Min, Max		-33.3, 0.0	-100.0, -100.0	-100.0, 0.0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Diarrhea	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Baseline				
n	4	28	12	44
Mean (StdDev)	25.00 (50.000)	39.29 (40.626)	50.00 (41.439)	40.91 (41.211)
Median	0.00	33.33	66.67	33.33
Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	19	7	29
Mean (StdDev)	11.11 (19.245)	-31.58 (32.344)	-14.29 (53.945)	-22.99 (38.938)
Median	0.00	-33.33	0.00	0.00
Min, Max	0.0, 33.3	-100.0, 0.0	-100.0, 33.3	-100.0, 33.3
Change from Baseline to Cycle 2 Day 1				
n	2	26	11	39
Mean (StdDev)	0.00 (0.000)	-21.79 (43.146)	-12.12 (37.335)	-17.95 (40.354)
Median	0.00	-16.67	0.00	0.00
Min, Max	0.0, 0.0	-100.0, 66.7	-66.7, 33.3	-100.0, 66.7
Change from Baseline to Cycle 3 Day 1				
n	3	25	9	37
Mean (StdDev)	0.00 (0.000)	-22.67 (42.731)	-7.41 (46.481)	-17.12 (42.033)
Median	0.00	-33.33	0.00	0.00
Min, Max	0.0, 0.0	-100.0, 66.7	-100.0, 66.7	-100.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Diarrhea	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		0.00 (60.858)	-33.33 (60.858)	-16.67 (59.094)
Median		0.00	-33.33	-16.67
Min, Max		-66.7, 66.7	-100.0, 33.3	-100.0, 66.7
Change from Baseline to Cycle 5 Day 1				
n	1	15	9	25
Mean (StdDev)	0.00 (-)	-22.22 (44.840)	-14.81 (50.308)	-18.67 (45.216)
Median	0.00	-33.33	0.00	-33.33
Min, Max	0.0, 0.0	-100.0, 66.7	-100.0, 66.7	-100.0, 66.7
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		-11.11 (101.835)	-25.00 (56.928)	-19.05 (71.640)
Median		-33.33	-16.67	-33.33
Min, Max		-100.0, 100.0	-100.0, 33.3	-100.0, 100.0
Change from Baseline to Cycle 7 Day 1				
n	1	16	5	22
Mean (StdDev)	33.33 (-)	-27.08 (40.768)	-20.00 (50.553)	-22.73 (42.893)
Median	33.33	-33.33	0.00	-33.33
Min, Max	33.3, 33.3	-100.0, 66.7	-100.0, 33.3	-100.0, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Diarrhea	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		-50.00 (23.570)	-66.67 (47.140)	-58.33 (31.914)
Median		-50.00	-66.67	-50.00
Min, Max		-66.7, -33.3	-100.0, -33.3	-100.0, -33.3
Change from Baseline to Cycle 9 Day 1				
n	0	12	4	16
Mean (StdDev)		-27.78 (42.243)	-8.33 (16.667)	-22.92 (37.945)
Median		-33.33	0.00	-33.33
Min, Max		-100.0, 66.7	-33.3, 0.0	-100.0, 66.7
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		-66.67 (-)	0.00 (0.000)	-22.22 (38.490)
Median		-66.67	0.00	0.00
Min, Max		-66.7, -66.7	0.0, 0.0	-66.7, 0.0
Change from Baseline to Cycle 11 Day 1				
n	0	7	3	10
Mean (StdDev)		-33.33 (27.217)	-22.22 (19.245)	-30.00 (24.595)
Median		-33.33	-33.33	-33.33
Min, Max		-66.7, 0.0	-33.3, 0.0	-66.7, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Diarrhea	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		-33.33 (-)	-33.33 (0.000)	-33.33 (0.000)
Median		-33.33	-33.33	-33.33
Min, Max		-33.3, -33.3	-33.3, -33.3	-33.3, -33.3
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-11.11 (19.245)	0.00 (-)	-8.33 (16.667)
Median		0.00	0.00	0.00
Min, Max		-33.3, 0.0	0.0, 0.0	-33.3, 0.0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		0.00 (-)		0.00 (-)
Median		0.00		0.00
Min, Max		0.0, 0.0		0.0, 0.0

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Financial Difficulties	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Baseline				
n	4	28	12	44
Mean (StdDev)	41.67 (31.914)	25.00 (32.235)	36.11 (38.817)	29.55 (33.884)
Median	50.00	0.00	33.33	33.33
Min, Max	0.0, 66.7	0.0, 100.0	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 1 Day 15				
n	3	19	7	29
Mean (StdDev)	0.00 (33.333)	1.75 (25.995)	-19.05 (42.414)	-3.45 (31.301)
Median	0.00	0.00	0.00	0.00
Min, Max	-33.3, 33.3	-66.7, 33.3	-100.0, 33.3	-100.0, 33.3
Change from Baseline to Cycle 2 Day 1				
n	2	26	11	39
Mean (StdDev)	0.00 (0.000)	-2.56 (24.807)	-12.12 (26.968)	-5.13 (24.825)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 0.0	-66.7, 33.3	-66.7, 33.3	-66.7, 33.3
Change from Baseline to Cycle 3 Day 1				
n	3	25	9	37
Mean (StdDev)	11.11 (19.245)	-2.67 (25.313)	0.00 (23.570)	-0.90 (24.199)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 33.3	-66.7, 33.3	-33.3, 33.3	-66.7, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Financial Difficulties	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 4 Day 1				
n	0	4	4	8
Mean (StdDev)		-8.33 (16.667)	-8.33 (16.667)	-8.33 (15.430)
Median		0.00	0.00	0.00
Min, Max		-33.3, 0.0	-33.3, 0.0	-33.3, 0.0
Change from Baseline to Cycle 5 Day 1				
n	1	15	9	25
Mean (StdDev)	-66.67 (-)	-8.89 (26.627)	7.41 (27.778)	-5.33 (29.938)
Median	-66.67	0.00	0.00	0.00
Min, Max	-66.7, -66.7	-66.7, 33.3	-33.3, 66.7	-66.7, 66.7
Change from Baseline to Cycle 6 Day 1				
n	0	3	4	7
Mean (StdDev)		-11.11 (19.245)	-8.33 (31.914)	-9.52 (25.198)
Median		0.00	-16.67	0.00
Min, Max		-33.3, 0.0	-33.3, 33.3	-33.3, 33.3
Change from Baseline to Cycle 7 Day 1				
n	1	16	5	22
Mean (StdDev)	0.00 (-)	-6.25 (25.000)	0.00 (23.570)	-4.55 (23.672)
Median	0.00	0.00	0.00	0.00
Min, Max	0.0, 0.0	-66.7, 33.3	-33.3, 33.3	-66.7, 33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
Date: 20:50/20OCT2021

Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Financial Difficulties	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 8 Day 1				
n	0	2	2	4
Mean (StdDev)		0.00 (0.000)	33.33 (47.140)	16.67 (33.333)
Median		0.00	33.33	0.00
Min, Max		0.0, 0.0	0.0, 66.7	0.0, 66.7
Change from Baseline to Cycle 9 Day 1				
n	0	12	4	16
Mean (StdDev)		8.33 (25.126)	16.67 (33.333)	10.42 (26.440)
Median		0.00	0.00	0.00
Min, Max		-33.3, 66.7	0.0, 66.7	-33.3, 66.7
Change from Baseline to Cycle 10 Day 1				
n	0	1	2	3
Mean (StdDev)		-33.33 (-)	33.33 (47.140)	11.11 (50.918)
Median		-33.33	33.33	0.00
Min, Max		-33.3, -33.3	0.0, 66.7	-33.3, 66.7
Change from Baseline to Cycle 11 Day 1				
n	0	7	3	10
Mean (StdDev)		9.52 (31.706)	22.22 (38.490)	13.33 (32.203)
Median		0.00	0.00	0.00
Min, Max		-33.3, 66.7	0.0, 66.7	-33.3, 66.7

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas
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Table 35.2.11.2
Summary of Quality of Life by EORTC QLQ-C30 Change from Baseline
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

Financial Difficulties	ASM (N=5)	SM-AHN (N=32)	MCL (N=13)	All AdvSM (N=50)
Change from Baseline to Cycle 12 Day 1				
n	0	1	2	3
Mean (StdDev)		0.00 (-)	16.67 (23.570)	11.11 (19.245)
Median		0.00	16.67	0.00
Min, Max		0.0, 0.0	0.0, 33.3	0.0, 33.3
Change from Baseline to Cycle 14 Day 1				
n	0	3	1	4
Mean (StdDev)		-11.11 (19.245)	0.00 (-)	-8.33 (16.667)
Median		0.00	0.00	0.00
Min, Max		-33.3, 0.0	0.0, 0.0	-33.3, 0.0
Change from Baseline to Cycle 17 Day 1				
n	0	1	0	1
Mean (StdDev)		-33.33 (-)		-33.33 (-)
Median		-33.33		-33.33
Min, Max		-33.3, -33.3		-33.3, -33.3

Source: Listing 16.3.13
Abbreviations: AP=Appetite loss, CF=Cognitive functioning, CO=Constipation, DI=DIarrhea, DY=Dyspnea, EF=Emotional functioning, FA=Fatigue, FI=Financial difficulties, NV=Nausea and vomiting, PA=Pain, PF=Physical functioning, QL=Global health status, RF=Role functioning, SF=Social function, SL=Insomnia.
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-qual-chg.sas Date: 20:50/20OCT2021

Table 35.2.11.1a
Summary of Compliance - Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

	Baseline (N=27)	C2D1 (N=27)	C3D1 (N=27)	C4D1 (N=27)	C5D1 (N=27)	C6D1 (N=27)	C7D1 (N=27)
Treated	27	27	26	26	25	24	24
Global Health Status/QoL	25 (92.6)	23 (85.2)	22 (84.6)	22 (84.6)	21 (84.0)	20 (83.3)	18 (75.0)
Physical Functioning	25 (92.6)	23 (85.2)	22 (84.6)	22 (84.6)	21 (84.0)	20 (83.3)	18 (75.0)
Role Functioning	25 (92.6)	23 (85.2)	22 (84.6)	22 (84.6)	21 (84.0)	20 (83.3)	18 (75.0)
Emotional Functioning	25 (92.6)	23 (85.2)	22 (84.6)	22 (84.6)	21 (84.0)	20 (83.3)	18 (75.0)
Cognitive Functioning	25 (92.6)	23 (85.2)	22 (84.6)	22 (84.6)	21 (84.0)	20 (83.3)	18 (75.0)
Social Function	25 (92.6)	23 (85.2)	22 (84.6)	22 (84.6)	21 (84.0)	20 (83.3)	18 (75.0)
Fatigue	25 (92.6)	23 (85.2)	22 (84.6)	22 (84.6)	21 (84.0)	20 (83.3)	18 (75.0)
Nausea and Vomiting	25 (92.6)	23 (85.2)	22 (84.6)	22 (84.6)	21 (84.0)	20 (83.3)	18 (75.0)
Pain	25 (92.6)	23 (85.2)	22 (84.6)	22 (84.6)	21 (84.0)	20 (83.3)	18 (75.0)
Dyspnea	25 (92.6)	23 (85.2)	22 (84.6)	22 (84.6)	21 (84.0)	20 (83.3)	18 (75.0)
Insomnia	25 (92.6)	23 (85.2)	22 (84.6)	22 (84.6)	21 (84.0)	20 (83.3)	18 (75.0)
Appetite Loss	25 (92.6)	23 (85.2)	22 (84.6)	22 (84.6)	21 (84.0)	20 (83.3)	18 (75.0)
Constipation	25 (92.6)	23 (85.2)	22 (84.6)	22 (84.6)	21 (84.0)	20 (83.3)	18 (75.0)
Diarrhea	25 (92.6)	23 (85.2)	22 (84.6)	21 (80.8)	21 (84.0)	20 (83.3)	18 (75.0)
Financial Difficulties	25 (92.6)	23 (85.2)	22 (84.6)	22 (84.6)	21 (84.0)	20 (83.3)	18 (75.0)

Source: Listing 16.3.13
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-qual.sas Date: 16:06/18JAN2022

Table 35.2.11.1a
Summary of Compliance - Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

All Doses

	C8D1 (N=27)	C9D1 (N=27)	C10D1 (N=27)	C11D1 (N=27)	C12D1 (N=27)
Treated	23	23	19	18	17
Global Health Status/QoL	16 (69.6)	16 (69.6)	16 (84.2)	17 (94.4)	12 (70.6)
Physical Functioning	16 (69.6)	16 (69.6)	16 (84.2)	17 (94.4)	12 (70.6)
Role Functioning	16 (69.6)	16 (69.6)	16 (84.2)	17 (94.4)	12 (70.6)
Emotional Functioning	16 (69.6)	16 (69.6)	16 (84.2)	17 (94.4)	12 (70.6)
Cognitive Functioning	16 (69.6)	16 (69.6)	16 (84.2)	17 (94.4)	12 (70.6)
Social Function	16 (69.6)	16 (69.6)	16 (84.2)	17 (94.4)	12 (70.6)
Fatigue	16 (69.6)	16 (69.6)	16 (84.2)	17 (94.4)	12 (70.6)
Nausea and Vomiting	16 (69.6)	16 (69.6)	16 (84.2)	17 (94.4)	12 (70.6)
Pain	16 (69.6)	16 (69.6)	16 (84.2)	17 (94.4)	12 (70.6)
Dyspnea	16 (69.6)	16 (69.6)	16 (84.2)	17 (94.4)	11 (64.7)
Insomnia	16 (69.6)	16 (69.6)	16 (84.2)	17 (94.4)	12 (70.6)
Appetite Loss	16 (69.6)	16 (69.6)	16 (84.2)	17 (94.4)	12 (70.6)
Constipation	16 (69.6)	16 (69.6)	16 (84.2)	17 (94.4)	12 (70.6)
Diarrhea	16 (69.6)	16 (69.6)	16 (84.2)	17 (94.4)	12 (70.6)
Financial Difficulties	16 (69.6)	16 (69.6)	16 (84.2)	17 (94.4)	12 (70.6)

Source: Listing 16.3.13
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-qual.sas Date: 16:06/18JAN2022

Table 35.2.11.1a
Summary of Compliance - Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

	Baseline (N=10)	C2D1 (N=10)	C3D1 (N=10)	C4D1 (N=10)	C5D1 (N=10)	C6D1 (N=10)	C7D1 (N=10)
Treated	10	10	9	9	8	8	8
Global Health Status/QoL	10 (100)	8 (80.0)	7 (77.8)	8 (88.9)	6 (75.0)	7 (87.5)	6 (75.0)
Physical Functioning	10 (100)	8 (80.0)	7 (77.8)	8 (88.9)	6 (75.0)	7 (87.5)	6 (75.0)
Role Functioning	10 (100)	8 (80.0)	7 (77.8)	8 (88.9)	6 (75.0)	7 (87.5)	6 (75.0)
Emotional Functioning	10 (100)	8 (80.0)	7 (77.8)	8 (88.9)	6 (75.0)	7 (87.5)	6 (75.0)
Cognitive Functioning	10 (100)	8 (80.0)	7 (77.8)	8 (88.9)	6 (75.0)	7 (87.5)	6 (75.0)
Social Function	10 (100)	8 (80.0)	7 (77.8)	8 (88.9)	6 (75.0)	7 (87.5)	6 (75.0)
Fatigue	10 (100)	8 (80.0)	7 (77.8)	8 (88.9)	6 (75.0)	7 (87.5)	6 (75.0)
Nausea and Vomiting	10 (100)	8 (80.0)	7 (77.8)	8 (88.9)	6 (75.0)	7 (87.5)	6 (75.0)
Pain	10 (100)	8 (80.0)	7 (77.8)	8 (88.9)	6 (75.0)	7 (87.5)	6 (75.0)
Dyspnea	10 (100)	8 (80.0)	7 (77.8)	8 (88.9)	6 (75.0)	7 (87.5)	6 (75.0)
Insomnia	10 (100)	8 (80.0)	7 (77.8)	8 (88.9)	6 (75.0)	7 (87.5)	6 (75.0)
Appetite Loss	10 (100)	8 (80.0)	7 (77.8)	8 (88.9)	6 (75.0)	7 (87.5)	6 (75.0)
Constipation	10 (100)	8 (80.0)	7 (77.8)	8 (88.9)	6 (75.0)	7 (87.5)	6 (75.0)
Diarrhea	10 (100)	8 (80.0)	7 (77.8)	8 (88.9)	6 (75.0)	7 (87.5)	6 (75.0)
Financial Difficulties	10 (100)	8 (80.0)	7 (77.8)	8 (88.9)	6 (75.0)	7 (87.5)	6 (75.0)

Source: Listing 16.3.13
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-qual.sas Date: 16:06/18JAN2022

Table 35.2.11.1a
Summary of Compliance - Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: <= 200 mg

	C8D1 (N=10)	C9D1 (N=10)	C10D1 (N=10)	C11D1 (N=10)	C12D1 (N=10)
Treated	7	7	6	5	4
Global Health Status/QoL	4 (57.1)	4 (57.1)	3 (50.0)	4 (80.0)	3 (75.0)
Physical Functioning	4 (57.1)	4 (57.1)	3 (50.0)	4 (80.0)	3 (75.0)
Role Functioning	4 (57.1)	4 (57.1)	3 (50.0)	4 (80.0)	3 (75.0)
Emotional Functioning	4 (57.1)	4 (57.1)	3 (50.0)	4 (80.0)	3 (75.0)
Cognitive Functioning	4 (57.1)	4 (57.1)	3 (50.0)	4 (80.0)	3 (75.0)
Social Function	4 (57.1)	4 (57.1)	3 (50.0)	4 (80.0)	3 (75.0)
Fatigue	4 (57.1)	4 (57.1)	3 (50.0)	4 (80.0)	3 (75.0)
Nausea and Vomiting	4 (57.1)	4 (57.1)	3 (50.0)	4 (80.0)	3 (75.0)
Pain	4 (57.1)	4 (57.1)	3 (50.0)	4 (80.0)	3 (75.0)
Dyspnea	4 (57.1)	4 (57.1)	3 (50.0)	4 (80.0)	3 (75.0)
Insomnia	4 (57.1)	4 (57.1)	3 (50.0)	4 (80.0)	3 (75.0)
Appetite Loss	4 (57.1)	4 (57.1)	3 (50.0)	4 (80.0)	3 (75.0)
Constipation	4 (57.1)	4 (57.1)	3 (50.0)	4 (80.0)	3 (75.0)
Diarrhea	4 (57.1)	4 (57.1)	3 (50.0)	4 (80.0)	3 (75.0)
Financial Difficulties	4 (57.1)	4 (57.1)	3 (50.0)	4 (80.0)	3 (75.0)

Source: Listing 16.3.13
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-qual.sas Date: 16:06/18JAN2022

Table 35.2.11.1a
Summary of Compliance - Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

	Baseline (N=10)	C2D1 (N=10)	C3D1 (N=10)	C4D1 (N=10)	C5D1 (N=10)	C6D1 (N=10)	C7D1 (N=10)
Treated	10	10	9	9	8	8	8
Global Health Status/QoL	10 (100)	8 (80.0)	7 (77.8)	8 (88.9)	6 (75.0)	7 (87.5)	6 (75.0)
Physical Functioning	10 (100)	8 (80.0)	7 (77.8)	8 (88.9)	6 (75.0)	7 (87.5)	6 (75.0)
Role Functioning	10 (100)	8 (80.0)	7 (77.8)	8 (88.9)	6 (75.0)	7 (87.5)	6 (75.0)
Emotional Functioning	10 (100)	8 (80.0)	7 (77.8)	8 (88.9)	6 (75.0)	7 (87.5)	6 (75.0)
Cognitive Functioning	10 (100)	8 (80.0)	7 (77.8)	8 (88.9)	6 (75.0)	7 (87.5)	6 (75.0)
Social Function	10 (100)	8 (80.0)	7 (77.8)	8 (88.9)	6 (75.0)	7 (87.5)	6 (75.0)
Fatigue	10 (100)	8 (80.0)	7 (77.8)	8 (88.9)	6 (75.0)	7 (87.5)	6 (75.0)
Nausea and Vomiting	10 (100)	8 (80.0)	7 (77.8)	8 (88.9)	6 (75.0)	7 (87.5)	6 (75.0)
Pain	10 (100)	8 (80.0)	7 (77.8)	8 (88.9)	6 (75.0)	7 (87.5)	6 (75.0)
Dyspnea	10 (100)	8 (80.0)	7 (77.8)	8 (88.9)	6 (75.0)	7 (87.5)	6 (75.0)
Insomnia	10 (100)	8 (80.0)	7 (77.8)	8 (88.9)	6 (75.0)	7 (87.5)	6 (75.0)
Appetite Loss	10 (100)	8 (80.0)	7 (77.8)	8 (88.9)	6 (75.0)	7 (87.5)	6 (75.0)
Constipation	10 (100)	8 (80.0)	7 (77.8)	8 (88.9)	6 (75.0)	7 (87.5)	6 (75.0)
Diarrhea	10 (100)	8 (80.0)	7 (77.8)	8 (88.9)	6 (75.0)	7 (87.5)	6 (75.0)
Financial Difficulties	10 (100)	8 (80.0)	7 (77.8)	8 (88.9)	6 (75.0)	7 (87.5)	6 (75.0)

Source: Listing 16.3.13
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-qual.sas Date: 16:06/18JAN2022

Table 35.2.11.1a
Summary of Compliance - Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2101

Starting Dose: 200 mg

	C8D1 (N=10)	C9D1 (N=10)	C10D1 (N=10)	C11D1 (N=10)	C12D1 (N=10)
Treated	7	7	6	5	4
Global Health Status/QoL	4 (57.1)	4 (57.1)	3 (50.0)	4 (80.0)	3 (75.0)
Physical Functioning	4 (57.1)	4 (57.1)	3 (50.0)	4 (80.0)	3 (75.0)
Role Functioning	4 (57.1)	4 (57.1)	3 (50.0)	4 (80.0)	3 (75.0)
Emotional Functioning	4 (57.1)	4 (57.1)	3 (50.0)	4 (80.0)	3 (75.0)
Cognitive Functioning	4 (57.1)	4 (57.1)	3 (50.0)	4 (80.0)	3 (75.0)
Social Function	4 (57.1)	4 (57.1)	3 (50.0)	4 (80.0)	3 (75.0)
Fatigue	4 (57.1)	4 (57.1)	3 (50.0)	4 (80.0)	3 (75.0)
Nausea and Vomiting	4 (57.1)	4 (57.1)	3 (50.0)	4 (80.0)	3 (75.0)
Pain	4 (57.1)	4 (57.1)	3 (50.0)	4 (80.0)	3 (75.0)
Dyspnea	4 (57.1)	4 (57.1)	3 (50.0)	4 (80.0)	3 (75.0)
Insomnia	4 (57.1)	4 (57.1)	3 (50.0)	4 (80.0)	3 (75.0)
Appetite Loss	4 (57.1)	4 (57.1)	3 (50.0)	4 (80.0)	3 (75.0)
Constipation	4 (57.1)	4 (57.1)	3 (50.0)	4 (80.0)	3 (75.0)
Diarrhea	4 (57.1)	4 (57.1)	3 (50.0)	4 (80.0)	3 (75.0)
Financial Difficulties	4 (57.1)	4 (57.1)	3 (50.0)	4 (80.0)	3 (75.0)

Source: Listing 16.3.13
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-qual.sas Date: 16:06/18JAN2022

Table 35.2.11.1a
Summary of Compliance - Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

	Baseline (N=42)	C1D15 (N=42)	C2D1 (N=42)	C3D1 (N=42)	C5D1 (N=42)	C7D1 (N=42)	C9D1 (N=42)
Treated	42	42	40	37	32	22	18
Global Health Status/QoL	35 (83.3)	33 (78.6)	34 (85.0)	32 (86.5)	21 (65.6)	17 (77.3)	13 (72.2)
Physical Functioning	35 (83.3)	33 (78.6)	34 (85.0)	32 (86.5)	21 (65.6)	17 (77.3)	13 (72.2)
Role Functioning	35 (83.3)	33 (78.6)	34 (85.0)	32 (86.5)	21 (65.6)	17 (77.3)	13 (72.2)
Emotional Functioning	35 (83.3)	33 (78.6)	34 (85.0)	32 (86.5)	21 (65.6)	17 (77.3)	13 (72.2)
Cognitive Functioning	35 (83.3)	33 (78.6)	34 (85.0)	32 (86.5)	21 (65.6)	17 (77.3)	13 (72.2)
Social Function	35 (83.3)	33 (78.6)	34 (85.0)	32 (86.5)	21 (65.6)	17 (77.3)	13 (72.2)
Fatigue	35 (83.3)	33 (78.6)	34 (85.0)	32 (86.5)	21 (65.6)	17 (77.3)	13 (72.2)
Nausea and Vomiting	35 (83.3)	33 (78.6)	34 (85.0)	32 (86.5)	21 (65.6)	17 (77.3)	13 (72.2)
Pain	35 (83.3)	33 (78.6)	34 (85.0)	32 (86.5)	21 (65.6)	17 (77.3)	13 (72.2)
Dyspnea	35 (83.3)	33 (78.6)	34 (85.0)	32 (86.5)	21 (65.6)	17 (77.3)	13 (72.2)
Insomnia	35 (83.3)	33 (78.6)	34 (85.0)	32 (86.5)	21 (65.6)	17 (77.3)	13 (72.2)
Appetite Loss	35 (83.3)	33 (78.6)	34 (85.0)	32 (86.5)	21 (65.6)	17 (77.3)	13 (72.2)
Constipation	35 (83.3)	33 (78.6)	34 (85.0)	32 (86.5)	21 (65.6)	17 (77.3)	13 (72.2)
Diarrhea	35 (83.3)	33 (78.6)	34 (85.0)	32 (86.5)	21 (65.6)	17 (77.3)	13 (72.2)
Financial Difficulties	35 (83.3)	33 (78.6)	34 (85.0)	32 (86.5)	21 (65.6)	17 (77.3)	13 (72.2)

Table 35.2.11.1a
Summary of Compliance - Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

All Doses

	C11D1 (N=42)	C14D1 (N=42)	C17D1 (N=42)
Treated	12	6	5
Global Health Status/QoL	7 (58.3)	4 (66.7)	1 (20.0)
Physical Functioning	7 (58.3)	4 (66.7)	1 (20.0)
Role Functioning	7 (58.3)	4 (66.7)	1 (20.0)
Emotional Functioning	7 (58.3)	4 (66.7)	1 (20.0)
Cognitive Functioning	7 (58.3)	4 (66.7)	1 (20.0)
Social Function	7 (58.3)	4 (66.7)	1 (20.0)
Fatigue	7 (58.3)	4 (66.7)	1 (20.0)
Nausea and Vomiting	7 (58.3)	4 (66.7)	1 (20.0)
Pain	7 (58.3)	4 (66.7)	1 (20.0)
Dyspnea	7 (58.3)	4 (66.7)	1 (20.0)
Insomnia	7 (58.3)	4 (66.7)	1 (20.0)
Appetite Loss	7 (58.3)	4 (66.7)	1 (20.0)
Constipation	7 (58.3)	4 (66.7)	1 (20.0)
Diarrhea	7 (58.3)	4 (66.7)	1 (20.0)
Financial Difficulties	7 (58.3)	4 (66.7)	1 (20.0)

Source: Listing 16.3.13
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-qual.sas Date: 16:06/18JAN2022

Table 35.2.11.1a
Summary of Compliance - Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

	Baseline (N=40)	C1D15 (N=40)	C2D1 (N=40)	C3D1 (N=40)	C5D1 (N=40)	C7D1 (N=40)	C9D1 (N=40)
Treated	40	40	39	36	31	21	17
Global Health Status/QoL	34 (85.0)	32 (80.0)	33 (84.6)	31 (86.1)	20 (64.5)	16 (76.2)	12 (70.6)
Physical Functioning	34 (85.0)	32 (80.0)	33 (84.6)	31 (86.1)	20 (64.5)	16 (76.2)	12 (70.6)
Role Functioning	34 (85.0)	32 (80.0)	33 (84.6)	31 (86.1)	20 (64.5)	16 (76.2)	12 (70.6)
Emotional Functioning	34 (85.0)	32 (80.0)	33 (84.6)	31 (86.1)	20 (64.5)	16 (76.2)	12 (70.6)
Cognitive Functioning	34 (85.0)	32 (80.0)	33 (84.6)	31 (86.1)	20 (64.5)	16 (76.2)	12 (70.6)
Social Function	34 (85.0)	32 (80.0)	33 (84.6)	31 (86.1)	20 (64.5)	16 (76.2)	12 (70.6)
Fatigue	34 (85.0)	32 (80.0)	33 (84.6)	31 (86.1)	20 (64.5)	16 (76.2)	12 (70.6)
Nausea and Vomiting	34 (85.0)	32 (80.0)	33 (84.6)	31 (86.1)	20 (64.5)	16 (76.2)	12 (70.6)
Pain	34 (85.0)	32 (80.0)	33 (84.6)	31 (86.1)	20 (64.5)	16 (76.2)	12 (70.6)
Dyspnea	34 (85.0)	32 (80.0)	33 (84.6)	31 (86.1)	20 (64.5)	16 (76.2)	12 (70.6)
Insomnia	34 (85.0)	32 (80.0)	33 (84.6)	31 (86.1)	20 (64.5)	16 (76.2)	12 (70.6)
Appetite Loss	34 (85.0)	32 (80.0)	33 (84.6)	31 (86.1)	20 (64.5)	16 (76.2)	12 (70.6)
Constipation	34 (85.0)	32 (80.0)	33 (84.6)	31 (86.1)	20 (64.5)	16 (76.2)	12 (70.6)
Diarrhea	34 (85.0)	32 (80.0)	33 (84.6)	31 (86.1)	20 (64.5)	16 (76.2)	12 (70.6)
Financial Difficulties	34 (85.0)	32 (80.0)	33 (84.6)	31 (86.1)	20 (64.5)	16 (76.2)	12 (70.6)

Source: Listing 16.3.13
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-qual.sas Date: 16:06/18JAN2022

Table 35.2.11.1a
Summary of Compliance - Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Study BLU-285-2202

Starting Dose: 200 mg

	C11D1 (N=40)	C14D1 (N=40)	C17D1 (N=40)
Treated	11	5	5
Global Health Status/QoL	6 (54.5)	4 (80.0)	1 (20.0)
Physical Functioning	6 (54.5)	4 (80.0)	1 (20.0)
Role Functioning	6 (54.5)	4 (80.0)	1 (20.0)
Emotional Functioning	6 (54.5)	4 (80.0)	1 (20.0)
Cognitive Functioning	6 (54.5)	4 (80.0)	1 (20.0)
Social Function	6 (54.5)	4 (80.0)	1 (20.0)
Fatigue	6 (54.5)	4 (80.0)	1 (20.0)
Nausea and Vomiting	6 (54.5)	4 (80.0)	1 (20.0)
Pain	6 (54.5)	4 (80.0)	1 (20.0)
Dyspnea	6 (54.5)	4 (80.0)	1 (20.0)
Insomnia	6 (54.5)	4 (80.0)	1 (20.0)
Appetite Loss	6 (54.5)	4 (80.0)	1 (20.0)
Constipation	6 (54.5)	4 (80.0)	1 (20.0)
Diarrhea	6 (54.5)	4 (80.0)	1 (20.0)
Financial Difficulties	6 (54.5)	4 (80.0)	1 (20.0)

Source: Listing 16.3.13
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-qual.sas Date: 16:06/18JAN2022

Table 35.2.11.1a
Summary of Compliance - Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

	Baseline (N=69)	C1D15 (N=69)	C2D1 (N=69)	C3D1 (N=69)	C4D1 (N=69)	C5D1 (N=69)	C6D1 (N=69)
Treated	69	42	67	63	63	57	49
Global Health Status/QoL	60 (87.0)	33 (78.6)	57 (85.1)	54 (85.7)	22 (34.9)	42 (73.7)	20 (40.8)
Physical Functioning	60 (87.0)	33 (78.6)	57 (85.1)	54 (85.7)	22 (34.9)	42 (73.7)	20 (40.8)
Role Functioning	60 (87.0)	33 (78.6)	57 (85.1)	54 (85.7)	22 (34.9)	42 (73.7)	20 (40.8)
Emotional Functioning	60 (87.0)	33 (78.6)	57 (85.1)	54 (85.7)	22 (34.9)	42 (73.7)	20 (40.8)
Cognitive Functioning	60 (87.0)	33 (78.6)	57 (85.1)	54 (85.7)	22 (34.9)	42 (73.7)	20 (40.8)
Social Function	60 (87.0)	33 (78.6)	57 (85.1)	54 (85.7)	22 (34.9)	42 (73.7)	20 (40.8)
Fatigue	60 (87.0)	33 (78.6)	57 (85.1)	54 (85.7)	22 (34.9)	42 (73.7)	20 (40.8)
Nausea and Vomiting	60 (87.0)	33 (78.6)	57 (85.1)	54 (85.7)	22 (34.9)	42 (73.7)	20 (40.8)
Pain	60 (87.0)	33 (78.6)	57 (85.1)	54 (85.7)	22 (34.9)	42 (73.7)	20 (40.8)
Dyspnea	60 (87.0)	33 (78.6)	57 (85.1)	54 (85.7)	22 (34.9)	42 (73.7)	20 (40.8)
Insomnia	60 (87.0)	33 (78.6)	57 (85.1)	54 (85.7)	22 (34.9)	42 (73.7)	20 (40.8)
Appetite Loss	60 (87.0)	33 (78.6)	57 (85.1)	54 (85.7)	22 (34.9)	42 (73.7)	20 (40.8)
Constipation	60 (87.0)	33 (78.6)	57 (85.1)	54 (85.7)	22 (34.9)	42 (73.7)	20 (40.8)
Diarrhea	60 (87.0)	33 (78.6)	57 (85.1)	54 (85.7)	21 (33.3)	42 (73.7)	20 (40.8)
Financial Difficulties	60 (87.0)	33 (78.6)	57 (85.1)	54 (85.7)	22 (34.9)	42 (73.7)	20 (40.8)

Source: Listing 16.3.13
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-qual.sas Date: 16:06/18JAN2022

Table 35.2.11.1a
Summary of Compliance - Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

All Doses

	C7D1 (N=69)	C8D1 (N=69)	C9D1 (N=69)	C10D1 (N=69)	C11D1 (N=69)	C12D1 (N=69)	C14D1 (N=69)	C17D1 (N=69)
Treated	46	44	41	32	30	27	22	21
Global Health Status/QoL	35 (76.1)	16 (36.4)	29 (70.7)	16 (50.0)	24 (80.0)	12 (44.4)	4 (18.2)	1 (4.8)
Physical Functioning	35 (76.1)	16 (36.4)	29 (70.7)	16 (50.0)	24 (80.0)	12 (44.4)	4 (18.2)	1 (4.8)
Role Functioning	35 (76.1)	16 (36.4)	29 (70.7)	16 (50.0)	24 (80.0)	12 (44.4)	4 (18.2)	1 (4.8)
Emotional Functioning	35 (76.1)	16 (36.4)	29 (70.7)	16 (50.0)	24 (80.0)	12 (44.4)	4 (18.2)	1 (4.8)
Cognitive Functioning	35 (76.1)	16 (36.4)	29 (70.7)	16 (50.0)	24 (80.0)	12 (44.4)	4 (18.2)	1 (4.8)
Social Function	35 (76.1)	16 (36.4)	29 (70.7)	16 (50.0)	24 (80.0)	12 (44.4)	4 (18.2)	1 (4.8)
Fatigue	35 (76.1)	16 (36.4)	29 (70.7)	16 (50.0)	24 (80.0)	12 (44.4)	4 (18.2)	1 (4.8)
Nausea and Vomiting	35 (76.1)	16 (36.4)	29 (70.7)	16 (50.0)	24 (80.0)	12 (44.4)	4 (18.2)	1 (4.8)
Pain	35 (76.1)	16 (36.4)	29 (70.7)	16 (50.0)	24 (80.0)	12 (44.4)	4 (18.2)	1 (4.8)
Dyspnea	35 (76.1)	16 (36.4)	29 (70.7)	16 (50.0)	24 (80.0)	11 (40.7)	4 (18.2)	1 (4.8)
Insomnia	35 (76.1)	16 (36.4)	29 (70.7)	16 (50.0)	24 (80.0)	12 (44.4)	4 (18.2)	1 (4.8)
Appetite Loss	35 (76.1)	16 (36.4)	29 (70.7)	16 (50.0)	24 (80.0)	12 (44.4)	4 (18.2)	1 (4.8)
Constipation	35 (76.1)	16 (36.4)	29 (70.7)	16 (50.0)	24 (80.0)	12 (44.4)	4 (18.2)	1 (4.8)
Diarrhea	35 (76.1)	16 (36.4)	29 (70.7)	16 (50.0)	24 (80.0)	12 (44.4)	4 (18.2)	1 (4.8)
Financial Difficulties	35 (76.1)	16 (36.4)	29 (70.7)	16 (50.0)	24 (80.0)	12 (44.4)	4 (18.2)	1 (4.8)

Source: Listing 16.3.13
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-qual.sas
Date: 16:06/18JAN2022

Table 35.2.11.1a
Summary of Compliance - Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

	Baseline (N=52)	C1D15 (N=52)	C2D1 (N=52)	C3D1 (N=52)	C4D1 (N=52)	C5D1 (N=52)	C6D1 (N=52)
Treated	52	42	50	46	46	40	33
Global Health Status/QoL	45 (86.5)	33 (78.6)	42 (84.0)	39 (84.8)	8 (17.4)	27 (67.5)	7 (21.2)
Physical Functioning	45 (86.5)	33 (78.6)	42 (84.0)	39 (84.8)	8 (17.4)	27 (67.5)	7 (21.2)
Role Functioning	45 (86.5)	33 (78.6)	42 (84.0)	39 (84.8)	8 (17.4)	27 (67.5)	7 (21.2)
Emotional Functioning	45 (86.5)	33 (78.6)	42 (84.0)	39 (84.8)	8 (17.4)	27 (67.5)	7 (21.2)
Cognitive Functioning	45 (86.5)	33 (78.6)	42 (84.0)	39 (84.8)	8 (17.4)	27 (67.5)	7 (21.2)
Social Function	45 (86.5)	33 (78.6)	42 (84.0)	39 (84.8)	8 (17.4)	27 (67.5)	7 (21.2)
Fatigue	45 (86.5)	33 (78.6)	42 (84.0)	39 (84.8)	8 (17.4)	27 (67.5)	7 (21.2)
Nausea and Vomiting	45 (86.5)	33 (78.6)	42 (84.0)	39 (84.8)	8 (17.4)	27 (67.5)	7 (21.2)
Pain	45 (86.5)	33 (78.6)	42 (84.0)	39 (84.8)	8 (17.4)	27 (67.5)	7 (21.2)
Dyspnea	45 (86.5)	33 (78.6)	42 (84.0)	39 (84.8)	8 (17.4)	27 (67.5)	7 (21.2)
Insomnia	45 (86.5)	33 (78.6)	42 (84.0)	39 (84.8)	8 (17.4)	27 (67.5)	7 (21.2)
Appetite Loss	45 (86.5)	33 (78.6)	42 (84.0)	39 (84.8)	8 (17.4)	27 (67.5)	7 (21.2)
Constipation	45 (86.5)	33 (78.6)	42 (84.0)	39 (84.8)	8 (17.4)	27 (67.5)	7 (21.2)
Diarrhea	45 (86.5)	33 (78.6)	42 (84.0)	39 (84.8)	8 (17.4)	27 (67.5)	7 (21.2)
Financial Difficulties	45 (86.5)	33 (78.6)	42 (84.0)	39 (84.8)	8 (17.4)	27 (67.5)	7 (21.2)

Source: Listing 16.3.13
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-qual.sas Date: 16:06/18JAN2022

Table 35.2.11.1a
Summary of Compliance - Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: <= 200 mg

	C7D1 (N=52)	C8D1 (N=52)	C9D1 (N=52)	C10D1 (N=52)	C11D1 (N=52)	C12D1 (N=52)	C14D1 (N=52)	C17D1 (N=52)
Treated	30	28	25	19	17	14	9	8
Global Health Status/QoL	23 (76.7)	4 (14.3)	17 (68.0)	3 (15.8)	11 (64.7)	3 (21.4)	4 (44.4)	1 (12.5)
Physical Functioning	23 (76.7)	4 (14.3)	17 (68.0)	3 (15.8)	11 (64.7)	3 (21.4)	4 (44.4)	1 (12.5)
Role Functioning	23 (76.7)	4 (14.3)	17 (68.0)	3 (15.8)	11 (64.7)	3 (21.4)	4 (44.4)	1 (12.5)
Emotional Functioning	23 (76.7)	4 (14.3)	17 (68.0)	3 (15.8)	11 (64.7)	3 (21.4)	4 (44.4)	1 (12.5)
Cognitive Functioning	23 (76.7)	4 (14.3)	17 (68.0)	3 (15.8)	11 (64.7)	3 (21.4)	4 (44.4)	1 (12.5)
Social Function	23 (76.7)	4 (14.3)	17 (68.0)	3 (15.8)	11 (64.7)	3 (21.4)	4 (44.4)	1 (12.5)
Fatigue	23 (76.7)	4 (14.3)	17 (68.0)	3 (15.8)	11 (64.7)	3 (21.4)	4 (44.4)	1 (12.5)
Nausea and Vomiting	23 (76.7)	4 (14.3)	17 (68.0)	3 (15.8)	11 (64.7)	3 (21.4)	4 (44.4)	1 (12.5)
Pain	23 (76.7)	4 (14.3)	17 (68.0)	3 (15.8)	11 (64.7)	3 (21.4)	4 (44.4)	1 (12.5)
Dyspnea	23 (76.7)	4 (14.3)	17 (68.0)	3 (15.8)	11 (64.7)	3 (21.4)	4 (44.4)	1 (12.5)
Insomnia	23 (76.7)	4 (14.3)	17 (68.0)	3 (15.8)	11 (64.7)	3 (21.4)	4 (44.4)	1 (12.5)
Appetite Loss	23 (76.7)	4 (14.3)	17 (68.0)	3 (15.8)	11 (64.7)	3 (21.4)	4 (44.4)	1 (12.5)
Constipation	23 (76.7)	4 (14.3)	17 (68.0)	3 (15.8)	11 (64.7)	3 (21.4)	4 (44.4)	1 (12.5)
Diarrhea	23 (76.7)	4 (14.3)	17 (68.0)	3 (15.8)	11 (64.7)	3 (21.4)	4 (44.4)	1 (12.5)
Financial Difficulties	23 (76.7)	4 (14.3)	17 (68.0)	3 (15.8)	11 (64.7)	3 (21.4)	4 (44.4)	1 (12.5)

Source: Listing 16.3.13
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-qual.sas
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Table 35.2.11.1a
Summary of Compliance - Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

	Baseline (N=50)	C1D15 (N=50)	C2D1 (N=50)	C3D1 (N=50)	C4D1 (N=50)	C5D1 (N=50)	C6D1 (N=50)
Treated	50	40	49	45	45	39	32
Global Health Status/QoL	44 (88.0)	32 (80.0)	41 (83.7)	38 (84.4)	8 (17.8)	26 (66.7)	7 (21.9)
Physical Functioning	44 (88.0)	32 (80.0)	41 (83.7)	38 (84.4)	8 (17.8)	26 (66.7)	7 (21.9)
Role Functioning	44 (88.0)	32 (80.0)	41 (83.7)	38 (84.4)	8 (17.8)	26 (66.7)	7 (21.9)
Emotional Functioning	44 (88.0)	32 (80.0)	41 (83.7)	38 (84.4)	8 (17.8)	26 (66.7)	7 (21.9)
Cognitive Functioning	44 (88.0)	32 (80.0)	41 (83.7)	38 (84.4)	8 (17.8)	26 (66.7)	7 (21.9)
Social Function	44 (88.0)	32 (80.0)	41 (83.7)	38 (84.4)	8 (17.8)	26 (66.7)	7 (21.9)
Fatigue	44 (88.0)	32 (80.0)	41 (83.7)	38 (84.4)	8 (17.8)	26 (66.7)	7 (21.9)
Nausea and Vomiting	44 (88.0)	32 (80.0)	41 (83.7)	38 (84.4)	8 (17.8)	26 (66.7)	7 (21.9)
Pain	44 (88.0)	32 (80.0)	41 (83.7)	38 (84.4)	8 (17.8)	26 (66.7)	7 (21.9)
Dyspnea	44 (88.0)	32 (80.0)	41 (83.7)	38 (84.4)	8 (17.8)	26 (66.7)	7 (21.9)
Insomnia	44 (88.0)	32 (80.0)	41 (83.7)	38 (84.4)	8 (17.8)	26 (66.7)	7 (21.9)
Appetite Loss	44 (88.0)	32 (80.0)	41 (83.7)	38 (84.4)	8 (17.8)	26 (66.7)	7 (21.9)
Constipation	44 (88.0)	32 (80.0)	41 (83.7)	38 (84.4)	8 (17.8)	26 (66.7)	7 (21.9)
Diarrhea	44 (88.0)	32 (80.0)	41 (83.7)	38 (84.4)	8 (17.8)	26 (66.7)	7 (21.9)
Financial Difficulties	44 (88.0)	32 (80.0)	41 (83.7)	38 (84.4)	8 (17.8)	26 (66.7)	7 (21.9)

Source: Listing 16.3.13
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-qual.sas Date: 16:06/18JAN2022

Table 35.2.11.1a
Summary of Compliance - Quality of Life by EORTC QLQ-C30
AdvSM Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202

Starting Dose: 200 mg

	C7D1 (N=50)	C8D1 (N=50)	C9D1 (N=50)	C10D1 (N=50)	C11D1 (N=50)	C12D1 (N=50)	C14D1 (N=50)	C17D1 (N=50)
Treated	29	27	24	18	16	13	8	8
Global Health Status/QoL	22 (75.9)	4 (14.8)	16 (66.7)	3 (16.7)	10 (62.5)	3 (23.1)	4 (50.0)	1 (12.5)
Physical Functioning	22 (75.9)	4 (14.8)	16 (66.7)	3 (16.7)	10 (62.5)	3 (23.1)	4 (50.0)	1 (12.5)
Role Functioning	22 (75.9)	4 (14.8)	16 (66.7)	3 (16.7)	10 (62.5)	3 (23.1)	4 (50.0)	1 (12.5)
Emotional Functioning	22 (75.9)	4 (14.8)	16 (66.7)	3 (16.7)	10 (62.5)	3 (23.1)	4 (50.0)	1 (12.5)
Cognitive Functioning	22 (75.9)	4 (14.8)	16 (66.7)	3 (16.7)	10 (62.5)	3 (23.1)	4 (50.0)	1 (12.5)
Social Function	22 (75.9)	4 (14.8)	16 (66.7)	3 (16.7)	10 (62.5)	3 (23.1)	4 (50.0)	1 (12.5)
Fatigue	22 (75.9)	4 (14.8)	16 (66.7)	3 (16.7)	10 (62.5)	3 (23.1)	4 (50.0)	1 (12.5)
Nausea and Vomiting	22 (75.9)	4 (14.8)	16 (66.7)	3 (16.7)	10 (62.5)	3 (23.1)	4 (50.0)	1 (12.5)
Pain	22 (75.9)	4 (14.8)	16 (66.7)	3 (16.7)	10 (62.5)	3 (23.1)	4 (50.0)	1 (12.5)
Dyspnea	22 (75.9)	4 (14.8)	16 (66.7)	3 (16.7)	10 (62.5)	3 (23.1)	4 (50.0)	1 (12.5)
Insomnia	22 (75.9)	4 (14.8)	16 (66.7)	3 (16.7)	10 (62.5)	3 (23.1)	4 (50.0)	1 (12.5)
Appetite Loss	22 (75.9)	4 (14.8)	16 (66.7)	3 (16.7)	10 (62.5)	3 (23.1)	4 (50.0)	1 (12.5)
Constipation	22 (75.9)	4 (14.8)	16 (66.7)	3 (16.7)	10 (62.5)	3 (23.1)	4 (50.0)	1 (12.5)
Diarrhea	22 (75.9)	4 (14.8)	16 (66.7)	3 (16.7)	10 (62.5)	3 (23.1)	4 (50.0)	1 (12.5)
Financial Difficulties	22 (75.9)	4 (14.8)	16 (66.7)	3 (16.7)	10 (62.5)	3 (23.1)	4 (50.0)	1 (12.5)

Source: Listing 16.3.13
Program: ../BLU-285/ISE_2101_sNDA/Final/Programs/Prod/Adhoc/GermanyHTA/t-comp-qual.sas
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Table 35.3.3.1.1
Overall Summary of Adverse Events
AdvSM Population & Prior Neoplastic Therapy = Yes

Category	BLU-285-2101 200 mg (N=12) n (%)	BLU-285-2101 <=200 mg (N=16) n (%)	BLU-285-2101 All Doses (N=41) n (%)
Patients with AE	12 (100.0)	16 (100.0)	41 (100.0)
Patients with Serious AE	5 (41.7)	7 (43.8)	27 (65.9)
Patients with Grade 3+ AE	8 (66.7)	11 (68.8)	35 (85.4)
Patients with Treatment-Related AE	11 (91.7)	15 (93.8)	40 (97.6)
Patients with Serious Treatment-Related AE	2 (16.7)	3 (18.8)	12 (29.3)
Patients with Grade 3+ Treatment-Related AE	7 (58.3)	9 (56.3)	30 (73.2)
Patients with AE Leading to Discontinuation from Study Drug	0	0	9 (22.0)
Patients with Treatment-Related AE Leading to Discontinuation from Study Drug	0	0	6 (14.6)
Patients with AE Leading to Dose Interruption	9 (75.0)	13 (81.3)	31 (75.6)
Patients with AE Leading to Dose Reduction	8 (66.7)	9 (56.3)	32 (78.0)
Patients with AESI of Cognitive Effects	2 (16.7)	2 (12.5)	15 (36.6)
Patients with AESI of Intracranial Bleeding	1 (8.3)	1 (6.3)	4 (9.8)
Patients with Treatment-Related AESI of Cognitive Effects	2 (16.7)	2 (12.5)	13 (31.7)
Patients with Treatment-Related AESI of Intracranial Bleeding	1 (8.3)	1 (6.3)	4 (9.8)

Abbreviations: AESI = Adverse Event of Special Interest; AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experiences more than 1 event within an AE category, that patient is counted only once under category.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Program: ../BLU-285/ISS_BLU285/Final/Programs/Prod/Adhoc/German Request/t-35-3-3-1-1-aesum.sas
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Table 35.3.3.1.1
Overall Summary of Adverse Events
AdvSM Population & Prior Neoplastic Therapy = Yes

Category	BLU-285-2202 200 mg (N=40) n (%)	BLU-285-2202 <=200 mg (N=42) n (%)	BLU-285-2202 All Doses (N=42) n (%)
Patients with AE	40 (100.0)	42 (100.0)	42 (100.0)
Patients with Serious AE	16 (40.0)	17 (40.5)	17 (40.5)
Patients with Grade 3+ AE	27 (67.5)	28 (66.7)	28 (66.7)
Patients with Treatment-Related AE	38 (95.0)	39 (92.9)	39 (92.9)
Patients with Serious Treatment-Related AE	4 (10.0)	4 (9.5)	4 (9.5)
Patients with Grade 3+ Treatment-Related AE	19 (47.5)	20 (47.6)	20 (47.6)
Patients with AE Leading to Discontinuation from Study Drug	6 (15.0)	6 (14.3)	6 (14.3)
Patients with Treatment-Related AE Leading to Discontinuation from Study Drug	2 (5.0)	2 (4.8)	2 (4.8)
Patients with AE Leading to Dose Interruption	23 (57.5)	24 (57.1)	24 (57.1)
Patients with AE Leading to Dose Reduction	27 (67.5)	28 (66.7)	28 (66.7)
Patients with AESI of Cognitive Effects	7 (17.5)	7 (16.7)	7 (16.7)
Patients with AESI of Intracranial Bleeding	1 (2.5)	1 (2.4)	1 (2.4)
Patients with Treatment-Related AESI of Cognitive Effects	5 (12.5)	5 (11.9)	5 (11.9)
Patients with Treatment-Related AESI of Intracranial Bleeding	1 (2.5)	1 (2.4)	1 (2.4)

Abbreviations: AESI = Adverse Event of Special Interest; AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experiences more than 1 event within an AE category, that patient is counted only once under category.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
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Table 35.3.3.1.1
Overall Summary of Adverse Events
AdvSM Population & Prior Neoplastic Therapy = Yes

Category	BLU-285-2101 + BLU-285-2202		
	200 mg (N=52) n (%)	<=200 mg (N=58) n (%)	All Doses (N=83) n (%)
Patients with AE	52 (100.0)	58 (100.0)	83 (100.0)
Patients with Serious AE	21 (40.4)	24 (41.4)	44 (53.0)
Patients with Grade 3+ AE	35 (67.3)	39 (67.2)	63 (75.9)
Patients with Treatment-Related AE	49 (94.2)	54 (93.1)	79 (95.2)
Patients with Serious Treatment-Related AE	6 (11.5)	7 (12.1)	16 (19.3)
Patients with Grade 3+ Treatment-Related AE	26 (50.0)	29 (50.0)	50 (60.2)
Patients with AE Leading to Discontinuation from Study Drug	6 (11.5)	6 (10.3)	15 (18.1)
Patients with Treatment-Related AE Leading to Discontinuation from Study Drug	2 (3.8)	2 (3.4)	8 (9.6)
Patients with AE Leading to Dose Interruption	32 (61.5)	37 (63.8)	55 (66.3)
Patients with AE Leading to Dose Reduction	35 (67.3)	37 (63.8)	60 (72.3)
Patients with AESI of Cognitive Effects	9 (17.3)	9 (15.5)	22 (26.5)
Patients with AESI of Intracranial Bleeding	2 (3.8)	2 (3.4)	5 (6.0)
Patients with Treatment-Related AESI of Cognitive Effects	7 (13.5)	7 (12.1)	18 (21.7)
Patients with Treatment-Related AESI of Intracranial Bleeding	2 (3.8)	2 (3.4)	5 (6.0)

Abbreviations: AESI = Adverse Event of Special Interest; AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experiences more than 1 event within an AE category, that patient is counted only once under category.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
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Table 35.3.3.1.1
Overall Summary of Adverse Events
AdvSM Population & Prior Neoplastic Therapy = Yes

Category	BLU-285-2101 200 mg (N=12) n (%)	BLU-285-2101 <=200 mg (N=16) n (%)	BLU-285-2101 All Doses (N=41) n (%)
Patients with Serious AESI of Cognitive Effects	0	0	3 (7.3)
Patients with Serious AESI of Intracranial Bleeding	1 (8.3)	1 (6.3)	3 (7.3)
Patients with AESI of Cognitive Effects Leading to Discontinuation from Study Drug	0	0	2 (4.9)
Patients with AESI of Intracranial Bleeding Leading to Discontinuation from Study Drug	0	0	1 (2.4)
Patients with AE Leading to Death	0	0	2 (4.9)
Patients with Treatment-Related AE Leading to Death	0	0	1 (2.4)
Patients with Grade <=2 AE	4 (33.3)	5 (31.3)	6 (14.6)
Patients with Any AESI	3 (25.0)	3 (18.8)	17 (41.5)
Patients with Grade <=2 AESI	3 (25.0)	3 (18.8)	13 (31.7)
Patients with Grade 3+ AESI	0	0	4 (9.8)
Patients with Any Serious AESI	1 (8.3)	1 (6.3)	6 (14.6)

Abbreviations: AESI = Adverse Event of Special Interest; AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experiences more than 1 event within an AE category, that patient is counted only once under category.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Program: ../BLU-285/ISS_BLU285/Final/Programs/Prod/Adhoc/German Request/t-35-3-3-1-1-aesum.sas
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Table 35.3.3.1.1
Overall Summary of Adverse Events
AdvSM Population & Prior Neoplastic Therapy = Yes

Category	BLU-285-2202 200 mg (N=40) n (%)	BLU-285-2202 <=200 mg (N=42) n (%)	BLU-285-2202 All Doses (N=42) n (%)
Patients with Serious AESI of Cognitive Effects	0	0	0
Patients with Serious AESI of Intracranial Bleeding	1 (2.5)	1 (2.4)	1 (2.4)
Patients with AESI of Cognitive Effects Leading to Discontinuation from Study Drug	0	0	0
Patients with AESI of Intracranial Bleeding Leading to Discontinuation from Study Drug	1 (2.5)	1 (2.4)	1 (2.4)
Patients with AE Leading to Death	3 (7.5)	3 (7.1)	3 (7.1)
Patients with Treatment-Related AE Leading to Death	0	0	0
Patients with Grade <=2 AE	13 (32.5)	14 (33.3)	14 (33.3)
Patients with Any AESI	7 (17.5)	7 (16.7)	7 (16.7)
Patients with Grade <=2 AESI	5 (12.5)	5 (11.9)	5 (11.9)
Patients with Grade 3+ AESI	2 (5.0)	2 (4.8)	2 (4.8)
Patients with Any Serious AESI	1 (2.5)	1 (2.4)	1 (2.4)

Abbreviations: AESI = Adverse Event of Special Interest; AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experiences more than 1 event within an AE category, that patient is counted only once under category.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Program: ../BLU-285/ISS_BLU285/Final/Programs/Prod/Adhoc/German Request/t-35-3-3-1-1-aesum.sas
Date: 9:42/24JAN2022

Table 35.3.3.1.1
Overall Summary of Adverse Events
AdvSM Population & Prior Neoplastic Therapy = Yes

Category	BLU-285-2101 + BLU-285-2202		
	200 mg (N=52) n (%)	<=200 mg (N=58) n (%)	All Doses (N=83) n (%)
Patients with Serious AESI of Cognitive Effects	0	0	3 (3.6)
Patients with Serious AESI of Intracranial Bleeding	2 (3.8)	2 (3.4)	4 (4.8)
Patients with AESI of Cognitive Effects Leading to Discontinuation from Study Drug	0	0	2 (2.4)
Patients with AESI of Intracranial Bleeding Leading to Discontinuation from Study Drug	1 (1.9)	1 (1.7)	2 (2.4)
Patients with AE Leading to Death	3 (5.8)	3 (5.2)	5 (6.0)
Patients with Treatment-Related AE Leading to Death	0	0	1 (1.2)
Patients with Grade <=2 AE	17 (32.7)	19 (32.8)	20 (24.1)
Patients with Any AESI	10 (19.2)	10 (17.2)	24 (28.9)
Patients with Grade <=2 AESI	8 (15.4)	8 (13.8)	18 (21.7)
Patients with Grade 3+ AESI	2 (3.8)	2 (3.4)	6 (7.2)
Patients with Any Serious AESI	2 (3.8)	2 (3.4)	7 (8.4)

Abbreviations: AESI = Adverse Event of Special Interest; AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experiences more than 1 event within an AE category, that patient is counted only once under category.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
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Table T.35.3.3.1.2.1
Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	<=200 mg (N=16) n (%)	All Doses (N=41) n (%)
Patients with at least one Event	12 (100)	16 (100)	41 (100)
Blood and lymphatic system disorders	9 (75.0)	11 (68.8)	33 (80.5)
Anaemia	5 (41.7)	6 (37.5)	20 (48.8)
Thrombocytopenia	5 (41.7)	6 (37.5)	16 (39.0)
Neutropenia	3 (25.0)	3 (18.8)	7 (17.1)
Increased tendency to bruise	2 (16.7)	2 (12.5)	2 (4.9)
Leukocytosis	0	0	2 (4.9)
Leukopenia	0	1 (6.3)	2 (4.9)
Lymphadenopathy	1 (8.3)	1 (6.3)	2 (4.9)
Lymphopenia	1 (8.3)	1 (6.3)	2 (4.9)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: System Organ Classes are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'All Doses' column.
Program: ../BLU-285/ISS_BLU285/Final/Programs/Prod/Adhoc/German Request/t-35-3-3-1-2-1-aesocpt.sas
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Table T.35.3.3.1.2.1
Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	 <=200 mg (N=16) n (%)	 All Doses (N=41) n (%)
Blood and lymphatic system disorders (cont.)			
Anaemia macrocytic	1 (8.3)	1 (6.3)	1 (2.4)
Autoimmune haemolytic anaemia	0	0	1 (2.4)
Haemolysis	0	0	1 (2.4)
Haemorrhagic diathesis	1 (8.3)	1 (6.3)	1 (2.4)
Mast cell activation syndrome	0	0	1 (2.4)
Pancytopenia	0	0	1 (2.4)
Splenic lesion	0	0	1 (2.4)
Splenomegaly	0	0	1 (2.4)
Cardiac disorders	1 (8.3)	1 (6.3)	5 (12.2)
Acute myocardial infarction	0	0	1 (2.4)

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Table T.35.3.3.1.2.1
Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	<=200 mg (N=16) n (%)	All Doses (N=41) n (%)
Cardiac disorders (cont.)			
Angina pectoris	0	0	1 (2.4)
Cardiac failure congestive	1 (8.3)	1 (6.3)	1 (2.4)
Cyanosis	0	0	1 (2.4)
Palpitations	0	0	1 (2.4)
Sinus tachycardia	0	0	1 (2.4)
Congenital, familial and genetic disorders	1 (8.3)	1 (6.3)	1 (2.4)
Right-to-left cardiac shunt	1 (8.3)	1 (6.3)	1 (2.4)
Ear and labyrinth disorders	1 (8.3)	1 (6.3)	6 (14.6)
Vertigo	0	0	2 (4.9)
Cerumen impaction	0	0	1 (2.4)

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Table T.35.3.3.1.2.1
Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	 <=200 mg (N=16) n (%)	 All Doses (N=41) n (%)
Ear and labyrinth disorders (cont.)			
Deafness	1 (8.3)	1 (6.3)	1 (2.4)
Deafness neurosensory	0	0	1 (2.4)
Ear discomfort	0	0	1 (2.4)
Ear pain	0	0	1 (2.4)
Hypoacusis	0	0	1 (2.4)
Tinnitus	0	0	1 (2.4)
Endocrine disorders	0	0	1 (2.4)
Inappropriate antidiuretic hormone secretion	0	0	1 (2.4)
Eye disorders	9 (75.0)	11 (68.8)	32 (78.0)
Periorbital oedema	6 (50.0)	8 (50.0)	28 (68.3)

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Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	<=200 mg (N=16) n (%)	All Doses (N=41) n (%)
Eye disorders (cont.)			
Lacrimation increased	1 (8.3)	2 (12.5)	7 (17.1)
Vision blurred	1 (8.3)	1 (6.3)	4 (9.8)
Conjunctival haemorrhage	1 (8.3)	2 (12.5)	3 (7.3)
Eye swelling	1 (8.3)	2 (12.5)	2 (4.9)
Photophobia	0	0	2 (4.9)
Blepharitis	0	0	1 (2.4)
Cataract nuclear	0	0	1 (2.4)
Conjunctival oedema	0	0	1 (2.4)
Eye haemorrhage	0	0	1 (2.4)
Eye inflammation	0	0	1 (2.4)

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Summary of Adverse Events by System Organ Class and Preferred Term
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System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	<=200 mg (N=16) n (%)	All Doses (N=41) n (%)
Eye disorders (cont.)			
Eye pruritus	0	1 (6.3)	1 (2.4)
Macular fibrosis	1 (8.3)	1 (6.3)	1 (2.4)
Ocular hyperaemia	1 (8.3)	1 (6.3)	1 (2.4)
Papilloedema	0	1 (6.3)	1 (2.4)
Periorbital haemorrhage	1 (8.3)	1 (6.3)	1 (2.4)
Retinal tear	0	0	1 (2.4)
Scleral haemorrhage	0	0	1 (2.4)
Trichiasis	0	0	1 (2.4)
Uveitis	0	1 (6.3)	1 (2.4)
Visual acuity reduced	0	0	1 (2.4)

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Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	BLU-285-2101 <=200 mg (N=16) n (%)	BLU-285-2101 All Doses (N=41) n (%)
Gastrointestinal disorders	11 (91.7)	15 (93.8)	40 (97.6)
Diarrhoea	7 (58.3)	9 (56.3)	17 (41.5)
Nausea	4 (33.3)	6 (37.5)	16 (39.0)
Vomiting	3 (25.0)	4 (25.0)	14 (34.1)
Abdominal pain	3 (25.0)	4 (25.0)	8 (19.5)
Constipation	2 (16.7)	2 (12.5)	8 (19.5)
Ascites	3 (25.0)	3 (18.8)	7 (17.1)
Abdominal distension	2 (16.7)	2 (12.5)	6 (14.6)
Dry mouth	1 (8.3)	1 (6.3)	6 (14.6)
Dyspepsia	2 (16.7)	2 (12.5)	5 (12.2)

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Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	<=200 mg (N=16) n (%)	All Doses (N=41) n (%)
Gastrointestinal disorders (cont.)			
Abdominal discomfort	1 (8.3)	1 (6.3)	4 (9.8)
Abdominal pain upper	0	1 (6.3)	4 (9.8)
Gastrooesophageal reflux disease	0	0	3 (7.3)
Gastric haemorrhage	0	0	2 (4.9)
Gastrointestinal haemorrhage	0	0	2 (4.9)
Gingival pain	1 (8.3)	1 (6.3)	2 (4.9)
Haematochezia	0	0	2 (4.9)
Haemorrhoidal haemorrhage	0	0	2 (4.9)
Inguinal hernia	1 (8.3)	1 (6.3)	2 (4.9)
Retching	0	0	2 (4.9)

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Summary of Adverse Events by System Organ Class and Preferred Term
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System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	<=200 mg (N=16) n (%)	All Doses (N=41) n (%)
Gastrointestinal disorders (cont.)			
Varices oesophageal	0	0	2 (4.9)
Anorectal discomfort	0	1 (6.3)	1 (2.4)
Chapped lips	0	0	1 (2.4)
Colitis	1 (8.3)	1 (6.3)	1 (2.4)
Flatulence	1 (8.3)	1 (6.3)	1 (2.4)
Gastritis	0	1 (6.3)	1 (2.4)
Gastritis haemorrhagic	0	0	1 (2.4)
Gastrointestinal perforation	0	0	1 (2.4)
Gingival swelling	0	1 (6.3)	1 (2.4)
Haemorrhoids	0	0	1 (2.4)

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AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	<=200 mg (N=16) n (%)	All Doses (N=41) n (%)
Gastrointestinal disorders (cont.)			
Incarcerated umbilical hernia	1 (8.3)	1 (6.3)	1 (2.4)
Large intestine perforation	1 (8.3)	1 (6.3)	1 (2.4)
Large intestine polyp	0	1 (6.3)	1 (2.4)
Lip ulceration	0	0	1 (2.4)
Melaena	0	0	1 (2.4)
Mouth ulceration	1 (8.3)	1 (6.3)	1 (2.4)
Oesophagitis	0	0	1 (2.4)
Oral disorder	1 (8.3)	1 (6.3)	1 (2.4)
Oral pain	0	0	1 (2.4)
Pancreatitis	0	0	1 (2.4)

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Summary of Adverse Events by System Organ Class and Preferred Term
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System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	 <=200 mg (N=16) n (%)	 All Doses (N=41) n (%)
Gastrointestinal disorders (cont.)			
Parotid gland enlargement	0	0	1 (2.4)
Periodontal disease	1 (8.3)	1 (6.3)	1 (2.4)
Rectal haemorrhage	0	1 (6.3)	1 (2.4)
Small intestinal obstruction	1 (8.3)	1 (6.3)	1 (2.4)
Tongue discolouration	0	0	1 (2.4)
General disorders and administration site conditions	11 (91.7)	13 (81.3)	32 (78.0)
Oedema peripheral	8 (66.7)	10 (62.5)	24 (58.5)
Fatigue	4 (33.3)	5 (31.3)	14 (34.1)
Asthenia	1 (8.3)	1 (6.3)	4 (9.8)
Face oedema	1 (8.3)	1 (6.3)	4 (9.8)

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System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	 <=200 mg (N=16) n (%)	 All Doses (N=41) n (%)
General disorders and administration site conditions (cont.)			
Peripheral swelling	1 (8.3)	2 (12.5)	4 (9.8)
Pyrexia	1 (8.3)	1 (6.3)	4 (9.8)
Chills	0	0	3 (7.3)
Feeling abnormal	1 (8.3)	2 (12.5)	3 (7.3)
Gait disturbance	1 (8.3)	1 (6.3)	2 (4.9)
Generalised oedema	1 (8.3)	1 (6.3)	2 (4.9)
Influenza like illness	1 (8.3)	1 (6.3)	2 (4.9)
Chest discomfort	0	0	1 (2.4)
Decreased activity	1 (8.3)	1 (6.3)	1 (2.4)
Malaise	1 (8.3)	1 (6.3)	1 (2.4)

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Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	<=200 mg (N=16) n (%)	All Doses (N=41) n (%)
General disorders and administration site conditions (cont.)			
Non-cardiac chest pain	0	0	1 (2.4)
Oedema	1 (8.3)	1 (6.3)	1 (2.4)
Pain	1 (8.3)	1 (6.3)	1 (2.4)
Temperature intolerance	1 (8.3)	1 (6.3)	1 (2.4)
Hepatobiliary disorders	1 (8.3)	1 (6.3)	7 (17.1)
Hyperbilirubinaemia	0	0	3 (7.3)
Cholelithiasis	1 (8.3)	1 (6.3)	2 (4.9)
Hepatic cirrhosis	0	0	1 (2.4)
Jaundice	0	0	1 (2.4)
Nodular regenerative hyperplasia	0	0	1 (2.4)

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AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	<=200 mg (N=16) n (%)	All Doses (N=41) n (%)
Immune system disorders	1 (8.3)	1 (6.3)	7 (17.1)
Drug hypersensitivity	1 (8.3)	1 (6.3)	2 (4.9)
Anaphylactic reaction	0	0	1 (2.4)
Anaphylactic shock	0	0	1 (2.4)
Contrast media allergy	0	0	1 (2.4)
Hypersensitivity	0	0	1 (2.4)
Iodine allergy	0	0	1 (2.4)
Infections and infestations	7 (58.3)	11 (68.8)	31 (75.6)
Upper respiratory tract infection	3 (25.0)	5 (31.3)	8 (19.5)
Urinary tract infection	0	1 (6.3)	6 (14.6)

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System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	<=200 mg (N=16) n (%)	All Doses (N=41) n (%)
Infections and infestations (cont.)			
Herpes zoster	0	2 (12.5)	4 (9.8)
Oral candidiasis	1 (8.3)	1 (6.3)	4 (9.8)
Pneumonia	0	0	4 (9.8)
Sinusitis	1 (8.3)	2 (12.5)	4 (9.8)
Cellulitis	1 (8.3)	1 (6.3)	2 (4.9)
Conjunctivitis	0	0	2 (4.9)
Diverticulitis	1 (8.3)	2 (12.5)	2 (4.9)
Gastroenteritis	0	1 (6.3)	2 (4.9)
Nasopharyngitis	0	0	2 (4.9)
Bronchitis	0	0	1 (2.4)

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System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	 <=200 mg (N=16) n (%)	 All Doses (N=41) n (%)
Infections and infestations (cont.)			
Cellulitis orbital	0	0	1 (2.4)
Clostridium difficile infection	0	0	1 (2.4)
Diarrhoea infectious	0	0	1 (2.4)
Ear infection	0	0	1 (2.4)
Escherichia bacteraemia	0	0	1 (2.4)
Escherichia urinary tract infection	0	0	1 (2.4)
Folliculitis	0	0	1 (2.4)
Genital infection	0	0	1 (2.4)
Hordeolum	0	0	1 (2.4)
Influenza	0	1 (6.3)	1 (2.4)

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System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	 <=200 mg (N=16) n (%)	 All Doses (N=41) n (%)
Infections and infestations (cont.)			
Localised infection	1 (8.3)	1 (6.3)	1 (2.4)
Mastoiditis	0	0	1 (2.4)
Otitis externa	1 (8.3)	1 (6.3)	1 (2.4)
Peritonitis bacterial	0	0	1 (2.4)
Pharyngitis	0	0	1 (2.4)
Rhinovirus infection	0	0	1 (2.4)
Sepsis	0	0	1 (2.4)
Septic shock	0	0	1 (2.4)
Tooth abscess	0	0	1 (2.4)
Urinary tract infection staphylococcal	0	1 (6.3)	1 (2.4)

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Infections and infestations (cont.)			
Viral upper respiratory tract infection	1 (8.3)	1 (6.3)	1 (2.4)
Vulvovaginal mycotic infection	0	0	1 (2.4)
Injury, poisoning and procedural complications	6 (50.0)	9 (56.3)	20 (48.8)
Fall	1 (8.3)	1 (6.3)	5 (12.2)
Contusion	2 (16.7)	2 (12.5)	4 (9.8)
Laceration	2 (16.7)	2 (12.5)	3 (7.3)
Arthropod bite	0	0	2 (4.9)
Lumbar vertebral fracture	1 (8.3)	1 (6.3)	2 (4.9)
Procedural pain	0	2 (12.5)	2 (4.9)
Subdural haematoma	1 (8.3)	1 (6.3)	2 (4.9)

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Table T.35.3.3.1.2.1
Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	 <=200 mg (N=16) n (%)	 All Doses (N=41) n (%)
Injury, poisoning and procedural complications (cont.)			
Electrical burn	1 (8.3)	1 (6.3)	1 (2.4)
Femoral neck fracture	0	0	1 (2.4)
Femur fracture	0	0	1 (2.4)
Foot fracture	0	0	1 (2.4)
Fractured sacrum	1 (8.3)	1 (6.3)	1 (2.4)
Limb injury	0	0	1 (2.4)
Overdose	0	0	1 (2.4)
Post procedural haemorrhage	1 (8.3)	1 (6.3)	1 (2.4)
Rib fracture	0	0	1 (2.4)
Skin wound	1 (8.3)	1 (6.3)	1 (2.4)

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Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	 <=200 mg (N=16) n (%)	 All Doses (N=41) n (%)
Injury, poisoning and procedural complications (cont.)			
Spinal compression fracture	0	1 (6.3)	1 (2.4)
Tendon injury	0	0	1 (2.4)
Thermal burn	0	0	1 (2.4)
Tooth fracture	0	0	1 (2.4)
Wound	0	0	1 (2.4)
Investigations	5 (41.7)	8 (50.0)	19 (46.3)
Weight increased	2 (16.7)	4 (25.0)	6 (14.6)
White blood cell count decreased	1 (8.3)	2 (12.5)	5 (12.2)
Blood alkaline phosphatase increased	0	1 (6.3)	4 (9.8)
Blood bilirubin increased	1 (8.3)	1 (6.3)	4 (9.8)

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Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	<=200 mg (N=16) n (%)	All Doses (N=41) n (%)
Investigations (cont.)			
Cardiac murmur	2 (16.7)	2 (12.5)	4 (9.8)
Blood creatinine increased	3 (25.0)	3 (18.8)	3 (7.3)
Alanine aminotransferase increased	0	0	2 (4.9)
Aspartate aminotransferase increased	0	0	2 (4.9)
Platelet count decreased	1 (8.3)	2 (12.5)	2 (4.9)
Electrocardiogram QT prolonged	0	0	1 (2.4)
Gamma-glutamyltransferase increased	0	1 (6.3)	1 (2.4)
Neutrophil count decreased	0	0	1 (2.4)
Neutrophil count increased	0	0	1 (2.4)
Occult blood positive	0	0	1 (2.4)

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AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	 <=200 mg (N=16) n (%)	 All Doses (N=41) n (%)
Investigations (cont.)			
Urine output increased	0	0	1 (2.4)
Weight decreased	0	0	1 (2.4)
Metabolism and nutrition disorders	8 (66.7)	12 (75.0)	27 (65.9)
Hypokalaemia	4 (33.3)	4 (25.0)	10 (24.4)
Decreased appetite	3 (25.0)	4 (25.0)	9 (22.0)
Hypophosphataemia	0	1 (6.3)	7 (17.1)
Dehydration	1 (8.3)	2 (12.5)	3 (7.3)
Hypocalcaemia	0	1 (6.3)	3 (7.3)
Hyperglycaemia	1 (8.3)	1 (6.3)	2 (4.9)
Fluid retention	0	1 (6.3)	1 (2.4)

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Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

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Metabolism and nutrition disorders (cont.)			
Hypernatraemia	0	0	1 (2.4)
Hyperuricaemia	0	0	1 (2.4)
Hypoalbuminaemia	0	0	1 (2.4)
Hypoglycaemia	0	0	1 (2.4)
Hypomagnesaemia	1 (8.3)	1 (6.3)	1 (2.4)
Hyponatraemia	0	0	1 (2.4)
Increased appetite	0	1 (6.3)	1 (2.4)
Metabolic acidosis	0	0	1 (2.4)
Vitamin D deficiency	1 (8.3)	1 (6.3)	1 (2.4)
Musculoskeletal and connective tissue disorders	5 (41.7)	8 (50.0)	25 (61.0)

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Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	<=200 mg (N=16) n (%)	All Doses (N=41) n (%)
Musculoskeletal and connective tissue disorders (cont.)			
Arthralgia	3 (25.0)	5 (31.3)	15 (36.6)
Pain in extremity	2 (16.7)	2 (12.5)	7 (17.1)
Back pain	1 (8.3)	2 (12.5)	4 (9.8)
Muscular weakness	2 (16.7)	3 (18.8)	4 (9.8)
Musculoskeletal pain	0	1 (6.3)	3 (7.3)
Exostosis	0	0	2 (4.9)
Muscle spasms	0	1 (6.3)	2 (4.9)
Musculoskeletal chest pain	0	1 (6.3)	2 (4.9)
Bone pain	0	1 (6.3)	1 (2.4)
Extraskeletal ossification	0	0	1 (2.4)

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System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	<=200 mg (N=16) n (%)	All Doses (N=41) n (%)
Musculoskeletal and connective tissue disorders (cont.)			
Groin pain	0	0	1 (2.4)
Intervertebral disc protrusion	0	1 (6.3)	1 (2.4)
Joint effusion	0	0	1 (2.4)
Joint stiffness	0	0	1 (2.4)
Joint swelling	0	1 (6.3)	1 (2.4)
Muscle twitching	0	0	1 (2.4)
Myalgia	0	1 (6.3)	1 (2.4)
Osteoporosis	0	0	1 (2.4)
Rotator cuff syndrome	0	0	1 (2.4)
Tenosynovitis	1 (8.3)	1 (6.3)	1 (2.4)

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Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	 <=200 mg (N=16) n (%)	 All Doses (N=41) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (25.0)	5 (31.3)	11 (26.8)
Squamous cell carcinoma	1 (8.3)	1 (6.3)	2 (4.9)
Acrochordon	0	0	1 (2.4)
Gastrointestinal neoplasm	0	0	1 (2.4)
Haemangioma	0	1 (6.3)	1 (2.4)
Intraductal proliferative breast lesion	0	1 (6.3)	1 (2.4)
Intravascular papillary endothelial hyperplasia	0	0	1 (2.4)
Keratoacanthoma	1 (8.3)	1 (6.3)	1 (2.4)
Lip neoplasm	0	0	1 (2.4)
Malignant melanoma	0	0	1 (2.4)

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Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont.)			
Myelodysplastic syndrome	1 (8.3)	1 (6.3)	1 (2.4)
Penile wart	1 (8.3)	1 (6.3)	1 (2.4)
Renal neoplasm	0	0	1 (2.4)
Seborrhoeic keratosis	0	0	1 (2.4)
Transitional cell carcinoma	0	0	1 (2.4)
Nervous system disorders	7 (58.3)	10 (62.5)	32 (78.0)
Dizziness	3 (25.0)	3 (18.8)	11 (26.8)
Memory impairment	1 (8.3)	1 (6.3)	9 (22.0)
Dysgeusia	1 (8.3)	3 (18.8)	7 (17.1)
Headache	4 (33.3)	5 (31.3)	7 (17.1)

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System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	 <=200 mg (N=16) n (%)	 All Doses (N=41) n (%)
Nervous system disorders (cont.)			
Hypoaesthesia	1 (8.3)	1 (6.3)	6 (14.6)
Cognitive disorder	1 (8.3)	1 (6.3)	5 (12.2)
Ageusia	0	0	3 (7.3)
Paraesthesia	1 (8.3)	1 (6.3)	3 (7.3)
Dizziness postural	1 (8.3)	1 (6.3)	2 (4.9)
Encephalopathy	0	0	2 (4.9)
Haemorrhage intracranial	0	0	2 (4.9)
Peripheral sensory neuropathy	0	0	2 (4.9)
Aphasia	0	0	1 (2.4)
Central nervous system lesion	0	0	1 (2.4)

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System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	 <=200 mg (N=16) n (%)	 All Doses (N=41) n (%)
Nervous system disorders (cont.)			
Cerebral atrophy	0	0	1 (2.4)
Cerebral ventricle dilatation	0	0	1 (2.4)
Dementia	0	0	1 (2.4)
Dysarthria	0	1 (6.3)	1 (2.4)
Hydrocephalus	0	0	1 (2.4)
Myoclonus	1 (8.3)	1 (6.3)	1 (2.4)
Neuropathy peripheral	0	0	1 (2.4)
Post herpetic neuralgia	0	0	1 (2.4)
Seizure	0	0	1 (2.4)
Somnolence	0	0	1 (2.4)

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Nervous system disorders (cont.)			
Syncope	0	0	1 (2.4)
Transient ischaemic attack	1 (8.3)	1 (6.3)	1 (2.4)
Psychiatric disorders	3 (25.0)	5 (31.3)	13 (31.7)
Insomnia	2 (16.7)	3 (18.8)	7 (17.1)
Anxiety	0	0	2 (4.9)
Confusional state	0	0	2 (4.9)
Depression	0	0	2 (4.9)
Depressed mood	1 (8.3)	1 (6.3)	1 (2.4)
Dysphoria	0	0	1 (2.4)
Irritability	0	1 (6.3)	1 (2.4)

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Psychiatric disorders (cont.)			
Libido decreased	1 (8.3)	1 (6.3)	1 (2.4)
Mental status changes	0	0	1 (2.4)
Suicidal ideation	0	0	1 (2.4)
Renal and urinary disorders	2 (16.7)	4 (25.0)	14 (34.1)
Dysuria	1 (8.3)	2 (12.5)	6 (14.6)
Acute kidney injury	2 (16.7)	2 (12.5)	5 (12.2)
Haematuria	0	1 (6.3)	4 (9.8)
Pollakiuria	1 (8.3)	1 (6.3)	2 (4.9)
Urinary incontinence	1 (8.3)	1 (6.3)	2 (4.9)
Chronic kidney disease	1 (8.3)	1 (6.3)	1 (2.4)

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Renal and urinary disorders (cont.)			
Hypertonic bladder	0	1 (6.3)	1 (2.4)
Nephrolithiasis	0	0	1 (2.4)
Polyuria	0	0	1 (2.4)
Renal colic	0	0	1 (2.4)
Renal impairment	0	0	1 (2.4)
Renal mass	0	0	1 (2.4)
Urinary retention	1 (8.3)	1 (6.3)	1 (2.4)
Reproductive system and breast disorders	2 (16.7)	2 (12.5)	4 (9.8)
Haematospermia	0	0	1 (2.4)
Penile pain	1 (8.3)	1 (6.3)	1 (2.4)

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System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	 <=200 mg (N=16) n (%)	 All Doses (N=41) n (%)
Reproductive system and breast disorders (cont.)			
Scrotal oedema	1 (8.3)	1 (6.3)	1 (2.4)
Vulvovaginal pain	0	0	1 (2.4)
Respiratory, thoracic and mediastinal disorders	7 (58.3)	10 (62.5)	27 (65.9)
Cough	1 (8.3)	3 (18.8)	9 (22.0)
Dyspnoea	2 (16.7)	3 (18.8)	7 (17.1)
Epistaxis	3 (25.0)	3 (18.8)	7 (17.1)
Pleural effusion	2 (16.7)	2 (12.5)	5 (12.2)
Productive cough	1 (8.3)	1 (6.3)	4 (9.8)
Nasal congestion	1 (8.3)	1 (6.3)	3 (7.3)
Rhinorrhoea	0	0	3 (7.3)

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Respiratory, thoracic and mediastinal disorders (cont.)			
Upper-airway cough syndrome	1 (8.3)	1 (6.3)	3 (7.3)
Dysphonia	0	0	2 (4.9)
Haemoptysis	1 (8.3)	1 (6.3)	2 (4.9)
Pulmonary congestion	1 (8.3)	2 (12.5)	2 (4.9)
Acute respiratory failure	0	0	1 (2.4)
Chronic obstructive pulmonary disease	0	0	1 (2.4)
Dyspnoea exertional	0	0	1 (2.4)
Emphysema	0	0	1 (2.4)
Hypoxia	1 (8.3)	1 (6.3)	1 (2.4)
Laryngeal oedema	0	0	1 (2.4)

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Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	 <=200 mg (N=16) n (%)	 All Doses (N=41) n (%)
Respiratory, thoracic and mediastinal disorders (cont.)			
Oropharyngeal pain	0	0	1 (2.4)
Pneumothorax	1 (8.3)	1 (6.3)	1 (2.4)
Pulmonary hypertension	1 (8.3)	1 (6.3)	1 (2.4)
Pulmonary mass	0	0	1 (2.4)
Rales	0	0	1 (2.4)
Rhinitis allergic	0	0	1 (2.4)
Rhonchi	1 (8.3)	1 (6.3)	1 (2.4)
Sinus disorder	0	0	1 (2.4)
Wheezing	0	0	1 (2.4)
Skin and subcutaneous tissue disorders	6 (50.0)	9 (56.3)	28 (68.3)

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Note 3: System Organ Classes are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.3.3.1.2.1
Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	BLU-285-2101 <=200 mg (N=16) n (%)	BLU-285-2101 All Doses (N=41) n (%)
Skin and subcutaneous tissue disorders (cont.)			
Hair colour changes	1 (8.3)	2 (12.5)	10 (24.4)
Rash	1 (8.3)	3 (18.8)	7 (17.1)
Pruritus	0	1 (6.3)	6 (14.6)
Alopecia	0	0	5 (12.2)
Photosensitivity reaction	1 (8.3)	2 (12.5)	5 (12.2)
Rash maculo-papular	1 (8.3)	1 (6.3)	5 (12.2)
Ecchymosis	1 (8.3)	1 (6.3)	3 (7.3)
Rash pruritic	0	0	3 (7.3)
Skin lesion	0	0	3 (7.3)
Erythema	2 (16.7)	2 (12.5)	2 (4.9)

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Table T.35.3.3.1.2.1
Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	<=200 mg (N=16) n (%)	All Doses (N=41) n (%)
Skin and subcutaneous tissue disorders (cont.)			
Hyperhidrosis	0	0	2 (4.9)
Livedo reticularis	0	0	2 (4.9)
Nail bed disorder	0	1 (6.3)	2 (4.9)
Night sweats	1 (8.3)	2 (12.5)	2 (4.9)
Rash erythematous	0	0	2 (4.9)
Rash papular	0	0	2 (4.9)
Urticaria	0	0	2 (4.9)
Blood blister	1 (8.3)	1 (6.3)	1 (2.4)
Dermatitis	0	0	1 (2.4)
Dermatitis acneiform	0	0	1 (2.4)

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Table T.35.3.3.1.2.1
Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	 <=200 mg (N=16) n (%)	 All Doses (N=41) n (%)
Skin and subcutaneous tissue disorders (cont.)			
Dry skin	0	0	1 (2.4)
Eczema	0	0	1 (2.4)
Hair growth abnormal	0	0	1 (2.4)
Melanocytic hyperplasia	0	0	1 (2.4)
Nail growth abnormal	0	0	1 (2.4)
Scab	0	0	1 (2.4)
Skin depigmentation	0	1 (6.3)	1 (2.4)
Skin discolouration	0	1 (6.3)	1 (2.4)
Skin ulcer	0	0	1 (2.4)
Swelling face	1 (8.3)	1 (6.3)	1 (2.4)

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Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	BLU-285-2101 <=200 mg (N=16) n (%)	BLU-285-2101 All Doses (N=41) n (%)
Skin and subcutaneous tissue disorders (cont.)			
Telangiectasia	0	1 (6.3)	1 (2.4)
Vascular disorders	5 (41.7)	5 (31.3)	18 (43.9)
Hypertension	0	0	6 (14.6)
Hypotension	2 (16.7)	2 (12.5)	5 (12.2)
Flushing	1 (8.3)	1 (6.3)	4 (9.8)
Embolism	0	0	1 (2.4)
Epistaxis	1 (8.3)	1 (6.3)	1 (2.4)
Hot flush	0	0	1 (2.4)
Pallor	1 (8.3)	1 (6.3)	1 (2.4)
Peripheral vascular disorder	0	0	1 (2.4)

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Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	 <=200 mg (N=16) n (%)	 All Doses (N=41) n (%)
Vascular disorders (cont.)			
Thrombophlebitis	1 (8.3)	1 (6.3)	1 (2.4)

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Table T.35.3.3.1.2.1
Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 200 mg (N=40) n (%)	 <=200 mg (N=42) n (%)	 All Doses (N=42) n (%)
Patients with at least one Event	40 (100)	42 (100)	42 (100)
Blood and lymphatic system disorders	25 (62.5)	26 (61.9)	26 (61.9)
Thrombocytopenia	13 (32.5)	13 (31.0)	13 (31.0)
Anaemia	11 (27.5)	11 (26.2)	11 (26.2)
Neutropenia	4 (10.0)	5 (11.9)	5 (11.9)
Leukocytosis	2 (5.0)	2 (4.8)	2 (4.8)
Coagulopathy	1 (2.5)	1 (2.4)	1 (2.4)
Haemolysis	1 (2.5)	1 (2.4)	1 (2.4)
Haemorrhagic diathesis	1 (2.5)	1 (2.4)	1 (2.4)
Mast cell activation syndrome	1 (2.5)	1 (2.4)	1 (2.4)

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Table T.35.3.3.1.2.1
Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 200 mg (N=40) n (%)	 <=200 mg (N=42) n (%)	 All Doses (N=42) n (%)
Cardiac disorders	7 (17.5)	7 (16.7)	7 (16.7)
Cardiac failure	2 (5.0)	2 (4.8)	2 (4.8)
Atrial flutter	1 (2.5)	1 (2.4)	1 (2.4)
Bradycardia	1 (2.5)	1 (2.4)	1 (2.4)
Palpitations	1 (2.5)	1 (2.4)	1 (2.4)
Pericardial effusion	1 (2.5)	1 (2.4)	1 (2.4)
Supraventricular extrasystoles	1 (2.5)	1 (2.4)	1 (2.4)
Ventricular extrasystoles	1 (2.5)	1 (2.4)	1 (2.4)
Ear and labyrinth disorders	1 (2.5)	1 (2.4)	1 (2.4)
Vertigo	1 (2.5)	1 (2.4)	1 (2.4)

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Table T.35.3.3.1.2.1
Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 200 mg (N=40) n (%)	 <=200 mg (N=42) n (%)	 All Doses (N=42) n (%)
Eye disorders	21 (52.5)	22 (52.4)	22 (52.4)
Periorbital oedema	9 (22.5)	9 (21.4)	9 (21.4)
Eyelid oedema	7 (17.5)	7 (16.7)	7 (16.7)
Lacrimation increased	4 (10.0)	4 (9.5)	4 (9.5)
Cataract	0	1 (2.4)	1 (2.4)
Conjunctival haemorrhage	1 (2.5)	1 (2.4)	1 (2.4)
Eye haemorrhage	1 (2.5)	1 (2.4)	1 (2.4)
Eye swelling	1 (2.5)	1 (2.4)	1 (2.4)
Vision blurred	1 (2.5)	1 (2.4)	1 (2.4)
Visual acuity reduced	1 (2.5)	1 (2.4)	1 (2.4)

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Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 200 mg (N=40) n (%)	 <=200 mg (N=42) n (%)	 All Doses (N=42) n (%)
Eye disorders (cont.)			
Vitreous floaters	1 (2.5)	1 (2.4)	1 (2.4)
Vitreous haemorrhage	1 (2.5)	1 (2.4)	1 (2.4)
Gastrointestinal disorders	29 (72.5)	30 (71.4)	30 (71.4)
Diarrhoea	9 (22.5)	10 (23.8)	10 (23.8)
Vomiting	8 (20.0)	9 (21.4)	9 (21.4)
Nausea	8 (20.0)	8 (19.0)	8 (19.0)
Constipation	5 (12.5)	5 (11.9)	5 (11.9)
Abdominal pain	4 (10.0)	4 (9.5)	4 (9.5)
Dyspepsia	2 (5.0)	2 (4.8)	2 (4.8)
Gastrooesophageal reflux disease	2 (5.0)	2 (4.8)	2 (4.8)

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AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 200 mg (N=40) n (%)	 <=200 mg (N=42) n (%)	 All Doses (N=42) n (%)
Gastrointestinal disorders (cont.)			
Melaena	2 (5.0)	2 (4.8)	2 (4.8)
Salivary hypersecretion	2 (5.0)	2 (4.8)	2 (4.8)
Abdominal distension	1 (2.5)	1 (2.4)	1 (2.4)
Abdominal pain upper	1 (2.5)	1 (2.4)	1 (2.4)
Ascites	1 (2.5)	1 (2.4)	1 (2.4)
Dental caries	1 (2.5)	1 (2.4)	1 (2.4)
Duodenal ulcer haemorrhage	1 (2.5)	1 (2.4)	1 (2.4)
Faeces discoloured	1 (2.5)	1 (2.4)	1 (2.4)
Gastrointestinal haemorrhage	1 (2.5)	1 (2.4)	1 (2.4)
Gingival bleeding	1 (2.5)	1 (2.4)	1 (2.4)

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AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 200 mg (N=40) n (%)	 <=200 mg (N=42) n (%)	 All Doses (N=42) n (%)
Gastrointestinal disorders (cont.)			
Intra-abdominal haematoma	1 (2.5)	1 (2.4)	1 (2.4)
Intra-abdominal haemorrhage	1 (2.5)	1 (2.4)	1 (2.4)
Lip dry	1 (2.5)	1 (2.4)	1 (2.4)
Lower gastrointestinal haemorrhage	1 (2.5)	1 (2.4)	1 (2.4)
Portal hypertensive gastropathy	1 (2.5)	1 (2.4)	1 (2.4)
Tooth deposit	1 (2.5)	1 (2.4)	1 (2.4)
Toothache	1 (2.5)	1 (2.4)	1 (2.4)
General disorders and administration site conditions	27 (67.5)	27 (64.3)	27 (64.3)
Oedema peripheral	20 (50.0)	20 (47.6)	20 (47.6)
Face oedema	7 (17.5)	7 (16.7)	7 (16.7)

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Summary of Adverse Events by System Organ Class and Preferred Term
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System Organ Class Preferred Term	BLU-285-2202 200 mg (N=40) n (%)	 <=200 mg (N=42) n (%)	 All Doses (N=42) n (%)
General disorders and administration site conditions (cont.)			
Asthenia	4 (10.0)	4 (9.5)	4 (9.5)
Fatigue	3 (7.5)	3 (7.1)	3 (7.1)
Pain	3 (7.5)	3 (7.1)	3 (7.1)
Pyrexia	3 (7.5)	3 (7.1)	3 (7.1)
Non-cardiac chest pain	2 (5.0)	2 (4.8)	2 (4.8)
Disease progression	1 (2.5)	1 (2.4)	1 (2.4)
Generalised oedema	1 (2.5)	1 (2.4)	1 (2.4)
Oedema	1 (2.5)	1 (2.4)	1 (2.4)
Peripheral swelling	1 (2.5)	1 (2.4)	1 (2.4)
Systemic inflammatory response syndrome	1 (2.5)	1 (2.4)	1 (2.4)

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System Organ Class Preferred Term	BLU-285-2202 200 mg (N=40) n (%)	 <=200 mg (N=42) n (%)	 All Doses (N=42) n (%)
Hepatobiliary disorders	1 (2.5)	1 (2.4)	1 (2.4)
Hyperbilirubinaemia	1 (2.5)	1 (2.4)	1 (2.4)
Immune system disorders	1 (2.5)	1 (2.4)	1 (2.4)
Hypogammaglobulinaemia	1 (2.5)	1 (2.4)	1 (2.4)
Immune system disorder	1 (2.5)	1 (2.4)	1 (2.4)
Infections and infestations	19 (47.5)	20 (47.6)	20 (47.6)
Herpes zoster	2 (5.0)	3 (7.1)	3 (7.1)
Urinary tract infection	2 (5.0)	2 (4.8)	2 (4.8)
Appendiceal abscess	1 (2.5)	1 (2.4)	1 (2.4)
Catheter site cellulitis	1 (2.5)	1 (2.4)	1 (2.4)

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Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 200 mg (N=40) n (%)	 <=200 mg (N=42) n (%)	 All Doses (N=42) n (%)
Infections and infestations (cont.)			
Cellulitis	1 (2.5)	1 (2.4)	1 (2.4)
Clostridium difficile colitis	0	1 (2.4)	1 (2.4)
Corona virus infection	1 (2.5)	1 (2.4)	1 (2.4)
Cystitis	1 (2.5)	1 (2.4)	1 (2.4)
Gastrointestinal fungal infection	1 (2.5)	1 (2.4)	1 (2.4)
Herpes simplex	1 (2.5)	1 (2.4)	1 (2.4)
Necrotising fasciitis	1 (2.5)	1 (2.4)	1 (2.4)
Oral candidiasis	1 (2.5)	1 (2.4)	1 (2.4)
Oral herpes	1 (2.5)	1 (2.4)	1 (2.4)
Oropharyngeal candidiasis	1 (2.5)	1 (2.4)	1 (2.4)

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Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 200 mg (N=40) n (%)	 <=200 mg (N=42) n (%)	 All Doses (N=42) n (%)
Infections and infestations (cont.)			
Otitis media	1 (2.5)	1 (2.4)	1 (2.4)
Paronychia	1 (2.5)	1 (2.4)	1 (2.4)
Pneumonia	1 (2.5)	1 (2.4)	1 (2.4)
Respiratory tract infection	1 (2.5)	1 (2.4)	1 (2.4)
Sepsis	1 (2.5)	1 (2.4)	1 (2.4)
Sinusitis	1 (2.5)	1 (2.4)	1 (2.4)
Skin infection	1 (2.5)	1 (2.4)	1 (2.4)
Stoma site cellulitis	1 (2.5)	1 (2.4)	1 (2.4)
Upper respiratory tract infection	1 (2.5)	1 (2.4)	1 (2.4)
Wound infection	1 (2.5)	1 (2.4)	1 (2.4)

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Table T.35.3.3.1.2.1
Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 200 mg (N=40) n (%)	 <=200 mg (N=42) n (%)	 All Doses (N=42) n (%)
Injury, poisoning and procedural complications	8 (20.0)	8 (19.0)	8 (19.0)
Fall	2 (5.0)	2 (4.8)	2 (4.8)
Anaemia postoperative	1 (2.5)	1 (2.4)	1 (2.4)
Contusion	1 (2.5)	1 (2.4)	1 (2.4)
Joint injury	1 (2.5)	1 (2.4)	1 (2.4)
Post procedural haemorrhage	1 (2.5)	1 (2.4)	1 (2.4)
Procedural pain	1 (2.5)	1 (2.4)	1 (2.4)
Skin abrasion	1 (2.5)	1 (2.4)	1 (2.4)
Subdural haematoma	1 (2.5)	1 (2.4)	1 (2.4)
Tendon rupture	1 (2.5)	1 (2.4)	1 (2.4)

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Table T.35.3.3.1.2.1
Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 200 mg (N=40) n (%)	 <=200 mg (N=42) n (%)	 All Doses (N=42) n (%)
Injury, poisoning and procedural complications (cont.)			
Traumatic haematoma	1 (2.5)	1 (2.4)	1 (2.4)
Investigations	19 (47.5)	19 (45.2)	19 (45.2)
Blood bilirubin increased	6 (15.0)	6 (14.3)	6 (14.3)
Platelet count decreased	6 (15.0)	6 (14.3)	6 (14.3)
Blood creatinine increased	4 (10.0)	4 (9.5)	4 (9.5)
Neutrophil count decreased	3 (7.5)	3 (7.1)	3 (7.1)
White blood cell count decreased	3 (7.5)	3 (7.1)	3 (7.1)
Blood alkaline phosphatase increased	2 (5.0)	2 (4.8)	2 (4.8)
Blood uric acid increased	2 (5.0)	2 (4.8)	2 (4.8)
Gamma-glutamyltransferase increased	2 (5.0)	2 (4.8)	2 (4.8)

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Table T.35.3.3.1.2.1
Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 200 mg (N=40) n (%)	 <=200 mg (N=42) n (%)	 All Doses (N=42) n (%)
Investigations (cont.)			
Urine uric acid increased	2 (5.0)	2 (4.8)	2 (4.8)
Weight increased	2 (5.0)	2 (4.8)	2 (4.8)
Alanine aminotransferase decreased	1 (2.5)	1 (2.4)	1 (2.4)
Alanine aminotransferase increased	1 (2.5)	1 (2.4)	1 (2.4)
Aspartate aminotransferase increased	1 (2.5)	1 (2.4)	1 (2.4)
Blood albumin decreased	1 (2.5)	1 (2.4)	1 (2.4)
Blood bilirubin unconjugated increased	1 (2.5)	1 (2.4)	1 (2.4)
Blood phosphorus decreased	1 (2.5)	1 (2.4)	1 (2.4)
Blood thyroid stimulating hormone increased	1 (2.5)	1 (2.4)	1 (2.4)
C-reactive protein increased	1 (2.5)	1 (2.4)	1 (2.4)

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Table T.35.3.3.1.2.1
Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 200 mg (N=40) n (%)	 <=200 mg (N=42) n (%)	 All Doses (N=42) n (%)
Investigations (cont.)			
Cardiac murmur	1 (2.5)	1 (2.4)	1 (2.4)
Electrocardiogram QT prolonged	1 (2.5)	1 (2.4)	1 (2.4)
Haemoglobin decreased	1 (2.5)	1 (2.4)	1 (2.4)
Lipase increased	1 (2.5)	1 (2.4)	1 (2.4)
Lymphocyte count decreased	1 (2.5)	1 (2.4)	1 (2.4)
Monocyte count increased	1 (2.5)	1 (2.4)	1 (2.4)
Prothrombin time shortened	1 (2.5)	1 (2.4)	1 (2.4)
Red blood cell count decreased	1 (2.5)	1 (2.4)	1 (2.4)
Reticulocyte count increased	1 (2.5)	1 (2.4)	1 (2.4)
White blood cell count increased	1 (2.5)	1 (2.4)	1 (2.4)

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Table T.35.3.3.1.2.1
Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 200 mg (N=40) n (%)	BLU-285-2202 <=200 mg (N=42) n (%)	BLU-285-2202 All Doses (N=42) n (%)
Metabolism and nutrition disorders	9 (22.5)	10 (23.8)	10 (23.8)
Decreased appetite	2 (5.0)	2 (4.8)	2 (4.8)
Hypomagnesaemia	2 (5.0)	2 (4.8)	2 (4.8)
Hypophosphataemia	2 (5.0)	2 (4.8)	2 (4.8)
Cachexia	1 (2.5)	1 (2.4)	1 (2.4)
Gout	1 (2.5)	1 (2.4)	1 (2.4)
Hyperphosphataemia	1 (2.5)	1 (2.4)	1 (2.4)
Hyperuricaemia	1 (2.5)	1 (2.4)	1 (2.4)
Hypocalcaemia	1 (2.5)	1 (2.4)	1 (2.4)
Hypokalaemia	0	1 (2.4)	1 (2.4)

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Table T.35.3.3.1.2.1
Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 200 mg (N=40) n (%)	 <=200 mg (N=42) n (%)	 All Doses (N=42) n (%)
Metabolism and nutrition disorders (cont.)			
Tumour lysis syndrome	1 (2.5)	1 (2.4)	1 (2.4)
Musculoskeletal and connective tissue disorders	10 (25.0)	11 (26.2)	11 (26.2)
Arthralgia	2 (5.0)	2 (4.8)	2 (4.8)
Back pain	2 (5.0)	2 (4.8)	2 (4.8)
Myalgia	2 (5.0)	2 (4.8)	2 (4.8)
Pain in extremity	1 (2.5)	2 (4.8)	2 (4.8)
Muscular weakness	1 (2.5)	1 (2.4)	1 (2.4)
Musculoskeletal pain	1 (2.5)	1 (2.4)	1 (2.4)
Neck pain	1 (2.5)	1 (2.4)	1 (2.4)
Osteonecrosis of jaw	1 (2.5)	1 (2.4)	1 (2.4)

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Table T.35.3.3.1.2.1
Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 200 mg (N=40) n (%)	 <=200 mg (N=42) n (%)	 All Doses (N=42) n (%)
Musculoskeletal and connective tissue disorders (cont.)			
Osteoporosis	1 (2.5)	1 (2.4)	1 (2.4)
Pain in jaw	1 (2.5)	1 (2.4)	1 (2.4)
Spinal column stenosis	1 (2.5)	1 (2.4)	1 (2.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4 (10.0)	4 (9.5)	4 (9.5)
Acute myeloid leukaemia	1 (2.5)	1 (2.4)	1 (2.4)
Basal cell carcinoma	1 (2.5)	1 (2.4)	1 (2.4)
Benign gastrointestinal neoplasm	1 (2.5)	1 (2.4)	1 (2.4)
Malignant melanoma	1 (2.5)	1 (2.4)	1 (2.4)
Salivary gland neoplasm	1 (2.5)	1 (2.4)	1 (2.4)
Squamous cell carcinoma of skin	1 (2.5)	1 (2.4)	1 (2.4)

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Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 200 mg (N=40) n (%)	BLU-285-2202 <=200 mg (N=42) n (%)	BLU-285-2202 All Doses (N=42) n (%)
Nervous system disorders	16 (40.0)	16 (38.1)	16 (38.1)
Dysgeusia	6 (15.0)	6 (14.3)	6 (14.3)
Headache	5 (12.5)	5 (11.9)	5 (11.9)
Dizziness	4 (10.0)	4 (9.5)	4 (9.5)
Cognitive disorder	2 (5.0)	2 (4.8)	2 (4.8)
Memory impairment	2 (5.0)	2 (4.8)	2 (4.8)
Restless legs syndrome	2 (5.0)	2 (4.8)	2 (4.8)
Aphasia	1 (2.5)	1 (2.4)	1 (2.4)
Balance disorder	1 (2.5)	1 (2.4)	1 (2.4)
Dizziness postural	1 (2.5)	1 (2.4)	1 (2.4)

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Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 200 mg (N=40) n (%)	 <=200 mg (N=42) n (%)	 All Doses (N=42) n (%)
Nervous system disorders (cont.)			
Hypogeusia	1 (2.5)	1 (2.4)	1 (2.4)
Parkinson's disease	1 (2.5)	1 (2.4)	1 (2.4)
Sensory disturbance	1 (2.5)	1 (2.4)	1 (2.4)
Tremor	1 (2.5)	1 (2.4)	1 (2.4)
Psychiatric disorders	9 (22.5)	9 (21.4)	9 (21.4)
Insomnia	2 (5.0)	2 (4.8)	2 (4.8)
Sleep disorder	2 (5.0)	2 (4.8)	2 (4.8)
Adjustment disorder with depressed mood	1 (2.5)	1 (2.4)	1 (2.4)
Confusional state	1 (2.5)	1 (2.4)	1 (2.4)
Delirium	1 (2.5)	1 (2.4)	1 (2.4)

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Summary of Adverse Events by System Organ Class and Preferred Term
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System Organ Class Preferred Term	BLU-285-2202 200 mg (N=40) n (%)	 <=200 mg (N=42) n (%)	 All Doses (N=42) n (%)
Psychiatric disorders (cont.)			
Depressed mood	1 (2.5)	1 (2.4)	1 (2.4)
Depression	1 (2.5)	1 (2.4)	1 (2.4)
Disorientation	1 (2.5)	1 (2.4)	1 (2.4)
Mental disorder	1 (2.5)	1 (2.4)	1 (2.4)
Renal and urinary disorders	4 (10.0)	4 (9.5)	4 (9.5)
Nephrolithiasis	2 (5.0)	2 (4.8)	2 (4.8)
Acute kidney injury	1 (2.5)	1 (2.4)	1 (2.4)
Haematuria	1 (2.5)	1 (2.4)	1 (2.4)
Obstructive uropathy	1 (2.5)	1 (2.4)	1 (2.4)
Reproductive system and breast disorders	2 (5.0)	2 (4.8)	2 (4.8)

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AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 200 mg (N=40) n (%)	 <=200 mg (N=42) n (%)	 All Doses (N=42) n (%)
Reproductive system and breast disorders (cont.)			
Oedema genital	1 (2.5)	1 (2.4)	1 (2.4)
Scrotal oedema	1 (2.5)	1 (2.4)	1 (2.4)
Respiratory, thoracic and mediastinal disorders	11 (27.5)	11 (26.2)	11 (26.2)
Epistaxis	4 (10.0)	4 (9.5)	4 (9.5)
Dyspnoea	2 (5.0)	2 (4.8)	2 (4.8)
Pleural effusion	2 (5.0)	2 (4.8)	2 (4.8)
Bronchial haemorrhage	1 (2.5)	1 (2.4)	1 (2.4)
Cough	1 (2.5)	1 (2.4)	1 (2.4)
Dyspnoea exertional	1 (2.5)	1 (2.4)	1 (2.4)
Haemoptysis	1 (2.5)	1 (2.4)	1 (2.4)

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Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 200 mg (N=40) n (%)	 <=200 mg (N=42) n (%)	 All Doses (N=42) n (%)
Respiratory, thoracic and mediastinal disorders (cont.)			
Haemothorax	1 (2.5)	1 (2.4)	1 (2.4)
Nasal congestion	1 (2.5)	1 (2.4)	1 (2.4)
Oropharyngeal pain	1 (2.5)	1 (2.4)	1 (2.4)
Pulmonary oedema	1 (2.5)	1 (2.4)	1 (2.4)
Rales	1 (2.5)	1 (2.4)	1 (2.4)
Respiratory symptom	1 (2.5)	1 (2.4)	1 (2.4)
Throat irritation	1 (2.5)	1 (2.4)	1 (2.4)
Skin and subcutaneous tissue disorders	12 (30.0)	12 (28.6)	12 (28.6)
Alopecia	3 (7.5)	3 (7.1)	3 (7.1)
Hair colour changes	3 (7.5)	3 (7.1)	3 (7.1)

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Table T.35.3.3.1.2.1
Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 200 mg (N=40) n (%)	 <=200 mg (N=42) n (%)	 All Doses (N=42) n (%)
Skin and subcutaneous tissue disorders (cont.)			
Pruritus	3 (7.5)	3 (7.1)	3 (7.1)
Petechiae	2 (5.0)	2 (4.8)	2 (4.8)
Dermatitis contact	1 (2.5)	1 (2.4)	1 (2.4)
Hyperhidrosis	1 (2.5)	1 (2.4)	1 (2.4)
Night sweats	1 (2.5)	1 (2.4)	1 (2.4)
Psoriasis	1 (2.5)	1 (2.4)	1 (2.4)
Rash	1 (2.5)	1 (2.4)	1 (2.4)
Seborrhoeic dermatitis	1 (2.5)	1 (2.4)	1 (2.4)
Skin haemorrhage	1 (2.5)	1 (2.4)	1 (2.4)
Skin ulcer	1 (2.5)	1 (2.4)	1 (2.4)

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Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 200 mg (N=40) n (%)	 <=200 mg (N=42) n (%)	 All Doses (N=42) n (%)
Skin and subcutaneous tissue disorders (cont.)			
Swelling face	1 (2.5)	1 (2.4)	1 (2.4)
Vascular disorders	8 (20.0)	8 (19.0)	8 (19.0)
Flushing	2 (5.0)	2 (4.8)	2 (4.8)
Hypertension	2 (5.0)	2 (4.8)	2 (4.8)
Haematoma	1 (2.5)	1 (2.4)	1 (2.4)
Haemorrhage	1 (2.5)	1 (2.4)	1 (2.4)
Hot flush	1 (2.5)	1 (2.4)	1 (2.4)
Hypotension	1 (2.5)	1 (2.4)	1 (2.4)
Shock haemorrhagic	1 (2.5)	1 (2.4)	1 (2.4)

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Table T.35.3.3.1.2.1
Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	 <=200 mg (N=58) n (%)	 All Doses (N=83) n (%)
Patients with at least one Event	52 (100)	58 (100)	83 (100)
Blood and lymphatic system disorders	34 (65.4)	37 (63.8)	59 (71.1)
Anaemia	16 (30.8)	17 (29.3)	31 (37.3)
Thrombocytopenia	18 (34.6)	19 (32.8)	29 (34.9)
Neutropenia	7 (13.5)	8 (13.8)	12 (14.5)
Leukocytosis	2 (3.8)	2 (3.4)	4 (4.8)
Haemolysis	1 (1.9)	1 (1.7)	2 (2.4)
Haemorrhagic diathesis	2 (3.8)	2 (3.4)	2 (2.4)
Increased tendency to bruise	2 (3.8)	2 (3.4)	2 (2.4)
Leukopenia	0	1 (1.7)	2 (2.4)

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Table T.35.3.3.1.2.1
Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	 <=200 mg (N=58) n (%)	 All Doses (N=83) n (%)
Blood and lymphatic system disorders (cont.)			
Lymphadenopathy	1 (1.9)	1 (1.7)	2 (2.4)
Lymphopenia	1 (1.9)	1 (1.7)	2 (2.4)
Mast cell activation syndrome	1 (1.9)	1 (1.7)	2 (2.4)
Anaemia macrocytic	1 (1.9)	1 (1.7)	1 (1.2)
Autoimmune haemolytic anaemia	0	0	1 (1.2)
Coagulopathy	1 (1.9)	1 (1.7)	1 (1.2)
Pancytopenia	0	0	1 (1.2)
Splenic lesion	0	0	1 (1.2)
Splenomegaly	0	0	1 (1.2)
Cardiac disorders	8 (15.4)	8 (13.8)	12 (14.5)

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AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	 <=200 mg (N=58) n (%)	 All Doses (N=83) n (%)
Cardiac disorders (cont.)			
Cardiac failure	2 (3.8)	2 (3.4)	2 (2.4)
Palpitations	1 (1.9)	1 (1.7)	2 (2.4)
Acute myocardial infarction	0	0	1 (1.2)
Angina pectoris	0	0	1 (1.2)
Atrial flutter	1 (1.9)	1 (1.7)	1 (1.2)
Bradycardia	1 (1.9)	1 (1.7)	1 (1.2)
Cardiac failure congestive	1 (1.9)	1 (1.7)	1 (1.2)
Cyanosis	0	0	1 (1.2)
Pericardial effusion	1 (1.9)	1 (1.7)	1 (1.2)
Sinus tachycardia	0	0	1 (1.2)

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Cardiac disorders (cont.)			
Supraventricular extrasystoles	1 (1.9)	1 (1.7)	1 (1.2)
Ventricular extrasystoles	1 (1.9)	1 (1.7)	1 (1.2)
Congenital, familial and genetic disorders	1 (1.9)	1 (1.7)	1 (1.2)
Right-to-left cardiac shunt	1 (1.9)	1 (1.7)	1 (1.2)
Ear and labyrinth disorders	2 (3.8)	2 (3.4)	7 (8.4)
Vertigo	1 (1.9)	1 (1.7)	3 (3.6)
Cerumen impaction	0	0	1 (1.2)
Deafness	1 (1.9)	1 (1.7)	1 (1.2)
Deafness neurosensory	0	0	1 (1.2)
Ear discomfort	0	0	1 (1.2)

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Ear and labyrinth disorders (cont.)			
Ear pain	0	0	1 (1.2)
Hypoacusis	0	0	1 (1.2)
Tinnitus	0	0	1 (1.2)
Endocrine disorders	0	0	1 (1.2)
Inappropriate antidiuretic hormone secretion	0	0	1 (1.2)
Eye disorders	30 (57.7)	33 (56.9)	54 (65.1)
Periorbital oedema	15 (28.8)	17 (29.3)	37 (44.6)
Lacrimation increased	5 (9.6)	6 (10.3)	11 (13.3)
Eyelid oedema	7 (13.5)	7 (12.1)	7 (8.4)
Vision blurred	2 (3.8)	2 (3.4)	5 (6.0)

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AdvSM Population & Prior Neoplastic Therapy = Yes

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Eye disorders (cont.)			
Conjunctival haemorrhage	2 (3.8)	3 (5.2)	4 (4.8)
Eye swelling	2 (3.8)	3 (5.2)	3 (3.6)
Eye haemorrhage	1 (1.9)	1 (1.7)	2 (2.4)
Photophobia	0	0	2 (2.4)
Visual acuity reduced	1 (1.9)	1 (1.7)	2 (2.4)
Blepharitis	0	0	1 (1.2)
Cataract	0	1 (1.7)	1 (1.2)
Cataract nuclear	0	0	1 (1.2)
Conjunctival oedema	0	0	1 (1.2)
Eye inflammation	0	0	1 (1.2)

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AdvSM Population & Prior Neoplastic Therapy = Yes

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Eye disorders (cont.)			
Eye pruritus	0	1 (1.7)	1 (1.2)
Macular fibrosis	1 (1.9)	1 (1.7)	1 (1.2)
Ocular hyperaemia	1 (1.9)	1 (1.7)	1 (1.2)
Papilloedema	0	1 (1.7)	1 (1.2)
Periorbital haemorrhage	1 (1.9)	1 (1.7)	1 (1.2)
Retinal tear	0	0	1 (1.2)
Scleral haemorrhage	0	0	1 (1.2)
Trichiasis	0	0	1 (1.2)
Uveitis	0	1 (1.7)	1 (1.2)
Vitreous floaters	1 (1.9)	1 (1.7)	1 (1.2)

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AdvSM Population & Prior Neoplastic Therapy = Yes

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Eye disorders (cont.)			
Vitreous haemorrhage	1 (1.9)	1 (1.7)	1 (1.2)
Gastrointestinal disorders	40 (76.9)	45 (77.6)	70 (84.3)
Diarrhoea	16 (30.8)	19 (32.8)	27 (32.5)
Nausea	12 (23.1)	14 (24.1)	24 (28.9)
Vomiting	11 (21.2)	13 (22.4)	23 (27.7)
Constipation	7 (13.5)	7 (12.1)	13 (15.7)
Abdominal pain	7 (13.5)	8 (13.8)	12 (14.5)
Ascites	4 (7.7)	4 (6.9)	8 (9.6)
Abdominal distension	3 (5.8)	3 (5.2)	7 (8.4)
Dyspepsia	4 (7.7)	4 (6.9)	7 (8.4)

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Gastrointestinal disorders (cont.)			
Dry mouth	1 (1.9)	1 (1.7)	6 (7.2)
Abdominal pain upper	1 (1.9)	2 (3.4)	5 (6.0)
Gastrooesophageal reflux disease	2 (3.8)	2 (3.4)	5 (6.0)
Abdominal discomfort	1 (1.9)	1 (1.7)	4 (4.8)
Gastrointestinal haemorrhage	1 (1.9)	1 (1.7)	3 (3.6)
Melaena	2 (3.8)	2 (3.4)	3 (3.6)
Gastric haemorrhage	0	0	2 (2.4)
Gingival pain	1 (1.9)	1 (1.7)	2 (2.4)
Haematochezia	0	0	2 (2.4)
Haemorrhoidal haemorrhage	0	0	2 (2.4)

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Gastrointestinal disorders (cont.)			
Inguinal hernia	1 (1.9)	1 (1.7)	2 (2.4)
Retching	0	0	2 (2.4)
Salivary hypersecretion	2 (3.8)	2 (3.4)	2 (2.4)
Varices oesophageal	0	0	2 (2.4)
Anorectal discomfort	0	1 (1.7)	1 (1.2)
Chapped lips	0	0	1 (1.2)
Colitis	1 (1.9)	1 (1.7)	1 (1.2)
Dental caries	1 (1.9)	1 (1.7)	1 (1.2)
Duodenal ulcer haemorrhage	1 (1.9)	1 (1.7)	1 (1.2)
Faeces discoloured	1 (1.9)	1 (1.7)	1 (1.2)

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Gastrointestinal disorders (cont.)			
Flatulence	1 (1.9)	1 (1.7)	1 (1.2)
Gastritis	0	1 (1.7)	1 (1.2)
Gastritis haemorrhagic	0	0	1 (1.2)
Gastrointestinal perforation	0	0	1 (1.2)
Gingival bleeding	1 (1.9)	1 (1.7)	1 (1.2)
Gingival swelling	0	1 (1.7)	1 (1.2)
Haemorrhoids	0	0	1 (1.2)
Incarcerated umbilical hernia	1 (1.9)	1 (1.7)	1 (1.2)
Intra-abdominal haematoma	1 (1.9)	1 (1.7)	1 (1.2)
Intra-abdominal haemorrhage	1 (1.9)	1 (1.7)	1 (1.2)

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Gastrointestinal disorders (cont.)			
Large intestine perforation	1 (1.9)	1 (1.7)	1 (1.2)
Large intestine polyp	0	1 (1.7)	1 (1.2)
Lip dry	1 (1.9)	1 (1.7)	1 (1.2)
Lip ulceration	0	0	1 (1.2)
Lower gastrointestinal haemorrhage	1 (1.9)	1 (1.7)	1 (1.2)
Mouth ulceration	1 (1.9)	1 (1.7)	1 (1.2)
Oesophagitis	0	0	1 (1.2)
Oral disorder	1 (1.9)	1 (1.7)	1 (1.2)
Oral pain	0	0	1 (1.2)
Pancreatitis	0	0	1 (1.2)

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Gastrointestinal disorders (cont.)			
Parotid gland enlargement	0	0	1 (1.2)
Periodontal disease	1 (1.9)	1 (1.7)	1 (1.2)
Portal hypertensive gastropathy	1 (1.9)	1 (1.7)	1 (1.2)
Rectal haemorrhage	0	1 (1.7)	1 (1.2)
Small intestinal obstruction	1 (1.9)	1 (1.7)	1 (1.2)
Tongue discolouration	0	0	1 (1.2)
Tooth deposit	1 (1.9)	1 (1.7)	1 (1.2)
Toothache	1 (1.9)	1 (1.7)	1 (1.2)
General disorders and administration site conditions	38 (73.1)	40 (69.0)	59 (71.1)
Oedema peripheral	28 (53.8)	30 (51.7)	44 (53.0)

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General disorders and administration site conditions (cont.)			
Fatigue	7 (13.5)	8 (13.8)	17 (20.5)
Face oedema	8 (15.4)	8 (13.8)	11 (13.3)
Asthenia	5 (9.6)	5 (8.6)	8 (9.6)
Pyrexia	4 (7.7)	4 (6.9)	7 (8.4)
Peripheral swelling	2 (3.8)	3 (5.2)	5 (6.0)
Pain	4 (7.7)	4 (6.9)	4 (4.8)
Chills	0	0	3 (3.6)
Feeling abnormal	1 (1.9)	2 (3.4)	3 (3.6)
Generalised oedema	2 (3.8)	2 (3.4)	3 (3.6)
Non-cardiac chest pain	2 (3.8)	2 (3.4)	3 (3.6)

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General disorders and administration site conditions (cont.)			
Gait disturbance	1 (1.9)	1 (1.7)	2 (2.4)
Influenza like illness	1 (1.9)	1 (1.7)	2 (2.4)
Oedema	2 (3.8)	2 (3.4)	2 (2.4)
Chest discomfort	0	0	1 (1.2)
Decreased activity	1 (1.9)	1 (1.7)	1 (1.2)
Disease progression	1 (1.9)	1 (1.7)	1 (1.2)
Malaise	1 (1.9)	1 (1.7)	1 (1.2)
Systemic inflammatory response syndrome	1 (1.9)	1 (1.7)	1 (1.2)
Temperature intolerance	1 (1.9)	1 (1.7)	1 (1.2)
Hepatobiliary disorders	2 (3.8)	2 (3.4)	8 (9.6)

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Hepatobiliary disorders (cont.)			
Hyperbilirubinaemia	1 (1.9)	1 (1.7)	4 (4.8)
Cholelithiasis	1 (1.9)	1 (1.7)	2 (2.4)
Hepatic cirrhosis	0	0	1 (1.2)
Jaundice	0	0	1 (1.2)
Nodular regenerative hyperplasia	0	0	1 (1.2)
Immune system disorders	2 (3.8)	2 (3.4)	8 (9.6)
Drug hypersensitivity	1 (1.9)	1 (1.7)	2 (2.4)
Anaphylactic reaction	0	0	1 (1.2)
Anaphylactic shock	0	0	1 (1.2)
Contrast media allergy	0	0	1 (1.2)

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Immune system disorders (cont.)			
Hypersensitivity	0	0	1 (1.2)
Hypogammaglobulinaemia	1 (1.9)	1 (1.7)	1 (1.2)
Immune system disorder	1 (1.9)	1 (1.7)	1 (1.2)
Iodine allergy	0	0	1 (1.2)
Infections and infestations	26 (50.0)	31 (53.4)	51 (61.4)
Upper respiratory tract infection	4 (7.7)	6 (10.3)	9 (10.8)
Urinary tract infection	2 (3.8)	3 (5.2)	8 (9.6)
Herpes zoster	2 (3.8)	5 (8.6)	7 (8.4)
Oral candidiasis	2 (3.8)	2 (3.4)	5 (6.0)
Pneumonia	1 (1.9)	1 (1.7)	5 (6.0)

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Table T.35.3.3.1.2.1
Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	 <=200 mg (N=58) n (%)	 All Doses (N=83) n (%)
Infections and infestations (cont.)			
Sinusitis	2 (3.8)	3 (5.2)	5 (6.0)
Cellulitis	2 (3.8)	2 (3.4)	3 (3.6)
Conjunctivitis	0	0	2 (2.4)
Diverticulitis	1 (1.9)	2 (3.4)	2 (2.4)
Gastroenteritis	0	1 (1.7)	2 (2.4)
Nasopharyngitis	0	0	2 (2.4)
Sepsis	1 (1.9)	1 (1.7)	2 (2.4)
Appendiceal abscess	1 (1.9)	1 (1.7)	1 (1.2)
Bronchitis	0	0	1 (1.2)
Catheter site cellulitis	1 (1.9)	1 (1.7)	1 (1.2)

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AdvSM Population & Prior Neoplastic Therapy = Yes

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Infections and infestations (cont.)			
Cellulitis orbital	0	0	1 (1.2)
Clostridium difficile colitis	0	1 (1.7)	1 (1.2)
Clostridium difficile infection	0	0	1 (1.2)
Corona virus infection	1 (1.9)	1 (1.7)	1 (1.2)
Cystitis	1 (1.9)	1 (1.7)	1 (1.2)
Diarrhoea infectious	0	0	1 (1.2)
Ear infection	0	0	1 (1.2)
Escherichia bacteraemia	0	0	1 (1.2)
Escherichia urinary tract infection	0	0	1 (1.2)
Folliculitis	0	0	1 (1.2)

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Infections and infestations (cont.)			
Gastrointestinal fungal infection	1 (1.9)	1 (1.7)	1 (1.2)
Genital infection	0	0	1 (1.2)
Herpes simplex	1 (1.9)	1 (1.7)	1 (1.2)
Hordeolum	0	0	1 (1.2)
Influenza	0	1 (1.7)	1 (1.2)
Localised infection	1 (1.9)	1 (1.7)	1 (1.2)
Mastoiditis	0	0	1 (1.2)
Necrotising fasciitis	1 (1.9)	1 (1.7)	1 (1.2)
Oral herpes	1 (1.9)	1 (1.7)	1 (1.2)
Oropharyngeal candidiasis	1 (1.9)	1 (1.7)	1 (1.2)

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Infections and infestations (cont.)			
Otitis externa	1 (1.9)	1 (1.7)	1 (1.2)
Otitis media	1 (1.9)	1 (1.7)	1 (1.2)
Paronychia	1 (1.9)	1 (1.7)	1 (1.2)
Peritonitis bacterial	0	0	1 (1.2)
Pharyngitis	0	0	1 (1.2)
Respiratory tract infection	1 (1.9)	1 (1.7)	1 (1.2)
Rhinovirus infection	0	0	1 (1.2)
Septic shock	0	0	1 (1.2)
Skin infection	1 (1.9)	1 (1.7)	1 (1.2)
Stoma site cellulitis	1 (1.9)	1 (1.7)	1 (1.2)

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System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	 <=200 mg (N=58) n (%)	 All Doses (N=83) n (%)
Infections and infestations (cont.)			
Tooth abscess	0	0	1 (1.2)
Urinary tract infection staphylococcal	0	1 (1.7)	1 (1.2)
Viral upper respiratory tract infection	1 (1.9)	1 (1.7)	1 (1.2)
Vulvovaginal mycotic infection	0	0	1 (1.2)
Wound infection	1 (1.9)	1 (1.7)	1 (1.2)
Injury, poisoning and procedural complications	14 (26.9)	17 (29.3)	28 (33.7)
Fall	3 (5.8)	3 (5.2)	7 (8.4)
Contusion	3 (5.8)	3 (5.2)	5 (6.0)
Laceration	2 (3.8)	2 (3.4)	3 (3.6)
Procedural pain	1 (1.9)	3 (5.2)	3 (3.6)

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Injury, poisoning and procedural complications (cont.)			
Subdural haematoma	2 (3.8)	2 (3.4)	3 (3.6)
Arthropod bite	0	0	2 (2.4)
Lumbar vertebral fracture	1 (1.9)	1 (1.7)	2 (2.4)
Post procedural haemorrhage	2 (3.8)	2 (3.4)	2 (2.4)
Anaemia postoperative	1 (1.9)	1 (1.7)	1 (1.2)
Electrical burn	1 (1.9)	1 (1.7)	1 (1.2)
Femoral neck fracture	0	0	1 (1.2)
Femur fracture	0	0	1 (1.2)
Foot fracture	0	0	1 (1.2)
Fractured sacrum	1 (1.9)	1 (1.7)	1 (1.2)

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Injury, poisoning and procedural complications (cont.)			
Joint injury	1 (1.9)	1 (1.7)	1 (1.2)
Limb injury	0	0	1 (1.2)
Overdose	0	0	1 (1.2)
Rib fracture	0	0	1 (1.2)
Skin abrasion	1 (1.9)	1 (1.7)	1 (1.2)
Skin wound	1 (1.9)	1 (1.7)	1 (1.2)
Spinal compression fracture	0	1 (1.7)	1 (1.2)
Tendon injury	0	0	1 (1.2)
Tendon rupture	1 (1.9)	1 (1.7)	1 (1.2)
Thermal burn	0	0	1 (1.2)

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Injury, poisoning and procedural complications (cont.)			
Tooth fracture	0	0	1 (1.2)
Traumatic haematoma	1 (1.9)	1 (1.7)	1 (1.2)
Wound	0	0	1 (1.2)
Investigations	24 (46.2)	27 (46.6)	38 (45.8)
Blood bilirubin increased	7 (13.5)	7 (12.1)	10 (12.0)
Platelet count decreased	7 (13.5)	8 (13.8)	8 (9.6)
Weight increased	4 (7.7)	6 (10.3)	8 (9.6)
White blood cell count decreased	4 (7.7)	5 (8.6)	8 (9.6)
Blood creatinine increased	7 (13.5)	7 (12.1)	7 (8.4)
Blood alkaline phosphatase increased	2 (3.8)	3 (5.2)	6 (7.2)

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Investigations (cont.)			
Cardiac murmur	3 (5.8)	3 (5.2)	5 (6.0)
Neutrophil count decreased	3 (5.8)	3 (5.2)	4 (4.8)
Alanine aminotransferase increased	1 (1.9)	1 (1.7)	3 (3.6)
Aspartate aminotransferase increased	1 (1.9)	1 (1.7)	3 (3.6)
Gamma-glutamyltransferase increased	2 (3.8)	3 (5.2)	3 (3.6)
Blood uric acid increased	2 (3.8)	2 (3.4)	2 (2.4)
Electrocardiogram QT prolonged	1 (1.9)	1 (1.7)	2 (2.4)
Urine uric acid increased	2 (3.8)	2 (3.4)	2 (2.4)
Alanine aminotransferase decreased	1 (1.9)	1 (1.7)	1 (1.2)
Blood albumin decreased	1 (1.9)	1 (1.7)	1 (1.2)

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Investigations (cont.)			
Blood bilirubin unconjugated increased	1 (1.9)	1 (1.7)	1 (1.2)
Blood phosphorus decreased	1 (1.9)	1 (1.7)	1 (1.2)
Blood thyroid stimulating hormone increased	1 (1.9)	1 (1.7)	1 (1.2)
C-reactive protein increased	1 (1.9)	1 (1.7)	1 (1.2)
Haemoglobin decreased	1 (1.9)	1 (1.7)	1 (1.2)
Lipase increased	1 (1.9)	1 (1.7)	1 (1.2)
Lymphocyte count decreased	1 (1.9)	1 (1.7)	1 (1.2)
Monocyte count increased	1 (1.9)	1 (1.7)	1 (1.2)
Neutrophil count increased	0	0	1 (1.2)
Occult blood positive	0	0	1 (1.2)

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Investigations (cont.)			
Prothrombin time shortened	1 (1.9)	1 (1.7)	1 (1.2)
Red blood cell count decreased	1 (1.9)	1 (1.7)	1 (1.2)
Reticulocyte count increased	1 (1.9)	1 (1.7)	1 (1.2)
Urine output increased	0	0	1 (1.2)
Weight decreased	0	0	1 (1.2)
White blood cell count increased	1 (1.9)	1 (1.7)	1 (1.2)
Metabolism and nutrition disorders	17 (32.7)	22 (37.9)	37 (44.6)
Decreased appetite	5 (9.6)	6 (10.3)	11 (13.3)
Hypokalaemia	4 (7.7)	5 (8.6)	11 (13.3)
Hypophosphataemia	2 (3.8)	3 (5.2)	9 (10.8)

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Metabolism and nutrition disorders (cont.)			
Hypocalcaemia	1 (1.9)	2 (3.4)	4 (4.8)
Dehydration	1 (1.9)	2 (3.4)	3 (3.6)
Hypomagnesaemia	3 (5.8)	3 (5.2)	3 (3.6)
Hyperglycaemia	1 (1.9)	1 (1.7)	2 (2.4)
Hyperuricaemia	1 (1.9)	1 (1.7)	2 (2.4)
Cachexia	1 (1.9)	1 (1.7)	1 (1.2)
Fluid retention	0	1 (1.7)	1 (1.2)
Gout	1 (1.9)	1 (1.7)	1 (1.2)
Hypernatraemia	0	0	1 (1.2)
Hyperphosphataemia	1 (1.9)	1 (1.7)	1 (1.2)

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Metabolism and nutrition disorders (cont.)			
Hypoalbuminaemia	0	0	1 (1.2)
Hypoglycaemia	0	0	1 (1.2)
Hyponatraemia	0	0	1 (1.2)
Increased appetite	0	1 (1.7)	1 (1.2)
Metabolic acidosis	0	0	1 (1.2)
Tumour lysis syndrome	1 (1.9)	1 (1.7)	1 (1.2)
Vitamin D deficiency	1 (1.9)	1 (1.7)	1 (1.2)
Musculoskeletal and connective tissue disorders	15 (28.8)	19 (32.8)	36 (43.4)
Arthralgia	5 (9.6)	7 (12.1)	17 (20.5)
Pain in extremity	3 (5.8)	4 (6.9)	9 (10.8)

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Musculoskeletal and connective tissue disorders (cont.)			
Back pain	3 (5.8)	4 (6.9)	6 (7.2)
Muscular weakness	3 (5.8)	4 (6.9)	5 (6.0)
Musculoskeletal pain	1 (1.9)	2 (3.4)	4 (4.8)
Myalgia	2 (3.8)	3 (5.2)	3 (3.6)
Exostosis	0	0	2 (2.4)
Muscle spasms	0	1 (1.7)	2 (2.4)
Musculoskeletal chest pain	0	1 (1.7)	2 (2.4)
Osteoporosis	1 (1.9)	1 (1.7)	2 (2.4)
Bone pain	0	1 (1.7)	1 (1.2)
Extraskeletal ossification	0	0	1 (1.2)

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Musculoskeletal and connective tissue disorders (cont.)			
Groin pain	0	0	1 (1.2)
Intervertebral disc protrusion	0	1 (1.7)	1 (1.2)
Joint effusion	0	0	1 (1.2)
Joint stiffness	0	0	1 (1.2)
Joint swelling	0	1 (1.7)	1 (1.2)
Muscle twitching	0	0	1 (1.2)
Neck pain	1 (1.9)	1 (1.7)	1 (1.2)
Osteonecrosis of jaw	1 (1.9)	1 (1.7)	1 (1.2)
Pain in jaw	1 (1.9)	1 (1.7)	1 (1.2)
Rotator cuff syndrome	0	0	1 (1.2)

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Musculoskeletal and connective tissue disorders (cont.)			
Spinal column stenosis	1 (1.9)	1 (1.7)	1 (1.2)
Tenosynovitis	1 (1.9)	1 (1.7)	1 (1.2)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	7 (13.5)	9 (15.5)	15 (18.1)
Malignant melanoma	1 (1.9)	1 (1.7)	2 (2.4)
Squamous cell carcinoma	1 (1.9)	1 (1.7)	2 (2.4)
Acrochordon	0	0	1 (1.2)
Acute myeloid leukaemia	1 (1.9)	1 (1.7)	1 (1.2)
Basal cell carcinoma	1 (1.9)	1 (1.7)	1 (1.2)
Benign gastrointestinal neoplasm	1 (1.9)	1 (1.7)	1 (1.2)
Gastrointestinal neoplasm	0	0	1 (1.2)

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Table T.35.3.3.1.2.1
Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	 <=200 mg (N=58) n (%)	 All Doses (N=83) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont.)			
Haemangioma	0	1 (1.7)	1 (1.2)
Intraductal proliferative breast lesion	0	1 (1.7)	1 (1.2)
Intravascular papillary endothelial hyperplasia	0	0	1 (1.2)
Keratoacanthoma	1 (1.9)	1 (1.7)	1 (1.2)
Lip neoplasm	0	0	1 (1.2)
Myelodysplastic syndrome	1 (1.9)	1 (1.7)	1 (1.2)
Penile wart	1 (1.9)	1 (1.7)	1 (1.2)
Renal neoplasm	0	0	1 (1.2)
Salivary gland neoplasm	1 (1.9)	1 (1.7)	1 (1.2)
Seborrhoeic keratosis	0	0	1 (1.2)

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Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont.)			
Squamous cell carcinoma of skin	1 (1.9)	1 (1.7)	1 (1.2)
Transitional cell carcinoma	0	0	1 (1.2)
Nervous system disorders	23 (44.2)	26 (44.8)	48 (57.8)
Dizziness	7 (13.5)	7 (12.1)	15 (18.1)
Dysgeusia	7 (13.5)	9 (15.5)	13 (15.7)
Headache	9 (17.3)	10 (17.2)	12 (14.5)
Memory impairment	3 (5.8)	3 (5.2)	11 (13.3)
Cognitive disorder	3 (5.8)	3 (5.2)	7 (8.4)
Hypoaesthesia	1 (1.9)	1 (1.7)	6 (7.2)
Ageusia	0	0	3 (3.6)

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AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	 <=200 mg (N=58) n (%)	 All Doses (N=83) n (%)
Nervous system disorders (cont.)			
Dizziness postural	2 (3.8)	2 (3.4)	3 (3.6)
Paraesthesia	1 (1.9)	1 (1.7)	3 (3.6)
Aphasia	1 (1.9)	1 (1.7)	2 (2.4)
Encephalopathy	0	0	2 (2.4)
Haemorrhage intracranial	0	0	2 (2.4)
Peripheral sensory neuropathy	0	0	2 (2.4)
Restless legs syndrome	2 (3.8)	2 (3.4)	2 (2.4)
Balance disorder	1 (1.9)	1 (1.7)	1 (1.2)
Central nervous system lesion	0	0	1 (1.2)
Cerebral atrophy	0	0	1 (1.2)

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Nervous system disorders (cont.)			
Cerebral ventricle dilatation	0	0	1 (1.2)
Dementia	0	0	1 (1.2)
Dysarthria	0	1 (1.7)	1 (1.2)
Hydrocephalus	0	0	1 (1.2)
Hypogeusia	1 (1.9)	1 (1.7)	1 (1.2)
Myoclonus	1 (1.9)	1 (1.7)	1 (1.2)
Neuropathy peripheral	0	0	1 (1.2)
Parkinson's disease	1 (1.9)	1 (1.7)	1 (1.2)
Post herpetic neuralgia	0	0	1 (1.2)
Seizure	0	0	1 (1.2)

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Nervous system disorders (cont.)			
Sensory disturbance	1 (1.9)	1 (1.7)	1 (1.2)
Somnolence	0	0	1 (1.2)
Syncope	0	0	1 (1.2)
Transient ischaemic attack	1 (1.9)	1 (1.7)	1 (1.2)
Tremor	1 (1.9)	1 (1.7)	1 (1.2)
Psychiatric disorders	12 (23.1)	14 (24.1)	22 (26.5)
Insomnia	4 (7.7)	5 (8.6)	9 (10.8)
Confusional state	1 (1.9)	1 (1.7)	3 (3.6)
Depression	1 (1.9)	1 (1.7)	3 (3.6)
Anxiety	0	0	2 (2.4)

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Psychiatric disorders (cont.)			
Depressed mood	2 (3.8)	2 (3.4)	2 (2.4)
Sleep disorder	2 (3.8)	2 (3.4)	2 (2.4)
Adjustment disorder with depressed mood	1 (1.9)	1 (1.7)	1 (1.2)
Delirium	1 (1.9)	1 (1.7)	1 (1.2)
Disorientation	1 (1.9)	1 (1.7)	1 (1.2)
Dysphoria	0	0	1 (1.2)
Irritability	0	1 (1.7)	1 (1.2)
Libido decreased	1 (1.9)	1 (1.7)	1 (1.2)
Mental disorder	1 (1.9)	1 (1.7)	1 (1.2)
Mental status changes	0	0	1 (1.2)

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Psychiatric disorders (cont.)			
Suicidal ideation	0	0	1 (1.2)
Renal and urinary disorders	6 (11.5)	8 (13.8)	18 (21.7)
Acute kidney injury	3 (5.8)	3 (5.2)	6 (7.2)
Dysuria	1 (1.9)	2 (3.4)	6 (7.2)
Haematuria	1 (1.9)	2 (3.4)	5 (6.0)
Nephrolithiasis	2 (3.8)	2 (3.4)	3 (3.6)
Pollakiuria	1 (1.9)	1 (1.7)	2 (2.4)
Urinary incontinence	1 (1.9)	1 (1.7)	2 (2.4)
Chronic kidney disease	1 (1.9)	1 (1.7)	1 (1.2)
Hypertonic bladder	0	1 (1.7)	1 (1.2)

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Renal and urinary disorders (cont.)			
Obstructive uropathy	1 (1.9)	1 (1.7)	1 (1.2)
Polyuria	0	0	1 (1.2)
Renal colic	0	0	1 (1.2)
Renal impairment	0	0	1 (1.2)
Renal mass	0	0	1 (1.2)
Urinary retention	1 (1.9)	1 (1.7)	1 (1.2)
Reproductive system and breast disorders	4 (7.7)	4 (6.9)	6 (7.2)
Scrotal oedema	2 (3.8)	2 (3.4)	2 (2.4)
Haematospermia	0	0	1 (1.2)
Oedema genital	1 (1.9)	1 (1.7)	1 (1.2)

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Reproductive system and breast disorders (cont.)			
Penile pain	1 (1.9)	1 (1.7)	1 (1.2)
Vulvovaginal pain	0	0	1 (1.2)
Respiratory, thoracic and mediastinal disorders	18 (34.6)	21 (36.2)	38 (45.8)
Epistaxis	7 (13.5)	7 (12.1)	11 (13.3)
Cough	2 (3.8)	4 (6.9)	10 (12.0)
Dyspnoea	4 (7.7)	5 (8.6)	9 (10.8)
Pleural effusion	4 (7.7)	4 (6.9)	7 (8.4)
Nasal congestion	2 (3.8)	2 (3.4)	4 (4.8)
Productive cough	1 (1.9)	1 (1.7)	4 (4.8)
Haemoptysis	2 (3.8)	2 (3.4)	3 (3.6)

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Respiratory, thoracic and mediastinal disorders (cont.)			
Rhinorrhoea	0	0	3 (3.6)
Upper-airway cough syndrome	1 (1.9)	1 (1.7)	3 (3.6)
Dysphonia	0	0	2 (2.4)
Dyspnoea exertional	1 (1.9)	1 (1.7)	2 (2.4)
Oropharyngeal pain	1 (1.9)	1 (1.7)	2 (2.4)
Pulmonary congestion	1 (1.9)	2 (3.4)	2 (2.4)
Rales	1 (1.9)	1 (1.7)	2 (2.4)
Acute respiratory failure	0	0	1 (1.2)
Bronchial haemorrhage	1 (1.9)	1 (1.7)	1 (1.2)
Chronic obstructive pulmonary disease	0	0	1 (1.2)

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Respiratory, thoracic and mediastinal disorders (cont.)			
Emphysema	0	0	1 (1.2)
Haemothorax	1 (1.9)	1 (1.7)	1 (1.2)
Hypoxia	1 (1.9)	1 (1.7)	1 (1.2)
Laryngeal oedema	0	0	1 (1.2)
Pneumothorax	1 (1.9)	1 (1.7)	1 (1.2)
Pulmonary hypertension	1 (1.9)	1 (1.7)	1 (1.2)
Pulmonary mass	0	0	1 (1.2)
Pulmonary oedema	1 (1.9)	1 (1.7)	1 (1.2)
Respiratory symptom	1 (1.9)	1 (1.7)	1 (1.2)
Rhinitis allergic	0	0	1 (1.2)

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Respiratory, thoracic and mediastinal disorders (cont.)			
Rhonchi	1 (1.9)	1 (1.7)	1 (1.2)
Sinus disorder	0	0	1 (1.2)
Throat irritation	1 (1.9)	1 (1.7)	1 (1.2)
Wheezing	0	0	1 (1.2)
Skin and subcutaneous tissue disorders	18 (34.6)	21 (36.2)	40 (48.2)
Hair colour changes	4 (7.7)	5 (8.6)	13 (15.7)
Pruritus	3 (5.8)	4 (6.9)	9 (10.8)
Alopecia	3 (5.8)	3 (5.2)	8 (9.6)
Rash	2 (3.8)	4 (6.9)	8 (9.6)
Photosensitivity reaction	1 (1.9)	2 (3.4)	5 (6.0)

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Skin and subcutaneous tissue disorders (cont.)			
Rash maculo-papular	1 (1.9)	1 (1.7)	5 (6.0)
Ecchymosis	1 (1.9)	1 (1.7)	3 (3.6)
Hyperhidrosis	1 (1.9)	1 (1.7)	3 (3.6)
Night sweats	2 (3.8)	3 (5.2)	3 (3.6)
Rash pruritic	0	0	3 (3.6)
Skin lesion	0	0	3 (3.6)
Erythema	2 (3.8)	2 (3.4)	2 (2.4)
Livedo reticularis	0	0	2 (2.4)
Nail bed disorder	0	1 (1.7)	2 (2.4)
Petechiae	2 (3.8)	2 (3.4)	2 (2.4)

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Skin and subcutaneous tissue disorders (cont.)			
Rash erythematous	0	0	2 (2.4)
Rash papular	0	0	2 (2.4)
Skin ulcer	1 (1.9)	1 (1.7)	2 (2.4)
Swelling face	2 (3.8)	2 (3.4)	2 (2.4)
Urticaria	0	0	2 (2.4)
Blood blister	1 (1.9)	1 (1.7)	1 (1.2)
Dermatitis	0	0	1 (1.2)
Dermatitis acneiform	0	0	1 (1.2)
Dermatitis contact	1 (1.9)	1 (1.7)	1 (1.2)
Dry skin	0	0	1 (1.2)

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Skin and subcutaneous tissue disorders (cont.)			
Eczema	0	0	1 (1.2)
Hair growth abnormal	0	0	1 (1.2)
Melanocytic hyperplasia	0	0	1 (1.2)
Nail growth abnormal	0	0	1 (1.2)
Psoriasis	1 (1.9)	1 (1.7)	1 (1.2)
Scab	0	0	1 (1.2)
Seborrhoeic dermatitis	1 (1.9)	1 (1.7)	1 (1.2)
Skin depigmentation	0	1 (1.7)	1 (1.2)
Skin discolouration	0	1 (1.7)	1 (1.2)
Skin haemorrhage	1 (1.9)	1 (1.7)	1 (1.2)

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Table T.35.3.3.1.2.1
Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	 <=200 mg (N=58) n (%)	 All Doses (N=83) n (%)
Skin and subcutaneous tissue disorders (cont.)			
Telangiectasia	0	1 (1.7)	1 (1.2)
Vascular disorders	13 (25.0)	13 (22.4)	26 (31.3)
Hypertension	2 (3.8)	2 (3.4)	8 (9.6)
Flushing	3 (5.8)	3 (5.2)	6 (7.2)
Hypotension	3 (5.8)	3 (5.2)	6 (7.2)
Hot flush	1 (1.9)	1 (1.7)	2 (2.4)
Embolism	0	0	1 (1.2)
Epistaxis	1 (1.9)	1 (1.7)	1 (1.2)
Haematoma	1 (1.9)	1 (1.7)	1 (1.2)
Haemorrhage	1 (1.9)	1 (1.7)	1 (1.2)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: System Organ Classes are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.3.3.1.2.1
Summary of Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	 <=200 mg (N=58) n (%)	 All Doses (N=83) n (%)
Vascular disorders (cont.)			
Pallor	1 (1.9)	1 (1.7)	1 (1.2)
Peripheral vascular disorder	0	0	1 (1.2)
Shock haemorrhagic	1 (1.9)	1 (1.7)	1 (1.2)
Thrombophlebitis	1 (1.9)	1 (1.7)	1 (1.2)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & 200 mg Dose Group (N=12) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Patients with at least one Event	1 (8.3)	3 (25.0)	5 (41.7)	3 (25.0)	0	12 (100.0)
Blood and lymphatic system disorders	2 (16.7)	1 (8.3)	4 (33.3)	2 (16.7)	0	9 (75.0)
Anaemia	0	1 (8.3)	4 (33.3)	0	0	5 (41.7)
Thrombocytopenia	0	1 (8.3)	3 (25.0)	1 (8.3)	0	5 (41.7)
Neutropenia	0	1 (8.3)	1 (8.3)	1 (8.3)	0	3 (25.0)
Increased tendency to bruise	2 (16.7)	0	0	0	0	2 (16.7)
Anaemia macrocytic	0	0	1 (8.3)	0	0	1 (8.3)
Haemorrhagic diathesis	1 (8.3)	0	0	0	0	1 (8.3)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
Note 1: In each treatment group, if a patient experiences more than 1 event within a given System Organ Class or Preferred term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column and treatment group.
Note 3: System Organ Classes are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'Any Grade' column.
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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & 200 mg Dose Group (N=12) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Blood and lymphatic system disorders (cont.)						
Lymphadenopathy	1 (8.3)	0	0	0	0	1 (8.3)
Lymphopenia	1 (8.3)	0	0	0	0	1 (8.3)
Cardiac disorders	0	0	1 (8.3)	0	0	1 (8.3)
Cardiac failure congestive	0	0	1 (8.3)	0	0	1 (8.3)
Congenital, familial and genetic disorders	0	1 (8.3)	0	0	0	1 (8.3)
Right-to-left cardiac shunt	0	1 (8.3)	0	0	0	1 (8.3)
Ear and labyrinth disorders	1 (8.3)	0	0	0	0	1 (8.3)
Deafness	1 (8.3)	0	0	0	0	1 (8.3)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
Note 1: In each treatment group, if a patient experiences more than 1 event within a given System Organ Class or Preferred term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & 200 mg Dose Group (N=12) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Eye disorders	9 (75.0)	0	0	0	0	9 (75.0)
Periorbital oedema	6 (50.0)	0	0	0	0	6 (50.0)
Conjunctival haemorrhage	1 (8.3)	0	0	0	0	1 (8.3)
Eye swelling	1 (8.3)	0	0	0	0	1 (8.3)
Lacrimation increased	1 (8.3)	0	0	0	0	1 (8.3)
Macular fibrosis	1 (8.3)	0	0	0	0	1 (8.3)
Ocular hyperaemia	1 (8.3)	0	0	0	0	1 (8.3)
Periorbital haemorrhage	1 (8.3)	0	0	0	0	1 (8.3)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
Note 1: In each treatment group, if a patient experiences more than 1 event within a given System Organ Class or Preferred term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column and treatment group.
Note 3: System Organ Classes are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'Any Grade' column.
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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & 200 mg Dose Group (N=12) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Eye disorders (cont.)						
Vision blurred	1 (8.3)	0	0	0	0	1 (8.3)
Gastrointestinal disorders	6 (50.0)	3 (25.0)	1 (8.3)	1 (8.3)	0	11 (91.7)
Diarrhoea	6 (50.0)	1 (8.3)	0	0	0	7 (58.3)
Nausea	4 (33.3)	0	0	0	0	4 (33.3)
Abdominal pain	2 (16.7)	1 (8.3)	0	0	0	3 (25.0)
Ascites	2 (16.7)	1 (8.3)	0	0	0	3 (25.0)
Vomiting	2 (16.7)	1 (8.3)	0	0	0	3 (25.0)
Abdominal distension	2 (16.7)	0	0	0	0	2 (16.7)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
Note 1: In each treatment group, if a patient experiences more than 1 event within a given System Organ Class or Preferred term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & 200 mg Dose Group (N=12) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Gastrointestinal disorders (cont.)						
Constipation	1 (8.3)	1 (8.3)	0	0	0	2 (16.7)
Dyspepsia	2 (16.7)	0	0	0	0	2 (16.7)
Abdominal discomfort	1 (8.3)	0	0	0	0	1 (8.3)
Colitis	0	0	1 (8.3)	0	0	1 (8.3)
Dry mouth	1 (8.3)	0	0	0	0	1 (8.3)
Flatulence	1 (8.3)	0	0	0	0	1 (8.3)
Gingival pain	1 (8.3)	0	0	0	0	1 (8.3)
Incarcerated umbilical hernia	0	0	0	1 (8.3)	0	1 (8.3)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & 200 mg Dose Group (N=12) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Gastrointestinal disorders (cont.)						
Inguinal hernia	1 (8.3)	0	0	0	0	1 (8.3)
Large intestine perforation	0	0	1 (8.3)	0	0	1 (8.3)
Mouth ulceration	1 (8.3)	0	0	0	0	1 (8.3)
Oral disorder	1 (8.3)	0	0	0	0	1 (8.3)
Periodontal disease	1 (8.3)	0	0	0	0	1 (8.3)
Small intestinal obstruction	1 (8.3)	0	0	0	0	1 (8.3)
General disorders and administration site conditions	4 (33.3)	6 (50.0)	1 (8.3)	0	0	11 (91.7)
Oedema peripheral	5 (41.7)	3 (25.0)	0	0	0	8 (66.7)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & 200 mg Dose Group (N=12) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
General disorders and administration site conditions (cont.)						
Fatigue	2 (16.7)	1 (8.3)	1 (8.3)	0	0	4 (33.3)
Asthenia	1 (8.3)	0	0	0	0	1 (8.3)
Decreased activity	0	1 (8.3)	0	0	0	1 (8.3)
Face oedema	0	1 (8.3)	0	0	0	1 (8.3)
Feeling abnormal	1 (8.3)	0	0	0	0	1 (8.3)
Gait disturbance	1 (8.3)	0	0	0	0	1 (8.3)
Generalised oedema	1 (8.3)	0	0	0	0	1 (8.3)
Influenza like illness	0	1 (8.3)	0	0	0	1 (8.3)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & 200 mg Dose Group (N=12) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
General disorders and administration site conditions (cont.)						
Malaise	1 (8.3)	0	0	0	0	1 (8.3)
Oedema	1 (8.3)	0	0	0	0	1 (8.3)
Pain	0	1 (8.3)	0	0	0	1 (8.3)
Peripheral swelling	1 (8.3)	0	0	0	0	1 (8.3)
Pyrexia	1 (8.3)	0	0	0	0	1 (8.3)
Temperature intolerance	1 (8.3)	0	0	0	0	1 (8.3)
Hepatobiliary disorders	1 (8.3)	0	0	0	0	1 (8.3)
Cholelithiasis	1 (8.3)	0	0	0	0	1 (8.3)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & 200 mg Dose Group (N=12) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Immune system disorders	1 (8.3)	0	0	0	0	1 (8.3)
Drug hypersensitivity	1 (8.3)	0	0	0	0	1 (8.3)
Infections and infestations	2 (16.7)	2 (16.7)	3 (25.0)	0	0	7 (58.3)
Upper respiratory tract infection	1 (8.3)	1 (8.3)	1 (8.3)	0	0	3 (25.0)
Cellulitis	0	1 (8.3)	0	0	0	1 (8.3)
Diverticulitis	0	0	1 (8.3)	0	0	1 (8.3)
Localised infection	0	0	1 (8.3)	0	0	1 (8.3)
Oral candidiasis	0	1 (8.3)	0	0	0	1 (8.3)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & 200 mg Dose Group (N=12) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Infections and infestations (cont.)						
Otitis externa	0	1 (8.3)	0	0	0	1 (8.3)
Sinusitis	0	1 (8.3)	0	0	0	1 (8.3)
Viral upper respiratory tract infection	1 (8.3)	0	0	0	0	1 (8.3)
Injury, poisoning and procedural complications	2 (16.7)	4 (33.3)	0	0	0	6 (50.0)
Contusion	1 (8.3)	1 (8.3)	0	0	0	2 (16.7)
Laceration	2 (16.7)	0	0	0	0	2 (16.7)
Electrical burn	0	1 (8.3)	0	0	0	1 (8.3)
Fall	0	1 (8.3)	0	0	0	1 (8.3)

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Note 1: In each treatment group, if a patient experiences more than 1 event within a given System Organ Class or Preferred term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & 200 mg Dose Group (N=12) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Injury, poisoning and procedural complications (cont.)						
Fractured sacrum	0	1 (8.3)	0	0	0	1 (8.3)
Lumbar vertebral fracture	0	1 (8.3)	0	0	0	1 (8.3)
Post procedural haemorrhage	1 (8.3)	0	0	0	0	1 (8.3)
Skin wound	1 (8.3)	0	0	0	0	1 (8.3)
Subdural haematoma	1 (8.3)	0	0	0	0	1 (8.3)
Investigations	1 (8.3)	2 (16.7)	1 (8.3)	1 (8.3)	0	5 (41.7)
Blood creatinine increased	3 (25.0)	0	0	0	0	3 (25.0)
Cardiac murmur	2 (16.7)	0	0	0	0	2 (16.7)

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Note 1: In each treatment group, if a patient experiences more than 1 event within a given System Organ Class or Preferred term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & 200 mg Dose Group (N=12) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Investigations (cont.)						
Weight increased	1 (8.3)	1 (8.3)	0	0	0	2 (16.7)
Blood bilirubin increased	0	1 (8.3)	0	0	0	1 (8.3)
Platelet count decreased	0	0	0	1 (8.3)	0	1 (8.3)
White blood cell count decreased	0	0	1 (8.3)	0	0	1 (8.3)
Metabolism and nutrition disorders	4 (33.3)	3 (25.0)	1 (8.3)	0	0	8 (66.7)
Hypokalaemia	3 (25.0)	1 (8.3)	0	0	0	4 (33.3)
Decreased appetite	2 (16.7)	1 (8.3)	0	0	0	3 (25.0)
Dehydration	0	1 (8.3)	0	0	0	1 (8.3)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & 200 mg Dose Group (N=12) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Metabolism and nutrition disorders (cont.)						
Hyperglycaemia	0	0	1 (8.3)	0	0	1 (8.3)
Hypomagnesaemia	1 (8.3)	0	0	0	0	1 (8.3)
Vitamin D deficiency	0	1 (8.3)	0	0	0	1 (8.3)
Musculoskeletal and connective tissue disorders	0	3 (25.0)	2 (16.7)	0	0	5 (41.7)
Arthralgia	0	2 (16.7)	1 (8.3)	0	0	3 (25.0)
Muscular weakness	0	2 (16.7)	0	0	0	2 (16.7)
Pain in extremity	1 (8.3)	1 (8.3)	0	0	0	2 (16.7)
Back pain	0	0	1 (8.3)	0	0	1 (8.3)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & 200 mg Dose Group (N=12) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Musculoskeletal and connective tissue disorders (cont.)						
Tenosynovitis	1 (8.3)	0	0	0	0	1 (8.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (8.3)	1 (8.3)	1 (8.3)	0	0	3 (25.0)
Keratoacanthoma	1 (8.3)	0	0	0	0	1 (8.3)
Myelodysplastic syndrome	0	0	1 (8.3)	0	0	1 (8.3)
Penile wart	0	1 (8.3)	0	0	0	1 (8.3)
Squamous cell carcinoma	0	1 (8.3)	0	0	0	1 (8.3)
Nervous system disorders	4 (33.3)	2 (16.7)	1 (8.3)	0	0	7 (58.3)
Headache	3 (25.0)	1 (8.3)	0	0	0	4 (33.3)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
Note 1: In each treatment group, if a patient experiences more than 1 event within a given System Organ Class or Preferred term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & 200 mg Dose Group (N=12) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Nervous system disorders (cont.)						
Dizziness	2 (16.7)	1 (8.3)	0	0	0	3 (25.0)
Cognitive disorder	1 (8.3)	0	0	0	0	1 (8.3)
Dizziness postural	1 (8.3)	0	0	0	0	1 (8.3)
Dysgeusia	1 (8.3)	0	0	0	0	1 (8.3)
Hypoaesthesia	1 (8.3)	0	0	0	0	1 (8.3)
Memory impairment	1 (8.3)	0	0	0	0	1 (8.3)
Myoclonus	0	0	1 (8.3)	0	0	1 (8.3)
Paraesthesia	1 (8.3)	0	0	0	0	1 (8.3)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & 200 mg Dose Group (N=12) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Nervous system disorders (cont.)						
Transient ischaemic attack	1 (8.3)	0	0	0	0	1 (8.3)
Psychiatric disorders	3 (25.0)	0	0	0	0	3 (25.0)
Insomnia	2 (16.7)	0	0	0	0	2 (16.7)
Depressed mood	1 (8.3)	0	0	0	0	1 (8.3)
Libido decreased	1 (8.3)	0	0	0	0	1 (8.3)
Renal and urinary disorders	0	1 (8.3)	1 (8.3)	0	0	2 (16.7)
Acute kidney injury	1 (8.3)	0	1 (8.3)	0	0	2 (16.7)
Chronic kidney disease	0	1 (8.3)	0	0	0	1 (8.3)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & 200 mg Dose Group (N=12) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Renal and urinary disorders (cont.)						
Dysuria	1 (8.3)	0	0	0	0	1 (8.3)
Pollakiuria	1 (8.3)	0	0	0	0	1 (8.3)
Urinary incontinence	0	1 (8.3)	0	0	0	1 (8.3)
Urinary retention	0	1 (8.3)	0	0	0	1 (8.3)
Reproductive system and breast disorders	1 (8.3)	1 (8.3)	0	0	0	2 (16.7)
Penile pain	1 (8.3)	0	0	0	0	1 (8.3)
Scrotal oedema	0	1 (8.3)	0	0	0	1 (8.3)
Respiratory, thoracic and mediastinal disorders	3 (25.0)	3 (25.0)	1 (8.3)	0	0	7 (58.3)

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Note 1: In each treatment group, if a patient experiences more than 1 event within a given System Organ Class or Preferred term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & 200 mg Dose Group (N=12) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Respiratory, thoracic and mediastinal disorders (cont.)						
Epistaxis	3 (25.0)	0	0	0	0	3 (25.0)
Dyspnoea	1 (8.3)	1 (8.3)	0	0	0	2 (16.7)
Pleural effusion	0	1 (8.3)	1 (8.3)	0	0	2 (16.7)
Cough	0	1 (8.3)	0	0	0	1 (8.3)
Haemoptysis	1 (8.3)	0	0	0	0	1 (8.3)
Hypoxia	0	0	1 (8.3)	0	0	1 (8.3)
Nasal congestion	1 (8.3)	0	0	0	0	1 (8.3)
Pneumothorax	0	1 (8.3)	0	0	0	1 (8.3)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & 200 mg Dose Group (N=12) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Respiratory, thoracic and mediastinal disorders (cont.)						
Productive cough	1 (8.3)	0	0	0	0	1 (8.3)
Pulmonary congestion	0	1 (8.3)	0	0	0	1 (8.3)
Pulmonary hypertension	0	0	1 (8.3)	0	0	1 (8.3)
Rhonchi	1 (8.3)	0	0	0	0	1 (8.3)
Upper-airway cough syndrome	1 (8.3)	0	0	0	0	1 (8.3)
Skin and subcutaneous tissue disorders	4 (33.3)	2 (16.7)	0	0	0	6 (50.0)
Erythema	2 (16.7)	0	0	0	0	2 (16.7)
Blood blister	1 (8.3)	0	0	0	0	1 (8.3)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & 200 mg Dose Group (N=12) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Skin and subcutaneous tissue disorders (cont.)						
Ecchymosis	1 (8.3)	0	0	0	0	1 (8.3)
Hair colour changes	1 (8.3)	0	0	0	0	1 (8.3)
Night sweats	0	1 (8.3)	0	0	0	1 (8.3)
Photosensitivity reaction	1 (8.3)	0	0	0	0	1 (8.3)
Rash	1 (8.3)	0	0	0	0	1 (8.3)
Rash maculo-papular	0	1 (8.3)	0	0	0	1 (8.3)
Swelling face	1 (8.3)	0	0	0	0	1 (8.3)
Vascular disorders	3 (25.0)	2 (16.7)	0	0	0	5 (41.7)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & 200 mg Dose Group (N=12) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Vascular disorders (cont.)						
Hypotension	1 (8.3)	1 (8.3)	0	0	0	2 (16.7)
Epistaxis	1 (8.3)	0	0	0	0	1 (8.3)
Flushing	1 (8.3)	0	0	0	0	1 (8.3)
Pallor	1 (8.3)	0	0	0	0	1 (8.3)
Thrombophlebitis	0	1 (8.3)	0	0	0	1 (8.3)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & <=200 mg Dose Group (N=16) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Patients with at least one Event	1 (6.3)	4 (25.0)	7 (43.8)	4 (25.0)	0	16 (100.0)
Blood and lymphatic system disorders	4 (25.0)	1 (6.3)	4 (25.0)	2 (12.5)	0	11 (68.8)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & <=200 mg Dose Group (N=16) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Blood and lymphatic system disorders (cont.)						
Anaemia	1 (6.3)	1 (6.3)	4 (25.0)	0	0	6 (37.5)
Thrombocytopenia	1 (6.3)	1 (6.3)	3 (18.8)	1 (6.3)	0	6 (37.5)
Neutropenia	0	1 (6.3)	1 (6.3)	1 (6.3)	0	3 (18.8)
Increased tendency to bruise	2 (12.5)	0	0	0	0	2 (12.5)
Anaemia macrocytic	0	0	1 (6.3)	0	0	1 (6.3)
Haemorrhagic diathesis	1 (6.3)	0	0	0	0	1 (6.3)
Leukopenia	1 (6.3)	0	0	0	0	1 (6.3)
Lymphadenopathy	1 (6.3)	0	0	0	0	1 (6.3)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & <=200 mg Dose Group (N=16) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Blood and lymphatic system disorders (cont.)						
Lymphopenia	1 (6.3)	0	0	0	0	1 (6.3)
Cardiac disorders	0	0	1 (6.3)	0	0	1 (6.3)
Cardiac failure congestive	0	0	1 (6.3)	0	0	1 (6.3)
Congenital, familial and genetic disorders	0	1 (6.3)	0	0	0	1 (6.3)
Right-to-left cardiac shunt	0	1 (6.3)	0	0	0	1 (6.3)
Ear and labyrinth disorders	1 (6.3)	0	0	0	0	1 (6.3)
Deafness	1 (6.3)	0	0	0	0	1 (6.3)
Eye disorders	9 (56.3)	1 (6.3)	1 (6.3)	0	0	11 (68.8)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & <=200 mg Dose Group (N=16) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Eye disorders (cont.)						
Periorbital oedema	8 (50.0)	0	0	0	0	8 (50.0)
Conjunctival haemorrhage	2 (12.5)	0	0	0	0	2 (12.5)
Eye swelling	1 (6.3)	1 (6.3)	0	0	0	2 (12.5)
Lacrimation increased	2 (12.5)	0	0	0	0	2 (12.5)
Eye pruritus	0	1 (6.3)	0	0	0	1 (6.3)
Macular fibrosis	1 (6.3)	0	0	0	0	1 (6.3)
Ocular hyperaemia	1 (6.3)	0	0	0	0	1 (6.3)
Papilloedema	0	1 (6.3)	0	0	0	1 (6.3)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & <=200 mg Dose Group (N=16) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Eye disorders (cont.)						
Periorbital haemorrhage	1 (6.3)	0	0	0	0	1 (6.3)
Uveitis	0	0	1 (6.3)	0	0	1 (6.3)
Vision blurred	1 (6.3)	0	0	0	0	1 (6.3)
Gastrointestinal disorders	7 (43.8)	6 (37.5)	1 (6.3)	1 (6.3)	0	15 (93.8)
Diarrhoea	7 (43.8)	2 (12.5)	0	0	0	9 (56.3)
Nausea	6 (37.5)	0	0	0	0	6 (37.5)
Abdominal pain	2 (12.5)	2 (12.5)	0	0	0	4 (25.0)
Vomiting	3 (18.8)	1 (6.3)	0	0	0	4 (25.0)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & <=200 mg Dose Group (N=16) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Gastrointestinal disorders (cont.)						
Ascites	2 (12.5)	1 (6.3)	0	0	0	3 (18.8)
Abdominal distension	2 (12.5)	0	0	0	0	2 (12.5)
Constipation	1 (6.3)	1 (6.3)	0	0	0	2 (12.5)
Dyspepsia	2 (12.5)	0	0	0	0	2 (12.5)
Abdominal discomfort	1 (6.3)	0	0	0	0	1 (6.3)
Abdominal pain upper	0	1 (6.3)	0	0	0	1 (6.3)
Anorectal discomfort	1 (6.3)	0	0	0	0	1 (6.3)
Colitis	0	0	1 (6.3)	0	0	1 (6.3)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & <=200 mg Dose Group (N=16) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Gastrointestinal disorders (cont.)						
Dry mouth	1 (6.3)	0	0	0	0	1 (6.3)
Flatulence	1 (6.3)	0	0	0	0	1 (6.3)
Gastritis	0	1 (6.3)	0	0	0	1 (6.3)
Gingival pain	1 (6.3)	0	0	0	0	1 (6.3)
Gingival swelling	1 (6.3)	0	0	0	0	1 (6.3)
Incarcerated umbilical hernia	0	0	0	1 (6.3)	0	1 (6.3)
Inguinal hernia	1 (6.3)	0	0	0	0	1 (6.3)
Large intestine perforation	0	0	1 (6.3)	0	0	1 (6.3)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & <=200 mg Dose Group (N=16) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Gastrointestinal disorders (cont.)						
Large intestine polyp	1 (6.3)	0	0	0	0	1 (6.3)
Mouth ulceration	1 (6.3)	0	0	0	0	1 (6.3)
Oral disorder	1 (6.3)	0	0	0	0	1 (6.3)
Periodontal disease	1 (6.3)	0	0	0	0	1 (6.3)
Rectal haemorrhage	1 (6.3)	0	0	0	0	1 (6.3)
Small intestinal obstruction	1 (6.3)	0	0	0	0	1 (6.3)
General disorders and administration site conditions	5 (31.3)	7 (43.8)	1 (6.3)	0	0	13 (81.3)
Oedema peripheral	7 (43.8)	3 (18.8)	0	0	0	10 (62.5)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
Note 1: In each treatment group, if a patient experiences more than 1 event within a given System Organ Class or Preferred term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & <=200 mg Dose Group (N=16) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
General disorders and administration site conditions (cont.)						
Fatigue	2 (12.5)	2 (12.5)	1 (6.3)	0	0	5 (31.3)
Feeling abnormal	2 (12.5)	0	0	0	0	2 (12.5)
Peripheral swelling	2 (12.5)	0	0	0	0	2 (12.5)
Asthenia	1 (6.3)	0	0	0	0	1 (6.3)
Decreased activity	0	1 (6.3)	0	0	0	1 (6.3)
Face oedema	0	1 (6.3)	0	0	0	1 (6.3)
Gait disturbance	1 (6.3)	0	0	0	0	1 (6.3)
Generalised oedema	1 (6.3)	0	0	0	0	1 (6.3)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & <=200 mg Dose Group (N=16) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
General disorders and administration site conditions (cont.)						
Influenza like illness	0	1 (6.3)	0	0	0	1 (6.3)
Malaise	1 (6.3)	0	0	0	0	1 (6.3)
Oedema	1 (6.3)	0	0	0	0	1 (6.3)
Pain	0	1 (6.3)	0	0	0	1 (6.3)
Pyrexia	1 (6.3)	0	0	0	0	1 (6.3)
Temperature intolerance	1 (6.3)	0	0	0	0	1 (6.3)
Hepatobiliary disorders	1 (6.3)	0	0	0	0	1 (6.3)
Cholelithiasis	1 (6.3)	0	0	0	0	1 (6.3)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & <=200 mg Dose Group (N=16) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Immune system disorders	1 (6.3)	0	0	0	0	1 (6.3)
Drug hypersensitivity	1 (6.3)	0	0	0	0	1 (6.3)
Infections and infestations	2 (12.5)	6 (37.5)	3 (18.8)	0	0	11 (68.8)
Upper respiratory tract infection	2 (12.5)	2 (12.5)	1 (6.3)	0	0	5 (31.3)
Diverticulitis	0	1 (6.3)	1 (6.3)	0	0	2 (12.5)
Herpes zoster	0	2 (12.5)	0	0	0	2 (12.5)
Sinusitis	0	2 (12.5)	0	0	0	2 (12.5)
Cellulitis	0	1 (6.3)	0	0	0	1 (6.3)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & <=200 mg Dose Group (N=16) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Infections and infestations (cont.)						
Gastroenteritis	0	1 (6.3)	0	0	0	1 (6.3)
Influenza	1 (6.3)	0	0	0	0	1 (6.3)
Localised infection	0	0	1 (6.3)	0	0	1 (6.3)
Oral candidiasis	0	1 (6.3)	0	0	0	1 (6.3)
Otitis externa	0	1 (6.3)	0	0	0	1 (6.3)
Urinary tract infection	0	1 (6.3)	0	0	0	1 (6.3)
Urinary tract infection staphylococcal	0	1 (6.3)	0	0	0	1 (6.3)
Viral upper respiratory tract infection	1 (6.3)	0	0	0	0	1 (6.3)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & <=200 mg Dose Group (N=16) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Injury, poisoning and procedural complications	5 (31.3)	4 (25.0)	0	0	0	9 (56.3)
Contusion	1 (6.3)	1 (6.3)	0	0	0	2 (12.5)
Laceration	2 (12.5)	0	0	0	0	2 (12.5)
Procedural pain	2 (12.5)	0	0	0	0	2 (12.5)
Electrical burn	0	1 (6.3)	0	0	0	1 (6.3)
Fall	0	1 (6.3)	0	0	0	1 (6.3)
Fractured sacrum	0	1 (6.3)	0	0	0	1 (6.3)
Lumbar vertebral fracture	0	1 (6.3)	0	0	0	1 (6.3)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & <=200 mg Dose Group (N=16) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Injury, poisoning and procedural complications (cont.)						
Post procedural haemorrhage	1 (6.3)	0	0	0	0	1 (6.3)
Skin wound	1 (6.3)	0	0	0	0	1 (6.3)
Spinal compression fracture	1 (6.3)	0	0	0	0	1 (6.3)
Subdural haematoma	1 (6.3)	0	0	0	0	1 (6.3)
Investigations	2 (12.5)	2 (12.5)	2 (12.5)	2 (12.5)	0	8 (50.0)
Weight increased	2 (12.5)	2 (12.5)	0	0	0	4 (25.0)
Blood creatinine increased	3 (18.8)	0	0	0	0	3 (18.8)
Cardiac murmur	2 (12.5)	0	0	0	0	2 (12.5)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & <=200 mg Dose Group (N=16) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Investigations (cont.)						
Platelet count decreased	0	0	0	2 (12.5)	0	2 (12.5)
White blood cell count decreased	0	0	1 (6.3)	1 (6.3)	0	2 (12.5)
Blood alkaline phosphatase increased	0	0	1 (6.3)	0	0	1 (6.3)
Blood bilirubin increased	0	1 (6.3)	0	0	0	1 (6.3)
Gamma-glutamyltransferase increased	0	1 (6.3)	0	0	0	1 (6.3)
Metabolism and nutrition disorders	6 (37.5)	5 (31.3)	1 (6.3)	0	0	12 (75.0)
Decreased appetite	3 (18.8)	1 (6.3)	0	0	0	4 (25.0)
Hypokalaemia	3 (18.8)	1 (6.3)	0	0	0	4 (25.0)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & <=200 mg Dose Group (N=16) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Metabolism and nutrition disorders (cont.)						
Dehydration	0	2 (12.5)	0	0	0	2 (12.5)
Fluid retention	1 (6.3)	0	0	0	0	1 (6.3)
Hyperglycaemia	0	0	1 (6.3)	0	0	1 (6.3)
Hypocalcaemia	0	1 (6.3)	0	0	0	1 (6.3)
Hypomagnesaemia	1 (6.3)	0	0	0	0	1 (6.3)
Hypophosphataemia	0	1 (6.3)	0	0	0	1 (6.3)
Increased appetite	1 (6.3)	0	0	0	0	1 (6.3)
Vitamin D deficiency	0	1 (6.3)	0	0	0	1 (6.3)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & <=200 mg Dose Group (N=16) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Musculoskeletal and connective tissue disorders	2 (12.5)	3 (18.8)	3 (18.8)	0	0	8 (50.0)
Arthralgia	1 (6.3)	2 (12.5)	2 (12.5)	0	0	5 (31.3)
Muscular weakness	0	2 (12.5)	1 (6.3)	0	0	3 (18.8)
Back pain	1 (6.3)	0	1 (6.3)	0	0	2 (12.5)
Pain in extremity	1 (6.3)	1 (6.3)	0	0	0	2 (12.5)
Bone pain	0	1 (6.3)	0	0	0	1 (6.3)
Intervertebral disc protrusion	0	1 (6.3)	0	0	0	1 (6.3)
Joint swelling	1 (6.3)	0	0	0	0	1 (6.3)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & <=200 mg Dose Group (N=16) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Musculoskeletal and connective tissue disorders (cont.)						
Muscle spasms	0	1 (6.3)	0	0	0	1 (6.3)
Musculoskeletal chest pain	1 (6.3)	0	0	0	0	1 (6.3)
Musculoskeletal pain	0	1 (6.3)	0	0	0	1 (6.3)
Myalgia	1 (6.3)	0	0	0	0	1 (6.3)
Tenosynovitis	1 (6.3)	0	0	0	0	1 (6.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (12.5)	1 (6.3)	2 (12.5)	0	0	5 (31.3)
Haemangioma	1 (6.3)	0	0	0	0	1 (6.3)
Intraductal proliferative breast lesion	0	0	1 (6.3)	0	0	1 (6.3)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & <=200 mg Dose Group (N=16) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont.)						
Keratoacanthoma	1 (6.3)	0	0	0	0	1 (6.3)
Myelodysplastic syndrome	0	0	1 (6.3)	0	0	1 (6.3)
Penile wart	0	1 (6.3)	0	0	0	1 (6.3)
Squamous cell carcinoma	0	1 (6.3)	0	0	0	1 (6.3)
Nervous system disorders	7 (43.8)	2 (12.5)	1 (6.3)	0	0	10 (62.5)
Headache	4 (25.0)	1 (6.3)	0	0	0	5 (31.3)
Dizziness	2 (12.5)	1 (6.3)	0	0	0	3 (18.8)
Dysgeusia	3 (18.8)	0	0	0	0	3 (18.8)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & <=200 mg Dose Group (N=16) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Nervous system disorders (cont.)						
Cognitive disorder	1 (6.3)	0	0	0	0	1 (6.3)
Dizziness postural	1 (6.3)	0	0	0	0	1 (6.3)
Dysarthria	1 (6.3)	0	0	0	0	1 (6.3)
Hypoaesthesia	1 (6.3)	0	0	0	0	1 (6.3)
Memory impairment	1 (6.3)	0	0	0	0	1 (6.3)
Myoclonus	0	0	1 (6.3)	0	0	1 (6.3)
Paraesthesia	1 (6.3)	0	0	0	0	1 (6.3)
Transient ischaemic attack	1 (6.3)	0	0	0	0	1 (6.3)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & <=200 mg Dose Group (N=16) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Psychiatric disorders	4 (25.0)	1 (6.3)	0	0	0	5 (31.3)
Insomnia	2 (12.5)	1 (6.3)	0	0	0	3 (18.8)
Depressed mood	1 (6.3)	0	0	0	0	1 (6.3)
Irritability	1 (6.3)	0	0	0	0	1 (6.3)
Libido decreased	1 (6.3)	0	0	0	0	1 (6.3)
Renal and urinary disorders	1 (6.3)	2 (12.5)	1 (6.3)	0	0	4 (25.0)
Acute kidney injury	1 (6.3)	0	1 (6.3)	0	0	2 (12.5)
Dysuria	2 (12.5)	0	0	0	0	2 (12.5)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & <=200 mg Dose Group (N=16) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Renal and urinary disorders (cont.)						
Chronic kidney disease	0	1 (6.3)	0	0	0	1 (6.3)
Haematuria	1 (6.3)	0	0	0	0	1 (6.3)
Hypertonic bladder	0	1 (6.3)	0	0	0	1 (6.3)
Pollakiuria	1 (6.3)	0	0	0	0	1 (6.3)
Urinary incontinence	0	1 (6.3)	0	0	0	1 (6.3)
Urinary retention	0	1 (6.3)	0	0	0	1 (6.3)
Reproductive system and breast disorders	1 (6.3)	1 (6.3)	0	0	0	2 (12.5)
Penile pain	1 (6.3)	0	0	0	0	1 (6.3)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
Note 1: In each treatment group, if a patient experiences more than 1 event within a given System Organ Class or Preferred term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column and treatment group.
Note 3: System Organ Classes are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'Any Grade' column.
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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & <=200 mg Dose Group (N=16) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Reproductive system and breast disorders (cont.)						
Scrotal oedema	0	1 (6.3)	0	0	0	1 (6.3)
Respiratory, thoracic and mediastinal disorders	5 (31.3)	4 (25.0)	1 (6.3)	0	0	10 (62.5)
Cough	2 (12.5)	1 (6.3)	0	0	0	3 (18.8)
Dyspnoea	1 (6.3)	2 (12.5)	0	0	0	3 (18.8)
Epistaxis	3 (18.8)	0	0	0	0	3 (18.8)
Pleural effusion	0	1 (6.3)	1 (6.3)	0	0	2 (12.5)
Pulmonary congestion	1 (6.3)	1 (6.3)	0	0	0	2 (12.5)
Haemoptysis	1 (6.3)	0	0	0	0	1 (6.3)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
Note 1: In each treatment group, if a patient experiences more than 1 event within a given System Organ Class or Preferred term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & <=200 mg Dose Group (N=16) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Respiratory, thoracic and mediastinal disorders (cont.)						
Hypoxia	0	0	1 (6.3)	0	0	1 (6.3)
Nasal congestion	1 (6.3)	0	0	0	0	1 (6.3)
Pneumothorax	0	1 (6.3)	0	0	0	1 (6.3)
Productive cough	1 (6.3)	0	0	0	0	1 (6.3)
Pulmonary hypertension	0	0	1 (6.3)	0	0	1 (6.3)
Rhonchi	1 (6.3)	0	0	0	0	1 (6.3)
Upper-airway cough syndrome	1 (6.3)	0	0	0	0	1 (6.3)
Skin and subcutaneous tissue disorders	6 (37.5)	3 (18.8)	0	0	0	9 (56.3)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & <=200 mg Dose Group (N=16) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Skin and subcutaneous tissue disorders (cont.)						
Rash	2 (12.5)	1 (6.3)	0	0	0	3 (18.8)
Erythema	2 (12.5)	0	0	0	0	2 (12.5)
Hair colour changes	2 (12.5)	0	0	0	0	2 (12.5)
Night sweats	1 (6.3)	1 (6.3)	0	0	0	2 (12.5)
Photosensitivity reaction	2 (12.5)	0	0	0	0	2 (12.5)
Blood blister	1 (6.3)	0	0	0	0	1 (6.3)
Ecchymosis	1 (6.3)	0	0	0	0	1 (6.3)
Nail bed disorder	1 (6.3)	0	0	0	0	1 (6.3)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & <=200 mg Dose Group (N=16) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Skin and subcutaneous tissue disorders (cont.)						
Pruritus	1 (6.3)	0	0	0	0	1 (6.3)
Rash maculo-papular	0	1 (6.3)	0	0	0	1 (6.3)
Skin depigmentation	1 (6.3)	0	0	0	0	1 (6.3)
Skin discolouration	1 (6.3)	0	0	0	0	1 (6.3)
Swelling face	1 (6.3)	0	0	0	0	1 (6.3)
Telangiectasia	1 (6.3)	0	0	0	0	1 (6.3)
Vascular disorders	3 (18.8)	2 (12.5)	0	0	0	5 (31.3)
Hypotension	1 (6.3)	1 (6.3)	0	0	0	2 (12.5)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & <=200 mg Dose Group (N=16) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Vascular disorders (cont.)						
Epistaxis	1 (6.3)	0	0	0	0	1 (6.3)
Flushing	1 (6.3)	0	0	0	0	1 (6.3)
Pallor	1 (6.3)	0	0	0	0	1 (6.3)
Thrombophlebitis	0	1 (6.3)	0	0	0	1 (6.3)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Patients with at least one Event	1 (2.4)	5 (12.2)	21 (51.2)	12 (29.3)	2 (4.9)	41 (100.0)
Blood and lymphatic system disorders	5 (12.2)	5 (12.2)	15 (36.6)	8 (19.5)	0	33 (80.5)
Anaemia	1 (2.4)	6 (14.6)	12 (29.3)	1 (2.4)	0	20 (48.8)

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Note 1: In each treatment group, if a patient experiences more than 1 event within a given System Organ Class or Preferred term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Blood and lymphatic system disorders (cont.)						
Thrombocytopenia	2 (4.9)	3 (7.3)	7 (17.1)	4 (9.8)	0	16 (39.0)
Neutropenia	0	1 (2.4)	4 (9.8)	2 (4.9)	0	7 (17.1)
Increased tendency to bruise	2 (4.9)	0	0	0	0	2 (4.9)
Leukocytosis	0	1 (2.4)	1 (2.4)	0	0	2 (4.9)
Leukopenia	2 (4.9)	0	0	0	0	2 (4.9)
Lymphadenopathy	2 (4.9)	0	0	0	0	2 (4.9)
Lymphopenia	1 (2.4)	0	0	1 (2.4)	0	2 (4.9)
Anaemia macrocytic	0	0	1 (2.4)	0	0	1 (2.4)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Blood and lymphatic system disorders (cont.)						
Autoimmune haemolytic anaemia	0	0	1 (2.4)	0	0	1 (2.4)
Haemolysis	0	0	1 (2.4)	0	0	1 (2.4)
Haemorrhagic diathesis	1 (2.4)	0	0	0	0	1 (2.4)
Mast cell activation syndrome	0	1 (2.4)	0	0	0	1 (2.4)
Pancytopenia	0	0	1 (2.4)	0	0	1 (2.4)
Splenic lesion	1 (2.4)	0	0	0	0	1 (2.4)
Splenomegaly	1 (2.4)	0	0	0	0	1 (2.4)
Cardiac disorders	3 (7.3)	0	2 (4.9)	0	0	5 (12.2)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Cardiac disorders (cont.)						
Acute myocardial infarction	0	0	1 (2.4)	0	0	1 (2.4)
Angina pectoris	1 (2.4)	0	0	0	0	1 (2.4)
Cardiac failure congestive	0	0	1 (2.4)	0	0	1 (2.4)
Cyanosis	1 (2.4)	0	0	0	0	1 (2.4)
Palpitations	1 (2.4)	0	0	0	0	1 (2.4)
Sinus tachycardia	1 (2.4)	0	0	0	0	1 (2.4)
Congenital, familial and genetic disorders	0	1 (2.4)	0	0	0	1 (2.4)
Right-to-left cardiac shunt	0	1 (2.4)	0	0	0	1 (2.4)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Ear and labyrinth disorders	3 (7.3)	2 (4.9)	1 (2.4)	0	0	6 (14.6)
Vertigo	1 (2.4)	1 (2.4)	0	0	0	2 (4.9)
Cerumen impaction	0	1 (2.4)	0	0	0	1 (2.4)
Deafness	1 (2.4)	0	0	0	0	1 (2.4)
Deafness neurosensory	0	0	1 (2.4)	0	0	1 (2.4)
Ear discomfort	1 (2.4)	0	0	0	0	1 (2.4)
Ear pain	1 (2.4)	0	0	0	0	1 (2.4)
Hypoacusis	1 (2.4)	0	0	0	0	1 (2.4)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Ear and labyrinth disorders (cont.)						
Tinnitus	0	1 (2.4)	0	0	0	1 (2.4)
Endocrine disorders	0	0	1 (2.4)	0	0	1 (2.4)
Inappropriate antidiuretic hormone secretion	0	0	1 (2.4)	0	0	1 (2.4)
Eye disorders	24 (58.5)	7 (17.1)	1 (2.4)	0	0	32 (78.0)
Periorbital oedema	25 (61.0)	3 (7.3)	0	0	0	28 (68.3)
Lacrimation increased	7 (17.1)	0	0	0	0	7 (17.1)
Vision blurred	3 (7.3)	1 (2.4)	0	0	0	4 (9.8)
Conjunctival haemorrhage	3 (7.3)	0	0	0	0	3 (7.3)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Eye disorders (cont.)						
Eye swelling	1 (2.4)	1 (2.4)	0	0	0	2 (4.9)
Photophobia	2 (4.9)	0	0	0	0	2 (4.9)
Blepharitis	1 (2.4)	0	0	0	0	1 (2.4)
Cataract nuclear	0	1 (2.4)	0	0	0	1 (2.4)
Conjunctival oedema	1 (2.4)	0	0	0	0	1 (2.4)
Eye haemorrhage	1 (2.4)	0	0	0	0	1 (2.4)
Eye inflammation	0	1 (2.4)	0	0	0	1 (2.4)
Eye pruritus	0	1 (2.4)	0	0	0	1 (2.4)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Eye disorders (cont.)						
Macular fibrosis	1 (2.4)	0	0	0	0	1 (2.4)
Ocular hyperaemia	1 (2.4)	0	0	0	0	1 (2.4)
Papilloedema	0	1 (2.4)	0	0	0	1 (2.4)
Periorbital haemorrhage	1 (2.4)	0	0	0	0	1 (2.4)
Retinal tear	0	1 (2.4)	0	0	0	1 (2.4)
Scleral haemorrhage	1 (2.4)	0	0	0	0	1 (2.4)
Trichiasis	1 (2.4)	0	0	0	0	1 (2.4)
Uveitis	0	0	1 (2.4)	0	0	1 (2.4)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Eye disorders (cont.)						
Visual acuity reduced	1 (2.4)	0	0	0	0	1 (2.4)
Gastrointestinal disorders	15 (36.6)	16 (39.0)	6 (14.6)	3 (7.3)	0	40 (97.6)
Diarrhoea	14 (34.1)	3 (7.3)	0	0	0	17 (41.5)
Nausea	10 (24.4)	5 (12.2)	0	1 (2.4)	0	16 (39.0)
Vomiting	10 (24.4)	3 (7.3)	0	1 (2.4)	0	14 (34.1)
Abdominal pain	5 (12.2)	3 (7.3)	0	0	0	8 (19.5)
Constipation	5 (12.2)	3 (7.3)	0	0	0	8 (19.5)
Ascites	3 (7.3)	2 (4.9)	1 (2.4)	1 (2.4)	0	7 (17.1)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Gastrointestinal disorders (cont.)						
Abdominal distension	6 (14.6)	0	0	0	0	6 (14.6)
Dry mouth	5 (12.2)	1 (2.4)	0	0	0	6 (14.6)
Dyspepsia	2 (4.9)	3 (7.3)	0	0	0	5 (12.2)
Abdominal discomfort	4 (9.8)	0	0	0	0	4 (9.8)
Abdominal pain upper	2 (4.9)	2 (4.9)	0	0	0	4 (9.8)
Gastrooesophageal reflux disease	0	3 (7.3)	0	0	0	3 (7.3)
Gastric haemorrhage	0	0	2 (4.9)	0	0	2 (4.9)
Gastrointestinal haemorrhage	0	1 (2.4)	1 (2.4)	0	0	2 (4.9)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Gastrointestinal disorders (cont.)						
Gingival pain	2 (4.9)	0	0	0	0	2 (4.9)
Haematochezia	2 (4.9)	0	0	0	0	2 (4.9)
Haemorrhoidal haemorrhage	1 (2.4)	1 (2.4)	0	0	0	2 (4.9)
Inguinal hernia	1 (2.4)	1 (2.4)	0	0	0	2 (4.9)
Retching	2 (4.9)	0	0	0	0	2 (4.9)
Varices oesophageal	0	2 (4.9)	0	0	0	2 (4.9)
Anorectal discomfort	1 (2.4)	0	0	0	0	1 (2.4)
Chapped lips	1 (2.4)	0	0	0	0	1 (2.4)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Gastrointestinal disorders (cont.)						
Colitis	0	0	1 (2.4)	0	0	1 (2.4)
Flatulence	1 (2.4)	0	0	0	0	1 (2.4)
Gastritis	0	1 (2.4)	0	0	0	1 (2.4)
Gastritis haemorrhagic	0	0	1 (2.4)	0	0	1 (2.4)
Gastrointestinal perforation	0	0	1 (2.4)	0	0	1 (2.4)
Gingival swelling	1 (2.4)	0	0	0	0	1 (2.4)
Haemorrhoids	0	1 (2.4)	0	0	0	1 (2.4)
Incarcerated umbilical hernia	0	0	0	1 (2.4)	0	1 (2.4)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Gastrointestinal disorders (cont.)						
Large intestine perforation	0	0	1 (2.4)	0	0	1 (2.4)
Large intestine polyp	1 (2.4)	0	0	0	0	1 (2.4)
Lip ulceration	1 (2.4)	0	0	0	0	1 (2.4)
Melaena	1 (2.4)	0	0	0	0	1 (2.4)
Mouth ulceration	1 (2.4)	0	0	0	0	1 (2.4)
Oesophagitis	0	0	1 (2.4)	0	0	1 (2.4)
Oral disorder	1 (2.4)	0	0	0	0	1 (2.4)
Oral pain	1 (2.4)	0	0	0	0	1 (2.4)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Gastrointestinal disorders (cont.)						
Pancreatitis	0	0	1 (2.4)	0	0	1 (2.4)
Parotid gland enlargement	1 (2.4)	0	0	0	0	1 (2.4)
Periodontal disease	1 (2.4)	0	0	0	0	1 (2.4)
Rectal haemorrhage	1 (2.4)	0	0	0	0	1 (2.4)
Small intestinal obstruction	1 (2.4)	0	0	0	0	1 (2.4)
Tongue discolouration	1 (2.4)	0	0	0	0	1 (2.4)
General disorders and administration site conditions	13 (31.7)	12 (29.3)	7 (17.1)	0	0	32 (78.0)
Oedema peripheral	17 (41.5)	7 (17.1)	0	0	0	24 (58.5)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
General disorders and administration site conditions (cont.)						
Fatigue	5 (12.2)	3 (7.3)	6 (14.6)	0	0	14 (34.1)
Asthenia	3 (7.3)	1 (2.4)	0	0	0	4 (9.8)
Face oedema	3 (7.3)	1 (2.4)	0	0	0	4 (9.8)
Peripheral swelling	4 (9.8)	0	0	0	0	4 (9.8)
Pyrexia	2 (4.9)	0	2 (4.9)	0	0	4 (9.8)
Chills	3 (7.3)	0	0	0	0	3 (7.3)
Feeling abnormal	3 (7.3)	0	0	0	0	3 (7.3)
Gait disturbance	2 (4.9)	0	0	0	0	2 (4.9)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
General disorders and administration site conditions (cont.)						
Generalised oedema	1 (2.4)	1 (2.4)	0	0	0	2 (4.9)
Influenza like illness	1 (2.4)	1 (2.4)	0	0	0	2 (4.9)
Chest discomfort	1 (2.4)	0	0	0	0	1 (2.4)
Decreased activity	0	1 (2.4)	0	0	0	1 (2.4)
Malaise	1 (2.4)	0	0	0	0	1 (2.4)
Non-cardiac chest pain	0	1 (2.4)	0	0	0	1 (2.4)
Oedema	1 (2.4)	0	0	0	0	1 (2.4)
Pain	0	1 (2.4)	0	0	0	1 (2.4)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
General disorders and administration site conditions (cont.)						
Temperature intolerance	1 (2.4)	0	0	0	0	1 (2.4)
Hepatobiliary disorders	2 (4.9)	4 (9.8)	1 (2.4)	0	0	7 (17.1)
Hyperbilirubinaemia	0	3 (7.3)	0	0	0	3 (7.3)
Cholelithiasis	1 (2.4)	0	1 (2.4)	0	0	2 (4.9)
Hepatic cirrhosis	0	1 (2.4)	0	0	0	1 (2.4)
Jaundice	1 (2.4)	0	0	0	0	1 (2.4)
Nodular regenerative hyperplasia	0	1 (2.4)	0	0	0	1 (2.4)
Immune system disorders	4 (9.8)	1 (2.4)	2 (4.9)	0	0	7 (17.1)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Immune system disorders (cont.)						
Drug hypersensitivity	2 (4.9)	0	0	0	0	2 (4.9)
Anaphylactic reaction	0	0	1 (2.4)	0	0	1 (2.4)
Anaphylactic shock	0	0	1 (2.4)	0	0	1 (2.4)
Contrast media allergy	0	1 (2.4)	0	0	0	1 (2.4)
Hypersensitivity	1 (2.4)	0	0	0	0	1 (2.4)
Iodine allergy	1 (2.4)	0	0	0	0	1 (2.4)
Infections and infestations	8 (19.5)	11 (26.8)	11 (26.8)	0	1 (2.4)	31 (75.6)
Upper respiratory tract infection	3 (7.3)	4 (9.8)	1 (2.4)	0	0	8 (19.5)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Infections and infestations (cont.)						
Urinary tract infection	1 (2.4)	4 (9.8)	1 (2.4)	0	0	6 (14.6)
Herpes zoster	1 (2.4)	3 (7.3)	0	0	0	4 (9.8)
Oral candidiasis	1 (2.4)	3 (7.3)	0	0	0	4 (9.8)
Pneumonia	0	0	4 (9.8)	0	0	4 (9.8)
Sinusitis	2 (4.9)	2 (4.9)	0	0	0	4 (9.8)
Cellulitis	0	2 (4.9)	0	0	0	2 (4.9)
Conjunctivitis	1 (2.4)	1 (2.4)	0	0	0	2 (4.9)
Diverticulitis	0	1 (2.4)	1 (2.4)	0	0	2 (4.9)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Infections and infestations (cont.)						
Gastroenteritis	1 (2.4)	1 (2.4)	0	0	0	2 (4.9)
Nasopharyngitis	2 (4.9)	0	0	0	0	2 (4.9)
Bronchitis	0	1 (2.4)	0	0	0	1 (2.4)
Cellulitis orbital	0	1 (2.4)	0	0	0	1 (2.4)
Clostridium difficile infection	0	0	1 (2.4)	0	0	1 (2.4)
Diarrhoea infectious	0	1 (2.4)	0	0	0	1 (2.4)
Ear infection	0	1 (2.4)	0	0	0	1 (2.4)
Escherichia bacteraemia	0	0	1 (2.4)	0	0	1 (2.4)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Infections and infestations (cont.)						
Escherichia urinary tract infection	0	1 (2.4)	0	0	0	1 (2.4)
Folliculitis	1 (2.4)	0	0	0	0	1 (2.4)
Genital infection	1 (2.4)	0	0	0	0	1 (2.4)
Hordeolum	1 (2.4)	0	0	0	0	1 (2.4)
Influenza	1 (2.4)	0	0	0	0	1 (2.4)
Localised infection	0	0	1 (2.4)	0	0	1 (2.4)
Mastoiditis	1 (2.4)	0	0	0	0	1 (2.4)
Otitis externa	0	1 (2.4)	0	0	0	1 (2.4)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Infections and infestations (cont.)						
Peritonitis bacterial	0	0	1 (2.4)	0	0	1 (2.4)
Pharyngitis	0	1 (2.4)	0	0	0	1 (2.4)
Rhinovirus infection	1 (2.4)	0	0	0	0	1 (2.4)
Sepsis	0	1 (2.4)	0	0	0	1 (2.4)
Septic shock	0	0	0	0	1 (2.4)	1 (2.4)
Tooth abscess	0	0	1 (2.4)	0	0	1 (2.4)
Urinary tract infection staphylococcal	0	1 (2.4)	0	0	0	1 (2.4)
Viral upper respiratory tract infection	1 (2.4)	0	0	0	0	1 (2.4)

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AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Infections and infestations (cont.)						
Vulvovaginal mycotic infection	0	1 (2.4)	0	0	0	1 (2.4)
Injury, poisoning and procedural complications	11 (26.8)	8 (19.5)	1 (2.4)	0	0	20 (48.8)
Fall	2 (4.9)	3 (7.3)	0	0	0	5 (12.2)
Contusion	2 (4.9)	2 (4.9)	0	0	0	4 (9.8)
Laceration	3 (7.3)	0	0	0	0	3 (7.3)
Arthropod bite	2 (4.9)	0	0	0	0	2 (4.9)
Lumbar vertebral fracture	0	2 (4.9)	0	0	0	2 (4.9)
Procedural pain	2 (4.9)	0	0	0	0	2 (4.9)

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AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Injury, poisoning and procedural complications (cont.)						
Subdural haematoma	2 (4.9)	0	0	0	0	2 (4.9)
Electrical burn	0	1 (2.4)	0	0	0	1 (2.4)
Femoral neck fracture	0	0	1 (2.4)	0	0	1 (2.4)
Femur fracture	0	1 (2.4)	0	0	0	1 (2.4)
Foot fracture	0	1 (2.4)	0	0	0	1 (2.4)
Fractured sacrum	0	1 (2.4)	0	0	0	1 (2.4)
Limb injury	1 (2.4)	0	0	0	0	1 (2.4)
Overdose	1 (2.4)	0	0	0	0	1 (2.4)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Injury, poisoning and procedural complications (cont.)						
Post procedural haemorrhage	1 (2.4)	0	0	0	0	1 (2.4)
Rib fracture	0	1 (2.4)	0	0	0	1 (2.4)
Skin wound	1 (2.4)	0	0	0	0	1 (2.4)
Spinal compression fracture	1 (2.4)	0	0	0	0	1 (2.4)
Tendon injury	1 (2.4)	0	0	0	0	1 (2.4)
Thermal burn	0	1 (2.4)	0	0	0	1 (2.4)
Tooth fracture	0	1 (2.4)	0	0	0	1 (2.4)
Wound	1 (2.4)	0	0	0	0	1 (2.4)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Investigations	6 (14.6)	4 (9.8)	6 (14.6)	3 (7.3)	0	19 (46.3)
Weight increased	3 (7.3)	2 (4.9)	1 (2.4)	0	0	6 (14.6)
White blood cell count decreased	1 (2.4)	1 (2.4)	2 (4.9)	1 (2.4)	0	5 (12.2)
Blood alkaline phosphatase increased	0	1 (2.4)	2 (4.9)	1 (2.4)	0	4 (9.8)
Blood bilirubin increased	1 (2.4)	2 (4.9)	1 (2.4)	0	0	4 (9.8)
Cardiac murmur	4 (9.8)	0	0	0	0	4 (9.8)
Blood creatinine increased	3 (7.3)	0	0	0	0	3 (7.3)
Alanine aminotransferase increased	1 (2.4)	1 (2.4)	0	0	0	2 (4.9)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Investigations (cont.)						
Aspartate aminotransferase increased	2 (4.9)	0	0	0	0	2 (4.9)
Platelet count decreased	0	0	0	2 (4.9)	0	2 (4.9)
Electrocardiogram QT prolonged	1 (2.4)	0	0	0	0	1 (2.4)
Gamma-glutamyltransferase increased	0	1 (2.4)	0	0	0	1 (2.4)
Neutrophil count decreased	1 (2.4)	0	0	0	0	1 (2.4)
Neutrophil count increased	1 (2.4)	0	0	0	0	1 (2.4)
Occult blood positive	1 (2.4)	0	0	0	0	1 (2.4)
Urine output increased	1 (2.4)	0	0	0	0	1 (2.4)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Investigations (cont.)						
Weight decreased	1 (2.4)	0	0	0	0	1 (2.4)
Metabolism and nutrition disorders	11 (26.8)	8 (19.5)	6 (14.6)	2 (4.9)	0	27 (65.9)
Hypokalaemia	6 (14.6)	2 (4.9)	2 (4.9)	0	0	10 (24.4)
Decreased appetite	6 (14.6)	2 (4.9)	1 (2.4)	0	0	9 (22.0)
Hypophosphataemia	1 (2.4)	3 (7.3)	2 (4.9)	1 (2.4)	0	7 (17.1)
Dehydration	1 (2.4)	2 (4.9)	0	0	0	3 (7.3)
Hypocalcaemia	0	3 (7.3)	0	0	0	3 (7.3)
Hyperglycaemia	0	1 (2.4)	1 (2.4)	0	0	2 (4.9)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Metabolism and nutrition disorders (cont.)						
Fluid retention	1 (2.4)	0	0	0	0	1 (2.4)
Hypernatraemia	0	0	1 (2.4)	0	0	1 (2.4)
Hyperuricaemia	1 (2.4)	0	0	0	0	1 (2.4)
Hypoalbuminaemia	0	0	1 (2.4)	0	0	1 (2.4)
Hypoglycaemia	0	0	1 (2.4)	0	0	1 (2.4)
Hypomagnesaemia	1 (2.4)	0	0	0	0	1 (2.4)
Hyponatraemia	0	0	0	1 (2.4)	0	1 (2.4)
Increased appetite	1 (2.4)	0	0	0	0	1 (2.4)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Metabolism and nutrition disorders (cont.)						
Metabolic acidosis	1 (2.4)	0	0	0	0	1 (2.4)
Vitamin D deficiency	0	1 (2.4)	0	0	0	1 (2.4)
Musculoskeletal and connective tissue disorders	12 (29.3)	10 (24.4)	3 (7.3)	0	0	25 (61.0)
Arthralgia	10 (24.4)	3 (7.3)	2 (4.9)	0	0	15 (36.6)
Pain in extremity	4 (9.8)	3 (7.3)	0	0	0	7 (17.1)
Back pain	2 (4.9)	1 (2.4)	1 (2.4)	0	0	4 (9.8)
Muscular weakness	1 (2.4)	2 (4.9)	1 (2.4)	0	0	4 (9.8)
Musculoskeletal pain	1 (2.4)	2 (4.9)	0	0	0	3 (7.3)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Musculoskeletal and connective tissue disorders (cont.)						
Exostosis	2 (4.9)	0	0	0	0	2 (4.9)
Muscle spasms	1 (2.4)	1 (2.4)	0	0	0	2 (4.9)
Musculoskeletal chest pain	2 (4.9)	0	0	0	0	2 (4.9)
Bone pain	0	1 (2.4)	0	0	0	1 (2.4)
Extraskeletal ossification	1 (2.4)	0	0	0	0	1 (2.4)
Groin pain	0	1 (2.4)	0	0	0	1 (2.4)
Intervertebral disc protrusion	0	1 (2.4)	0	0	0	1 (2.4)
Joint effusion	1 (2.4)	0	0	0	0	1 (2.4)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Musculoskeletal and connective tissue disorders (cont.)						
Joint stiffness	1 (2.4)	0	0	0	0	1 (2.4)
Joint swelling	1 (2.4)	0	0	0	0	1 (2.4)
Muscle twitching	0	1 (2.4)	0	0	0	1 (2.4)
Myalgia	1 (2.4)	0	0	0	0	1 (2.4)
Osteoporosis	0	1 (2.4)	0	0	0	1 (2.4)
Rotator cuff syndrome	0	1 (2.4)	0	0	0	1 (2.4)
Tenosynovitis	1 (2.4)	0	0	0	0	1 (2.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4 (9.8)	4 (9.8)	3 (7.3)	0	0	11 (26.8)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont.)						
Squamous cell carcinoma	1 (2.4)	1 (2.4)	0	0	0	2 (4.9)
Acrochordon	1 (2.4)	0	0	0	0	1 (2.4)
Gastrointestinal neoplasm	0	1 (2.4)	0	0	0	1 (2.4)
Haemangioma	1 (2.4)	0	0	0	0	1 (2.4)
Intraductal proliferative breast lesion	0	0	1 (2.4)	0	0	1 (2.4)
Intravascular papillary endothelial hyperplasia	0	0	1 (2.4)	0	0	1 (2.4)
Keratoacanthoma	1 (2.4)	0	0	0	0	1 (2.4)
Lip neoplasm	1 (2.4)	0	0	0	0	1 (2.4)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont.)						
Malignant melanoma	0	1 (2.4)	0	0	0	1 (2.4)
Myelodysplastic syndrome	0	0	1 (2.4)	0	0	1 (2.4)
Penile wart	0	1 (2.4)	0	0	0	1 (2.4)
Renal neoplasm	1 (2.4)	0	0	0	0	1 (2.4)
Seborrhoeic keratosis	1 (2.4)	0	0	0	0	1 (2.4)
Transitional cell carcinoma	0	1 (2.4)	0	0	0	1 (2.4)
Nervous system disorders	19 (46.3)	7 (17.1)	5 (12.2)	0	1 (2.4)	32 (78.0)
Dizziness	9 (22.0)	1 (2.4)	1 (2.4)	0	0	11 (26.8)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Nervous system disorders (cont.)						
Memory impairment	7 (17.1)	2 (4.9)	0	0	0	9 (22.0)
Dysgeusia	6 (14.6)	1 (2.4)	0	0	0	7 (17.1)
Headache	4 (9.8)	2 (4.9)	1 (2.4)	0	0	7 (17.1)
Hypoaesthesia	5 (12.2)	1 (2.4)	0	0	0	6 (14.6)
Cognitive disorder	2 (4.9)	2 (4.9)	1 (2.4)	0	0	5 (12.2)
Ageusia	3 (7.3)	0	0	0	0	3 (7.3)
Paraesthesia	3 (7.3)	0	0	0	0	3 (7.3)
Dizziness postural	2 (4.9)	0	0	0	0	2 (4.9)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Nervous system disorders (cont.)						
Encephalopathy	0	0	2 (4.9)	0	0	2 (4.9)
Haemorrhage intracranial	0	0	1 (2.4)	0	1 (2.4)	2 (4.9)
Peripheral sensory neuropathy	2 (4.9)	0	0	0	0	2 (4.9)
Aphasia	1 (2.4)	0	0	0	0	1 (2.4)
Central nervous system lesion	1 (2.4)	0	0	0	0	1 (2.4)
Cerebral atrophy	1 (2.4)	0	0	0	0	1 (2.4)
Cerebral ventricle dilatation	1 (2.4)	0	0	0	0	1 (2.4)
Dementia	0	1 (2.4)	0	0	0	1 (2.4)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

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Nervous system disorders (cont.)						
Dysarthria	1 (2.4)	0	0	0	0	1 (2.4)
Hydrocephalus	1 (2.4)	0	0	0	0	1 (2.4)
Myoclonus	0	0	1 (2.4)	0	0	1 (2.4)
Neuropathy peripheral	0	1 (2.4)	0	0	0	1 (2.4)
Post herpetic neuralgia	0	1 (2.4)	0	0	0	1 (2.4)
Seizure	0	1 (2.4)	0	0	0	1 (2.4)
Somnolence	1 (2.4)	0	0	0	0	1 (2.4)
Syncope	0	0	1 (2.4)	0	0	1 (2.4)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Nervous system disorders (cont.)						
Transient ischaemic attack	1 (2.4)	0	0	0	0	1 (2.4)
Psychiatric disorders	6 (14.6)	5 (12.2)	2 (4.9)	0	0	13 (31.7)
Insomnia	3 (7.3)	2 (4.9)	2 (4.9)	0	0	7 (17.1)
Anxiety	0	2 (4.9)	0	0	0	2 (4.9)
Confusional state	0	2 (4.9)	0	0	0	2 (4.9)
Depression	1 (2.4)	1 (2.4)	0	0	0	2 (4.9)
Depressed mood	1 (2.4)	0	0	0	0	1 (2.4)
Dysphoria	1 (2.4)	0	0	0	0	1 (2.4)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Psychiatric disorders (cont.)						
Irritability	1 (2.4)	0	0	0	0	1 (2.4)
Libido decreased	1 (2.4)	0	0	0	0	1 (2.4)
Mental status changes	0	0	1 (2.4)	0	0	1 (2.4)
Suicidal ideation	0	1 (2.4)	0	0	0	1 (2.4)
Renal and urinary disorders	9 (22.0)	2 (4.9)	3 (7.3)	0	0	14 (34.1)
Dysuria	6 (14.6)	0	0	0	0	6 (14.6)
Acute kidney injury	2 (4.9)	0	3 (7.3)	0	0	5 (12.2)
Haematuria	4 (9.8)	0	0	0	0	4 (9.8)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Renal and urinary disorders (cont.)						
Pollakiuria	2 (4.9)	0	0	0	0	2 (4.9)
Urinary incontinence	1 (2.4)	1 (2.4)	0	0	0	2 (4.9)
Chronic kidney disease	0	1 (2.4)	0	0	0	1 (2.4)
Hypertonic bladder	0	1 (2.4)	0	0	0	1 (2.4)
Nephrolithiasis	1 (2.4)	0	0	0	0	1 (2.4)
Polyuria	1 (2.4)	0	0	0	0	1 (2.4)
Renal colic	1 (2.4)	0	0	0	0	1 (2.4)
Renal impairment	0	0	1 (2.4)	0	0	1 (2.4)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Renal and urinary disorders (cont.)						
Renal mass	1 (2.4)	0	0	0	0	1 (2.4)
Urinary retention	0	1 (2.4)	0	0	0	1 (2.4)
Reproductive system and breast disorders	3 (7.3)	1 (2.4)	0	0	0	4 (9.8)
Haematospermia	1 (2.4)	0	0	0	0	1 (2.4)
Penile pain	1 (2.4)	0	0	0	0	1 (2.4)
Scrotal oedema	0	1 (2.4)	0	0	0	1 (2.4)
Vulvovaginal pain	1 (2.4)	0	0	0	0	1 (2.4)
Respiratory, thoracic and mediastinal disorders	16 (39.0)	7 (17.1)	4 (9.8)	0	0	27 (65.9)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Respiratory, thoracic and mediastinal disorders (cont.)						
Cough	7 (17.1)	2 (4.9)	0	0	0	9 (22.0)
Dyspnoea	3 (7.3)	4 (9.8)	0	0	0	7 (17.1)
Epistaxis	7 (17.1)	0	0	0	0	7 (17.1)
Pleural effusion	1 (2.4)	3 (7.3)	1 (2.4)	0	0	5 (12.2)
Productive cough	4 (9.8)	0	0	0	0	4 (9.8)
Nasal congestion	3 (7.3)	0	0	0	0	3 (7.3)
Rhinorrhoea	3 (7.3)	0	0	0	0	3 (7.3)
Upper-airway cough syndrome	3 (7.3)	0	0	0	0	3 (7.3)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Respiratory, thoracic and mediastinal disorders (cont.)						
Dysphonia	2 (4.9)	0	0	0	0	2 (4.9)
Haemoptysis	1 (2.4)	1 (2.4)	0	0	0	2 (4.9)
Pulmonary congestion	1 (2.4)	1 (2.4)	0	0	0	2 (4.9)
Acute respiratory failure	0	0	1 (2.4)	0	0	1 (2.4)
Chronic obstructive pulmonary disease	0	0	1 (2.4)	0	0	1 (2.4)
Dyspnoea exertional	1 (2.4)	0	0	0	0	1 (2.4)
Emphysema	1 (2.4)	0	0	0	0	1 (2.4)
Hypoxia	0	0	1 (2.4)	0	0	1 (2.4)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Respiratory, thoracic and mediastinal disorders (cont.)						
Laryngeal oedema	0	0	1 (2.4)	0	0	1 (2.4)
Oropharyngeal pain	1 (2.4)	0	0	0	0	1 (2.4)
Pneumothorax	0	1 (2.4)	0	0	0	1 (2.4)
Pulmonary hypertension	0	0	1 (2.4)	0	0	1 (2.4)
Pulmonary mass	1 (2.4)	0	0	0	0	1 (2.4)
Rales	1 (2.4)	0	0	0	0	1 (2.4)
Rhinitis allergic	0	1 (2.4)	0	0	0	1 (2.4)
Rhonchi	1 (2.4)	0	0	0	0	1 (2.4)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Respiratory, thoracic and mediastinal disorders (cont.)						
Sinus disorder	1 (2.4)	0	0	0	0	1 (2.4)
Wheezing	1 (2.4)	0	0	0	0	1 (2.4)
Skin and subcutaneous tissue disorders	19 (46.3)	8 (19.5)	1 (2.4)	0	0	28 (68.3)
Hair colour changes	8 (19.5)	0	1 (2.4)	0	0	9 (22.0)
Rash	6 (14.6)	1 (2.4)	0	0	0	7 (17.1)
Pruritus	5 (12.2)	1 (2.4)	0	0	0	6 (14.6)
Alopecia	5 (12.2)	0	0	0	0	5 (12.2)
Photosensitivity reaction	3 (7.3)	2 (4.9)	0	0	0	5 (12.2)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Skin and subcutaneous tissue disorders (cont.)						
Rash maculo-papular	2 (4.9)	3 (7.3)	0	0	0	5 (12.2)
Ecchymosis	3 (7.3)	0	0	0	0	3 (7.3)
Rash pruritic	3 (7.3)	0	0	0	0	3 (7.3)
Skin lesion	3 (7.3)	0	0	0	0	3 (7.3)
Erythema	2 (4.9)	0	0	0	0	2 (4.9)
Hyperhidrosis	2 (4.9)	0	0	0	0	2 (4.9)
Livedo reticularis	2 (4.9)	0	0	0	0	2 (4.9)
Nail bed disorder	2 (4.9)	0	0	0	0	2 (4.9)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Skin and subcutaneous tissue disorders (cont.)						
Night sweats	1 (2.4)	1 (2.4)	0	0	0	2 (4.9)
Rash erythematous	2 (4.9)	0	0	0	0	2 (4.9)
Rash papular	2 (4.9)	0	0	0	0	2 (4.9)
Urticaria	0	2 (4.9)	0	0	0	2 (4.9)
Blood blister	1 (2.4)	0	0	0	0	1 (2.4)
Dermatitis	0	1 (2.4)	0	0	0	1 (2.4)
Dermatitis acneiform	1 (2.4)	0	0	0	0	1 (2.4)
Dry skin	1 (2.4)	0	0	0	0	1 (2.4)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Skin and subcutaneous tissue disorders (cont.)						
Eczema	1 (2.4)	0	0	0	0	1 (2.4)
Hair growth abnormal	1 (2.4)	0	0	0	0	1 (2.4)
Melanocytic hyperplasia	0	1 (2.4)	0	0	0	1 (2.4)
Nail growth abnormal	1 (2.4)	0	0	0	0	1 (2.4)
Scab	1 (2.4)	0	0	0	0	1 (2.4)
Skin depigmentation	1 (2.4)	0	0	0	0	1 (2.4)
Skin discolouration	1 (2.4)	0	0	0	0	1 (2.4)
Skin ulcer	0	1 (2.4)	0	0	0	1 (2.4)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Skin and subcutaneous tissue disorders (cont.)						
Swelling face	1 (2.4)	0	0	0	0	1 (2.4)
Telangiectasia	1 (2.4)	0	0	0	0	1 (2.4)
Vascular disorders	10 (24.4)	5 (12.2)	3 (7.3)	0	0	18 (43.9)
Hypertension	1 (2.4)	2 (4.9)	3 (7.3)	0	0	6 (14.6)
Hypotension	4 (9.8)	1 (2.4)	0	0	0	5 (12.2)
Flushing	4 (9.8)	0	0	0	0	4 (9.8)
Embolism	0	1 (2.4)	0	0	0	1 (2.4)
Epistaxis	1 (2.4)	0	0	0	0	1 (2.4)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Vascular disorders (cont.)						
Hot flush	1 (2.4)	0	0	0	0	1 (2.4)
Pallor	1 (2.4)	0	0	0	0	1 (2.4)
Peripheral vascular disorder	1 (2.4)	0	0	0	0	1 (2.4)
Thrombophlebitis	0	1 (2.4)	0	0	0	1 (2.4)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & 200 mg Dose Group (N=40) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Patients with at least one Event	5 (12.5)	8 (20.0)	20 (50.0)	4 (10.0)	3 (7.5)	40 (100.0)
Blood and lymphatic system disorders	2 (5.0)	7 (17.5)	14 (35.0)	2 (5.0)	0	25 (62.5)
Thrombocytopenia	3 (7.5)	6 (15.0)	3 (7.5)	1 (2.5)	0	13 (32.5)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & 200 mg Dose Group (N=40) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Blood and lymphatic system disorders (cont.)						
Anaemia	0	2 (5.0)	9 (22.5)	0	0	11 (27.5)
Neutropenia	0	0	3 (7.5)	1 (2.5)	0	4 (10.0)
Leukocytosis	0	0	2 (5.0)	0	0	2 (5.0)
Coagulopathy	1 (2.5)	0	0	0	0	1 (2.5)
Haemolysis	1 (2.5)	0	0	0	0	1 (2.5)
Haemorrhagic diathesis	0	1 (2.5)	0	0	0	1 (2.5)
Mast cell activation syndrome	0	1 (2.5)	0	0	0	1 (2.5)
Cardiac disorders	4 (10.0)	0	3 (7.5)	0	0	7 (17.5)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & 200 mg Dose Group (N=40) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Cardiac disorders (cont.)						
Cardiac failure	0	0	2 (5.0)	0	0	2 (5.0)
Atrial flutter	0	0	1 (2.5)	0	0	1 (2.5)
Bradycardia	1 (2.5)	0	0	0	0	1 (2.5)
Palpitations	1 (2.5)	0	0	0	0	1 (2.5)
Pericardial effusion	1 (2.5)	0	0	0	0	1 (2.5)
Supraventricular extrasystoles	1 (2.5)	0	0	0	0	1 (2.5)
Ventricular extrasystoles	1 (2.5)	0	0	0	0	1 (2.5)
Ear and labyrinth disorders	1 (2.5)	0	0	0	0	1 (2.5)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & 200 mg Dose Group (N=40) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Ear and labyrinth disorders (cont.)						
Vertigo	1 (2.5)	0	0	0	0	1 (2.5)
Eye disorders	15 (37.5)	4 (10.0)	1 (2.5)	1 (2.5)	0	21 (52.5)
Periorbital oedema	5 (12.5)	3 (7.5)	1 (2.5)	0	0	9 (22.5)
Eyelid oedema	7 (17.5)	0	0	0	0	7 (17.5)
Lacrimation increased	4 (10.0)	0	0	0	0	4 (10.0)
Conjunctival haemorrhage	0	1 (2.5)	0	0	0	1 (2.5)
Eye haemorrhage	1 (2.5)	0	0	0	0	1 (2.5)
Eye swelling	1 (2.5)	0	0	0	0	1 (2.5)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & 200 mg Dose Group (N=40) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Eye disorders (cont.)						
Vision blurred	1 (2.5)	0	0	0	0	1 (2.5)
Visual acuity reduced	1 (2.5)	0	0	0	0	1 (2.5)
Vitreous floaters	1 (2.5)	0	0	0	0	1 (2.5)
Vitreous haemorrhage	0	0	0	1 (2.5)	0	1 (2.5)
Gastrointestinal disorders	16 (40.0)	7 (17.5)	6 (15.0)	0	0	29 (72.5)
Diarrhoea	7 (17.5)	1 (2.5)	1 (2.5)	0	0	9 (22.5)
Nausea	7 (17.5)	0	1 (2.5)	0	0	8 (20.0)
Vomiting	5 (12.5)	2 (5.0)	1 (2.5)	0	0	8 (20.0)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & 200 mg Dose Group (N=40) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Gastrointestinal disorders (cont.)						
Constipation	5 (12.5)	0	0	0	0	5 (12.5)
Abdominal pain	3 (7.5)	0	1 (2.5)	0	0	4 (10.0)
Dyspepsia	1 (2.5)	1 (2.5)	0	0	0	2 (5.0)
Gastrooesophageal reflux disease	0	2 (5.0)	0	0	0	2 (5.0)
Melaena	0	1 (2.5)	1 (2.5)	0	0	2 (5.0)
Salivary hypersecretion	2 (5.0)	0	0	0	0	2 (5.0)
Abdominal distension	1 (2.5)	0	0	0	0	1 (2.5)
Abdominal pain upper	1 (2.5)	0	0	0	0	1 (2.5)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & 200 mg Dose Group (N=40) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Gastrointestinal disorders (cont.)						
Ascites	0	1 (2.5)	0	0	0	1 (2.5)
Dental caries	1 (2.5)	0	0	0	0	1 (2.5)
Duodenal ulcer haemorrhage	0	0	1 (2.5)	0	0	1 (2.5)
Faeces discoloured	1 (2.5)	0	0	0	0	1 (2.5)
Gastrointestinal haemorrhage	0	0	1 (2.5)	0	0	1 (2.5)
Gingival bleeding	1 (2.5)	0	0	0	0	1 (2.5)
Intra-abdominal haematoma	0	1 (2.5)	0	0	0	1 (2.5)
Intra-abdominal haemorrhage	0	0	1 (2.5)	0	0	1 (2.5)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & 200 mg Dose Group (N=40) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Gastrointestinal disorders (cont.)						
Lip dry	1 (2.5)	0	0	0	0	1 (2.5)
Lower gastrointestinal haemorrhage	0	0	1 (2.5)	0	0	1 (2.5)
Portal hypertensive gastropathy	1 (2.5)	0	0	0	0	1 (2.5)
Tooth deposit	1 (2.5)	0	0	0	0	1 (2.5)
Toothache	1 (2.5)	0	0	0	0	1 (2.5)
General disorders and administration site conditions	17 (42.5)	8 (20.0)	1 (2.5)	0	1 (2.5)	27 (67.5)
Oedema peripheral	16 (40.0)	4 (10.0)	0	0	0	20 (50.0)
Face oedema	6 (15.0)	1 (2.5)	0	0	0	7 (17.5)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & 200 mg Dose Group (N=40) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
General disorders and administration site conditions (cont.)						
Asthenia	2 (5.0)	2 (5.0)	0	0	0	4 (10.0)
Fatigue	1 (2.5)	1 (2.5)	1 (2.5)	0	0	3 (7.5)
Pain	3 (7.5)	0	0	0	0	3 (7.5)
Pyrexia	2 (5.0)	1 (2.5)	0	0	0	3 (7.5)
Non-cardiac chest pain	2 (5.0)	0	0	0	0	2 (5.0)
Disease progression	0	0	0	0	1 (2.5)	1 (2.5)
Generalised oedema	0	1 (2.5)	0	0	0	1 (2.5)
Oedema	1 (2.5)	0	0	0	0	1 (2.5)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & 200 mg Dose Group (N=40) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
General disorders and administration site conditions (cont.)						
Peripheral swelling	1 (2.5)	0	0	0	0	1 (2.5)
Systemic inflammatory response syndrome	0	1 (2.5)	0	0	0	1 (2.5)
Hepatobiliary disorders	1 (2.5)	0	0	0	0	1 (2.5)
Hyperbilirubinaemia	1 (2.5)	0	0	0	0	1 (2.5)
Immune system disorders	0	0	1 (2.5)	0	0	1 (2.5)
Hypogammaglobulinaemia	0	1 (2.5)	0	0	0	1 (2.5)
Immune system disorder	0	0	1 (2.5)	0	0	1 (2.5)
Infections and infestations	5 (12.5)	9 (22.5)	4 (10.0)	0	1 (2.5)	19 (47.5)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & 200 mg Dose Group (N=40) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Infections and infestations (cont.)						
Herpes zoster	2 (5.0)	0	0	0	0	2 (5.0)
Urinary tract infection	1 (2.5)	1 (2.5)	0	0	0	2 (5.0)
Appendiceal abscess	0	0	1 (2.5)	0	0	1 (2.5)
Catheter site cellulitis	0	1 (2.5)	0	0	0	1 (2.5)
Cellulitis	0	1 (2.5)	0	0	0	1 (2.5)
Corona virus infection	0	0	1 (2.5)	0	0	1 (2.5)
Cystitis	0	1 (2.5)	0	0	0	1 (2.5)
Gastrointestinal fungal infection	0	1 (2.5)	0	0	0	1 (2.5)

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AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & 200 mg Dose Group (N=40) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Infections and infestations (cont.)						
Herpes simplex	1 (2.5)	0	0	0	0	1 (2.5)
Necrotising fasciitis	0	0	0	0	1 (2.5)	1 (2.5)
Oral candidiasis	0	1 (2.5)	0	0	0	1 (2.5)
Oral herpes	1 (2.5)	0	0	0	0	1 (2.5)
Oropharyngeal candidiasis	0	1 (2.5)	0	0	0	1 (2.5)
Otitis media	1 (2.5)	0	0	0	0	1 (2.5)
Paronychia	0	1 (2.5)	0	0	0	1 (2.5)
Pneumonia	0	1 (2.5)	0	0	0	1 (2.5)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & 200 mg Dose Group (N=40) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Infections and infestations (cont.)						
Respiratory tract infection	0	1 (2.5)	0	0	0	1 (2.5)
Sepsis	0	0	1 (2.5)	0	0	1 (2.5)
Sinusitis	1 (2.5)	0	0	0	0	1 (2.5)
Skin infection	0	0	1 (2.5)	0	0	1 (2.5)
Stoma site cellulitis	0	1 (2.5)	0	0	0	1 (2.5)
Upper respiratory tract infection	1 (2.5)	0	0	0	0	1 (2.5)
Wound infection	0	1 (2.5)	0	0	0	1 (2.5)
Injury, poisoning and procedural complications	5 (12.5)	1 (2.5)	1 (2.5)	1 (2.5)	0	8 (20.0)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & 200 mg Dose Group (N=40) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Injury, poisoning and procedural complications (cont.)						
Fall	2 (5.0)	0	0	0	0	2 (5.0)
Anaemia postoperative	0	0	1 (2.5)	0	0	1 (2.5)
Contusion	1 (2.5)	0	0	0	0	1 (2.5)
Joint injury	1 (2.5)	0	0	0	0	1 (2.5)
Post procedural haemorrhage	1 (2.5)	0	0	0	0	1 (2.5)
Procedural pain	1 (2.5)	0	0	0	0	1 (2.5)
Skin abrasion	1 (2.5)	0	0	0	0	1 (2.5)
Subdural haematoma	0	0	0	1 (2.5)	0	1 (2.5)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & 200 mg Dose Group (N=40) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Injury, poisoning and procedural complications (cont.)						
Tendon rupture	0	1 (2.5)	0	0	0	1 (2.5)
Traumatic haematoma	1 (2.5)	0	0	0	0	1 (2.5)
Investigations	7 (17.5)	2 (5.0)	9 (22.5)	1 (2.5)	0	19 (47.5)
Blood bilirubin increased	3 (7.5)	3 (7.5)	0	0	0	6 (15.0)
Platelet count decreased	0	2 (5.0)	4 (10.0)	0	0	6 (15.0)
Blood creatinine increased	3 (7.5)	1 (2.5)	0	0	0	4 (10.0)
Neutrophil count decreased	0	0	2 (5.0)	1 (2.5)	0	3 (7.5)
White blood cell count decreased	0	0	3 (7.5)	0	0	3 (7.5)

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AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & 200 mg Dose Group (N=40) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Investigations (cont.)						
Blood alkaline phosphatase increased	0	0	2 (5.0)	0	0	2 (5.0)
Blood uric acid increased	2 (5.0)	0	0	0	0	2 (5.0)
Gamma-glutamyltransferase increased	1 (2.5)	0	1 (2.5)	0	0	2 (5.0)
Urine uric acid increased	2 (5.0)	0	0	0	0	2 (5.0)
Weight increased	1 (2.5)	0	1 (2.5)	0	0	2 (5.0)
Alanine aminotransferase decreased	0	1 (2.5)	0	0	0	1 (2.5)
Alanine aminotransferase increased	0	1 (2.5)	0	0	0	1 (2.5)
Aspartate aminotransferase increased	1 (2.5)	0	0	0	0	1 (2.5)

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Investigations (cont.)						
Blood albumin decreased	1 (2.5)	0	0	0	0	1 (2.5)
Blood bilirubin unconjugated increased	0	0	1 (2.5)	0	0	1 (2.5)
Blood phosphorus decreased	0	1 (2.5)	0	0	0	1 (2.5)
Blood thyroid stimulating hormone increased	1 (2.5)	0	0	0	0	1 (2.5)
C-reactive protein increased	0	1 (2.5)	0	0	0	1 (2.5)
Cardiac murmur	1 (2.5)	0	0	0	0	1 (2.5)
Electrocardiogram QT prolonged	1 (2.5)	0	0	0	0	1 (2.5)
Haemoglobin decreased	0	1 (2.5)	0	0	0	1 (2.5)

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AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & 200 mg Dose Group (N=40) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Investigations (cont.)						
Lipase increased	0	1 (2.5)	0	0	0	1 (2.5)
Lymphocyte count decreased	0	1 (2.5)	0	0	0	1 (2.5)
Monocyte count increased	0	1 (2.5)	0	0	0	1 (2.5)
Prothrombin time shortened	1 (2.5)	0	0	0	0	1 (2.5)
Red blood cell count decreased	1 (2.5)	0	0	0	0	1 (2.5)
Reticulocyte count increased	1 (2.5)	0	0	0	0	1 (2.5)
White blood cell count increased	1 (2.5)	0	0	0	0	1 (2.5)
Metabolism and nutrition disorders	5 (12.5)	3 (7.5)	1 (2.5)	0	0	9 (22.5)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
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System Organ Class Preferred Term	BLU-285-2202 & 200 mg Dose Group (N=40) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Metabolism and nutrition disorders (cont.)						
Decreased appetite	2 (5.0)	0	0	0	0	2 (5.0)
Hypomagnesaemia	2 (5.0)	0	0	0	0	2 (5.0)
Hypophosphataemia	2 (5.0)	0	0	0	0	2 (5.0)
Cachexia	0	1 (2.5)	0	0	0	1 (2.5)
Gout	0	1 (2.5)	0	0	0	1 (2.5)
Hyperphosphataemia	0	1 (2.5)	0	0	0	1 (2.5)
Hyperuricaemia	1 (2.5)	0	0	0	0	1 (2.5)
Hypocalcaemia	0	1 (2.5)	0	0	0	1 (2.5)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & 200 mg Dose Group (N=40) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Metabolism and nutrition disorders (cont.)						
Tumour lysis syndrome	0	0	1 (2.5)	0	0	1 (2.5)
Musculoskeletal and connective tissue disorders	6 (15.0)	4 (10.0)	0	0	0	10 (25.0)
Arthralgia	1 (2.5)	1 (2.5)	0	0	0	2 (5.0)
Back pain	2 (5.0)	0	0	0	0	2 (5.0)
Myalgia	2 (5.0)	0	0	0	0	2 (5.0)
Muscular weakness	1 (2.5)	0	0	0	0	1 (2.5)
Musculoskeletal pain	1 (2.5)	0	0	0	0	1 (2.5)
Neck pain	1 (2.5)	0	0	0	0	1 (2.5)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & 200 mg Dose Group (N=40) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Musculoskeletal and connective tissue disorders (cont.)						
Osteonecrosis of jaw	0	1 (2.5)	0	0	0	1 (2.5)
Osteoporosis	0	1 (2.5)	0	0	0	1 (2.5)
Pain in extremity	1 (2.5)	0	0	0	0	1 (2.5)
Pain in jaw	1 (2.5)	0	0	0	0	1 (2.5)
Spinal column stenosis	0	1 (2.5)	0	0	0	1 (2.5)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	1 (2.5)	3 (7.5)	0	0	4 (10.0)
Acute myeloid leukaemia	0	0	1 (2.5)	0	0	1 (2.5)
Basal cell carcinoma	0	0	1 (2.5)	0	0	1 (2.5)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & 200 mg Dose Group (N=40) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont.)						
Benign gastrointestinal neoplasm	0	0	1 (2.5)	0	0	1 (2.5)
Malignant melanoma	0	0	1 (2.5)	0	0	1 (2.5)
Salivary gland neoplasm	1 (2.5)	0	0	0	0	1 (2.5)
Squamous cell carcinoma of skin	0	1 (2.5)	0	0	0	1 (2.5)
Nervous system disorders	11 (27.5)	5 (12.5)	0	0	0	16 (40.0)
Dysgeusia	5 (12.5)	1 (2.5)	0	0	0	6 (15.0)
Headache	4 (10.0)	1 (2.5)	0	0	0	5 (12.5)
Dizziness	3 (7.5)	1 (2.5)	0	0	0	4 (10.0)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & 200 mg Dose Group (N=40) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Nervous system disorders (cont.)						
Cognitive disorder	1 (2.5)	1 (2.5)	0	0	0	2 (5.0)
Memory impairment	2 (5.0)	0	0	0	0	2 (5.0)
Restless legs syndrome	1 (2.5)	1 (2.5)	0	0	0	2 (5.0)
Aphasia	1 (2.5)	0	0	0	0	1 (2.5)
Balance disorder	1 (2.5)	0	0	0	0	1 (2.5)
Dizziness postural	1 (2.5)	0	0	0	0	1 (2.5)
Hypogeusia	1 (2.5)	0	0	0	0	1 (2.5)
Parkinson's disease	1 (2.5)	0	0	0	0	1 (2.5)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & 200 mg Dose Group (N=40) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Nervous system disorders (cont.)						
Sensory disturbance	1 (2.5)	0	0	0	0	1 (2.5)
Tremor	1 (2.5)	0	0	0	0	1 (2.5)
Psychiatric disorders	5 (12.5)	3 (7.5)	1 (2.5)	0	0	9 (22.5)
Insomnia	1 (2.5)	1 (2.5)	0	0	0	2 (5.0)
Sleep disorder	2 (5.0)	0	0	0	0	2 (5.0)
Adjustment disorder with depressed mood	0	1 (2.5)	0	0	0	1 (2.5)
Confusional state	1 (2.5)	0	0	0	0	1 (2.5)
Delirium	0	0	1 (2.5)	0	0	1 (2.5)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & 200 mg Dose Group (N=40) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Psychiatric disorders (cont.)						
Depressed mood	1 (2.5)	0	0	0	0	1 (2.5)
Depression	0	1 (2.5)	0	0	0	1 (2.5)
Disorientation	1 (2.5)	0	0	0	0	1 (2.5)
Mental disorder	1 (2.5)	0	0	0	0	1 (2.5)
Renal and urinary disorders	3 (7.5)	0	1 (2.5)	0	0	4 (10.0)
Nephrolithiasis	1 (2.5)	0	1 (2.5)	0	0	2 (5.0)
Acute kidney injury	1 (2.5)	0	0	0	0	1 (2.5)
Haematuria	1 (2.5)	0	0	0	0	1 (2.5)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & 200 mg Dose Group (N=40) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Renal and urinary disorders (cont.)						
Obstructive uropathy	0	0	1 (2.5)	0	0	1 (2.5)
Reproductive system and breast disorders	0	2 (5.0)	0	0	0	2 (5.0)
Oedema genital	0	1 (2.5)	0	0	0	1 (2.5)
Scrotal oedema	0	1 (2.5)	0	0	0	1 (2.5)
Respiratory, thoracic and mediastinal disorders	7 (17.5)	2 (5.0)	2 (5.0)	0	0	11 (27.5)
Epistaxis	4 (10.0)	0	0	0	0	4 (10.0)
Dyspnoea	2 (5.0)	0	0	0	0	2 (5.0)
Pleural effusion	1 (2.5)	0	1 (2.5)	0	0	2 (5.0)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & 200 mg Dose Group (N=40) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Respiratory, thoracic and mediastinal disorders (cont.)						
Bronchial haemorrhage	0	0	1 (2.5)	0	0	1 (2.5)
Cough	0	1 (2.5)	0	0	0	1 (2.5)
Dyspnoea exertional	1 (2.5)	0	0	0	0	1 (2.5)
Haemoptysis	1 (2.5)	0	0	0	0	1 (2.5)
Haemothorax	0	0	1 (2.5)	0	0	1 (2.5)
Nasal congestion	0	1 (2.5)	0	0	0	1 (2.5)
Oropharyngeal pain	1 (2.5)	0	0	0	0	1 (2.5)
Pulmonary oedema	0	1 (2.5)	0	0	0	1 (2.5)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & 200 mg Dose Group (N=40) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Respiratory, thoracic and mediastinal disorders (cont.)						
Rales	1 (2.5)	0	0	0	0	1 (2.5)
Respiratory symptom	1 (2.5)	0	0	0	0	1 (2.5)
Throat irritation	1 (2.5)	0	0	0	0	1 (2.5)
Skin and subcutaneous tissue disorders	7 (17.5)	5 (12.5)	0	0	0	12 (30.0)
Alopecia	3 (7.5)	0	0	0	0	3 (7.5)
Hair colour changes	3 (7.5)	0	0	0	0	3 (7.5)
Pruritus	2 (5.0)	1 (2.5)	0	0	0	3 (7.5)
Petechiae	2 (5.0)	0	0	0	0	2 (5.0)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & 200 mg Dose Group (N=40) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Skin and subcutaneous tissue disorders (cont.)						
Dermatitis contact	1 (2.5)	0	0	0	0	1 (2.5)
Hyperhidrosis	1 (2.5)	0	0	0	0	1 (2.5)
Night sweats	0	1 (2.5)	0	0	0	1 (2.5)
Psoriasis	0	1 (2.5)	0	0	0	1 (2.5)
Rash	1 (2.5)	0	0	0	0	1 (2.5)
Seborrhoeic dermatitis	1 (2.5)	0	0	0	0	1 (2.5)
Skin haemorrhage	0	1 (2.5)	0	0	0	1 (2.5)
Skin ulcer	0	1 (2.5)	0	0	0	1 (2.5)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & 200 mg Dose Group (N=40) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Skin and subcutaneous tissue disorders (cont.)						
Swelling face	1 (2.5)	0	0	0	0	1 (2.5)
Vascular disorders	4 (10.0)	1 (2.5)	2 (5.0)	0	1 (2.5)	8 (20.0)
Flushing	2 (5.0)	0	0	0	0	2 (5.0)
Hypertension	1 (2.5)	1 (2.5)	0	0	0	2 (5.0)
Haematoma	0	1 (2.5)	0	0	0	1 (2.5)
Haemorrhage	0	0	1 (2.5)	0	0	1 (2.5)
Hot flush	1 (2.5)	0	0	0	0	1 (2.5)
Hypotension	0	0	1 (2.5)	0	0	1 (2.5)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & 200 mg Dose Group (N=40) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Vascular disorders (cont.)						
Shock haemorrhagic	0	0	0	0	1 (2.5)	1 (2.5)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & <=200 mg Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Patients with at least one Event	6 (14.3)	8 (19.0)	21 (50.0)	4 (9.5)	3 (7.1)	42 (100.0)
Blood and lymphatic system disorders	2 (4.8)	7 (16.7)	15 (35.7)	2 (4.8)	0	26 (61.9)
Thrombocytopenia	3 (7.1)	6 (14.3)	3 (7.1)	1 (2.4)	0	13 (31.0)
Anaemia	0	2 (4.8)	9 (21.4)	0	0	11 (26.2)
Neutropenia	0	0	4 (9.5)	1 (2.4)	0	5 (11.9)
Leukocytosis	0	0	2 (4.8)	0	0	2 (4.8)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & <=200 mg Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Blood and lymphatic system disorders (cont.)						
Coagulopathy	1 (2.4)	0	0	0	0	1 (2.4)
Haemolysis	1 (2.4)	0	0	0	0	1 (2.4)
Haemorrhagic diathesis	0	1 (2.4)	0	0	0	1 (2.4)
Mast cell activation syndrome	0	1 (2.4)	0	0	0	1 (2.4)
Cardiac disorders	4 (9.5)	0	3 (7.1)	0	0	7 (16.7)
Cardiac failure	0	0	2 (4.8)	0	0	2 (4.8)
Atrial flutter	0	0	1 (2.4)	0	0	1 (2.4)
Bradycardia	1 (2.4)	0	0	0	0	1 (2.4)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & <=200 mg Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Cardiac disorders (cont.)						
Palpitations	1 (2.4)	0	0	0	0	1 (2.4)
Pericardial effusion	1 (2.4)	0	0	0	0	1 (2.4)
Supraventricular extrasystoles	1 (2.4)	0	0	0	0	1 (2.4)
Ventricular extrasystoles	1 (2.4)	0	0	0	0	1 (2.4)
Ear and labyrinth disorders	1 (2.4)	0	0	0	0	1 (2.4)
Vertigo	1 (2.4)	0	0	0	0	1 (2.4)
Eye disorders	15 (35.7)	5 (11.9)	1 (2.4)	1 (2.4)	0	22 (52.4)
Periorbital oedema	5 (11.9)	3 (7.1)	1 (2.4)	0	0	9 (21.4)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & <=200 mg Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Eye disorders (cont.)						
Eyelid oedema	7 (16.7)	0	0	0	0	7 (16.7)
Lacrimation increased	4 (9.5)	0	0	0	0	4 (9.5)
Cataract	0	1 (2.4)	0	0	0	1 (2.4)
Conjunctival haemorrhage	0	1 (2.4)	0	0	0	1 (2.4)
Eye haemorrhage	1 (2.4)	0	0	0	0	1 (2.4)
Eye swelling	1 (2.4)	0	0	0	0	1 (2.4)
Vision blurred	1 (2.4)	0	0	0	0	1 (2.4)
Visual acuity reduced	1 (2.4)	0	0	0	0	1 (2.4)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & <=200 mg Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Eye disorders (cont.)						
Vitreous floaters	1 (2.4)	0	0	0	0	1 (2.4)
Vitreous haemorrhage	0	0	0	1 (2.4)	0	1 (2.4)
Gastrointestinal disorders	17 (40.5)	7 (16.7)	6 (14.3)	0	0	30 (71.4)
Diarrhoea	8 (19.0)	1 (2.4)	1 (2.4)	0	0	10 (23.8)
Vomiting	6 (14.3)	2 (4.8)	1 (2.4)	0	0	9 (21.4)
Nausea	7 (16.7)	0	1 (2.4)	0	0	8 (19.0)
Constipation	5 (11.9)	0	0	0	0	5 (11.9)
Abdominal pain	3 (7.1)	0	1 (2.4)	0	0	4 (9.5)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & <=200 mg Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Gastrointestinal disorders (cont.)						
Dyspepsia	1 (2.4)	1 (2.4)	0	0	0	2 (4.8)
Gastrooesophageal reflux disease	0	2 (4.8)	0	0	0	2 (4.8)
Melaena	0	1 (2.4)	1 (2.4)	0	0	2 (4.8)
Salivary hypersecretion	2 (4.8)	0	0	0	0	2 (4.8)
Abdominal distension	1 (2.4)	0	0	0	0	1 (2.4)
Abdominal pain upper	1 (2.4)	0	0	0	0	1 (2.4)
Ascites	0	1 (2.4)	0	0	0	1 (2.4)
Dental caries	1 (2.4)	0	0	0	0	1 (2.4)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & <=200 mg Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Gastrointestinal disorders (cont.)						
Duodenal ulcer haemorrhage	0	0	1 (2.4)	0	0	1 (2.4)
Faeces discoloured	1 (2.4)	0	0	0	0	1 (2.4)
Gastrointestinal haemorrhage	0	0	1 (2.4)	0	0	1 (2.4)
Gingival bleeding	1 (2.4)	0	0	0	0	1 (2.4)
Intra-abdominal haematoma	0	1 (2.4)	0	0	0	1 (2.4)
Intra-abdominal haemorrhage	0	0	1 (2.4)	0	0	1 (2.4)
Lip dry	1 (2.4)	0	0	0	0	1 (2.4)
Lower gastrointestinal haemorrhage	0	0	1 (2.4)	0	0	1 (2.4)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & <=200 mg Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Gastrointestinal disorders (cont.)						
Portal hypertensive gastropathy	1 (2.4)	0	0	0	0	1 (2.4)
Tooth deposit	1 (2.4)	0	0	0	0	1 (2.4)
Toothache	1 (2.4)	0	0	0	0	1 (2.4)
General disorders and administration site conditions	17 (40.5)	8 (19.0)	1 (2.4)	0	1 (2.4)	27 (64.3)
Oedema peripheral	16 (38.1)	4 (9.5)	0	0	0	20 (47.6)
Face oedema	6 (14.3)	1 (2.4)	0	0	0	7 (16.7)
Asthenia	2 (4.8)	2 (4.8)	0	0	0	4 (9.5)
Fatigue	1 (2.4)	1 (2.4)	1 (2.4)	0	0	3 (7.1)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & <=200 mg Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
General disorders and administration site conditions (cont.)						
Pain	3 (7.1)	0	0	0	0	3 (7.1)
Pyrexia	2 (4.8)	1 (2.4)	0	0	0	3 (7.1)
Non-cardiac chest pain	2 (4.8)	0	0	0	0	2 (4.8)
Disease progression	0	0	0	0	1 (2.4)	1 (2.4)
Generalised oedema	0	1 (2.4)	0	0	0	1 (2.4)
Oedema	1 (2.4)	0	0	0	0	1 (2.4)
Peripheral swelling	1 (2.4)	0	0	0	0	1 (2.4)
Systemic inflammatory response syndrome	0	1 (2.4)	0	0	0	1 (2.4)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & <=200 mg Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Hepatobiliary disorders	1 (2.4)	0	0	0	0	1 (2.4)
Hyperbilirubinaemia	1 (2.4)	0	0	0	0	1 (2.4)
Immune system disorders	0	0	1 (2.4)	0	0	1 (2.4)
Hypogammaglobulinaemia	0	1 (2.4)	0	0	0	1 (2.4)
Immune system disorder	0	0	1 (2.4)	0	0	1 (2.4)
Infections and infestations	5 (11.9)	9 (21.4)	5 (11.9)	0	1 (2.4)	20 (47.6)
Herpes zoster	2 (4.8)	0	1 (2.4)	0	0	3 (7.1)
Urinary tract infection	1 (2.4)	1 (2.4)	0	0	0	2 (4.8)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & <=200 mg Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Infections and infestations (cont.)						
Appendiceal abscess	0	0	1 (2.4)	0	0	1 (2.4)
Catheter site cellulitis	0	1 (2.4)	0	0	0	1 (2.4)
Cellulitis	0	1 (2.4)	0	0	0	1 (2.4)
Clostridium difficile colitis	1 (2.4)	0	0	0	0	1 (2.4)
Corona virus infection	0	0	1 (2.4)	0	0	1 (2.4)
Cystitis	0	1 (2.4)	0	0	0	1 (2.4)
Gastrointestinal fungal infection	0	1 (2.4)	0	0	0	1 (2.4)
Herpes simplex	1 (2.4)	0	0	0	0	1 (2.4)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & <=200 mg Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Infections and infestations (cont.)						
Necrotising fasciitis	0	0	0	0	1 (2.4)	1 (2.4)
Oral candidiasis	0	1 (2.4)	0	0	0	1 (2.4)
Oral herpes	1 (2.4)	0	0	0	0	1 (2.4)
Oropharyngeal candidiasis	0	1 (2.4)	0	0	0	1 (2.4)
Otitis media	1 (2.4)	0	0	0	0	1 (2.4)
Paronychia	0	1 (2.4)	0	0	0	1 (2.4)
Pneumonia	0	1 (2.4)	0	0	0	1 (2.4)
Respiratory tract infection	0	1 (2.4)	0	0	0	1 (2.4)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & <=200 mg Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Infections and infestations (cont.)						
Sepsis	0	0	1 (2.4)	0	0	1 (2.4)
Sinusitis	1 (2.4)	0	0	0	0	1 (2.4)
Skin infection	0	0	1 (2.4)	0	0	1 (2.4)
Stoma site cellulitis	0	1 (2.4)	0	0	0	1 (2.4)
Upper respiratory tract infection	1 (2.4)	0	0	0	0	1 (2.4)
Wound infection	0	1 (2.4)	0	0	0	1 (2.4)
Injury, poisoning and procedural complications	5 (11.9)	1 (2.4)	1 (2.4)	1 (2.4)	0	8 (19.0)
Fall	2 (4.8)	0	0	0	0	2 (4.8)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & <=200 mg Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Injury, poisoning and procedural complications (cont.)						
Anaemia postoperative	0	0	1 (2.4)	0	0	1 (2.4)
Contusion	1 (2.4)	0	0	0	0	1 (2.4)
Joint injury	1 (2.4)	0	0	0	0	1 (2.4)
Post procedural haemorrhage	1 (2.4)	0	0	0	0	1 (2.4)
Procedural pain	1 (2.4)	0	0	0	0	1 (2.4)
Skin abrasion	1 (2.4)	0	0	0	0	1 (2.4)
Subdural haematoma	0	0	0	1 (2.4)	0	1 (2.4)
Tendon rupture	0	1 (2.4)	0	0	0	1 (2.4)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & <=200 mg Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Injury, poisoning and procedural complications (cont.)						
Traumatic haematoma	1 (2.4)	0	0	0	0	1 (2.4)
Investigations	7 (16.7)	2 (4.8)	9 (21.4)	1 (2.4)	0	19 (45.2)
Blood bilirubin increased	3 (7.1)	3 (7.1)	0	0	0	6 (14.3)
Platelet count decreased	0	2 (4.8)	4 (9.5)	0	0	6 (14.3)
Blood creatinine increased	3 (7.1)	1 (2.4)	0	0	0	4 (9.5)
Neutrophil count decreased	0	0	2 (4.8)	1 (2.4)	0	3 (7.1)
White blood cell count decreased	0	0	3 (7.1)	0	0	3 (7.1)
Blood alkaline phosphatase increased	0	0	2 (4.8)	0	0	2 (4.8)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & <=200 mg Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Investigations (cont.)						
Blood uric acid increased	2 (4.8)	0	0	0	0	2 (4.8)
Gamma-glutamyltransferase increased	1 (2.4)	0	1 (2.4)	0	0	2 (4.8)
Urine uric acid increased	2 (4.8)	0	0	0	0	2 (4.8)
Weight increased	1 (2.4)	0	1 (2.4)	0	0	2 (4.8)
Alanine aminotransferase decreased	0	1 (2.4)	0	0	0	1 (2.4)
Alanine aminotransferase increased	0	1 (2.4)	0	0	0	1 (2.4)
Aspartate aminotransferase increased	1 (2.4)	0	0	0	0	1 (2.4)
Blood albumin decreased	1 (2.4)	0	0	0	0	1 (2.4)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & <=200 mg Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Investigations (cont.)						
Blood bilirubin unconjugated increased	0	0	1 (2.4)	0	0	1 (2.4)
Blood phosphorus decreased	0	1 (2.4)	0	0	0	1 (2.4)
Blood thyroid stimulating hormone increased	1 (2.4)	0	0	0	0	1 (2.4)
C-reactive protein increased	0	1 (2.4)	0	0	0	1 (2.4)
Cardiac murmur	1 (2.4)	0	0	0	0	1 (2.4)
Electrocardiogram QT prolonged	1 (2.4)	0	0	0	0	1 (2.4)
Haemoglobin decreased	0	1 (2.4)	0	0	0	1 (2.4)
Lipase increased	0	1 (2.4)	0	0	0	1 (2.4)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & <=200 mg Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Investigations (cont.)						
Lymphocyte count decreased	0	1 (2.4)	0	0	0	1 (2.4)
Monocyte count increased	0	1 (2.4)	0	0	0	1 (2.4)
Prothrombin time shortened	1 (2.4)	0	0	0	0	1 (2.4)
Red blood cell count decreased	1 (2.4)	0	0	0	0	1 (2.4)
Reticulocyte count increased	1 (2.4)	0	0	0	0	1 (2.4)
White blood cell count increased	1 (2.4)	0	0	0	0	1 (2.4)
Metabolism and nutrition disorders	6 (14.3)	3 (7.1)	1 (2.4)	0	0	10 (23.8)
Decreased appetite	2 (4.8)	0	0	0	0	2 (4.8)

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Note 1: In each treatment group, if a patient experiences more than 1 event within a given System Organ Class or Preferred term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & <=200 mg Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Metabolism and nutrition disorders (cont.)						
Hypomagnesaemia	2 (4.8)	0	0	0	0	2 (4.8)
Hypophosphataemia	2 (4.8)	0	0	0	0	2 (4.8)
Cachexia	0	1 (2.4)	0	0	0	1 (2.4)
Gout	0	1 (2.4)	0	0	0	1 (2.4)
Hyperphosphataemia	0	1 (2.4)	0	0	0	1 (2.4)
Hyperuricaemia	1 (2.4)	0	0	0	0	1 (2.4)
Hypocalcaemia	0	1 (2.4)	0	0	0	1 (2.4)
Hypokalaemia	1 (2.4)	0	0	0	0	1 (2.4)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & <=200 mg Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Metabolism and nutrition disorders (cont.)						
Tumour lysis syndrome	0	0	1 (2.4)	0	0	1 (2.4)
Musculoskeletal and connective tissue disorders	7 (16.7)	4 (9.5)	0	0	0	11 (26.2)
Arthralgia	1 (2.4)	1 (2.4)	0	0	0	2 (4.8)
Back pain	2 (4.8)	0	0	0	0	2 (4.8)
Myalgia	2 (4.8)	0	0	0	0	2 (4.8)
Pain in extremity	2 (4.8)	0	0	0	0	2 (4.8)
Muscular weakness	1 (2.4)	0	0	0	0	1 (2.4)
Musculoskeletal pain	1 (2.4)	0	0	0	0	1 (2.4)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & <=200 mg Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Musculoskeletal and connective tissue disorders (cont.)						
Neck pain	1 (2.4)	0	0	0	0	1 (2.4)
Osteonecrosis of jaw	0	1 (2.4)	0	0	0	1 (2.4)
Osteoporosis	0	1 (2.4)	0	0	0	1 (2.4)
Pain in jaw	1 (2.4)	0	0	0	0	1 (2.4)
Spinal column stenosis	0	1 (2.4)	0	0	0	1 (2.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	1 (2.4)	3 (7.1)	0	0	4 (9.5)
Acute myeloid leukaemia	0	0	1 (2.4)	0	0	1 (2.4)
Basal cell carcinoma	0	0	1 (2.4)	0	0	1 (2.4)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & <=200 mg Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont.)						
Benign gastrointestinal neoplasm	0	0	1 (2.4)	0	0	1 (2.4)
Malignant melanoma	0	0	1 (2.4)	0	0	1 (2.4)
Salivary gland neoplasm	1 (2.4)	0	0	0	0	1 (2.4)
Squamous cell carcinoma of skin	0	1 (2.4)	0	0	0	1 (2.4)
Nervous system disorders	11 (26.2)	5 (11.9)	0	0	0	16 (38.1)
Dysgeusia	5 (11.9)	1 (2.4)	0	0	0	6 (14.3)
Headache	4 (9.5)	1 (2.4)	0	0	0	5 (11.9)
Dizziness	3 (7.1)	1 (2.4)	0	0	0	4 (9.5)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & <=200 mg Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Nervous system disorders (cont.)						
Cognitive disorder	1 (2.4)	1 (2.4)	0	0	0	2 (4.8)
Memory impairment	2 (4.8)	0	0	0	0	2 (4.8)
Restless legs syndrome	1 (2.4)	1 (2.4)	0	0	0	2 (4.8)
Aphasia	1 (2.4)	0	0	0	0	1 (2.4)
Balance disorder	1 (2.4)	0	0	0	0	1 (2.4)
Dizziness postural	1 (2.4)	0	0	0	0	1 (2.4)
Hypogeusia	1 (2.4)	0	0	0	0	1 (2.4)
Parkinson's disease	1 (2.4)	0	0	0	0	1 (2.4)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & <=200 mg Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Nervous system disorders (cont.)						
Sensory disturbance	1 (2.4)	0	0	0	0	1 (2.4)
Tremor	1 (2.4)	0	0	0	0	1 (2.4)
Psychiatric disorders	5 (11.9)	3 (7.1)	1 (2.4)	0	0	9 (21.4)
Insomnia	1 (2.4)	1 (2.4)	0	0	0	2 (4.8)
Sleep disorder	2 (4.8)	0	0	0	0	2 (4.8)
Adjustment disorder with depressed mood	0	1 (2.4)	0	0	0	1 (2.4)
Confusional state	1 (2.4)	0	0	0	0	1 (2.4)
Delirium	0	0	1 (2.4)	0	0	1 (2.4)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & <=200 mg Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Psychiatric disorders (cont.)						
Depressed mood	1 (2.4)	0	0	0	0	1 (2.4)
Depression	0	1 (2.4)	0	0	0	1 (2.4)
Disorientation	1 (2.4)	0	0	0	0	1 (2.4)
Mental disorder	1 (2.4)	0	0	0	0	1 (2.4)
Renal and urinary disorders	3 (7.1)	0	1 (2.4)	0	0	4 (9.5)
Nephrolithiasis	1 (2.4)	0	1 (2.4)	0	0	2 (4.8)
Acute kidney injury	1 (2.4)	0	0	0	0	1 (2.4)
Haematuria	1 (2.4)	0	0	0	0	1 (2.4)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & <=200 mg Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Renal and urinary disorders (cont.)						
Obstructive uropathy	0	0	1 (2.4)	0	0	1 (2.4)
Reproductive system and breast disorders	0	2 (4.8)	0	0	0	2 (4.8)
Oedema genital	0	1 (2.4)	0	0	0	1 (2.4)
Scrotal oedema	0	1 (2.4)	0	0	0	1 (2.4)
Respiratory, thoracic and mediastinal disorders	7 (16.7)	2 (4.8)	2 (4.8)	0	0	11 (26.2)
Epistaxis	4 (9.5)	0	0	0	0	4 (9.5)
Dyspnoea	2 (4.8)	0	0	0	0	2 (4.8)
Pleural effusion	1 (2.4)	0	1 (2.4)	0	0	2 (4.8)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & <=200 mg Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Respiratory, thoracic and mediastinal disorders (cont.)						
Bronchial haemorrhage	0	0	1 (2.4)	0	0	1 (2.4)
Cough	0	1 (2.4)	0	0	0	1 (2.4)
Dyspnoea exertional	1 (2.4)	0	0	0	0	1 (2.4)
Haemoptysis	1 (2.4)	0	0	0	0	1 (2.4)
Haemothorax	0	0	1 (2.4)	0	0	1 (2.4)
Nasal congestion	0	1 (2.4)	0	0	0	1 (2.4)
Oropharyngeal pain	1 (2.4)	0	0	0	0	1 (2.4)
Pulmonary oedema	0	1 (2.4)	0	0	0	1 (2.4)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & <=200 mg Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Respiratory, thoracic and mediastinal disorders (cont.)						
Rales	1 (2.4)	0	0	0	0	1 (2.4)
Respiratory symptom	1 (2.4)	0	0	0	0	1 (2.4)
Throat irritation	1 (2.4)	0	0	0	0	1 (2.4)
Skin and subcutaneous tissue disorders	7 (16.7)	5 (11.9)	0	0	0	12 (28.6)
Alopecia	3 (7.1)	0	0	0	0	3 (7.1)
Hair colour changes	3 (7.1)	0	0	0	0	3 (7.1)
Pruritus	2 (4.8)	1 (2.4)	0	0	0	3 (7.1)
Petechiae	2 (4.8)	0	0	0	0	2 (4.8)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & <=200 mg Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Skin and subcutaneous tissue disorders (cont.)						
Dermatitis contact	1 (2.4)	0	0	0	0	1 (2.4)
Hyperhidrosis	1 (2.4)	0	0	0	0	1 (2.4)
Night sweats	0	1 (2.4)	0	0	0	1 (2.4)
Psoriasis	0	1 (2.4)	0	0	0	1 (2.4)
Rash	1 (2.4)	0	0	0	0	1 (2.4)
Seborrhoeic dermatitis	1 (2.4)	0	0	0	0	1 (2.4)
Skin haemorrhage	0	1 (2.4)	0	0	0	1 (2.4)
Skin ulcer	0	1 (2.4)	0	0	0	1 (2.4)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & <=200 mg Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Skin and subcutaneous tissue disorders (cont.)						
Swelling face	1 (2.4)	0	0	0	0	1 (2.4)
Vascular disorders	4 (9.5)	1 (2.4)	2 (4.8)	0	1 (2.4)	8 (19.0)
Flushing	2 (4.8)	0	0	0	0	2 (4.8)
Hypertension	1 (2.4)	1 (2.4)	0	0	0	2 (4.8)
Haematoma	0	1 (2.4)	0	0	0	1 (2.4)
Haemorrhage	0	0	1 (2.4)	0	0	1 (2.4)
Hot flush	1 (2.4)	0	0	0	0	1 (2.4)
Hypotension	0	0	1 (2.4)	0	0	1 (2.4)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & <=200 mg Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Vascular disorders (cont.)						
Shock haemorrhagic	0	0	0	0	1 (2.4)	1 (2.4)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & All Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Patients with at least one Event	6 (14.3)	8 (19.0)	21 (50.0)	4 (9.5)	3 (7.1)	42 (100.0)
Blood and lymphatic system disorders	2 (4.8)	7 (16.7)	15 (35.7)	2 (4.8)	0	26 (61.9)
Thrombocytopenia	3 (7.1)	6 (14.3)	3 (7.1)	1 (2.4)	0	13 (31.0)
Anaemia	0	2 (4.8)	9 (21.4)	0	0	11 (26.2)
Neutropenia	0	0	4 (9.5)	1 (2.4)	0	5 (11.9)
Leukocytosis	0	0	2 (4.8)	0	0	2 (4.8)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & All Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Blood and lymphatic system disorders (cont.)						
Coagulopathy	1 (2.4)	0	0	0	0	1 (2.4)
Haemolysis	1 (2.4)	0	0	0	0	1 (2.4)
Haemorrhagic diathesis	0	1 (2.4)	0	0	0	1 (2.4)
Mast cell activation syndrome	0	1 (2.4)	0	0	0	1 (2.4)
Cardiac disorders	4 (9.5)	0	3 (7.1)	0	0	7 (16.7)
Cardiac failure	0	0	2 (4.8)	0	0	2 (4.8)
Atrial flutter	0	0	1 (2.4)	0	0	1 (2.4)
Bradycardia	1 (2.4)	0	0	0	0	1 (2.4)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & All Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Cardiac disorders (cont.)						
Palpitations	1 (2.4)	0	0	0	0	1 (2.4)
Pericardial effusion	1 (2.4)	0	0	0	0	1 (2.4)
Supraventricular extrasystoles	1 (2.4)	0	0	0	0	1 (2.4)
Ventricular extrasystoles	1 (2.4)	0	0	0	0	1 (2.4)
Ear and labyrinth disorders	1 (2.4)	0	0	0	0	1 (2.4)
Vertigo	1 (2.4)	0	0	0	0	1 (2.4)
Eye disorders	15 (35.7)	5 (11.9)	1 (2.4)	1 (2.4)	0	22 (52.4)
Periorbital oedema	5 (11.9)	3 (7.1)	1 (2.4)	0	0	9 (21.4)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & All Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Eye disorders (cont.)						
Eyelid oedema	7 (16.7)	0	0	0	0	7 (16.7)
Lacrimation increased	4 (9.5)	0	0	0	0	4 (9.5)
Cataract	0	1 (2.4)	0	0	0	1 (2.4)
Conjunctival haemorrhage	0	1 (2.4)	0	0	0	1 (2.4)
Eye haemorrhage	1 (2.4)	0	0	0	0	1 (2.4)
Eye swelling	1 (2.4)	0	0	0	0	1 (2.4)
Vision blurred	1 (2.4)	0	0	0	0	1 (2.4)
Visual acuity reduced	1 (2.4)	0	0	0	0	1 (2.4)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & All Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Eye disorders (cont.)						
Vitreous floaters	1 (2.4)	0	0	0	0	1 (2.4)
Vitreous haemorrhage	0	0	0	1 (2.4)	0	1 (2.4)
Gastrointestinal disorders	17 (40.5)	7 (16.7)	6 (14.3)	0	0	30 (71.4)
Diarrhoea	8 (19.0)	1 (2.4)	1 (2.4)	0	0	10 (23.8)
Vomiting	6 (14.3)	2 (4.8)	1 (2.4)	0	0	9 (21.4)
Nausea	7 (16.7)	0	1 (2.4)	0	0	8 (19.0)
Constipation	5 (11.9)	0	0	0	0	5 (11.9)
Abdominal pain	3 (7.1)	0	1 (2.4)	0	0	4 (9.5)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & All Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Gastrointestinal disorders (cont.)						
Dyspepsia	1 (2.4)	1 (2.4)	0	0	0	2 (4.8)
Gastrooesophageal reflux disease	0	2 (4.8)	0	0	0	2 (4.8)
Melaena	0	1 (2.4)	1 (2.4)	0	0	2 (4.8)
Salivary hypersecretion	2 (4.8)	0	0	0	0	2 (4.8)
Abdominal distension	1 (2.4)	0	0	0	0	1 (2.4)
Abdominal pain upper	1 (2.4)	0	0	0	0	1 (2.4)
Ascites	0	1 (2.4)	0	0	0	1 (2.4)
Dental caries	1 (2.4)	0	0	0	0	1 (2.4)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & All Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Gastrointestinal disorders (cont.)						
Duodenal ulcer haemorrhage	0	0	1 (2.4)	0	0	1 (2.4)
Faeces discoloured	1 (2.4)	0	0	0	0	1 (2.4)
Gastrointestinal haemorrhage	0	0	1 (2.4)	0	0	1 (2.4)
Gingival bleeding	1 (2.4)	0	0	0	0	1 (2.4)
Intra-abdominal haematoma	0	1 (2.4)	0	0	0	1 (2.4)
Intra-abdominal haemorrhage	0	0	1 (2.4)	0	0	1 (2.4)
Lip dry	1 (2.4)	0	0	0	0	1 (2.4)
Lower gastrointestinal haemorrhage	0	0	1 (2.4)	0	0	1 (2.4)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & All Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Gastrointestinal disorders (cont.)						
Portal hypertensive gastropathy	1 (2.4)	0	0	0	0	1 (2.4)
Tooth deposit	1 (2.4)	0	0	0	0	1 (2.4)
Toothache	1 (2.4)	0	0	0	0	1 (2.4)
General disorders and administration site conditions	17 (40.5)	8 (19.0)	1 (2.4)	0	1 (2.4)	27 (64.3)
Oedema peripheral	16 (38.1)	4 (9.5)	0	0	0	20 (47.6)
Face oedema	6 (14.3)	1 (2.4)	0	0	0	7 (16.7)
Asthenia	2 (4.8)	2 (4.8)	0	0	0	4 (9.5)
Fatigue	1 (2.4)	1 (2.4)	1 (2.4)	0	0	3 (7.1)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & All Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
General disorders and administration site conditions (cont.)						
Pain	3 (7.1)	0	0	0	0	3 (7.1)
Pyrexia	2 (4.8)	1 (2.4)	0	0	0	3 (7.1)
Non-cardiac chest pain	2 (4.8)	0	0	0	0	2 (4.8)
Disease progression	0	0	0	0	1 (2.4)	1 (2.4)
Generalised oedema	0	1 (2.4)	0	0	0	1 (2.4)
Oedema	1 (2.4)	0	0	0	0	1 (2.4)
Peripheral swelling	1 (2.4)	0	0	0	0	1 (2.4)
Systemic inflammatory response syndrome	0	1 (2.4)	0	0	0	1 (2.4)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & All Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Hepatobiliary disorders	1 (2.4)	0	0	0	0	1 (2.4)
Hyperbilirubinaemia	1 (2.4)	0	0	0	0	1 (2.4)
Immune system disorders	0	0	1 (2.4)	0	0	1 (2.4)
Hypogammaglobulinaemia	0	1 (2.4)	0	0	0	1 (2.4)
Immune system disorder	0	0	1 (2.4)	0	0	1 (2.4)
Infections and infestations	5 (11.9)	9 (21.4)	5 (11.9)	0	1 (2.4)	20 (47.6)
Herpes zoster	2 (4.8)	0	1 (2.4)	0	0	3 (7.1)
Urinary tract infection	1 (2.4)	1 (2.4)	0	0	0	2 (4.8)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & All Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Infections and infestations (cont.)						
Appendiceal abscess	0	0	1 (2.4)	0	0	1 (2.4)
Catheter site cellulitis	0	1 (2.4)	0	0	0	1 (2.4)
Cellulitis	0	1 (2.4)	0	0	0	1 (2.4)
Clostridium difficile colitis	1 (2.4)	0	0	0	0	1 (2.4)
Corona virus infection	0	0	1 (2.4)	0	0	1 (2.4)
Cystitis	0	1 (2.4)	0	0	0	1 (2.4)
Gastrointestinal fungal infection	0	1 (2.4)	0	0	0	1 (2.4)
Herpes simplex	1 (2.4)	0	0	0	0	1 (2.4)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & All Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Infections and infestations (cont.)						
Necrotising fasciitis	0	0	0	0	1 (2.4)	1 (2.4)
Oral candidiasis	0	1 (2.4)	0	0	0	1 (2.4)
Oral herpes	1 (2.4)	0	0	0	0	1 (2.4)
Oropharyngeal candidiasis	0	1 (2.4)	0	0	0	1 (2.4)
Otitis media	1 (2.4)	0	0	0	0	1 (2.4)
Paronychia	0	1 (2.4)	0	0	0	1 (2.4)
Pneumonia	0	1 (2.4)	0	0	0	1 (2.4)
Respiratory tract infection	0	1 (2.4)	0	0	0	1 (2.4)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & All Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Infections and infestations (cont.)						
Sepsis	0	0	1 (2.4)	0	0	1 (2.4)
Sinusitis	1 (2.4)	0	0	0	0	1 (2.4)
Skin infection	0	0	1 (2.4)	0	0	1 (2.4)
Stoma site cellulitis	0	1 (2.4)	0	0	0	1 (2.4)
Upper respiratory tract infection	1 (2.4)	0	0	0	0	1 (2.4)
Wound infection	0	1 (2.4)	0	0	0	1 (2.4)
Injury, poisoning and procedural complications	5 (11.9)	1 (2.4)	1 (2.4)	1 (2.4)	0	8 (19.0)
Fall	2 (4.8)	0	0	0	0	2 (4.8)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & All Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Injury, poisoning and procedural complications (cont.)						
Anaemia postoperative	0	0	1 (2.4)	0	0	1 (2.4)
Contusion	1 (2.4)	0	0	0	0	1 (2.4)
Joint injury	1 (2.4)	0	0	0	0	1 (2.4)
Post procedural haemorrhage	1 (2.4)	0	0	0	0	1 (2.4)
Procedural pain	1 (2.4)	0	0	0	0	1 (2.4)
Skin abrasion	1 (2.4)	0	0	0	0	1 (2.4)
Subdural haematoma	0	0	0	1 (2.4)	0	1 (2.4)
Tendon rupture	0	1 (2.4)	0	0	0	1 (2.4)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & All Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Injury, poisoning and procedural complications (cont.)						
Traumatic haematoma	1 (2.4)	0	0	0	0	1 (2.4)
Investigations	7 (16.7)	2 (4.8)	9 (21.4)	1 (2.4)	0	19 (45.2)
Blood bilirubin increased	3 (7.1)	3 (7.1)	0	0	0	6 (14.3)
Platelet count decreased	0	2 (4.8)	4 (9.5)	0	0	6 (14.3)
Blood creatinine increased	3 (7.1)	1 (2.4)	0	0	0	4 (9.5)
Neutrophil count decreased	0	0	2 (4.8)	1 (2.4)	0	3 (7.1)
White blood cell count decreased	0	0	3 (7.1)	0	0	3 (7.1)
Blood alkaline phosphatase increased	0	0	2 (4.8)	0	0	2 (4.8)

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AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & All Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Investigations (cont.)						
Blood uric acid increased	2 (4.8)	0	0	0	0	2 (4.8)
Gamma-glutamyltransferase increased	1 (2.4)	0	1 (2.4)	0	0	2 (4.8)
Urine uric acid increased	2 (4.8)	0	0	0	0	2 (4.8)
Weight increased	1 (2.4)	0	1 (2.4)	0	0	2 (4.8)
Alanine aminotransferase decreased	0	1 (2.4)	0	0	0	1 (2.4)
Alanine aminotransferase increased	0	1 (2.4)	0	0	0	1 (2.4)
Aspartate aminotransferase increased	1 (2.4)	0	0	0	0	1 (2.4)
Blood albumin decreased	1 (2.4)	0	0	0	0	1 (2.4)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & All Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Investigations (cont.)						
Blood bilirubin unconjugated increased	0	0	1 (2.4)	0	0	1 (2.4)
Blood phosphorus decreased	0	1 (2.4)	0	0	0	1 (2.4)
Blood thyroid stimulating hormone increased	1 (2.4)	0	0	0	0	1 (2.4)
C-reactive protein increased	0	1 (2.4)	0	0	0	1 (2.4)
Cardiac murmur	1 (2.4)	0	0	0	0	1 (2.4)
Electrocardiogram QT prolonged	1 (2.4)	0	0	0	0	1 (2.4)
Haemoglobin decreased	0	1 (2.4)	0	0	0	1 (2.4)
Lipase increased	0	1 (2.4)	0	0	0	1 (2.4)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & All Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Investigations (cont.)						
Lymphocyte count decreased	0	1 (2.4)	0	0	0	1 (2.4)
Monocyte count increased	0	1 (2.4)	0	0	0	1 (2.4)
Prothrombin time shortened	1 (2.4)	0	0	0	0	1 (2.4)
Red blood cell count decreased	1 (2.4)	0	0	0	0	1 (2.4)
Reticulocyte count increased	1 (2.4)	0	0	0	0	1 (2.4)
White blood cell count increased	1 (2.4)	0	0	0	0	1 (2.4)
Metabolism and nutrition disorders	6 (14.3)	3 (7.1)	1 (2.4)	0	0	10 (23.8)
Decreased appetite	2 (4.8)	0	0	0	0	2 (4.8)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & All Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Metabolism and nutrition disorders (cont.)						
Hypomagnesaemia	2 (4.8)	0	0	0	0	2 (4.8)
Hypophosphataemia	2 (4.8)	0	0	0	0	2 (4.8)
Cachexia	0	1 (2.4)	0	0	0	1 (2.4)
Gout	0	1 (2.4)	0	0	0	1 (2.4)
Hyperphosphataemia	0	1 (2.4)	0	0	0	1 (2.4)
Hyperuricaemia	1 (2.4)	0	0	0	0	1 (2.4)
Hypocalcaemia	0	1 (2.4)	0	0	0	1 (2.4)
Hypokalaemia	1 (2.4)	0	0	0	0	1 (2.4)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & All Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Metabolism and nutrition disorders (cont.)						
Tumour lysis syndrome	0	0	1 (2.4)	0	0	1 (2.4)
Musculoskeletal and connective tissue disorders	7 (16.7)	4 (9.5)	0	0	0	11 (26.2)
Arthralgia	1 (2.4)	1 (2.4)	0	0	0	2 (4.8)
Back pain	2 (4.8)	0	0	0	0	2 (4.8)
Myalgia	2 (4.8)	0	0	0	0	2 (4.8)
Pain in extremity	2 (4.8)	0	0	0	0	2 (4.8)
Muscular weakness	1 (2.4)	0	0	0	0	1 (2.4)
Musculoskeletal pain	1 (2.4)	0	0	0	0	1 (2.4)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & All Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Musculoskeletal and connective tissue disorders (cont.)						
Neck pain	1 (2.4)	0	0	0	0	1 (2.4)
Osteonecrosis of jaw	0	1 (2.4)	0	0	0	1 (2.4)
Osteoporosis	0	1 (2.4)	0	0	0	1 (2.4)
Pain in jaw	1 (2.4)	0	0	0	0	1 (2.4)
Spinal column stenosis	0	1 (2.4)	0	0	0	1 (2.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	1 (2.4)	3 (7.1)	0	0	4 (9.5)
Acute myeloid leukaemia	0	0	1 (2.4)	0	0	1 (2.4)
Basal cell carcinoma	0	0	1 (2.4)	0	0	1 (2.4)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & All Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont.)						
Benign gastrointestinal neoplasm	0	0	1 (2.4)	0	0	1 (2.4)
Malignant melanoma	0	0	1 (2.4)	0	0	1 (2.4)
Salivary gland neoplasm	1 (2.4)	0	0	0	0	1 (2.4)
Squamous cell carcinoma of skin	0	1 (2.4)	0	0	0	1 (2.4)
Nervous system disorders	11 (26.2)	5 (11.9)	0	0	0	16 (38.1)
Dysgeusia	5 (11.9)	1 (2.4)	0	0	0	6 (14.3)
Headache	4 (9.5)	1 (2.4)	0	0	0	5 (11.9)
Dizziness	3 (7.1)	1 (2.4)	0	0	0	4 (9.5)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & All Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Nervous system disorders (cont.)						
Cognitive disorder	1 (2.4)	1 (2.4)	0	0	0	2 (4.8)
Memory impairment	2 (4.8)	0	0	0	0	2 (4.8)
Restless legs syndrome	1 (2.4)	1 (2.4)	0	0	0	2 (4.8)
Aphasia	1 (2.4)	0	0	0	0	1 (2.4)
Balance disorder	1 (2.4)	0	0	0	0	1 (2.4)
Dizziness postural	1 (2.4)	0	0	0	0	1 (2.4)
Hypogeusia	1 (2.4)	0	0	0	0	1 (2.4)
Parkinson's disease	1 (2.4)	0	0	0	0	1 (2.4)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & All Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Nervous system disorders (cont.)						
Sensory disturbance	1 (2.4)	0	0	0	0	1 (2.4)
Tremor	1 (2.4)	0	0	0	0	1 (2.4)
Psychiatric disorders	5 (11.9)	3 (7.1)	1 (2.4)	0	0	9 (21.4)
Insomnia	1 (2.4)	1 (2.4)	0	0	0	2 (4.8)
Sleep disorder	2 (4.8)	0	0	0	0	2 (4.8)
Adjustment disorder with depressed mood	0	1 (2.4)	0	0	0	1 (2.4)
Confusional state	1 (2.4)	0	0	0	0	1 (2.4)
Delirium	0	0	1 (2.4)	0	0	1 (2.4)

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AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & All Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Psychiatric disorders (cont.)						
Depressed mood	1 (2.4)	0	0	0	0	1 (2.4)
Depression	0	1 (2.4)	0	0	0	1 (2.4)
Disorientation	1 (2.4)	0	0	0	0	1 (2.4)
Mental disorder	1 (2.4)	0	0	0	0	1 (2.4)
Renal and urinary disorders	3 (7.1)	0	1 (2.4)	0	0	4 (9.5)
Nephrolithiasis	1 (2.4)	0	1 (2.4)	0	0	2 (4.8)
Acute kidney injury	1 (2.4)	0	0	0	0	1 (2.4)
Haematuria	1 (2.4)	0	0	0	0	1 (2.4)

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AdvSM Population & Prior Neoplastic Therapy = Yes

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Renal and urinary disorders (cont.)						
Obstructive uropathy	0	0	1 (2.4)	0	0	1 (2.4)
Reproductive system and breast disorders	0	2 (4.8)	0	0	0	2 (4.8)
Oedema genital	0	1 (2.4)	0	0	0	1 (2.4)
Scrotal oedema	0	1 (2.4)	0	0	0	1 (2.4)
Respiratory, thoracic and mediastinal disorders	7 (16.7)	2 (4.8)	2 (4.8)	0	0	11 (26.2)
Epistaxis	4 (9.5)	0	0	0	0	4 (9.5)
Dyspnoea	2 (4.8)	0	0	0	0	2 (4.8)
Pleural effusion	1 (2.4)	0	1 (2.4)	0	0	2 (4.8)

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Respiratory, thoracic and mediastinal disorders (cont.)						
Bronchial haemorrhage	0	0	1 (2.4)	0	0	1 (2.4)
Cough	0	1 (2.4)	0	0	0	1 (2.4)
Dyspnoea exertional	1 (2.4)	0	0	0	0	1 (2.4)
Haemoptysis	1 (2.4)	0	0	0	0	1 (2.4)
Haemothorax	0	0	1 (2.4)	0	0	1 (2.4)
Nasal congestion	0	1 (2.4)	0	0	0	1 (2.4)
Oropharyngeal pain	1 (2.4)	0	0	0	0	1 (2.4)
Pulmonary oedema	0	1 (2.4)	0	0	0	1 (2.4)

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Respiratory, thoracic and mediastinal disorders (cont.)						
Rales	1 (2.4)	0	0	0	0	1 (2.4)
Respiratory symptom	1 (2.4)	0	0	0	0	1 (2.4)
Throat irritation	1 (2.4)	0	0	0	0	1 (2.4)
Skin and subcutaneous tissue disorders	7 (16.7)	5 (11.9)	0	0	0	12 (28.6)
Alopecia	3 (7.1)	0	0	0	0	3 (7.1)
Hair colour changes	3 (7.1)	0	0	0	0	3 (7.1)
Pruritus	2 (4.8)	1 (2.4)	0	0	0	3 (7.1)
Petechiae	2 (4.8)	0	0	0	0	2 (4.8)

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AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & All Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Skin and subcutaneous tissue disorders (cont.)						
Dermatitis contact	1 (2.4)	0	0	0	0	1 (2.4)
Hyperhidrosis	1 (2.4)	0	0	0	0	1 (2.4)
Night sweats	0	1 (2.4)	0	0	0	1 (2.4)
Psoriasis	0	1 (2.4)	0	0	0	1 (2.4)
Rash	1 (2.4)	0	0	0	0	1 (2.4)
Seborrhoeic dermatitis	1 (2.4)	0	0	0	0	1 (2.4)
Skin haemorrhage	0	1 (2.4)	0	0	0	1 (2.4)
Skin ulcer	0	1 (2.4)	0	0	0	1 (2.4)

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System Organ Class Preferred Term	BLU-285-2202 & All Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Skin and subcutaneous tissue disorders (cont.)						
Swelling face	1 (2.4)	0	0	0	0	1 (2.4)
Vascular disorders	4 (9.5)	1 (2.4)	2 (4.8)	0	1 (2.4)	8 (19.0)
Flushing	2 (4.8)	0	0	0	0	2 (4.8)
Hypertension	1 (2.4)	1 (2.4)	0	0	0	2 (4.8)
Haematoma	0	1 (2.4)	0	0	0	1 (2.4)
Haemorrhage	0	0	1 (2.4)	0	0	1 (2.4)
Hot flush	1 (2.4)	0	0	0	0	1 (2.4)
Hypotension	0	0	1 (2.4)	0	0	1 (2.4)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 & All Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Vascular disorders (cont.)						
Shock haemorrhagic	0	0	0	0	1 (2.4)	1 (2.4)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & 200 mg Dose Group (N=52) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Patients with at least one Event	6 (11.5)	11 (21.2)	25 (48.1)	7 (13.5)	3 (5.8)	52 (100.0)
Blood and lymphatic system disorders	4 (7.7)	8 (15.4)	18 (34.6)	4 (7.7)	0	34 (65.4)
Thrombocytopenia	3 (5.8)	7 (13.5)	6 (11.5)	2 (3.8)	0	18 (34.6)
Anaemia	0	3 (5.8)	13 (25.0)	0	0	16 (30.8)
Neutropenia	0	1 (1.9)	4 (7.7)	2 (3.8)	0	7 (13.5)
Haemorrhagic diathesis	1 (1.9)	1 (1.9)	0	0	0	2 (3.8)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
Note 1: In each treatment group, if a patient experiences more than 1 event within a given System Organ Class or Preferred term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & 200 mg Dose Group (N=52) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Blood and lymphatic system disorders (cont.)						
Increased tendency to bruise	2 (3.8)	0	0	0	0	2 (3.8)
Leukocytosis	0	0	2 (3.8)	0	0	2 (3.8)
Anaemia macrocytic	0	0	1 (1.9)	0	0	1 (1.9)
Coagulopathy	1 (1.9)	0	0	0	0	1 (1.9)
Haemolysis	1 (1.9)	0	0	0	0	1 (1.9)
Lymphadenopathy	1 (1.9)	0	0	0	0	1 (1.9)
Lymphopenia	1 (1.9)	0	0	0	0	1 (1.9)
Mast cell activation syndrome	0	1 (1.9)	0	0	0	1 (1.9)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & 200 mg Dose Group (N=52) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Cardiac disorders	4 (7.7)	0	4 (7.7)	0	0	8 (15.4)
Cardiac failure	0	0	2 (3.8)	0	0	2 (3.8)
Atrial flutter	0	0	1 (1.9)	0	0	1 (1.9)
Bradycardia	1 (1.9)	0	0	0	0	1 (1.9)
Cardiac failure congestive	0	0	1 (1.9)	0	0	1 (1.9)
Palpitations	1 (1.9)	0	0	0	0	1 (1.9)
Pericardial effusion	1 (1.9)	0	0	0	0	1 (1.9)
Supraventricular extrasystoles	1 (1.9)	0	0	0	0	1 (1.9)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & 200 mg Dose Group (N=52) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Cardiac disorders (cont.)						
Ventricular extrasystoles	1 (1.9)	0	0	0	0	1 (1.9)
Congenital, familial and genetic disorders	0	1 (1.9)	0	0	0	1 (1.9)
Right-to-left cardiac shunt	0	1 (1.9)	0	0	0	1 (1.9)
Ear and labyrinth disorders	2 (3.8)	0	0	0	0	2 (3.8)
Deafness	1 (1.9)	0	0	0	0	1 (1.9)
Vertigo	1 (1.9)	0	0	0	0	1 (1.9)
Eye disorders	24 (46.2)	4 (7.7)	1 (1.9)	1 (1.9)	0	30 (57.7)
Periorbital oedema	11 (21.2)	3 (5.8)	1 (1.9)	0	0	15 (28.8)

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Note 1: In each treatment group, if a patient experiences more than 1 event within a given System Organ Class or Preferred term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & 200 mg Dose Group (N=52) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Eye disorders (cont.)						
Eyelid oedema	7 (13.5)	0	0	0	0	7 (13.5)
Lacrimation increased	5 (9.6)	0	0	0	0	5 (9.6)
Conjunctival haemorrhage	1 (1.9)	1 (1.9)	0	0	0	2 (3.8)
Eye swelling	2 (3.8)	0	0	0	0	2 (3.8)
Vision blurred	2 (3.8)	0	0	0	0	2 (3.8)
Eye haemorrhage	1 (1.9)	0	0	0	0	1 (1.9)
Macular fibrosis	1 (1.9)	0	0	0	0	1 (1.9)
Ocular hyperaemia	1 (1.9)	0	0	0	0	1 (1.9)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & 200 mg Dose Group (N=52) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Eye disorders (cont.)						
Periorbital haemorrhage	1 (1.9)	0	0	0	0	1 (1.9)
Visual acuity reduced	1 (1.9)	0	0	0	0	1 (1.9)
Vitreous floaters	1 (1.9)	0	0	0	0	1 (1.9)
Vitreous haemorrhage	0	0	0	1 (1.9)	0	1 (1.9)
Gastrointestinal disorders	22 (42.3)	10 (19.2)	7 (13.5)	1 (1.9)	0	40 (76.9)
Diarrhoea	13 (25.0)	2 (3.8)	1 (1.9)	0	0	16 (30.8)
Nausea	11 (21.2)	0	1 (1.9)	0	0	12 (23.1)
Vomiting	7 (13.5)	3 (5.8)	1 (1.9)	0	0	11 (21.2)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & 200 mg Dose Group (N=52) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Gastrointestinal disorders (cont.)						
Abdominal pain	5 (9.6)	1 (1.9)	1 (1.9)	0	0	7 (13.5)
Constipation	6 (11.5)	1 (1.9)	0	0	0	7 (13.5)
Ascites	2 (3.8)	2 (3.8)	0	0	0	4 (7.7)
Dyspepsia	3 (5.8)	1 (1.9)	0	0	0	4 (7.7)
Abdominal distension	3 (5.8)	0	0	0	0	3 (5.8)
Gastrooesophageal reflux disease	0	2 (3.8)	0	0	0	2 (3.8)
Melaena	0	1 (1.9)	1 (1.9)	0	0	2 (3.8)
Salivary hypersecretion	2 (3.8)	0	0	0	0	2 (3.8)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & 200 mg Dose Group (N=52) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Gastrointestinal disorders (cont.)						
Abdominal discomfort	1 (1.9)	0	0	0	0	1 (1.9)
Abdominal pain upper	1 (1.9)	0	0	0	0	1 (1.9)
Colitis	0	0	1 (1.9)	0	0	1 (1.9)
Dental caries	1 (1.9)	0	0	0	0	1 (1.9)
Dry mouth	1 (1.9)	0	0	0	0	1 (1.9)
Duodenal ulcer haemorrhage	0	0	1 (1.9)	0	0	1 (1.9)
Faeces discoloured	1 (1.9)	0	0	0	0	1 (1.9)
Flatulence	1 (1.9)	0	0	0	0	1 (1.9)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & 200 mg Dose Group (N=52) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Gastrointestinal disorders (cont.)						
Gastrointestinal haemorrhage	0	0	1 (1.9)	0	0	1 (1.9)
Gingival bleeding	1 (1.9)	0	0	0	0	1 (1.9)
Gingival pain	1 (1.9)	0	0	0	0	1 (1.9)
Incarcerated umbilical hernia	0	0	0	1 (1.9)	0	1 (1.9)
Inguinal hernia	1 (1.9)	0	0	0	0	1 (1.9)
Intra-abdominal haematoma	0	1 (1.9)	0	0	0	1 (1.9)
Intra-abdominal haemorrhage	0	0	1 (1.9)	0	0	1 (1.9)
Large intestine perforation	0	0	1 (1.9)	0	0	1 (1.9)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & 200 mg Dose Group (N=52) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Gastrointestinal disorders (cont.)						
Lip dry	1 (1.9)	0	0	0	0	1 (1.9)
Lower gastrointestinal haemorrhage	0	0	1 (1.9)	0	0	1 (1.9)
Mouth ulceration	1 (1.9)	0	0	0	0	1 (1.9)
Oral disorder	1 (1.9)	0	0	0	0	1 (1.9)
Periodontal disease	1 (1.9)	0	0	0	0	1 (1.9)
Portal hypertensive gastropathy	1 (1.9)	0	0	0	0	1 (1.9)
Small intestinal obstruction	1 (1.9)	0	0	0	0	1 (1.9)
Tooth deposit	1 (1.9)	0	0	0	0	1 (1.9)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & 200 mg Dose Group (N=52) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Gastrointestinal disorders (cont.)						
Toothache	1 (1.9)	0	0	0	0	1 (1.9)
General disorders and administration site conditions	21 (40.4)	14 (26.9)	2 (3.8)	0	1 (1.9)	38 (73.1)
Oedema peripheral	21 (40.4)	7 (13.5)	0	0	0	28 (53.8)
Face oedema	6 (11.5)	2 (3.8)	0	0	0	8 (15.4)
Fatigue	3 (5.8)	2 (3.8)	2 (3.8)	0	0	7 (13.5)
Asthenia	3 (5.8)	2 (3.8)	0	0	0	5 (9.6)
Pain	3 (5.8)	1 (1.9)	0	0	0	4 (7.7)
Pyrexia	3 (5.8)	1 (1.9)	0	0	0	4 (7.7)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & 200 mg Dose Group (N=52) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
General disorders and administration site conditions (cont.)						
Generalised oedema	1 (1.9)	1 (1.9)	0	0	0	2 (3.8)
Non-cardiac chest pain	2 (3.8)	0	0	0	0	2 (3.8)
Oedema	2 (3.8)	0	0	0	0	2 (3.8)
Peripheral swelling	2 (3.8)	0	0	0	0	2 (3.8)
Decreased activity	0	1 (1.9)	0	0	0	1 (1.9)
Disease progression	0	0	0	0	1 (1.9)	1 (1.9)
Feeling abnormal	1 (1.9)	0	0	0	0	1 (1.9)
Gait disturbance	1 (1.9)	0	0	0	0	1 (1.9)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & 200 mg Dose Group (N=52) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
General disorders and administration site conditions (cont.)						
Influenza like illness	0	1 (1.9)	0	0	0	1 (1.9)
Malaise	1 (1.9)	0	0	0	0	1 (1.9)
Systemic inflammatory response syndrome	0	1 (1.9)	0	0	0	1 (1.9)
Temperature intolerance	1 (1.9)	0	0	0	0	1 (1.9)
Hepatobiliary disorders	2 (3.8)	0	0	0	0	2 (3.8)
Cholelithiasis	1 (1.9)	0	0	0	0	1 (1.9)
Hyperbilirubinaemia	1 (1.9)	0	0	0	0	1 (1.9)
Immune system disorders	1 (1.9)	0	1 (1.9)	0	0	2 (3.8)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & 200 mg Dose Group (N=52) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Immune system disorders (cont.)						
Drug hypersensitivity	1 (1.9)	0	0	0	0	1 (1.9)
Hypogammaglobulinaemia	0	1 (1.9)	0	0	0	1 (1.9)
Immune system disorder	0	0	1 (1.9)	0	0	1 (1.9)
Infections and infestations	7 (13.5)	11 (21.2)	7 (13.5)	0	1 (1.9)	26 (50.0)
Upper respiratory tract infection	2 (3.8)	1 (1.9)	1 (1.9)	0	0	4 (7.7)
Cellulitis	0	2 (3.8)	0	0	0	2 (3.8)
Herpes zoster	2 (3.8)	0	0	0	0	2 (3.8)
Oral candidiasis	0	2 (3.8)	0	0	0	2 (3.8)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & 200 mg Dose Group (N=52) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Infections and infestations (cont.)						
Sinusitis	1 (1.9)	1 (1.9)	0	0	0	2 (3.8)
Urinary tract infection	1 (1.9)	1 (1.9)	0	0	0	2 (3.8)
Appendiceal abscess	0	0	1 (1.9)	0	0	1 (1.9)
Catheter site cellulitis	0	1 (1.9)	0	0	0	1 (1.9)
Corona virus infection	0	0	1 (1.9)	0	0	1 (1.9)
Cystitis	0	1 (1.9)	0	0	0	1 (1.9)
Diverticulitis	0	0	1 (1.9)	0	0	1 (1.9)
Gastrointestinal fungal infection	0	1 (1.9)	0	0	0	1 (1.9)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & 200 mg Dose Group (N=52) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Infections and infestations (cont.)						
Herpes simplex	1 (1.9)	0	0	0	0	1 (1.9)
Localised infection	0	0	1 (1.9)	0	0	1 (1.9)
Necrotising fasciitis	0	0	0	0	1 (1.9)	1 (1.9)
Oral herpes	1 (1.9)	0	0	0	0	1 (1.9)
Oropharyngeal candidiasis	0	1 (1.9)	0	0	0	1 (1.9)
Otitis externa	0	1 (1.9)	0	0	0	1 (1.9)
Otitis media	1 (1.9)	0	0	0	0	1 (1.9)
Paronychia	0	1 (1.9)	0	0	0	1 (1.9)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & 200 mg Dose Group (N=52) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Infections and infestations (cont.)						
Pneumonia	0	1 (1.9)	0	0	0	1 (1.9)
Respiratory tract infection	0	1 (1.9)	0	0	0	1 (1.9)
Sepsis	0	0	1 (1.9)	0	0	1 (1.9)
Skin infection	0	0	1 (1.9)	0	0	1 (1.9)
Stoma site cellulitis	0	1 (1.9)	0	0	0	1 (1.9)
Viral upper respiratory tract infection	1 (1.9)	0	0	0	0	1 (1.9)
Wound infection	0	1 (1.9)	0	0	0	1 (1.9)
Injury, poisoning and procedural complications	7 (13.5)	5 (9.6)	1 (1.9)	1 (1.9)	0	14 (26.9)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & 200 mg Dose Group (N=52) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Injury, poisoning and procedural complications (cont.)						
Contusion	2 (3.8)	1 (1.9)	0	0	0	3 (5.8)
Fall	2 (3.8)	1 (1.9)	0	0	0	3 (5.8)
Laceration	2 (3.8)	0	0	0	0	2 (3.8)
Post procedural haemorrhage	2 (3.8)	0	0	0	0	2 (3.8)
Subdural haematoma	1 (1.9)	0	0	1 (1.9)	0	2 (3.8)
Anaemia postoperative	0	0	1 (1.9)	0	0	1 (1.9)
Electrical burn	0	1 (1.9)	0	0	0	1 (1.9)
Fractured sacrum	0	1 (1.9)	0	0	0	1 (1.9)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & 200 mg Dose Group (N=52) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Injury, poisoning and procedural complications (cont.)						
Joint injury	1 (1.9)	0	0	0	0	1 (1.9)
Lumbar vertebral fracture	0	1 (1.9)	0	0	0	1 (1.9)
Procedural pain	1 (1.9)	0	0	0	0	1 (1.9)
Skin abrasion	1 (1.9)	0	0	0	0	1 (1.9)
Skin wound	1 (1.9)	0	0	0	0	1 (1.9)
Tendon rupture	0	1 (1.9)	0	0	0	1 (1.9)
Traumatic haematoma	1 (1.9)	0	0	0	0	1 (1.9)
Investigations	8 (15.4)	4 (7.7)	10 (19.2)	2 (3.8)	0	24 (46.2)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & 200 mg Dose Group (N=52) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Investigations (cont.)						
Blood bilirubin increased	3 (5.8)	4 (7.7)	0	0	0	7 (13.5)
Blood creatinine increased	6 (11.5)	1 (1.9)	0	0	0	7 (13.5)
Platelet count decreased	0	2 (3.8)	4 (7.7)	1 (1.9)	0	7 (13.5)
Weight increased	2 (3.8)	1 (1.9)	1 (1.9)	0	0	4 (7.7)
White blood cell count decreased	0	0	4 (7.7)	0	0	4 (7.7)
Cardiac murmur	3 (5.8)	0	0	0	0	3 (5.8)
Neutrophil count decreased	0	0	2 (3.8)	1 (1.9)	0	3 (5.8)
Blood alkaline phosphatase increased	0	0	2 (3.8)	0	0	2 (3.8)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & 200 mg Dose Group (N=52) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Investigations (cont.)						
Blood uric acid increased	2 (3.8)	0	0	0	0	2 (3.8)
Gamma-glutamyltransferase increased	1 (1.9)	0	1 (1.9)	0	0	2 (3.8)
Urine uric acid increased	2 (3.8)	0	0	0	0	2 (3.8)
Alanine aminotransferase decreased	0	1 (1.9)	0	0	0	1 (1.9)
Alanine aminotransferase increased	0	1 (1.9)	0	0	0	1 (1.9)
Aspartate aminotransferase increased	1 (1.9)	0	0	0	0	1 (1.9)
Blood albumin decreased	1 (1.9)	0	0	0	0	1 (1.9)
Blood bilirubin unconjugated increased	0	0	1 (1.9)	0	0	1 (1.9)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & 200 mg Dose Group (N=52) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Investigations (cont.)						
Blood phosphorus decreased	0	1 (1.9)	0	0	0	1 (1.9)
Blood thyroid stimulating hormone increased	1 (1.9)	0	0	0	0	1 (1.9)
C-reactive protein increased	0	1 (1.9)	0	0	0	1 (1.9)
Electrocardiogram QT prolonged	1 (1.9)	0	0	0	0	1 (1.9)
Haemoglobin decreased	0	1 (1.9)	0	0	0	1 (1.9)
Lipase increased	0	1 (1.9)	0	0	0	1 (1.9)
Lymphocyte count decreased	0	1 (1.9)	0	0	0	1 (1.9)
Monocyte count increased	0	1 (1.9)	0	0	0	1 (1.9)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & 200 mg Dose Group (N=52) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Investigations (cont.)						
Prothrombin time shortened	1 (1.9)	0	0	0	0	1 (1.9)
Red blood cell count decreased	1 (1.9)	0	0	0	0	1 (1.9)
Reticulocyte count increased	1 (1.9)	0	0	0	0	1 (1.9)
White blood cell count increased	1 (1.9)	0	0	0	0	1 (1.9)
Metabolism and nutrition disorders	9 (17.3)	6 (11.5)	2 (3.8)	0	0	17 (32.7)
Decreased appetite	4 (7.7)	1 (1.9)	0	0	0	5 (9.6)
Hypokalaemia	3 (5.8)	1 (1.9)	0	0	0	4 (7.7)
Hypomagnesaemia	3 (5.8)	0	0	0	0	3 (5.8)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & 200 mg Dose Group (N=52) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Metabolism and nutrition disorders (cont.)						
Hypophosphataemia	2 (3.8)	0	0	0	0	2 (3.8)
Cachexia	0	1 (1.9)	0	0	0	1 (1.9)
Dehydration	0	1 (1.9)	0	0	0	1 (1.9)
Gout	0	1 (1.9)	0	0	0	1 (1.9)
Hyperglycaemia	0	0	1 (1.9)	0	0	1 (1.9)
Hyperphosphataemia	0	1 (1.9)	0	0	0	1 (1.9)
Hyperuricaemia	1 (1.9)	0	0	0	0	1 (1.9)
Hypocalcaemia	0	1 (1.9)	0	0	0	1 (1.9)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & 200 mg Dose Group (N=52) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Metabolism and nutrition disorders (cont.)						
Tumour lysis syndrome	0	0	1 (1.9)	0	0	1 (1.9)
Vitamin D deficiency	0	1 (1.9)	0	0	0	1 (1.9)
Musculoskeletal and connective tissue disorders	6 (11.5)	7 (13.5)	2 (3.8)	0	0	15 (28.8)
Arthralgia	1 (1.9)	3 (5.8)	1 (1.9)	0	0	5 (9.6)
Back pain	2 (3.8)	0	1 (1.9)	0	0	3 (5.8)
Muscular weakness	1 (1.9)	2 (3.8)	0	0	0	3 (5.8)
Pain in extremity	2 (3.8)	1 (1.9)	0	0	0	3 (5.8)
Myalgia	2 (3.8)	0	0	0	0	2 (3.8)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & 200 mg Dose Group (N=52) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Musculoskeletal and connective tissue disorders (cont.)						
Musculoskeletal pain	1 (1.9)	0	0	0	0	1 (1.9)
Neck pain	1 (1.9)	0	0	0	0	1 (1.9)
Osteonecrosis of jaw	0	1 (1.9)	0	0	0	1 (1.9)
Osteoporosis	0	1 (1.9)	0	0	0	1 (1.9)
Pain in jaw	1 (1.9)	0	0	0	0	1 (1.9)
Spinal column stenosis	0	1 (1.9)	0	0	0	1 (1.9)
Tenosynovitis	1 (1.9)	0	0	0	0	1 (1.9)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (1.9)	2 (3.8)	4 (7.7)	0	0	7 (13.5)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & 200 mg Dose Group (N=52) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont.)						
Acute myeloid leukaemia	0	0	1 (1.9)	0	0	1 (1.9)
Basal cell carcinoma	0	0	1 (1.9)	0	0	1 (1.9)
Benign gastrointestinal neoplasm	0	0	1 (1.9)	0	0	1 (1.9)
Keratoacanthoma	1 (1.9)	0	0	0	0	1 (1.9)
Malignant melanoma	0	0	1 (1.9)	0	0	1 (1.9)
Myelodysplastic syndrome	0	0	1 (1.9)	0	0	1 (1.9)
Penile wart	0	1 (1.9)	0	0	0	1 (1.9)
Salivary gland neoplasm	1 (1.9)	0	0	0	0	1 (1.9)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

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Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont.)						
Squamous cell carcinoma	0	1 (1.9)	0	0	0	1 (1.9)
Squamous cell carcinoma of skin	0	1 (1.9)	0	0	0	1 (1.9)
Nervous system disorders	15 (28.8)	7 (13.5)	1 (1.9)	0	0	23 (44.2)
Headache	7 (13.5)	2 (3.8)	0	0	0	9 (17.3)
Dizziness	5 (9.6)	2 (3.8)	0	0	0	7 (13.5)
Dysgeusia	6 (11.5)	1 (1.9)	0	0	0	7 (13.5)
Cognitive disorder	2 (3.8)	1 (1.9)	0	0	0	3 (5.8)
Memory impairment	3 (5.8)	0	0	0	0	3 (5.8)

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AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & 200 mg Dose Group (N=52) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Nervous system disorders (cont.)						
Dizziness postural	2 (3.8)	0	0	0	0	2 (3.8)
Restless legs syndrome	1 (1.9)	1 (1.9)	0	0	0	2 (3.8)
Aphasia	1 (1.9)	0	0	0	0	1 (1.9)
Balance disorder	1 (1.9)	0	0	0	0	1 (1.9)
Hypoaesthesia	1 (1.9)	0	0	0	0	1 (1.9)
Hypogeusia	1 (1.9)	0	0	0	0	1 (1.9)
Myoclonus	0	0	1 (1.9)	0	0	1 (1.9)
Paraesthesia	1 (1.9)	0	0	0	0	1 (1.9)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
Note 1: In each treatment group, if a patient experiences more than 1 event within a given System Organ Class or Preferred term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & 200 mg Dose Group (N=52) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Nervous system disorders (cont.)						
Parkinson's disease	1 (1.9)	0	0	0	0	1 (1.9)
Sensory disturbance	1 (1.9)	0	0	0	0	1 (1.9)
Transient ischaemic attack	1 (1.9)	0	0	0	0	1 (1.9)
Tremor	1 (1.9)	0	0	0	0	1 (1.9)
Psychiatric disorders	8 (15.4)	3 (5.8)	1 (1.9)	0	0	12 (23.1)
Insomnia	3 (5.8)	1 (1.9)	0	0	0	4 (7.7)
Depressed mood	2 (3.8)	0	0	0	0	2 (3.8)
Sleep disorder	2 (3.8)	0	0	0	0	2 (3.8)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & 200 mg Dose Group (N=52) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Psychiatric disorders (cont.)						
Adjustment disorder with depressed mood	0	1 (1.9)	0	0	0	1 (1.9)
Confusional state	1 (1.9)	0	0	0	0	1 (1.9)
Delirium	0	0	1 (1.9)	0	0	1 (1.9)
Depression	0	1 (1.9)	0	0	0	1 (1.9)
Disorientation	1 (1.9)	0	0	0	0	1 (1.9)
Libido decreased	1 (1.9)	0	0	0	0	1 (1.9)
Mental disorder	1 (1.9)	0	0	0	0	1 (1.9)
Renal and urinary disorders	3 (5.8)	1 (1.9)	2 (3.8)	0	0	6 (11.5)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & 200 mg Dose Group (N=52) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Renal and urinary disorders (cont.)						
Acute kidney injury	2 (3.8)	0	1 (1.9)	0	0	3 (5.8)
Nephrolithiasis	1 (1.9)	0	1 (1.9)	0	0	2 (3.8)
Chronic kidney disease	0	1 (1.9)	0	0	0	1 (1.9)
Dysuria	1 (1.9)	0	0	0	0	1 (1.9)
Haematuria	1 (1.9)	0	0	0	0	1 (1.9)
Obstructive uropathy	0	0	1 (1.9)	0	0	1 (1.9)
Pollakiuria	1 (1.9)	0	0	0	0	1 (1.9)
Urinary incontinence	0	1 (1.9)	0	0	0	1 (1.9)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & 200 mg Dose Group (N=52) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Renal and urinary disorders (cont.)						
Urinary retention	0	1 (1.9)	0	0	0	1 (1.9)
Reproductive system and breast disorders	1 (1.9)	3 (5.8)	0	0	0	4 (7.7)
Scrotal oedema	0	2 (3.8)	0	0	0	2 (3.8)
Oedema genital	0	1 (1.9)	0	0	0	1 (1.9)
Penile pain	1 (1.9)	0	0	0	0	1 (1.9)
Respiratory, thoracic and mediastinal disorders	10 (19.2)	5 (9.6)	3 (5.8)	0	0	18 (34.6)
Epistaxis	7 (13.5)	0	0	0	0	7 (13.5)
Dyspnoea	3 (5.8)	1 (1.9)	0	0	0	4 (7.7)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & 200 mg Dose Group (N=52) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Respiratory, thoracic and mediastinal disorders (cont.)						
Pleural effusion	1 (1.9)	1 (1.9)	2 (3.8)	0	0	4 (7.7)
Cough	0	2 (3.8)	0	0	0	2 (3.8)
Haemoptysis	2 (3.8)	0	0	0	0	2 (3.8)
Nasal congestion	1 (1.9)	1 (1.9)	0	0	0	2 (3.8)
Bronchial haemorrhage	0	0	1 (1.9)	0	0	1 (1.9)
Dyspnoea exertional	1 (1.9)	0	0	0	0	1 (1.9)
Haemothorax	0	0	1 (1.9)	0	0	1 (1.9)
Hypoxia	0	0	1 (1.9)	0	0	1 (1.9)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & 200 mg Dose Group (N=52) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Respiratory, thoracic and mediastinal disorders (cont.)						
Oropharyngeal pain	1 (1.9)	0	0	0	0	1 (1.9)
Pneumothorax	0	1 (1.9)	0	0	0	1 (1.9)
Productive cough	1 (1.9)	0	0	0	0	1 (1.9)
Pulmonary congestion	0	1 (1.9)	0	0	0	1 (1.9)
Pulmonary hypertension	0	0	1 (1.9)	0	0	1 (1.9)
Pulmonary oedema	0	1 (1.9)	0	0	0	1 (1.9)
Rales	1 (1.9)	0	0	0	0	1 (1.9)
Respiratory symptom	1 (1.9)	0	0	0	0	1 (1.9)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & 200 mg Dose Group (N=52) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Respiratory, thoracic and mediastinal disorders (cont.)						
Rhonchi	1 (1.9)	0	0	0	0	1 (1.9)
Throat irritation	1 (1.9)	0	0	0	0	1 (1.9)
Upper-airway cough syndrome	1 (1.9)	0	0	0	0	1 (1.9)
Skin and subcutaneous tissue disorders	11 (21.2)	7 (13.5)	0	0	0	18 (34.6)
Hair colour changes	4 (7.7)	0	0	0	0	4 (7.7)
Alopecia	3 (5.8)	0	0	0	0	3 (5.8)
Pruritus	2 (3.8)	1 (1.9)	0	0	0	3 (5.8)
Erythema	2 (3.8)	0	0	0	0	2 (3.8)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & 200 mg Dose Group (N=52) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Skin and subcutaneous tissue disorders (cont.)						
Night sweats	0	2 (3.8)	0	0	0	2 (3.8)
Petechiae	2 (3.8)	0	0	0	0	2 (3.8)
Rash	2 (3.8)	0	0	0	0	2 (3.8)
Swelling face	2 (3.8)	0	0	0	0	2 (3.8)
Blood blister	1 (1.9)	0	0	0	0	1 (1.9)
Dermatitis contact	1 (1.9)	0	0	0	0	1 (1.9)
Ecchymosis	1 (1.9)	0	0	0	0	1 (1.9)
Hyperhidrosis	1 (1.9)	0	0	0	0	1 (1.9)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & 200 mg Dose Group (N=52) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Skin and subcutaneous tissue disorders (cont.)						
Photosensitivity reaction	1 (1.9)	0	0	0	0	1 (1.9)
Psoriasis	0	1 (1.9)	0	0	0	1 (1.9)
Rash maculo-papular	0	1 (1.9)	0	0	0	1 (1.9)
Seborrhoeic dermatitis	1 (1.9)	0	0	0	0	1 (1.9)
Skin haemorrhage	0	1 (1.9)	0	0	0	1 (1.9)
Skin ulcer	0	1 (1.9)	0	0	0	1 (1.9)
Vascular disorders	7 (13.5)	3 (5.8)	2 (3.8)	0	1 (1.9)	13 (25.0)
Flushing	3 (5.8)	0	0	0	0	3 (5.8)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & 200 mg Dose Group (N=52) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Vascular disorders (cont.)						
Hypotension	1 (1.9)	1 (1.9)	1 (1.9)	0	0	3 (5.8)
Hypertension	1 (1.9)	1 (1.9)	0	0	0	2 (3.8)
Epistaxis	1 (1.9)	0	0	0	0	1 (1.9)
Haematoma	0	1 (1.9)	0	0	0	1 (1.9)
Haemorrhage	0	0	1 (1.9)	0	0	1 (1.9)
Hot flush	1 (1.9)	0	0	0	0	1 (1.9)
Pallor	1 (1.9)	0	0	0	0	1 (1.9)
Shock haemorrhagic	0	0	0	0	1 (1.9)	1 (1.9)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & 200 mg Dose Group (N=52) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Vascular disorders (cont.)						
Thrombophlebitis	0	1 (1.9)	0	0	0	1 (1.9)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & <=200 mg Dose Group (N=58) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Patients with at least one Event	7 (12.1)	12 (20.7)	28 (48.3)	8 (13.8)	3 (5.2)	58 (100.0)
Blood and lymphatic system disorders	6 (10.3)	8 (13.8)	19 (32.8)	4 (6.9)	0	37 (63.8)
Thrombocytopenia	4 (6.9)	7 (12.1)	6 (10.3)	2 (3.4)	0	19 (32.8)
Anaemia	1 (1.7)	3 (5.2)	13 (22.4)	0	0	17 (29.3)
Neutropenia	0	1 (1.7)	5 (8.6)	2 (3.4)	0	8 (13.8)
Haemorrhagic diathesis	1 (1.7)	1 (1.7)	0	0	0	2 (3.4)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & <=200 mg Dose Group (N=58) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Blood and lymphatic system disorders (cont.)						
Increased tendency to bruise	2 (3.4)	0	0	0	0	2 (3.4)
Leukocytosis	0	0	2 (3.4)	0	0	2 (3.4)
Anaemia macrocytic	0	0	1 (1.7)	0	0	1 (1.7)
Coagulopathy	1 (1.7)	0	0	0	0	1 (1.7)
Haemolysis	1 (1.7)	0	0	0	0	1 (1.7)
Leukopenia	1 (1.7)	0	0	0	0	1 (1.7)
Lymphadenopathy	1 (1.7)	0	0	0	0	1 (1.7)
Lymphopenia	1 (1.7)	0	0	0	0	1 (1.7)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & <=200 mg Dose Group (N=58) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Blood and lymphatic system disorders (cont.)						
Mast cell activation syndrome	0	1 (1.7)	0	0	0	1 (1.7)
Cardiac disorders	4 (6.9)	0	4 (6.9)	0	0	8 (13.8)
Cardiac failure	0	0	2 (3.4)	0	0	2 (3.4)
Atrial flutter	0	0	1 (1.7)	0	0	1 (1.7)
Bradycardia	1 (1.7)	0	0	0	0	1 (1.7)
Cardiac failure congestive	0	0	1 (1.7)	0	0	1 (1.7)
Palpitations	1 (1.7)	0	0	0	0	1 (1.7)
Pericardial effusion	1 (1.7)	0	0	0	0	1 (1.7)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & <=200 mg Dose Group (N=58) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Cardiac disorders (cont.)						
Supraventricular extrasystoles	1 (1.7)	0	0	0	0	1 (1.7)
Ventricular extrasystoles	1 (1.7)	0	0	0	0	1 (1.7)
Congenital, familial and genetic disorders	0	1 (1.7)	0	0	0	1 (1.7)
Right-to-left cardiac shunt	0	1 (1.7)	0	0	0	1 (1.7)
Ear and labyrinth disorders	2 (3.4)	0	0	0	0	2 (3.4)
Deafness	1 (1.7)	0	0	0	0	1 (1.7)
Vertigo	1 (1.7)	0	0	0	0	1 (1.7)
Eye disorders	24 (41.4)	6 (10.3)	2 (3.4)	1 (1.7)	0	33 (56.9)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & <=200 mg Dose Group (N=58) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Eye disorders (cont.)						
Periorbital oedema	13 (22.4)	3 (5.2)	1 (1.7)	0	0	17 (29.3)
Eyelid oedema	7 (12.1)	0	0	0	0	7 (12.1)
Lacrimation increased	6 (10.3)	0	0	0	0	6 (10.3)
Conjunctival haemorrhage	2 (3.4)	1 (1.7)	0	0	0	3 (5.2)
Eye swelling	2 (3.4)	1 (1.7)	0	0	0	3 (5.2)
Vision blurred	2 (3.4)	0	0	0	0	2 (3.4)
Cataract	0	1 (1.7)	0	0	0	1 (1.7)
Eye haemorrhage	1 (1.7)	0	0	0	0	1 (1.7)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & <=200 mg Dose Group (N=58) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Eye disorders (cont.)						
Eye pruritus	0	1 (1.7)	0	0	0	1 (1.7)
Macular fibrosis	1 (1.7)	0	0	0	0	1 (1.7)
Ocular hyperaemia	1 (1.7)	0	0	0	0	1 (1.7)
Papilloedema	0	1 (1.7)	0	0	0	1 (1.7)
Periorbital haemorrhage	1 (1.7)	0	0	0	0	1 (1.7)
Uveitis	0	0	1 (1.7)	0	0	1 (1.7)
Visual acuity reduced	1 (1.7)	0	0	0	0	1 (1.7)
Vitreous floaters	1 (1.7)	0	0	0	0	1 (1.7)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & <=200 mg Dose Group (N=58) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Eye disorders (cont.)						
Vitreous haemorrhage	0	0	0	1 (1.7)	0	1 (1.7)
Gastrointestinal disorders	24 (41.4)	13 (22.4)	7 (12.1)	1 (1.7)	0	45 (77.6)
Diarrhoea	15 (25.9)	3 (5.2)	1 (1.7)	0	0	19 (32.8)
Nausea	13 (22.4)	0	1 (1.7)	0	0	14 (24.1)
Vomiting	9 (15.5)	3 (5.2)	1 (1.7)	0	0	13 (22.4)
Abdominal pain	5 (8.6)	2 (3.4)	1 (1.7)	0	0	8 (13.8)
Constipation	6 (10.3)	1 (1.7)	0	0	0	7 (12.1)
Ascites	2 (3.4)	2 (3.4)	0	0	0	4 (6.9)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & <=200 mg Dose Group (N=58) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Gastrointestinal disorders (cont.)						
Dyspepsia	3 (5.2)	1 (1.7)	0	0	0	4 (6.9)
Abdominal distension	3 (5.2)	0	0	0	0	3 (5.2)
Abdominal pain upper	1 (1.7)	1 (1.7)	0	0	0	2 (3.4)
Gastrooesophageal reflux disease	0	2 (3.4)	0	0	0	2 (3.4)
Melaena	0	1 (1.7)	1 (1.7)	0	0	2 (3.4)
Salivary hypersecretion	2 (3.4)	0	0	0	0	2 (3.4)
Abdominal discomfort	1 (1.7)	0	0	0	0	1 (1.7)
Anorectal discomfort	1 (1.7)	0	0	0	0	1 (1.7)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & <=200 mg Dose Group (N=58) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Gastrointestinal disorders (cont.)						
Colitis	0	0	1 (1.7)	0	0	1 (1.7)
Dental caries	1 (1.7)	0	0	0	0	1 (1.7)
Dry mouth	1 (1.7)	0	0	0	0	1 (1.7)
Duodenal ulcer haemorrhage	0	0	1 (1.7)	0	0	1 (1.7)
Faeces discoloured	1 (1.7)	0	0	0	0	1 (1.7)
Flatulence	1 (1.7)	0	0	0	0	1 (1.7)
Gastritis	0	1 (1.7)	0	0	0	1 (1.7)
Gastrointestinal haemorrhage	0	0	1 (1.7)	0	0	1 (1.7)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & <=200 mg Dose Group (N=58) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Gastrointestinal disorders (cont.)						
Gingival bleeding	1 (1.7)	0	0	0	0	1 (1.7)
Gingival pain	1 (1.7)	0	0	0	0	1 (1.7)
Gingival swelling	1 (1.7)	0	0	0	0	1 (1.7)
Incarcerated umbilical hernia	0	0	0	1 (1.7)	0	1 (1.7)
Inguinal hernia	1 (1.7)	0	0	0	0	1 (1.7)
Intra-abdominal haematoma	0	1 (1.7)	0	0	0	1 (1.7)
Intra-abdominal haemorrhage	0	0	1 (1.7)	0	0	1 (1.7)
Large intestine perforation	0	0	1 (1.7)	0	0	1 (1.7)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & <=200 mg Dose Group (N=58) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Gastrointestinal disorders (cont.)						
Large intestine polyp	1 (1.7)	0	0	0	0	1 (1.7)
Lip dry	1 (1.7)	0	0	0	0	1 (1.7)
Lower gastrointestinal haemorrhage	0	0	1 (1.7)	0	0	1 (1.7)
Mouth ulceration	1 (1.7)	0	0	0	0	1 (1.7)
Oral disorder	1 (1.7)	0	0	0	0	1 (1.7)
Periodontal disease	1 (1.7)	0	0	0	0	1 (1.7)
Portal hypertensive gastropathy	1 (1.7)	0	0	0	0	1 (1.7)
Rectal haemorrhage	1 (1.7)	0	0	0	0	1 (1.7)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & <=200 mg Dose Group (N=58) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Gastrointestinal disorders (cont.)						
Small intestinal obstruction	1 (1.7)	0	0	0	0	1 (1.7)
Tooth deposit	1 (1.7)	0	0	0	0	1 (1.7)
Toothache	1 (1.7)	0	0	0	0	1 (1.7)
General disorders and administration site conditions	22 (37.9)	15 (25.9)	2 (3.4)	0	1 (1.7)	40 (69.0)
Oedema peripheral	23 (39.7)	7 (12.1)	0	0	0	30 (51.7)
Face oedema	6 (10.3)	2 (3.4)	0	0	0	8 (13.8)
Fatigue	3 (5.2)	3 (5.2)	2 (3.4)	0	0	8 (13.8)
Asthenia	3 (5.2)	2 (3.4)	0	0	0	5 (8.6)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & <=200 mg Dose Group (N=58) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
General disorders and administration site conditions (cont.)						
Pain	3 (5.2)	1 (1.7)	0	0	0	4 (6.9)
Pyrexia	3 (5.2)	1 (1.7)	0	0	0	4 (6.9)
Peripheral swelling	3 (5.2)	0	0	0	0	3 (5.2)
Feeling abnormal	2 (3.4)	0	0	0	0	2 (3.4)
Generalised oedema	1 (1.7)	1 (1.7)	0	0	0	2 (3.4)
Non-cardiac chest pain	2 (3.4)	0	0	0	0	2 (3.4)
Oedema	2 (3.4)	0	0	0	0	2 (3.4)
Decreased activity	0	1 (1.7)	0	0	0	1 (1.7)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

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General disorders and administration site conditions (cont.)						
Disease progression	0	0	0	0	1 (1.7)	1 (1.7)
Gait disturbance	1 (1.7)	0	0	0	0	1 (1.7)
Influenza like illness	0	1 (1.7)	0	0	0	1 (1.7)
Malaise	1 (1.7)	0	0	0	0	1 (1.7)
Systemic inflammatory response syndrome	0	1 (1.7)	0	0	0	1 (1.7)
Temperature intolerance	1 (1.7)	0	0	0	0	1 (1.7)
Hepatobiliary disorders	2 (3.4)	0	0	0	0	2 (3.4)
Cholelithiasis	1 (1.7)	0	0	0	0	1 (1.7)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

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Hepatobiliary disorders (cont.)						
Hyperbilirubinaemia	1 (1.7)	0	0	0	0	1 (1.7)
Immune system disorders	1 (1.7)	0	1 (1.7)	0	0	2 (3.4)
Drug hypersensitivity	1 (1.7)	0	0	0	0	1 (1.7)
Hypogammaglobulinaemia	0	1 (1.7)	0	0	0	1 (1.7)
Immune system disorder	0	0	1 (1.7)	0	0	1 (1.7)
Infections and infestations	7 (12.1)	15 (25.9)	8 (13.8)	0	1 (1.7)	31 (53.4)
Upper respiratory tract infection	3 (5.2)	2 (3.4)	1 (1.7)	0	0	6 (10.3)
Herpes zoster	2 (3.4)	2 (3.4)	1 (1.7)	0	0	5 (8.6)

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AdvSM Population & Prior Neoplastic Therapy = Yes

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Infections and infestations (cont.)						
Sinusitis	1 (1.7)	2 (3.4)	0	0	0	3 (5.2)
Urinary tract infection	1 (1.7)	2 (3.4)	0	0	0	3 (5.2)
Cellulitis	0	2 (3.4)	0	0	0	2 (3.4)
Diverticulitis	0	1 (1.7)	1 (1.7)	0	0	2 (3.4)
Oral candidiasis	0	2 (3.4)	0	0	0	2 (3.4)
Appendiceal abscess	0	0	1 (1.7)	0	0	1 (1.7)
Catheter site cellulitis	0	1 (1.7)	0	0	0	1 (1.7)
Clostridium difficile colitis	1 (1.7)	0	0	0	0	1 (1.7)

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AdvSM Population & Prior Neoplastic Therapy = Yes

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Infections and infestations (cont.)						
Corona virus infection	0	0	1 (1.7)	0	0	1 (1.7)
Cystitis	0	1 (1.7)	0	0	0	1 (1.7)
Gastroenteritis	0	1 (1.7)	0	0	0	1 (1.7)
Gastrointestinal fungal infection	0	1 (1.7)	0	0	0	1 (1.7)
Herpes simplex	1 (1.7)	0	0	0	0	1 (1.7)
Influenza	1 (1.7)	0	0	0	0	1 (1.7)
Localised infection	0	0	1 (1.7)	0	0	1 (1.7)
Necrotising fasciitis	0	0	0	0	1 (1.7)	1 (1.7)

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AdvSM Population & Prior Neoplastic Therapy = Yes

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Infections and infestations (cont.)						
Oral herpes	1 (1.7)	0	0	0	0	1 (1.7)
Oropharyngeal candidiasis	0	1 (1.7)	0	0	0	1 (1.7)
Otitis externa	0	1 (1.7)	0	0	0	1 (1.7)
Otitis media	1 (1.7)	0	0	0	0	1 (1.7)
Paronychia	0	1 (1.7)	0	0	0	1 (1.7)
Pneumonia	0	1 (1.7)	0	0	0	1 (1.7)
Respiratory tract infection	0	1 (1.7)	0	0	0	1 (1.7)
Sepsis	0	0	1 (1.7)	0	0	1 (1.7)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & <=200 mg Dose Group (N=58) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Infections and infestations (cont.)						
Skin infection	0	0	1 (1.7)	0	0	1 (1.7)
Stoma site cellulitis	0	1 (1.7)	0	0	0	1 (1.7)
Urinary tract infection staphylococcal	0	1 (1.7)	0	0	0	1 (1.7)
Viral upper respiratory tract infection	1 (1.7)	0	0	0	0	1 (1.7)
Wound infection	0	1 (1.7)	0	0	0	1 (1.7)
Injury, poisoning and procedural complications	10 (17.2)	5 (8.6)	1 (1.7)	1 (1.7)	0	17 (29.3)
Contusion	2 (3.4)	1 (1.7)	0	0	0	3 (5.2)
Fall	2 (3.4)	1 (1.7)	0	0	0	3 (5.2)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
Note 1: In each treatment group, if a patient experiences more than 1 event within a given System Organ Class or Preferred term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & <=200 mg Dose Group (N=58) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Injury, poisoning and procedural complications (cont.)						
Procedural pain	3 (5.2)	0	0	0	0	3 (5.2)
Laceration	2 (3.4)	0	0	0	0	2 (3.4)
Post procedural haemorrhage	2 (3.4)	0	0	0	0	2 (3.4)
Subdural haematoma	1 (1.7)	0	0	1 (1.7)	0	2 (3.4)
Anaemia postoperative	0	0	1 (1.7)	0	0	1 (1.7)
Electrical burn	0	1 (1.7)	0	0	0	1 (1.7)
Fractured sacrum	0	1 (1.7)	0	0	0	1 (1.7)
Joint injury	1 (1.7)	0	0	0	0	1 (1.7)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
Note 1: In each treatment group, if a patient experiences more than 1 event within a given System Organ Class or Preferred term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & <=200 mg Dose Group (N=58) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Injury, poisoning and procedural complications (cont.)						
Lumbar vertebral fracture	0	1 (1.7)	0	0	0	1 (1.7)
Skin abrasion	1 (1.7)	0	0	0	0	1 (1.7)
Skin wound	1 (1.7)	0	0	0	0	1 (1.7)
Spinal compression fracture	1 (1.7)	0	0	0	0	1 (1.7)
Tendon rupture	0	1 (1.7)	0	0	0	1 (1.7)
Traumatic haematoma	1 (1.7)	0	0	0	0	1 (1.7)
Investigations	9 (15.5)	4 (6.9)	11 (19.0)	3 (5.2)	0	27 (46.6)
Platelet count decreased	0	2 (3.4)	4 (6.9)	2 (3.4)	0	8 (13.8)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
Note 1: In each treatment group, if a patient experiences more than 1 event within a given System Organ Class or Preferred term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & <=200 mg Dose Group (N=58) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Investigations (cont.)						
Blood bilirubin increased	3 (5.2)	4 (6.9)	0	0	0	7 (12.1)
Blood creatinine increased	6 (10.3)	1 (1.7)	0	0	0	7 (12.1)
Weight increased	3 (5.2)	2 (3.4)	1 (1.7)	0	0	6 (10.3)
White blood cell count decreased	0	0	4 (6.9)	1 (1.7)	0	5 (8.6)
Blood alkaline phosphatase increased	0	0	3 (5.2)	0	0	3 (5.2)
Cardiac murmur	3 (5.2)	0	0	0	0	3 (5.2)
Gamma-glutamyltransferase increased	1 (1.7)	1 (1.7)	1 (1.7)	0	0	3 (5.2)
Neutrophil count decreased	0	0	2 (3.4)	1 (1.7)	0	3 (5.2)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
Note 1: In each treatment group, if a patient experiences more than 1 event within a given System Organ Class or Preferred term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & <=200 mg Dose Group (N=58) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Investigations (cont.)						
Blood uric acid increased	2 (3.4)	0	0	0	0	2 (3.4)
Urine uric acid increased	2 (3.4)	0	0	0	0	2 (3.4)
Alanine aminotransferase decreased	0	1 (1.7)	0	0	0	1 (1.7)
Alanine aminotransferase increased	0	1 (1.7)	0	0	0	1 (1.7)
Aspartate aminotransferase increased	1 (1.7)	0	0	0	0	1 (1.7)
Blood albumin decreased	1 (1.7)	0	0	0	0	1 (1.7)
Blood bilirubin unconjugated increased	0	0	1 (1.7)	0	0	1 (1.7)
Blood phosphorus decreased	0	1 (1.7)	0	0	0	1 (1.7)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & <=200 mg Dose Group (N=58) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Investigations (cont.)						
Blood thyroid stimulating hormone increased	1 (1.7)	0	0	0	0	1 (1.7)
C-reactive protein increased	0	1 (1.7)	0	0	0	1 (1.7)
Electrocardiogram QT prolonged	1 (1.7)	0	0	0	0	1 (1.7)
Haemoglobin decreased	0	1 (1.7)	0	0	0	1 (1.7)
Lipase increased	0	1 (1.7)	0	0	0	1 (1.7)
Lymphocyte count decreased	0	1 (1.7)	0	0	0	1 (1.7)
Monocyte count increased	0	1 (1.7)	0	0	0	1 (1.7)
Prothrombin time shortened	1 (1.7)	0	0	0	0	1 (1.7)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
Note 1: In each treatment group, if a patient experiences more than 1 event within a given System Organ Class or Preferred term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & <=200 mg Dose Group (N=58) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Investigations (cont.)						
Red blood cell count decreased	1 (1.7)	0	0	0	0	1 (1.7)
Reticulocyte count increased	1 (1.7)	0	0	0	0	1 (1.7)
White blood cell count increased	1 (1.7)	0	0	0	0	1 (1.7)
Metabolism and nutrition disorders	12 (20.7)	8 (13.8)	2 (3.4)	0	0	22 (37.9)
Decreased appetite	5 (8.6)	1 (1.7)	0	0	0	6 (10.3)
Hypokalaemia	4 (6.9)	1 (1.7)	0	0	0	5 (8.6)
Hypomagnesaemia	3 (5.2)	0	0	0	0	3 (5.2)
Hypophosphataemia	2 (3.4)	1 (1.7)	0	0	0	3 (5.2)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & <=200 mg Dose Group (N=58) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Metabolism and nutrition disorders (cont.)						
Dehydration	0	2 (3.4)	0	0	0	2 (3.4)
Hypocalcaemia	0	2 (3.4)	0	0	0	2 (3.4)
Cachexia	0	1 (1.7)	0	0	0	1 (1.7)
Fluid retention	1 (1.7)	0	0	0	0	1 (1.7)
Gout	0	1 (1.7)	0	0	0	1 (1.7)
Hyperglycaemia	0	0	1 (1.7)	0	0	1 (1.7)
Hyperphosphataemia	0	1 (1.7)	0	0	0	1 (1.7)
Hyperuricaemia	1 (1.7)	0	0	0	0	1 (1.7)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & <=200 mg Dose Group (N=58) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Metabolism and nutrition disorders (cont.)						
Increased appetite	1 (1.7)	0	0	0	0	1 (1.7)
Tumour lysis syndrome	0	0	1 (1.7)	0	0	1 (1.7)
Vitamin D deficiency	0	1 (1.7)	0	0	0	1 (1.7)
Musculoskeletal and connective tissue disorders	9 (15.5)	7 (12.1)	3 (5.2)	0	0	19 (32.8)
Arthralgia	2 (3.4)	3 (5.2)	2 (3.4)	0	0	7 (12.1)
Back pain	3 (5.2)	0	1 (1.7)	0	0	4 (6.9)
Muscular weakness	1 (1.7)	2 (3.4)	1 (1.7)	0	0	4 (6.9)
Pain in extremity	3 (5.2)	1 (1.7)	0	0	0	4 (6.9)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & <=200 mg Dose Group (N=58) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Musculoskeletal and connective tissue disorders (cont.)						
Myalgia	3 (5.2)	0	0	0	0	3 (5.2)
Musculoskeletal pain	1 (1.7)	1 (1.7)	0	0	0	2 (3.4)
Bone pain	0	1 (1.7)	0	0	0	1 (1.7)
Intervertebral disc protrusion	0	1 (1.7)	0	0	0	1 (1.7)
Joint swelling	1 (1.7)	0	0	0	0	1 (1.7)
Muscle spasms	0	1 (1.7)	0	0	0	1 (1.7)
Musculoskeletal chest pain	1 (1.7)	0	0	0	0	1 (1.7)
Neck pain	1 (1.7)	0	0	0	0	1 (1.7)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & <=200 mg Dose Group (N=58) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Musculoskeletal and connective tissue disorders (cont.)						
Osteonecrosis of jaw	0	1 (1.7)	0	0	0	1 (1.7)
Osteoporosis	0	1 (1.7)	0	0	0	1 (1.7)
Pain in jaw	1 (1.7)	0	0	0	0	1 (1.7)
Spinal column stenosis	0	1 (1.7)	0	0	0	1 (1.7)
Tenosynovitis	1 (1.7)	0	0	0	0	1 (1.7)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (3.4)	2 (3.4)	5 (8.6)	0	0	9 (15.5)
Acute myeloid leukaemia	0	0	1 (1.7)	0	0	1 (1.7)
Basal cell carcinoma	0	0	1 (1.7)	0	0	1 (1.7)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & <=200 mg Dose Group (N=58) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont.)						
Benign gastrointestinal neoplasm	0	0	1 (1.7)	0	0	1 (1.7)
Haemangioma	1 (1.7)	0	0	0	0	1 (1.7)
Intraductal proliferative breast lesion	0	0	1 (1.7)	0	0	1 (1.7)
Keratoacanthoma	1 (1.7)	0	0	0	0	1 (1.7)
Malignant melanoma	0	0	1 (1.7)	0	0	1 (1.7)
Myelodysplastic syndrome	0	0	1 (1.7)	0	0	1 (1.7)
Penile wart	0	1 (1.7)	0	0	0	1 (1.7)
Salivary gland neoplasm	1 (1.7)	0	0	0	0	1 (1.7)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & <=200 mg Dose Group (N=58) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont.)						
Squamous cell carcinoma	0	1 (1.7)	0	0	0	1 (1.7)
Squamous cell carcinoma of skin	0	1 (1.7)	0	0	0	1 (1.7)
Nervous system disorders	18 (31.0)	7 (12.1)	1 (1.7)	0	0	26 (44.8)
Headache	8 (13.8)	2 (3.4)	0	0	0	10 (17.2)
Dysgeusia	8 (13.8)	1 (1.7)	0	0	0	9 (15.5)
Dizziness	5 (8.6)	2 (3.4)	0	0	0	7 (12.1)
Cognitive disorder	2 (3.4)	1 (1.7)	0	0	0	3 (5.2)
Memory impairment	3 (5.2)	0	0	0	0	3 (5.2)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & <=200 mg Dose Group (N=58) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Nervous system disorders (cont.)						
Dizziness postural	2 (3.4)	0	0	0	0	2 (3.4)
Restless legs syndrome	1 (1.7)	1 (1.7)	0	0	0	2 (3.4)
Aphasia	1 (1.7)	0	0	0	0	1 (1.7)
Balance disorder	1 (1.7)	0	0	0	0	1 (1.7)
Dysarthria	1 (1.7)	0	0	0	0	1 (1.7)
Hypoaesthesia	1 (1.7)	0	0	0	0	1 (1.7)
Hypogeusia	1 (1.7)	0	0	0	0	1 (1.7)
Myoclonus	0	0	1 (1.7)	0	0	1 (1.7)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & <=200 mg Dose Group (N=58) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Nervous system disorders (cont.)						
Paraesthesia	1 (1.7)	0	0	0	0	1 (1.7)
Parkinson's disease	1 (1.7)	0	0	0	0	1 (1.7)
Sensory disturbance	1 (1.7)	0	0	0	0	1 (1.7)
Transient ischaemic attack	1 (1.7)	0	0	0	0	1 (1.7)
Tremor	1 (1.7)	0	0	0	0	1 (1.7)
Psychiatric disorders	9 (15.5)	4 (6.9)	1 (1.7)	0	0	14 (24.1)
Insomnia	3 (5.2)	2 (3.4)	0	0	0	5 (8.6)
Depressed mood	2 (3.4)	0	0	0	0	2 (3.4)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
Note 1: In each treatment group, if a patient experiences more than 1 event within a given System Organ Class or Preferred term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column and treatment group.
Note 3: System Organ Classes are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'Any Grade' column.
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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & <=200 mg Dose Group (N=58) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Psychiatric disorders (cont.)						
Sleep disorder	2 (3.4)	0	0	0	0	2 (3.4)
Adjustment disorder with depressed mood	0	1 (1.7)	0	0	0	1 (1.7)
Confusional state	1 (1.7)	0	0	0	0	1 (1.7)
Delirium	0	0	1 (1.7)	0	0	1 (1.7)
Depression	0	1 (1.7)	0	0	0	1 (1.7)
Disorientation	1 (1.7)	0	0	0	0	1 (1.7)
Irritability	1 (1.7)	0	0	0	0	1 (1.7)
Libido decreased	1 (1.7)	0	0	0	0	1 (1.7)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
Note 1: In each treatment group, if a patient experiences more than 1 event within a given System Organ Class or Preferred term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & <=200 mg Dose Group (N=58) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Psychiatric disorders (cont.)						
Mental disorder	1 (1.7)	0	0	0	0	1 (1.7)
Renal and urinary disorders	4 (6.9)	2 (3.4)	2 (3.4)	0	0	8 (13.8)
Acute kidney injury	2 (3.4)	0	1 (1.7)	0	0	3 (5.2)
Dysuria	2 (3.4)	0	0	0	0	2 (3.4)
Haematuria	2 (3.4)	0	0	0	0	2 (3.4)
Nephrolithiasis	1 (1.7)	0	1 (1.7)	0	0	2 (3.4)
Chronic kidney disease	0	1 (1.7)	0	0	0	1 (1.7)
Hypertonic bladder	0	1 (1.7)	0	0	0	1 (1.7)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
Note 1: In each treatment group, if a patient experiences more than 1 event within a given System Organ Class or Preferred term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & <=200 mg Dose Group (N=58) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Renal and urinary disorders (cont.)						
Obstructive uropathy	0	0	1 (1.7)	0	0	1 (1.7)
Pollakiuria	1 (1.7)	0	0	0	0	1 (1.7)
Urinary incontinence	0	1 (1.7)	0	0	0	1 (1.7)
Urinary retention	0	1 (1.7)	0	0	0	1 (1.7)
Reproductive system and breast disorders	1 (1.7)	3 (5.2)	0	0	0	4 (6.9)
Scrotal oedema	0	2 (3.4)	0	0	0	2 (3.4)
Oedema genital	0	1 (1.7)	0	0	0	1 (1.7)
Penile pain	1 (1.7)	0	0	0	0	1 (1.7)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
Note 1: In each treatment group, if a patient experiences more than 1 event within a given System Organ Class or Preferred term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & <=200 mg Dose Group (N=58) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Respiratory, thoracic and mediastinal disorders	12 (20.7)	6 (10.3)	3 (5.2)	0	0	21 (36.2)
Epistaxis	7 (12.1)	0	0	0	0	7 (12.1)
Dyspnoea	3 (5.2)	2 (3.4)	0	0	0	5 (8.6)
Cough	2 (3.4)	2 (3.4)	0	0	0	4 (6.9)
Pleural effusion	1 (1.7)	1 (1.7)	2 (3.4)	0	0	4 (6.9)
Haemoptysis	2 (3.4)	0	0	0	0	2 (3.4)
Nasal congestion	1 (1.7)	1 (1.7)	0	0	0	2 (3.4)
Pulmonary congestion	1 (1.7)	1 (1.7)	0	0	0	2 (3.4)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
Note 1: In each treatment group, if a patient experiences more than 1 event within a given System Organ Class or Preferred term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & <=200 mg Dose Group (N=58) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Respiratory, thoracic and mediastinal disorders (cont.)						
Bronchial haemorrhage	0	0	1 (1.7)	0	0	1 (1.7)
Dyspnoea exertional	1 (1.7)	0	0	0	0	1 (1.7)
Haemothorax	0	0	1 (1.7)	0	0	1 (1.7)
Hypoxia	0	0	1 (1.7)	0	0	1 (1.7)
Oropharyngeal pain	1 (1.7)	0	0	0	0	1 (1.7)
Pneumothorax	0	1 (1.7)	0	0	0	1 (1.7)
Productive cough	1 (1.7)	0	0	0	0	1 (1.7)
Pulmonary hypertension	0	0	1 (1.7)	0	0	1 (1.7)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
Note 1: In each treatment group, if a patient experiences more than 1 event within a given System Organ Class or Preferred term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & <=200 mg Dose Group (N=58) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Respiratory, thoracic and mediastinal disorders (cont.)						
Pulmonary oedema	0	1 (1.7)	0	0	0	1 (1.7)
Rales	1 (1.7)	0	0	0	0	1 (1.7)
Respiratory symptom	1 (1.7)	0	0	0	0	1 (1.7)
Rhonchi	1 (1.7)	0	0	0	0	1 (1.7)
Throat irritation	1 (1.7)	0	0	0	0	1 (1.7)
Upper-airway cough syndrome	1 (1.7)	0	0	0	0	1 (1.7)
Skin and subcutaneous tissue disorders	13 (22.4)	8 (13.8)	0	0	0	21 (36.2)
Hair colour changes	5 (8.6)	0	0	0	0	5 (8.6)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
Note 1: In each treatment group, if a patient experiences more than 1 event within a given System Organ Class or Preferred term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & <=200 mg Dose Group (N=58) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Skin and subcutaneous tissue disorders (cont.)						
Pruritus	3 (5.2)	1 (1.7)	0	0	0	4 (6.9)
Rash	3 (5.2)	1 (1.7)	0	0	0	4 (6.9)
Alopecia	3 (5.2)	0	0	0	0	3 (5.2)
Night sweats	1 (1.7)	2 (3.4)	0	0	0	3 (5.2)
Erythema	2 (3.4)	0	0	0	0	2 (3.4)
Petechiae	2 (3.4)	0	0	0	0	2 (3.4)
Photosensitivity reaction	2 (3.4)	0	0	0	0	2 (3.4)
Swelling face	2 (3.4)	0	0	0	0	2 (3.4)

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Note 1: In each treatment group, if a patient experiences more than 1 event within a given System Organ Class or Preferred term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & <=200 mg Dose Group (N=58) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Skin and subcutaneous tissue disorders (cont.)						
Blood blister	1 (1.7)	0	0	0	0	1 (1.7)
Dermatitis contact	1 (1.7)	0	0	0	0	1 (1.7)
Ecchymosis	1 (1.7)	0	0	0	0	1 (1.7)
Hyperhidrosis	1 (1.7)	0	0	0	0	1 (1.7)
Nail bed disorder	1 (1.7)	0	0	0	0	1 (1.7)
Psoriasis	0	1 (1.7)	0	0	0	1 (1.7)
Rash maculo-papular	0	1 (1.7)	0	0	0	1 (1.7)
Seborrhoeic dermatitis	1 (1.7)	0	0	0	0	1 (1.7)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & <=200 mg Dose Group (N=58) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Skin and subcutaneous tissue disorders (cont.)						
Skin depigmentation	1 (1.7)	0	0	0	0	1 (1.7)
Skin discolouration	1 (1.7)	0	0	0	0	1 (1.7)
Skin haemorrhage	0	1 (1.7)	0	0	0	1 (1.7)
Skin ulcer	0	1 (1.7)	0	0	0	1 (1.7)
Telangiectasia	1 (1.7)	0	0	0	0	1 (1.7)
Vascular disorders	7 (12.1)	3 (5.2)	2 (3.4)	0	1 (1.7)	13 (22.4)
Flushing	3 (5.2)	0	0	0	0	3 (5.2)
Hypotension	1 (1.7)	1 (1.7)	1 (1.7)	0	0	3 (5.2)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & <=200 mg Dose Group (N=58) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Vascular disorders (cont.)						
Hypertension	1 (1.7)	1 (1.7)	0	0	0	2 (3.4)
Epistaxis	1 (1.7)	0	0	0	0	1 (1.7)
Haematoma	0	1 (1.7)	0	0	0	1 (1.7)
Haemorrhage	0	0	1 (1.7)	0	0	1 (1.7)
Hot flush	1 (1.7)	0	0	0	0	1 (1.7)
Pallor	1 (1.7)	0	0	0	0	1 (1.7)
Shock haemorrhagic	0	0	0	0	1 (1.7)	1 (1.7)
Thrombophlebitis	0	1 (1.7)	0	0	0	1 (1.7)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & All Dose Group (N=83) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Patients with at least one Event	7 (8.4)	13 (15.7)	42 (50.6)	16 (19.3)	5 (6.0)	83 (100.0)
Blood and lymphatic system disorders	7 (8.4)	12 (14.5)	30 (36.1)	10 (12.0)	0	59 (71.1)
Anaemia	1 (1.2)	8 (9.6)	21 (25.3)	1 (1.2)	0	31 (37.3)
Thrombocytopenia	5 (6.0)	9 (10.8)	10 (12.0)	5 (6.0)	0	29 (34.9)
Neutropenia	0	1 (1.2)	8 (9.6)	3 (3.6)	0	12 (14.5)
Leukocytosis	0	1 (1.2)	3 (3.6)	0	0	4 (4.8)
Haemolysis	1 (1.2)	0	1 (1.2)	0	0	2 (2.4)
Haemorrhagic diathesis	1 (1.2)	1 (1.2)	0	0	0	2 (2.4)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & All Dose Group (N=83) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Blood and lymphatic system disorders (cont.)						
Increased tendency to bruise	2 (2.4)	0	0	0	0	2 (2.4)
Leukopenia	2 (2.4)	0	0	0	0	2 (2.4)
Lymphadenopathy	2 (2.4)	0	0	0	0	2 (2.4)
Lymphopenia	1 (1.2)	0	0	1 (1.2)	0	2 (2.4)
Mast cell activation syndrome	0	2 (2.4)	0	0	0	2 (2.4)
Anaemia macrocytic	0	0	1 (1.2)	0	0	1 (1.2)
Autoimmune haemolytic anaemia	0	0	1 (1.2)	0	0	1 (1.2)
Coagulopathy	1 (1.2)	0	0	0	0	1 (1.2)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & All Dose Group (N=83) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Blood and lymphatic system disorders (cont.)						
Pancytopenia	0	0	1 (1.2)	0	0	1 (1.2)
Splenic lesion	1 (1.2)	0	0	0	0	1 (1.2)
Splenomegaly	1 (1.2)	0	0	0	0	1 (1.2)
Cardiac disorders	7 (8.4)	0	5 (6.0)	0	0	12 (14.5)
Cardiac failure	0	0	2 (2.4)	0	0	2 (2.4)
Palpitations	2 (2.4)	0	0	0	0	2 (2.4)
Acute myocardial infarction	0	0	1 (1.2)	0	0	1 (1.2)
Angina pectoris	1 (1.2)	0	0	0	0	1 (1.2)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & All Dose Group (N=83) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Cardiac disorders (cont.)						
Atrial flutter	0	0	1 (1.2)	0	0	1 (1.2)
Bradycardia	1 (1.2)	0	0	0	0	1 (1.2)
Cardiac failure congestive	0	0	1 (1.2)	0	0	1 (1.2)
Cyanosis	1 (1.2)	0	0	0	0	1 (1.2)
Pericardial effusion	1 (1.2)	0	0	0	0	1 (1.2)
Sinus tachycardia	1 (1.2)	0	0	0	0	1 (1.2)
Supraventricular extrasystoles	1 (1.2)	0	0	0	0	1 (1.2)
Ventricular extrasystoles	1 (1.2)	0	0	0	0	1 (1.2)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & All Dose Group (N=83) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Congenital, familial and genetic disorders	0	1 (1.2)	0	0	0	1 (1.2)
Right-to-left cardiac shunt	0	1 (1.2)	0	0	0	1 (1.2)
Ear and labyrinth disorders	4 (4.8)	2 (2.4)	1 (1.2)	0	0	7 (8.4)
Vertigo	2 (2.4)	1 (1.2)	0	0	0	3 (3.6)
Cerumen impaction	0	1 (1.2)	0	0	0	1 (1.2)
Deafness	1 (1.2)	0	0	0	0	1 (1.2)
Deafness neurosensory	0	0	1 (1.2)	0	0	1 (1.2)
Ear discomfort	1 (1.2)	0	0	0	0	1 (1.2)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & All Dose Group (N=83) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Ear and labyrinth disorders (cont.)						
Ear pain	1 (1.2)	0	0	0	0	1 (1.2)
Hypoacusis	1 (1.2)	0	0	0	0	1 (1.2)
Tinnitus	0	1 (1.2)	0	0	0	1 (1.2)
Endocrine disorders	0	0	1 (1.2)	0	0	1 (1.2)
Inappropriate antidiuretic hormone secretion	0	0	1 (1.2)	0	0	1 (1.2)
Eye disorders	39 (47.0)	12 (14.5)	2 (2.4)	1 (1.2)	0	54 (65.1)
Periorbital oedema	30 (36.1)	6 (7.2)	1 (1.2)	0	0	37 (44.6)
Lacrimation increased	11 (13.3)	0	0	0	0	11 (13.3)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & All Dose Group (N=83) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Eye disorders (cont.)						
Eyelid oedema	7 (8.4)	0	0	0	0	7 (8.4)
Vision blurred	4 (4.8)	1 (1.2)	0	0	0	5 (6.0)
Conjunctival haemorrhage	3 (3.6)	1 (1.2)	0	0	0	4 (4.8)
Eye swelling	2 (2.4)	1 (1.2)	0	0	0	3 (3.6)
Eye haemorrhage	2 (2.4)	0	0	0	0	2 (2.4)
Photophobia	2 (2.4)	0	0	0	0	2 (2.4)
Visual acuity reduced	2 (2.4)	0	0	0	0	2 (2.4)
Blepharitis	1 (1.2)	0	0	0	0	1 (1.2)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & All Dose Group (N=83) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Eye disorders (cont.)						
Cataract	0	1 (1.2)	0	0	0	1 (1.2)
Cataract nuclear	0	1 (1.2)	0	0	0	1 (1.2)
Conjunctival oedema	1 (1.2)	0	0	0	0	1 (1.2)
Eye inflammation	0	1 (1.2)	0	0	0	1 (1.2)
Eye pruritus	0	1 (1.2)	0	0	0	1 (1.2)
Macular fibrosis	1 (1.2)	0	0	0	0	1 (1.2)
Ocular hyperaemia	1 (1.2)	0	0	0	0	1 (1.2)
Papilloedema	0	1 (1.2)	0	0	0	1 (1.2)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & All Dose Group (N=83) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Eye disorders (cont.)						
Periorbital haemorrhage	1 (1.2)	0	0	0	0	1 (1.2)
Retinal tear	0	1 (1.2)	0	0	0	1 (1.2)
Scleral haemorrhage	1 (1.2)	0	0	0	0	1 (1.2)
Trichiasis	1 (1.2)	0	0	0	0	1 (1.2)
Uveitis	0	0	1 (1.2)	0	0	1 (1.2)
Vitreous floaters	1 (1.2)	0	0	0	0	1 (1.2)
Vitreous haemorrhage	0	0	0	1 (1.2)	0	1 (1.2)
Gastrointestinal disorders	32 (38.6)	23 (27.7)	12 (14.5)	3 (3.6)	0	70 (84.3)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & All Dose Group (N=83) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Gastrointestinal disorders (cont.)						
Diarrhoea	22 (26.5)	4 (4.8)	1 (1.2)	0	0	27 (32.5)
Nausea	17 (20.5)	5 (6.0)	1 (1.2)	1 (1.2)	0	24 (28.9)
Vomiting	16 (19.3)	5 (6.0)	1 (1.2)	1 (1.2)	0	23 (27.7)
Constipation	10 (12.0)	3 (3.6)	0	0	0	13 (15.7)
Abdominal pain	8 (9.6)	3 (3.6)	1 (1.2)	0	0	12 (14.5)
Ascites	3 (3.6)	3 (3.6)	1 (1.2)	1 (1.2)	0	8 (9.6)
Abdominal distension	7 (8.4)	0	0	0	0	7 (8.4)
Dyspepsia	3 (3.6)	4 (4.8)	0	0	0	7 (8.4)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & All Dose Group (N=83) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Gastrointestinal disorders (cont.)						
Dry mouth	5 (6.0)	1 (1.2)	0	0	0	6 (7.2)
Abdominal pain upper	3 (3.6)	2 (2.4)	0	0	0	5 (6.0)
Gastrooesophageal reflux disease	0	5 (6.0)	0	0	0	5 (6.0)
Abdominal discomfort	4 (4.8)	0	0	0	0	4 (4.8)
Gastrointestinal haemorrhage	0	1 (1.2)	2 (2.4)	0	0	3 (3.6)
Melaena	1 (1.2)	1 (1.2)	1 (1.2)	0	0	3 (3.6)
Gastric haemorrhage	0	0	2 (2.4)	0	0	2 (2.4)
Gingival pain	2 (2.4)	0	0	0	0	2 (2.4)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & All Dose Group (N=83) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Gastrointestinal disorders (cont.)						
Haematochezia	2 (2.4)	0	0	0	0	2 (2.4)
Haemorrhoidal haemorrhage	1 (1.2)	1 (1.2)	0	0	0	2 (2.4)
Inguinal hernia	1 (1.2)	1 (1.2)	0	0	0	2 (2.4)
Retching	2 (2.4)	0	0	0	0	2 (2.4)
Salivary hypersecretion	2 (2.4)	0	0	0	0	2 (2.4)
Varices oesophageal	0	2 (2.4)	0	0	0	2 (2.4)
Anorectal discomfort	1 (1.2)	0	0	0	0	1 (1.2)
Chapped lips	1 (1.2)	0	0	0	0	1 (1.2)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

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Gastrointestinal disorders (cont.)						
Colitis	0	0	1 (1.2)	0	0	1 (1.2)
Dental caries	1 (1.2)	0	0	0	0	1 (1.2)
Duodenal ulcer haemorrhage	0	0	1 (1.2)	0	0	1 (1.2)
Faeces discoloured	1 (1.2)	0	0	0	0	1 (1.2)
Flatulence	1 (1.2)	0	0	0	0	1 (1.2)
Gastritis	0	1 (1.2)	0	0	0	1 (1.2)
Gastritis haemorrhagic	0	0	1 (1.2)	0	0	1 (1.2)
Gastrointestinal perforation	0	0	1 (1.2)	0	0	1 (1.2)

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AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & All Dose Group (N=83) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Gastrointestinal disorders (cont.)						
Gingival bleeding	1 (1.2)	0	0	0	0	1 (1.2)
Gingival swelling	1 (1.2)	0	0	0	0	1 (1.2)
Haemorrhoids	0	1 (1.2)	0	0	0	1 (1.2)
Incarcerated umbilical hernia	0	0	0	1 (1.2)	0	1 (1.2)
Intra-abdominal haematoma	0	1 (1.2)	0	0	0	1 (1.2)
Intra-abdominal haemorrhage	0	0	1 (1.2)	0	0	1 (1.2)
Large intestine perforation	0	0	1 (1.2)	0	0	1 (1.2)
Large intestine polyp	1 (1.2)	0	0	0	0	1 (1.2)

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AdvSM Population & Prior Neoplastic Therapy = Yes

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Gastrointestinal disorders (cont.)						
Lip dry	1 (1.2)	0	0	0	0	1 (1.2)
Lip ulceration	1 (1.2)	0	0	0	0	1 (1.2)
Lower gastrointestinal haemorrhage	0	0	1 (1.2)	0	0	1 (1.2)
Mouth ulceration	1 (1.2)	0	0	0	0	1 (1.2)
Oesophagitis	0	0	1 (1.2)	0	0	1 (1.2)
Oral disorder	1 (1.2)	0	0	0	0	1 (1.2)
Oral pain	1 (1.2)	0	0	0	0	1 (1.2)
Pancreatitis	0	0	1 (1.2)	0	0	1 (1.2)

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AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & All Dose Group (N=83) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Gastrointestinal disorders (cont.)						
Parotid gland enlargement	1 (1.2)	0	0	0	0	1 (1.2)
Periodontal disease	1 (1.2)	0	0	0	0	1 (1.2)
Portal hypertensive gastropathy	1 (1.2)	0	0	0	0	1 (1.2)
Rectal haemorrhage	1 (1.2)	0	0	0	0	1 (1.2)
Small intestinal obstruction	1 (1.2)	0	0	0	0	1 (1.2)
Tongue discolouration	1 (1.2)	0	0	0	0	1 (1.2)
Tooth deposit	1 (1.2)	0	0	0	0	1 (1.2)
Toothache	1 (1.2)	0	0	0	0	1 (1.2)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & All Dose Group (N=83) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
General disorders and administration site conditions	30 (36.1)	20 (24.1)	8 (9.6)	0	1 (1.2)	59 (71.1)
Oedema peripheral	33 (39.8)	11 (13.3)	0	0	0	44 (53.0)
Fatigue	6 (7.2)	4 (4.8)	7 (8.4)	0	0	17 (20.5)
Face oedema	9 (10.8)	2 (2.4)	0	0	0	11 (13.3)
Asthenia	5 (6.0)	3 (3.6)	0	0	0	8 (9.6)
Pyrexia	4 (4.8)	1 (1.2)	2 (2.4)	0	0	7 (8.4)
Peripheral swelling	5 (6.0)	0	0	0	0	5 (6.0)
Pain	3 (3.6)	1 (1.2)	0	0	0	4 (4.8)

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General disorders and administration site conditions (cont.)						
Chills	3 (3.6)	0	0	0	0	3 (3.6)
Feeling abnormal	3 (3.6)	0	0	0	0	3 (3.6)
Generalised oedema	1 (1.2)	2 (2.4)	0	0	0	3 (3.6)
Non-cardiac chest pain	2 (2.4)	1 (1.2)	0	0	0	3 (3.6)
Gait disturbance	2 (2.4)	0	0	0	0	2 (2.4)
Influenza like illness	1 (1.2)	1 (1.2)	0	0	0	2 (2.4)
Oedema	2 (2.4)	0	0	0	0	2 (2.4)
Chest discomfort	1 (1.2)	0	0	0	0	1 (1.2)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & All Dose Group (N=83) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
General disorders and administration site conditions (cont.)						
Decreased activity	0	1 (1.2)	0	0	0	1 (1.2)
Disease progression	0	0	0	0	1 (1.2)	1 (1.2)
Malaise	1 (1.2)	0	0	0	0	1 (1.2)
Systemic inflammatory response syndrome	0	1 (1.2)	0	0	0	1 (1.2)
Temperature intolerance	1 (1.2)	0	0	0	0	1 (1.2)
Hepatobiliary disorders	3 (3.6)	4 (4.8)	1 (1.2)	0	0	8 (9.6)
Hyperbilirubinaemia	1 (1.2)	3 (3.6)	0	0	0	4 (4.8)
Cholelithiasis	1 (1.2)	0	1 (1.2)	0	0	2 (2.4)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & All Dose Group (N=83) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Hepatobiliary disorders (cont.)						
Hepatic cirrhosis	0	1 (1.2)	0	0	0	1 (1.2)
Jaundice	1 (1.2)	0	0	0	0	1 (1.2)
Nodular regenerative hyperplasia	0	1 (1.2)	0	0	0	1 (1.2)
Immune system disorders	4 (4.8)	1 (1.2)	3 (3.6)	0	0	8 (9.6)
Drug hypersensitivity	2 (2.4)	0	0	0	0	2 (2.4)
Anaphylactic reaction	0	0	1 (1.2)	0	0	1 (1.2)
Anaphylactic shock	0	0	1 (1.2)	0	0	1 (1.2)
Contrast media allergy	0	1 (1.2)	0	0	0	1 (1.2)

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AdvSM Population & Prior Neoplastic Therapy = Yes

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Immune system disorders (cont.)						
Hypersensitivity	1 (1.2)	0	0	0	0	1 (1.2)
Hypogammaglobulinaemia	0	1 (1.2)	0	0	0	1 (1.2)
Immune system disorder	0	0	1 (1.2)	0	0	1 (1.2)
Iodine allergy	1 (1.2)	0	0	0	0	1 (1.2)
Infections and infestations	13 (15.7)	20 (24.1)	16 (19.3)	0	2 (2.4)	51 (61.4)
Upper respiratory tract infection	4 (4.8)	4 (4.8)	1 (1.2)	0	0	9 (10.8)
Urinary tract infection	2 (2.4)	5 (6.0)	1 (1.2)	0	0	8 (9.6)
Herpes zoster	3 (3.6)	3 (3.6)	1 (1.2)	0	0	7 (8.4)

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AdvSM Population & Prior Neoplastic Therapy = Yes

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Infections and infestations (cont.)						
Oral candidiasis	1 (1.2)	4 (4.8)	0	0	0	5 (6.0)
Pneumonia	0	1 (1.2)	4 (4.8)	0	0	5 (6.0)
Sinusitis	3 (3.6)	2 (2.4)	0	0	0	5 (6.0)
Cellulitis	0	3 (3.6)	0	0	0	3 (3.6)
Conjunctivitis	1 (1.2)	1 (1.2)	0	0	0	2 (2.4)
Diverticulitis	0	1 (1.2)	1 (1.2)	0	0	2 (2.4)
Gastroenteritis	1 (1.2)	1 (1.2)	0	0	0	2 (2.4)
Nasopharyngitis	2 (2.4)	0	0	0	0	2 (2.4)

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AdvSM Population & Prior Neoplastic Therapy = Yes

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Infections and infestations (cont.)						
Sepsis	0	1 (1.2)	1 (1.2)	0	0	2 (2.4)
Appendiceal abscess	0	0	1 (1.2)	0	0	1 (1.2)
Bronchitis	0	1 (1.2)	0	0	0	1 (1.2)
Catheter site cellulitis	0	1 (1.2)	0	0	0	1 (1.2)
Cellulitis orbital	0	1 (1.2)	0	0	0	1 (1.2)
Clostridium difficile colitis	1 (1.2)	0	0	0	0	1 (1.2)
Clostridium difficile infection	0	0	1 (1.2)	0	0	1 (1.2)
Corona virus infection	0	0	1 (1.2)	0	0	1 (1.2)

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AdvSM Population & Prior Neoplastic Therapy = Yes

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Infections and infestations (cont.)						
Cystitis	0	1 (1.2)	0	0	0	1 (1.2)
Diarrhoea infectious	0	1 (1.2)	0	0	0	1 (1.2)
Ear infection	0	1 (1.2)	0	0	0	1 (1.2)
Escherichia bacteraemia	0	0	1 (1.2)	0	0	1 (1.2)
Escherichia urinary tract infection	0	1 (1.2)	0	0	0	1 (1.2)
Folliculitis	1 (1.2)	0	0	0	0	1 (1.2)
Gastrointestinal fungal infection	0	1 (1.2)	0	0	0	1 (1.2)
Genital infection	1 (1.2)	0	0	0	0	1 (1.2)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & All Dose Group (N=83) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Infections and infestations (cont.)						
Herpes simplex	1 (1.2)	0	0	0	0	1 (1.2)
Hordeolum	1 (1.2)	0	0	0	0	1 (1.2)
Influenza	1 (1.2)	0	0	0	0	1 (1.2)
Localised infection	0	0	1 (1.2)	0	0	1 (1.2)
Mastoiditis	1 (1.2)	0	0	0	0	1 (1.2)
Necrotising fasciitis	0	0	0	0	1 (1.2)	1 (1.2)
Oral herpes	1 (1.2)	0	0	0	0	1 (1.2)
Oropharyngeal candidiasis	0	1 (1.2)	0	0	0	1 (1.2)

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AdvSM Population & Prior Neoplastic Therapy = Yes

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Infections and infestations (cont.)						
Otitis externa	0	1 (1.2)	0	0	0	1 (1.2)
Otitis media	1 (1.2)	0	0	0	0	1 (1.2)
Paronychia	0	1 (1.2)	0	0	0	1 (1.2)
Peritonitis bacterial	0	0	1 (1.2)	0	0	1 (1.2)
Pharyngitis	0	1 (1.2)	0	0	0	1 (1.2)
Respiratory tract infection	0	1 (1.2)	0	0	0	1 (1.2)
Rhinovirus infection	1 (1.2)	0	0	0	0	1 (1.2)
Septic shock	0	0	0	0	1 (1.2)	1 (1.2)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & All Dose Group (N=83) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Infections and infestations (cont.)						
Skin infection	0	0	1 (1.2)	0	0	1 (1.2)
Stoma site cellulitis	0	1 (1.2)	0	0	0	1 (1.2)
Tooth abscess	0	0	1 (1.2)	0	0	1 (1.2)
Urinary tract infection staphylococcal	0	1 (1.2)	0	0	0	1 (1.2)
Viral upper respiratory tract infection	1 (1.2)	0	0	0	0	1 (1.2)
Vulvovaginal mycotic infection	0	1 (1.2)	0	0	0	1 (1.2)
Wound infection	0	1 (1.2)	0	0	0	1 (1.2)
Injury, poisoning and procedural complications	16 (19.3)	9 (10.8)	2 (2.4)	1 (1.2)	0	28 (33.7)

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Injury, poisoning and procedural complications (cont.)						
Fall	4 (4.8)	3 (3.6)	0	0	0	7 (8.4)
Contusion	3 (3.6)	2 (2.4)	0	0	0	5 (6.0)
Laceration	3 (3.6)	0	0	0	0	3 (3.6)
Procedural pain	3 (3.6)	0	0	0	0	3 (3.6)
Subdural haematoma	2 (2.4)	0	0	1 (1.2)	0	3 (3.6)
Arthropod bite	2 (2.4)	0	0	0	0	2 (2.4)
Lumbar vertebral fracture	0	2 (2.4)	0	0	0	2 (2.4)
Post procedural haemorrhage	2 (2.4)	0	0	0	0	2 (2.4)

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Injury, poisoning and procedural complications (cont.)						
Anaemia postoperative	0	0	1 (1.2)	0	0	1 (1.2)
Electrical burn	0	1 (1.2)	0	0	0	1 (1.2)
Femoral neck fracture	0	0	1 (1.2)	0	0	1 (1.2)
Femur fracture	0	1 (1.2)	0	0	0	1 (1.2)
Foot fracture	0	1 (1.2)	0	0	0	1 (1.2)
Fractured sacrum	0	1 (1.2)	0	0	0	1 (1.2)
Joint injury	1 (1.2)	0	0	0	0	1 (1.2)
Limb injury	1 (1.2)	0	0	0	0	1 (1.2)

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Injury, poisoning and procedural complications (cont.)						
Overdose	1 (1.2)	0	0	0	0	1 (1.2)
Rib fracture	0	1 (1.2)	0	0	0	1 (1.2)
Skin abrasion	1 (1.2)	0	0	0	0	1 (1.2)
Skin wound	1 (1.2)	0	0	0	0	1 (1.2)
Spinal compression fracture	1 (1.2)	0	0	0	0	1 (1.2)
Tendon injury	1 (1.2)	0	0	0	0	1 (1.2)
Tendon rupture	0	1 (1.2)	0	0	0	1 (1.2)
Thermal burn	0	1 (1.2)	0	0	0	1 (1.2)

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Injury, poisoning and procedural complications (cont.)						
Tooth fracture	0	1 (1.2)	0	0	0	1 (1.2)
Traumatic haematoma	1 (1.2)	0	0	0	0	1 (1.2)
Wound	1 (1.2)	0	0	0	0	1 (1.2)
Investigations	13 (15.7)	6 (7.2)	15 (18.1)	4 (4.8)	0	38 (45.8)
Blood bilirubin increased	4 (4.8)	5 (6.0)	1 (1.2)	0	0	10 (12.0)
Platelet count decreased	0	2 (2.4)	4 (4.8)	2 (2.4)	0	8 (9.6)
Weight increased	4 (4.8)	2 (2.4)	2 (2.4)	0	0	8 (9.6)
White blood cell count decreased	1 (1.2)	1 (1.2)	5 (6.0)	1 (1.2)	0	8 (9.6)

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Investigations (cont.)						
Blood creatinine increased	6 (7.2)	1 (1.2)	0	0	0	7 (8.4)
Blood alkaline phosphatase increased	0	1 (1.2)	4 (4.8)	1 (1.2)	0	6 (7.2)
Cardiac murmur	5 (6.0)	0	0	0	0	5 (6.0)
Neutrophil count decreased	1 (1.2)	0	2 (2.4)	1 (1.2)	0	4 (4.8)
Alanine aminotransferase increased	1 (1.2)	2 (2.4)	0	0	0	3 (3.6)
Aspartate aminotransferase increased	3 (3.6)	0	0	0	0	3 (3.6)
Gamma-glutamyltransferase increased	1 (1.2)	1 (1.2)	1 (1.2)	0	0	3 (3.6)
Blood uric acid increased	2 (2.4)	0	0	0	0	2 (2.4)

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System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & All Dose Group (N=83) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Investigations (cont.)						
Electrocardiogram QT prolonged	2 (2.4)	0	0	0	0	2 (2.4)
Urine uric acid increased	2 (2.4)	0	0	0	0	2 (2.4)
Alanine aminotransferase decreased	0	1 (1.2)	0	0	0	1 (1.2)
Blood albumin decreased	1 (1.2)	0	0	0	0	1 (1.2)
Blood bilirubin unconjugated increased	0	0	1 (1.2)	0	0	1 (1.2)
Blood phosphorus decreased	0	1 (1.2)	0	0	0	1 (1.2)
Blood thyroid stimulating hormone increased	1 (1.2)	0	0	0	0	1 (1.2)
C-reactive protein increased	0	1 (1.2)	0	0	0	1 (1.2)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & All Dose Group (N=83) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Investigations (cont.)						
Haemoglobin decreased	0	1 (1.2)	0	0	0	1 (1.2)
Lipase increased	0	1 (1.2)	0	0	0	1 (1.2)
Lymphocyte count decreased	0	1 (1.2)	0	0	0	1 (1.2)
Monocyte count increased	0	1 (1.2)	0	0	0	1 (1.2)
Neutrophil count increased	1 (1.2)	0	0	0	0	1 (1.2)
Occult blood positive	1 (1.2)	0	0	0	0	1 (1.2)
Prothrombin time shortened	1 (1.2)	0	0	0	0	1 (1.2)
Red blood cell count decreased	1 (1.2)	0	0	0	0	1 (1.2)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & All Dose Group (N=83) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Investigations (cont.)						
Reticulocyte count increased	1 (1.2)	0	0	0	0	1 (1.2)
Urine output increased	1 (1.2)	0	0	0	0	1 (1.2)
Weight decreased	1 (1.2)	0	0	0	0	1 (1.2)
White blood cell count increased	1 (1.2)	0	0	0	0	1 (1.2)
Metabolism and nutrition disorders	17 (20.5)	11 (13.3)	7 (8.4)	2 (2.4)	0	37 (44.6)
Decreased appetite	8 (9.6)	2 (2.4)	1 (1.2)	0	0	11 (13.3)
Hypokalaemia	7 (8.4)	2 (2.4)	2 (2.4)	0	0	11 (13.3)
Hypophosphataemia	3 (3.6)	3 (3.6)	2 (2.4)	1 (1.2)	0	9 (10.8)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

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Metabolism and nutrition disorders (cont.)						
Hypocalcaemia	0	4 (4.8)	0	0	0	4 (4.8)
Dehydration	1 (1.2)	2 (2.4)	0	0	0	3 (3.6)
Hypomagnesaemia	3 (3.6)	0	0	0	0	3 (3.6)
Hyperglycaemia	0	1 (1.2)	1 (1.2)	0	0	2 (2.4)
Hyperuricaemia	2 (2.4)	0	0	0	0	2 (2.4)
Cachexia	0	1 (1.2)	0	0	0	1 (1.2)
Fluid retention	1 (1.2)	0	0	0	0	1 (1.2)
Gout	0	1 (1.2)	0	0	0	1 (1.2)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & All Dose Group (N=83) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Metabolism and nutrition disorders (cont.)						
Hypernatraemia	0	0	1 (1.2)	0	0	1 (1.2)
Hyperphosphataemia	0	1 (1.2)	0	0	0	1 (1.2)
Hypoalbuminaemia	0	0	1 (1.2)	0	0	1 (1.2)
Hypoglycaemia	0	0	1 (1.2)	0	0	1 (1.2)
Hyponatraemia	0	0	0	1 (1.2)	0	1 (1.2)
Increased appetite	1 (1.2)	0	0	0	0	1 (1.2)
Metabolic acidosis	1 (1.2)	0	0	0	0	1 (1.2)
Tumour lysis syndrome	0	0	1 (1.2)	0	0	1 (1.2)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & All Dose Group (N=83) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Metabolism and nutrition disorders (cont.)						
Vitamin D deficiency	0	1 (1.2)	0	0	0	1 (1.2)
Musculoskeletal and connective tissue disorders	19 (22.9)	14 (16.9)	3 (3.6)	0	0	36 (43.4)
Arthralgia	11 (13.3)	4 (4.8)	2 (2.4)	0	0	17 (20.5)
Pain in extremity	6 (7.2)	3 (3.6)	0	0	0	9 (10.8)
Back pain	4 (4.8)	1 (1.2)	1 (1.2)	0	0	6 (7.2)
Muscular weakness	2 (2.4)	2 (2.4)	1 (1.2)	0	0	5 (6.0)
Musculoskeletal pain	2 (2.4)	2 (2.4)	0	0	0	4 (4.8)
Myalgia	3 (3.6)	0	0	0	0	3 (3.6)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & All Dose Group (N=83) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Musculoskeletal and connective tissue disorders (cont.)						
Exostosis	2 (2.4)	0	0	0	0	2 (2.4)
Muscle spasms	1 (1.2)	1 (1.2)	0	0	0	2 (2.4)
Musculoskeletal chest pain	2 (2.4)	0	0	0	0	2 (2.4)
Osteoporosis	0	2 (2.4)	0	0	0	2 (2.4)
Bone pain	0	1 (1.2)	0	0	0	1 (1.2)
Extraskeletal ossification	1 (1.2)	0	0	0	0	1 (1.2)
Groin pain	0	1 (1.2)	0	0	0	1 (1.2)
Intervertebral disc protrusion	0	1 (1.2)	0	0	0	1 (1.2)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & All Dose Group (N=83) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Musculoskeletal and connective tissue disorders (cont.)						
Joint effusion	1 (1.2)	0	0	0	0	1 (1.2)
Joint stiffness	1 (1.2)	0	0	0	0	1 (1.2)
Joint swelling	1 (1.2)	0	0	0	0	1 (1.2)
Muscle twitching	0	1 (1.2)	0	0	0	1 (1.2)
Neck pain	1 (1.2)	0	0	0	0	1 (1.2)
Osteonecrosis of jaw	0	1 (1.2)	0	0	0	1 (1.2)
Pain in jaw	1 (1.2)	0	0	0	0	1 (1.2)
Rotator cuff syndrome	0	1 (1.2)	0	0	0	1 (1.2)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & All Dose Group (N=83) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Musculoskeletal and connective tissue disorders (cont.)						
Spinal column stenosis	0	1 (1.2)	0	0	0	1 (1.2)
Tenosynovitis	1 (1.2)	0	0	0	0	1 (1.2)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4 (4.8)	5 (6.0)	6 (7.2)	0	0	15 (18.1)
Malignant melanoma	0	1 (1.2)	1 (1.2)	0	0	2 (2.4)
Squamous cell carcinoma	1 (1.2)	1 (1.2)	0	0	0	2 (2.4)
Acrochordon	1 (1.2)	0	0	0	0	1 (1.2)
Acute myeloid leukaemia	0	0	1 (1.2)	0	0	1 (1.2)
Basal cell carcinoma	0	0	1 (1.2)	0	0	1 (1.2)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & All Dose Group (N=83) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont.)						
Benign gastrointestinal neoplasm	0	0	1 (1.2)	0	0	1 (1.2)
Gastrointestinal neoplasm	0	1 (1.2)	0	0	0	1 (1.2)
Haemangioma	1 (1.2)	0	0	0	0	1 (1.2)
Intraductal proliferative breast lesion	0	0	1 (1.2)	0	0	1 (1.2)
Intravascular papillary endothelial hyperplasia	0	0	1 (1.2)	0	0	1 (1.2)
Keratoacanthoma	1 (1.2)	0	0	0	0	1 (1.2)
Lip neoplasm	1 (1.2)	0	0	0	0	1 (1.2)
Myelodysplastic syndrome	0	0	1 (1.2)	0	0	1 (1.2)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & All Dose Group (N=83) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont.)						
Penile wart	0	1 (1.2)	0	0	0	1 (1.2)
Renal neoplasm	1 (1.2)	0	0	0	0	1 (1.2)
Salivary gland neoplasm	1 (1.2)	0	0	0	0	1 (1.2)
Seborrhoeic keratosis	1 (1.2)	0	0	0	0	1 (1.2)
Squamous cell carcinoma of skin	0	1 (1.2)	0	0	0	1 (1.2)
Transitional cell carcinoma	0	1 (1.2)	0	0	0	1 (1.2)
Nervous system disorders	30 (36.1)	12 (14.5)	5 (6.0)	0	1 (1.2)	48 (57.8)
Dizziness	12 (14.5)	2 (2.4)	1 (1.2)	0	0	15 (18.1)

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Nervous system disorders (cont.)						
Dysgeusia	11 (13.3)	2 (2.4)	0	0	0	13 (15.7)
Headache	8 (9.6)	3 (3.6)	1 (1.2)	0	0	12 (14.5)
Memory impairment	9 (10.8)	2 (2.4)	0	0	0	11 (13.3)
Cognitive disorder	3 (3.6)	3 (3.6)	1 (1.2)	0	0	7 (8.4)
Hypoaesthesia	5 (6.0)	1 (1.2)	0	0	0	6 (7.2)
Ageusia	3 (3.6)	0	0	0	0	3 (3.6)
Dizziness postural	3 (3.6)	0	0	0	0	3 (3.6)
Paraesthesia	3 (3.6)	0	0	0	0	3 (3.6)

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Nervous system disorders (cont.)						
Aphasia	2 (2.4)	0	0	0	0	2 (2.4)
Encephalopathy	0	0	2 (2.4)	0	0	2 (2.4)
Haemorrhage intracranial	0	0	1 (1.2)	0	1 (1.2)	2 (2.4)
Peripheral sensory neuropathy	2 (2.4)	0	0	0	0	2 (2.4)
Restless legs syndrome	1 (1.2)	1 (1.2)	0	0	0	2 (2.4)
Balance disorder	1 (1.2)	0	0	0	0	1 (1.2)
Central nervous system lesion	1 (1.2)	0	0	0	0	1 (1.2)
Cerebral atrophy	1 (1.2)	0	0	0	0	1 (1.2)

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Nervous system disorders (cont.)						
Cerebral ventricle dilatation	1 (1.2)	0	0	0	0	1 (1.2)
Dementia	0	1 (1.2)	0	0	0	1 (1.2)
Dysarthria	1 (1.2)	0	0	0	0	1 (1.2)
Hydrocephalus	1 (1.2)	0	0	0	0	1 (1.2)
Hypogeusia	1 (1.2)	0	0	0	0	1 (1.2)
Myoclonus	0	0	1 (1.2)	0	0	1 (1.2)
Neuropathy peripheral	0	1 (1.2)	0	0	0	1 (1.2)
Parkinson's disease	1 (1.2)	0	0	0	0	1 (1.2)

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Nervous system disorders (cont.)						
Post herpetic neuralgia	0	1 (1.2)	0	0	0	1 (1.2)
Seizure	0	1 (1.2)	0	0	0	1 (1.2)
Sensory disturbance	1 (1.2)	0	0	0	0	1 (1.2)
Somnolence	1 (1.2)	0	0	0	0	1 (1.2)
Syncope	0	0	1 (1.2)	0	0	1 (1.2)
Transient ischaemic attack	1 (1.2)	0	0	0	0	1 (1.2)
Tremor	1 (1.2)	0	0	0	0	1 (1.2)
Psychiatric disorders	11 (13.3)	8 (9.6)	3 (3.6)	0	0	22 (26.5)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & All Dose Group (N=83) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Psychiatric disorders (cont.)						
Insomnia	4 (4.8)	3 (3.6)	2 (2.4)	0	0	9 (10.8)
Confusional state	1 (1.2)	2 (2.4)	0	0	0	3 (3.6)
Depression	1 (1.2)	2 (2.4)	0	0	0	3 (3.6)
Anxiety	0	2 (2.4)	0	0	0	2 (2.4)
Depressed mood	2 (2.4)	0	0	0	0	2 (2.4)
Sleep disorder	2 (2.4)	0	0	0	0	2 (2.4)
Adjustment disorder with depressed mood	0	1 (1.2)	0	0	0	1 (1.2)
Delirium	0	0	1 (1.2)	0	0	1 (1.2)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & All Dose Group (N=83) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Psychiatric disorders (cont.)						
Disorientation	1 (1.2)	0	0	0	0	1 (1.2)
Dysphoria	1 (1.2)	0	0	0	0	1 (1.2)
Irritability	1 (1.2)	0	0	0	0	1 (1.2)
Libido decreased	1 (1.2)	0	0	0	0	1 (1.2)
Mental disorder	1 (1.2)	0	0	0	0	1 (1.2)
Mental status changes	0	0	1 (1.2)	0	0	1 (1.2)
Suicidal ideation	0	1 (1.2)	0	0	0	1 (1.2)
Renal and urinary disorders	12 (14.5)	2 (2.4)	4 (4.8)	0	0	18 (21.7)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & All Dose Group (N=83) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Renal and urinary disorders (cont.)						
Acute kidney injury	3 (3.6)	0	3 (3.6)	0	0	6 (7.2)
Dysuria	6 (7.2)	0	0	0	0	6 (7.2)
Haematuria	5 (6.0)	0	0	0	0	5 (6.0)
Nephrolithiasis	2 (2.4)	0	1 (1.2)	0	0	3 (3.6)
Pollakiuria	2 (2.4)	0	0	0	0	2 (2.4)
Urinary incontinence	1 (1.2)	1 (1.2)	0	0	0	2 (2.4)
Chronic kidney disease	0	1 (1.2)	0	0	0	1 (1.2)
Hypertonic bladder	0	1 (1.2)	0	0	0	1 (1.2)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & All Dose Group (N=83) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Renal and urinary disorders (cont.)						
Obstructive uropathy	0	0	1 (1.2)	0	0	1 (1.2)
Polyuria	1 (1.2)	0	0	0	0	1 (1.2)
Renal colic	1 (1.2)	0	0	0	0	1 (1.2)
Renal impairment	0	0	1 (1.2)	0	0	1 (1.2)
Renal mass	1 (1.2)	0	0	0	0	1 (1.2)
Urinary retention	0	1 (1.2)	0	0	0	1 (1.2)
Reproductive system and breast disorders	3 (3.6)	3 (3.6)	0	0	0	6 (7.2)
Scrotal oedema	0	2 (2.4)	0	0	0	2 (2.4)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & All Dose Group (N=83) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Reproductive system and breast disorders (cont.)						
Haematospermia	1 (1.2)	0	0	0	0	1 (1.2)
Oedema genital	0	1 (1.2)	0	0	0	1 (1.2)
Penile pain	1 (1.2)	0	0	0	0	1 (1.2)
Vulvovaginal pain	1 (1.2)	0	0	0	0	1 (1.2)
Respiratory, thoracic and mediastinal disorders	23 (27.7)	9 (10.8)	6 (7.2)	0	0	38 (45.8)
Epistaxis	11 (13.3)	0	0	0	0	11 (13.3)
Cough	7 (8.4)	3 (3.6)	0	0	0	10 (12.0)
Dyspnoea	5 (6.0)	4 (4.8)	0	0	0	9 (10.8)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & All Dose Group (N=83) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Respiratory, thoracic and mediastinal disorders (cont.)						
Pleural effusion	2 (2.4)	3 (3.6)	2 (2.4)	0	0	7 (8.4)
Nasal congestion	3 (3.6)	1 (1.2)	0	0	0	4 (4.8)
Productive cough	4 (4.8)	0	0	0	0	4 (4.8)
Haemoptysis	2 (2.4)	1 (1.2)	0	0	0	3 (3.6)
Rhinorrhoea	3 (3.6)	0	0	0	0	3 (3.6)
Upper-airway cough syndrome	3 (3.6)	0	0	0	0	3 (3.6)
Dysphonia	2 (2.4)	0	0	0	0	2 (2.4)
Dyspnoea exertional	2 (2.4)	0	0	0	0	2 (2.4)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & All Dose Group (N=83) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Respiratory, thoracic and mediastinal disorders (cont.)						
Oropharyngeal pain	2 (2.4)	0	0	0	0	2 (2.4)
Pulmonary congestion	1 (1.2)	1 (1.2)	0	0	0	2 (2.4)
Rales	2 (2.4)	0	0	0	0	2 (2.4)
Acute respiratory failure	0	0	1 (1.2)	0	0	1 (1.2)
Bronchial haemorrhage	0	0	1 (1.2)	0	0	1 (1.2)
Chronic obstructive pulmonary disease	0	0	1 (1.2)	0	0	1 (1.2)
Emphysema	1 (1.2)	0	0	0	0	1 (1.2)
Haemothorax	0	0	1 (1.2)	0	0	1 (1.2)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & All Dose Group (N=83) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Respiratory, thoracic and mediastinal disorders (cont.)						
Hypoxia	0	0	1 (1.2)	0	0	1 (1.2)
Laryngeal oedema	0	0	1 (1.2)	0	0	1 (1.2)
Pneumothorax	0	1 (1.2)	0	0	0	1 (1.2)
Pulmonary hypertension	0	0	1 (1.2)	0	0	1 (1.2)
Pulmonary mass	1 (1.2)	0	0	0	0	1 (1.2)
Pulmonary oedema	0	1 (1.2)	0	0	0	1 (1.2)
Respiratory symptom	1 (1.2)	0	0	0	0	1 (1.2)
Rhinitis allergic	0	1 (1.2)	0	0	0	1 (1.2)

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Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & All Dose Group (N=83) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Respiratory, thoracic and mediastinal disorders (cont.)						
Rhonchi	1 (1.2)	0	0	0	0	1 (1.2)
Sinus disorder	1 (1.2)	0	0	0	0	1 (1.2)
Throat irritation	1 (1.2)	0	0	0	0	1 (1.2)
Wheezing	1 (1.2)	0	0	0	0	1 (1.2)
Skin and subcutaneous tissue disorders	26 (31.3)	13 (15.7)	1 (1.2)	0	0	40 (48.2)
Hair colour changes	11 (13.3)	0	1 (1.2)	0	0	12 (14.5)
Pruritus	7 (8.4)	2 (2.4)	0	0	0	9 (10.8)
Alopecia	8 (9.6)	0	0	0	0	8 (9.6)

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AdvSM Population & Prior Neoplastic Therapy = Yes

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Skin and subcutaneous tissue disorders (cont.)						
Rash	7 (8.4)	1 (1.2)	0	0	0	8 (9.6)
Photosensitivity reaction	3 (3.6)	2 (2.4)	0	0	0	5 (6.0)
Rash maculo-papular	2 (2.4)	3 (3.6)	0	0	0	5 (6.0)
Ecchymosis	3 (3.6)	0	0	0	0	3 (3.6)
Hyperhidrosis	3 (3.6)	0	0	0	0	3 (3.6)
Night sweats	1 (1.2)	2 (2.4)	0	0	0	3 (3.6)
Rash pruritic	3 (3.6)	0	0	0	0	3 (3.6)
Skin lesion	3 (3.6)	0	0	0	0	3 (3.6)

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Skin and subcutaneous tissue disorders (cont.)						
Erythema	2 (2.4)	0	0	0	0	2 (2.4)
Livedo reticularis	2 (2.4)	0	0	0	0	2 (2.4)
Nail bed disorder	2 (2.4)	0	0	0	0	2 (2.4)
Petechiae	2 (2.4)	0	0	0	0	2 (2.4)
Rash erythematous	2 (2.4)	0	0	0	0	2 (2.4)
Rash papular	2 (2.4)	0	0	0	0	2 (2.4)
Skin ulcer	0	2 (2.4)	0	0	0	2 (2.4)
Swelling face	2 (2.4)	0	0	0	0	2 (2.4)

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Skin and subcutaneous tissue disorders (cont.)						
Urticaria	0	2 (2.4)	0	0	0	2 (2.4)
Blood blister	1 (1.2)	0	0	0	0	1 (1.2)
Dermatitis	0	1 (1.2)	0	0	0	1 (1.2)
Dermatitis acneiform	1 (1.2)	0	0	0	0	1 (1.2)
Dermatitis contact	1 (1.2)	0	0	0	0	1 (1.2)
Dry skin	1 (1.2)	0	0	0	0	1 (1.2)
Eczema	1 (1.2)	0	0	0	0	1 (1.2)
Hair growth abnormal	1 (1.2)	0	0	0	0	1 (1.2)

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Skin and subcutaneous tissue disorders (cont.)						
Melanocytic hyperplasia	0	1 (1.2)	0	0	0	1 (1.2)
Nail growth abnormal	1 (1.2)	0	0	0	0	1 (1.2)
Psoriasis	0	1 (1.2)	0	0	0	1 (1.2)
Scab	1 (1.2)	0	0	0	0	1 (1.2)
Seborrhoeic dermatitis	1 (1.2)	0	0	0	0	1 (1.2)
Skin depigmentation	1 (1.2)	0	0	0	0	1 (1.2)
Skin discolouration	1 (1.2)	0	0	0	0	1 (1.2)
Skin haemorrhage	0	1 (1.2)	0	0	0	1 (1.2)

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Skin and subcutaneous tissue disorders (cont.)						
Telangiectasia	1 (1.2)	0	0	0	0	1 (1.2)
Vascular disorders	14 (16.9)	6 (7.2)	5 (6.0)	0	1 (1.2)	26 (31.3)
Hypertension	2 (2.4)	3 (3.6)	3 (3.6)	0	0	8 (9.6)
Flushing	6 (7.2)	0	0	0	0	6 (7.2)
Hypotension	4 (4.8)	1 (1.2)	1 (1.2)	0	0	6 (7.2)
Hot flush	2 (2.4)	0	0	0	0	2 (2.4)
Embolism	0	1 (1.2)	0	0	0	1 (1.2)
Epistaxis	1 (1.2)	0	0	0	0	1 (1.2)

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Table T.35.3.3.1.2.3
Adverse Events by System Organ Class and Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 & All Dose Group (N=83) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Vascular disorders (cont.)						
Haematoma	0	1 (1.2)	0	0	0	1 (1.2)
Haemorrhage	0	0	1 (1.2)	0	0	1 (1.2)
Pallor	1 (1.2)	0	0	0	0	1 (1.2)
Peripheral vascular disorder	1 (1.2)	0	0	0	0	1 (1.2)
Shock haemorrhagic	0	0	0	0	1 (1.2)	1 (1.2)
Thrombophlebitis	0	1 (1.2)	0	0	0	1 (1.2)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
Note 1: In each treatment group, if a patient experiences more than 1 event within a given System Organ Class or Preferred term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column and treatment group.
Note 3: System Organ Classes are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'Any Grade' column.
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Table T.35.3.3.1.4.1
Summary of Grade 3/4/5 Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	 <=200 mg (N=16) n (%)	 All Doses (N=41) n (%)
Patients with at least one Event	8 (66.7)	11 (68.8)	35 (85.4)
Blood and lymphatic system disorders	6 (50.0)	6 (37.5)	23 (56.1)
Anaemia	4 (33.3)	4 (25.0)	13 (31.7)
Thrombocytopenia	4 (33.3)	4 (25.0)	11 (26.8)
Neutropenia	2 (16.7)	2 (12.5)	6 (14.6)
Anaemia macrocytic	1 (8.3)	1 (6.3)	1 (2.4)
Autoimmune haemolytic anaemia	0	0	1 (2.4)
Haemolysis	0	0	1 (2.4)
Leukocytosis	0	0	1 (2.4)
Lymphopenia	0	0	1 (2.4)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: System Organ Classes are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.3.3.1.4.1
Summary of Grade 3/4/5 Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	 <=200 mg (N=16) n (%)	 All Doses (N=41) n (%)
Blood and lymphatic system disorders (cont.)			
Pancytopenia	0	0	1 (2.4)
Cardiac disorders	1 (8.3)	1 (6.3)	2 (4.9)
Acute myocardial infarction	0	0	1 (2.4)
Cardiac failure congestive	1 (8.3)	1 (6.3)	1 (2.4)
Ear and labyrinth disorders	0	0	1 (2.4)
Deafness neurosensory	0	0	1 (2.4)
Endocrine disorders	0	0	1 (2.4)
Inappropriate antidiuretic hormone secretion	0	0	1 (2.4)
Eye disorders	0	1 (6.3)	1 (2.4)
Uveitis	0	1 (6.3)	1 (2.4)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: System Organ Classes are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.3.3.1.4.1
Summary of Grade 3/4/5 Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	 <=200 mg (N=16) n (%)	 All Doses (N=41) n (%)
Gastrointestinal disorders	2 (16.7)	2 (12.5)	9 (22.0)
Ascites	0	0	2 (4.9)
Gastric haemorrhage	0	0	2 (4.9)
Colitis	1 (8.3)	1 (6.3)	1 (2.4)
Gastritis haemorrhagic	0	0	1 (2.4)
Gastrointestinal haemorrhage	0	0	1 (2.4)
Gastrointestinal perforation	0	0	1 (2.4)
Incarcerated umbilical hernia	1 (8.3)	1 (6.3)	1 (2.4)
Large intestine perforation	1 (8.3)	1 (6.3)	1 (2.4)
Nausea	0	0	1 (2.4)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: System Organ Classes are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.3.3.1.4.1
Summary of Grade 3/4/5 Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	 <=200 mg (N=16) n (%)	 All Doses (N=41) n (%)
Gastrointestinal disorders (cont.)			
Oesophagitis	0	0	1 (2.4)
Pancreatitis	0	0	1 (2.4)
Vomiting	0	0	1 (2.4)
General disorders and administration site conditions	1 (8.3)	1 (6.3)	7 (17.1)
Fatigue	1 (8.3)	1 (6.3)	6 (14.6)
Pyrexia	0	0	2 (4.9)
Hepatobiliary disorders	0	0	1 (2.4)
Cholelithiasis	0	0	1 (2.4)
Immune system disorders	0	0	2 (4.9)
Anaphylactic reaction	0	0	1 (2.4)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: System Organ Classes are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.3.3.1.4.1
Summary of Grade 3/4/5 Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	 <=200 mg (N=16) n (%)	 All Doses (N=41) n (%)
Immune system disorders (cont.)			
Anaphylactic shock	0	0	1 (2.4)
Infections and infestations	3 (25.0)	3 (18.8)	12 (29.3)
Pneumonia	0	0	4 (9.8)
Clostridium difficile infection	0	0	1 (2.4)
Diverticulitis	1 (8.3)	1 (6.3)	1 (2.4)
Escherichia bacteraemia	0	0	1 (2.4)
Localised infection	1 (8.3)	1 (6.3)	1 (2.4)
Peritonitis bacterial	0	0	1 (2.4)
Septic shock	0	0	1 (2.4)
Tooth abscess	0	0	1 (2.4)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: System Organ Classes are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.3.3.1.4.1
Summary of Grade 3/4/5 Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	 <=200 mg (N=16) n (%)	 All Doses (N=41) n (%)
Infections and infestations (cont.)			
Upper respiratory tract infection	1 (8.3)	1 (6.3)	1 (2.4)
Urinary tract infection	0	0	1 (2.4)
Injury, poisoning and procedural complications	0	0	1 (2.4)
Femoral neck fracture	0	0	1 (2.4)
Investigations	2 (16.7)	4 (25.0)	9 (22.0)
Blood alkaline phosphatase increased	0	1 (6.3)	3 (7.3)
White blood cell count decreased	1 (8.3)	2 (12.5)	3 (7.3)
Platelet count decreased	1 (8.3)	2 (12.5)	2 (4.9)
Blood bilirubin increased	0	0	1 (2.4)
Weight increased	0	0	1 (2.4)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: System Organ Classes are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.3.3.1.4.1
Summary of Grade 3/4/5 Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	BLU-285-2101 <=200 mg (N=16) n (%)	BLU-285-2101 All Doses (N=41) n (%)
Metabolism and nutrition disorders	1 (8.3)	1 (6.3)	8 (19.5)
Hypophosphataemia	0	0	3 (7.3)
Hypokalaemia	0	0	2 (4.9)
Decreased appetite	0	0	1 (2.4)
Hyperglycaemia	1 (8.3)	1 (6.3)	1 (2.4)
Hypernatraemia	0	0	1 (2.4)
Hypoalbuminaemia	0	0	1 (2.4)
Hypoglycaemia	0	0	1 (2.4)
Hyponatraemia	0	0	1 (2.4)
Musculoskeletal and connective tissue disorders	2 (16.7)	3 (18.8)	3 (7.3)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: System Organ Classes are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.3.3.1.4.1
Summary of Grade 3/4/5 Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	 <=200 mg (N=16) n (%)	 All Doses (N=41) n (%)
Musculoskeletal and connective tissue disorders (cont.)			
Arthralgia	1 (8.3)	2 (12.5)	2 (4.9)
Back pain	1 (8.3)	1 (6.3)	1 (2.4)
Muscular weakness	0	1 (6.3)	1 (2.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (8.3)	2 (12.5)	3 (7.3)
Intraductal proliferative breast lesion	0	1 (6.3)	1 (2.4)
Intravascular papillary endothelial hyperplasia	0	0	1 (2.4)
Myelodysplastic syndrome	1 (8.3)	1 (6.3)	1 (2.4)
Nervous system disorders	1 (8.3)	1 (6.3)	6 (14.6)
Encephalopathy	0	0	2 (4.9)
Haemorrhage intracranial	0	0	2 (4.9)

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Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: System Organ Classes are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.3.3.1.4.1
Summary of Grade 3/4/5 Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	 <=200 mg (N=16) n (%)	 All Doses (N=41) n (%)
Nervous system disorders (cont.)			
Cognitive disorder	0	0	1 (2.4)
Dizziness	0	0	1 (2.4)
Headache	0	0	1 (2.4)
Myoclonus	1 (8.3)	1 (6.3)	1 (2.4)
Syncope	0	0	1 (2.4)
Psychiatric disorders	0	0	2 (4.9)
Insomnia	0	0	2 (4.9)
Mental status changes	0	0	1 (2.4)
Renal and urinary disorders	1 (8.3)	1 (6.3)	3 (7.3)
Acute kidney injury	1 (8.3)	1 (6.3)	3 (7.3)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: System Organ Classes are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.3.3.1.4.1
Summary of Grade 3/4/5 Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	 <=200 mg (N=16) n (%)	 All Doses (N=41) n (%)
Renal and urinary disorders (cont.)			
Renal impairment	0	0	1 (2.4)
Respiratory, thoracic and mediastinal disorders	1 (8.3)	1 (6.3)	4 (9.8)
Acute respiratory failure	0	0	1 (2.4)
Chronic obstructive pulmonary disease	0	0	1 (2.4)
Hypoxia	1 (8.3)	1 (6.3)	1 (2.4)
Laryngeal oedema	0	0	1 (2.4)
Pleural effusion	1 (8.3)	1 (6.3)	1 (2.4)
Pulmonary hypertension	1 (8.3)	1 (6.3)	1 (2.4)
Skin and subcutaneous tissue disorders	0	0	1 (2.4)
Hair colour changes	0	0	1 (2.4)

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Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: System Organ Classes are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.3.3.1.4.1
Summary of Grade 3/4/5 Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

	BLU-285-2101		
	200 mg (N=12)	<=200 mg (N=16)	All Doses (N=41)
System Organ Class Preferred Term	n (%)	n (%)	n (%)
Vascular disorders	0	0	3 (7.3)
Hypertension	0	0	3 (7.3)

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Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: System Organ Classes are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.3.3.1.4.1
Summary of Grade 3/4/5 Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 200 mg (N=40) n (%)	 <=200 mg (N=42) n (%)	 All Doses (N=42) n (%)
Patients with at least one Event	27 (67.5)	28 (66.7)	28 (66.7)
Blood and lymphatic system disorders	16 (40.0)	17 (40.5)	17 (40.5)
Anaemia	9 (22.5)	9 (21.4)	9 (21.4)
Neutropenia	4 (10.0)	5 (11.9)	5 (11.9)
Thrombocytopenia	4 (10.0)	4 (9.5)	4 (9.5)
Leukocytosis	2 (5.0)	2 (4.8)	2 (4.8)
Cardiac disorders	3 (7.5)	3 (7.1)	3 (7.1)
Cardiac failure	2 (5.0)	2 (4.8)	2 (4.8)
Atrial flutter	1 (2.5)	1 (2.4)	1 (2.4)
Eye disorders	2 (5.0)	2 (4.8)	2 (4.8)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: System Organ Classes are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.3.3.1.4.1
Summary of Grade 3/4/5 Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 200 mg (N=40) n (%)	 <=200 mg (N=42) n (%)	 All Doses (N=42) n (%)
Eye disorders (cont.)			
Periorbital oedema	1 (2.5)	1 (2.4)	1 (2.4)
Vitreous haemorrhage	1 (2.5)	1 (2.4)	1 (2.4)
Gastrointestinal disorders	6 (15.0)	6 (14.3)	6 (14.3)
Abdominal pain	1 (2.5)	1 (2.4)	1 (2.4)
Diarrhoea	1 (2.5)	1 (2.4)	1 (2.4)
Duodenal ulcer haemorrhage	1 (2.5)	1 (2.4)	1 (2.4)
Gastrointestinal haemorrhage	1 (2.5)	1 (2.4)	1 (2.4)
Intra-abdominal haemorrhage	1 (2.5)	1 (2.4)	1 (2.4)
Lower gastrointestinal haemorrhage	1 (2.5)	1 (2.4)	1 (2.4)
Melaena	1 (2.5)	1 (2.4)	1 (2.4)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
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Table T.35.3.3.1.4.1
Summary of Grade 3/4/5 Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 200 mg (N=40) n (%)	 <=200 mg (N=42) n (%)	 All Doses (N=42) n (%)
Gastrointestinal disorders (cont.)			
Nausea	1 (2.5)	1 (2.4)	1 (2.4)
Vomiting	1 (2.5)	1 (2.4)	1 (2.4)
General disorders and administration site conditions	2 (5.0)	2 (4.8)	2 (4.8)
Disease progression	1 (2.5)	1 (2.4)	1 (2.4)
Fatigue	1 (2.5)	1 (2.4)	1 (2.4)
Immune system disorders	1 (2.5)	1 (2.4)	1 (2.4)
Immune system disorder	1 (2.5)	1 (2.4)	1 (2.4)
Infections and infestations	5 (12.5)	6 (14.3)	6 (14.3)
Appendiceal abscess	1 (2.5)	1 (2.4)	1 (2.4)
Corona virus infection	1 (2.5)	1 (2.4)	1 (2.4)

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Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
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Table T.35.3.3.1.4.1
Summary of Grade 3/4/5 Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 200 mg (N=40) n (%)	 <=200 mg (N=42) n (%)	 All Doses (N=42) n (%)
Infections and infestations (cont.)			
Herpes zoster	0	1 (2.4)	1 (2.4)
Necrotising fasciitis	1 (2.5)	1 (2.4)	1 (2.4)
Sepsis	1 (2.5)	1 (2.4)	1 (2.4)
Skin infection	1 (2.5)	1 (2.4)	1 (2.4)
Injury, poisoning and procedural complications	2 (5.0)	2 (4.8)	2 (4.8)
Anaemia postoperative	1 (2.5)	1 (2.4)	1 (2.4)
Subdural haematoma	1 (2.5)	1 (2.4)	1 (2.4)
Investigations	10 (25.0)	10 (23.8)	10 (23.8)
Platelet count decreased	4 (10.0)	4 (9.5)	4 (9.5)
Neutrophil count decreased	3 (7.5)	3 (7.1)	3 (7.1)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
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Table T.35.3.3.1.4.1
Summary of Grade 3/4/5 Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 200 mg (N=40) n (%)	 <=200 mg (N=42) n (%)	 All Doses (N=42) n (%)
Investigations (cont.)			
White blood cell count decreased	3 (7.5)	3 (7.1)	3 (7.1)
Blood alkaline phosphatase increased	2 (5.0)	2 (4.8)	2 (4.8)
Blood bilirubin unconjugated increased	1 (2.5)	1 (2.4)	1 (2.4)
Gamma-glutamyltransferase increased	1 (2.5)	1 (2.4)	1 (2.4)
Weight increased	1 (2.5)	1 (2.4)	1 (2.4)
Metabolism and nutrition disorders	1 (2.5)	1 (2.4)	1 (2.4)
Tumour lysis syndrome	1 (2.5)	1 (2.4)	1 (2.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (7.5)	3 (7.1)	3 (7.1)
Acute myeloid leukaemia	1 (2.5)	1 (2.4)	1 (2.4)
Basal cell carcinoma	1 (2.5)	1 (2.4)	1 (2.4)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: System Organ Classes are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.3.3.1.4.1
Summary of Grade 3/4/5 Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 200 mg (N=40) n (%)	 <=200 mg (N=42) n (%)	 All Doses (N=42) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont.)			
Benign gastrointestinal neoplasm	1 (2.5)	1 (2.4)	1 (2.4)
Malignant melanoma	1 (2.5)	1 (2.4)	1 (2.4)
Psychiatric disorders	1 (2.5)	1 (2.4)	1 (2.4)
Delirium	1 (2.5)	1 (2.4)	1 (2.4)
Renal and urinary disorders	1 (2.5)	1 (2.4)	1 (2.4)
Nephrolithiasis	1 (2.5)	1 (2.4)	1 (2.4)
Obstructive uropathy	1 (2.5)	1 (2.4)	1 (2.4)
Respiratory, thoracic and mediastinal disorders	2 (5.0)	2 (4.8)	2 (4.8)
Bronchial haemorrhage	1 (2.5)	1 (2.4)	1 (2.4)
Haemothorax	1 (2.5)	1 (2.4)	1 (2.4)

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Table T.35.3.3.1.4.1
Summary of Grade 3/4/5 Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 200 mg (N=40) n (%)	 <=200 mg (N=42) n (%)	 All Doses (N=42) n (%)
Respiratory, thoracic and mediastinal disorders (cont.)			
Pleural effusion	1 (2.5)	1 (2.4)	1 (2.4)
Vascular disorders	3 (7.5)	3 (7.1)	3 (7.1)
Haemorrhage	1 (2.5)	1 (2.4)	1 (2.4)
Hypotension	1 (2.5)	1 (2.4)	1 (2.4)
Shock haemorrhagic	1 (2.5)	1 (2.4)	1 (2.4)

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Table T.35.3.3.1.4.1
Summary of Grade 3/4/5 Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	 <=200 mg (N=58) n (%)	 All Doses (N=83) n (%)
Patients with at least one Event	35 (67.3)	39 (67.2)	63 (75.9)
Blood and lymphatic system disorders	22 (42.3)	23 (39.7)	40 (48.2)
Anaemia	13 (25.0)	13 (22.4)	22 (26.5)
Thrombocytopenia	8 (15.4)	8 (13.8)	15 (18.1)
Neutropenia	6 (11.5)	7 (12.1)	11 (13.3)
Leukocytosis	2 (3.8)	2 (3.4)	3 (3.6)
Anaemia macrocytic	1 (1.9)	1 (1.7)	1 (1.2)
Autoimmune haemolytic anaemia	0	0	1 (1.2)
Haemolysis	0	0	1 (1.2)
Lymphopenia	0	0	1 (1.2)

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Table T.35.3.3.1.4.1
Summary of Grade 3/4/5 Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	 <=200 mg (N=58) n (%)	 All Doses (N=83) n (%)
Blood and lymphatic system disorders (cont.)			
Pancytopenia	0	0	1 (1.2)
Cardiac disorders	4 (7.7)	4 (6.9)	5 (6.0)
Cardiac failure	2 (3.8)	2 (3.4)	2 (2.4)
Acute myocardial infarction	0	0	1 (1.2)
Atrial flutter	1 (1.9)	1 (1.7)	1 (1.2)
Cardiac failure congestive	1 (1.9)	1 (1.7)	1 (1.2)
Ear and labyrinth disorders	0	0	1 (1.2)
Deafness neurosensory	0	0	1 (1.2)
Endocrine disorders	0	0	1 (1.2)
Inappropriate antidiuretic hormone secretion	0	0	1 (1.2)

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Table T.35.3.3.1.4.1
Summary of Grade 3/4/5 Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	 <=200 mg (N=58) n (%)	 All Doses (N=83) n (%)
Eye disorders	2 (3.8)	3 (5.2)	3 (3.6)
Periorbital oedema	1 (1.9)	1 (1.7)	1 (1.2)
Uveitis	0	1 (1.7)	1 (1.2)
Vitreous haemorrhage	1 (1.9)	1 (1.7)	1 (1.2)
Gastrointestinal disorders	8 (15.4)	8 (13.8)	15 (18.1)
Ascites	0	0	2 (2.4)
Gastric haemorrhage	0	0	2 (2.4)
Gastrointestinal haemorrhage	1 (1.9)	1 (1.7)	2 (2.4)
Nausea	1 (1.9)	1 (1.7)	2 (2.4)
Vomiting	1 (1.9)	1 (1.7)	2 (2.4)

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Table T.35.3.3.1.4.1
Summary of Grade 3/4/5 Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	 <=200 mg (N=58) n (%)	 All Doses (N=83) n (%)
Gastrointestinal disorders (cont.)			
Abdominal pain	1 (1.9)	1 (1.7)	1 (1.2)
Colitis	1 (1.9)	1 (1.7)	1 (1.2)
Diarrhoea	1 (1.9)	1 (1.7)	1 (1.2)
Duodenal ulcer haemorrhage	1 (1.9)	1 (1.7)	1 (1.2)
Gastritis haemorrhagic	0	0	1 (1.2)
Gastrointestinal perforation	0	0	1 (1.2)
Incarcerated umbilical hernia	1 (1.9)	1 (1.7)	1 (1.2)
Intra-abdominal haemorrhage	1 (1.9)	1 (1.7)	1 (1.2)
Large intestine perforation	1 (1.9)	1 (1.7)	1 (1.2)
Lower gastrointestinal haemorrhage	1 (1.9)	1 (1.7)	1 (1.2)

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Table T.35.3.3.1.4.1
Summary of Grade 3/4/5 Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	<=200 mg (N=58) n (%)	All Doses (N=83) n (%)
Gastrointestinal disorders (cont.)			
Melaena	1 (1.9)	1 (1.7)	1 (1.2)
Oesophagitis	0	0	1 (1.2)
Pancreatitis	0	0	1 (1.2)
General disorders and administration site conditions	3 (5.8)	3 (5.2)	9 (10.8)
Fatigue	2 (3.8)	2 (3.4)	7 (8.4)
Pyrexia	0	0	2 (2.4)
Disease progression	1 (1.9)	1 (1.7)	1 (1.2)
Hepatobiliary disorders	0	0	1 (1.2)
Cholelithiasis	0	0	1 (1.2)
Immune system disorders	1 (1.9)	1 (1.7)	3 (3.6)

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Table T.35.3.3.1.4.1
Summary of Grade 3/4/5 Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	 <=200 mg (N=58) n (%)	 All Doses (N=83) n (%)
Immune system disorders (cont.)			
Anaphylactic reaction	0	0	1 (1.2)
Anaphylactic shock	0	0	1 (1.2)
Immune system disorder	1 (1.9)	1 (1.7)	1 (1.2)
Infections and infestations	8 (15.4)	9 (15.5)	18 (21.7)
Pneumonia	0	0	4 (4.8)
Appendiceal abscess	1 (1.9)	1 (1.7)	1 (1.2)
Clostridium difficile infection	0	0	1 (1.2)
Corona virus infection	1 (1.9)	1 (1.7)	1 (1.2)
Diverticulitis	1 (1.9)	1 (1.7)	1 (1.2)
Escherichia bacteraemia	0	0	1 (1.2)

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Table T.35.3.3.1.4.1
Summary of Grade 3/4/5 Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	 <=200 mg (N=58) n (%)	 All Doses (N=83) n (%)
Infections and infestations (cont.)			
Herpes zoster	0	1 (1.7)	1 (1.2)
Localised infection	1 (1.9)	1 (1.7)	1 (1.2)
Necrotising fasciitis	1 (1.9)	1 (1.7)	1 (1.2)
Peritonitis bacterial	0	0	1 (1.2)
Sepsis	1 (1.9)	1 (1.7)	1 (1.2)
Septic shock	0	0	1 (1.2)
Skin infection	1 (1.9)	1 (1.7)	1 (1.2)
Tooth abscess	0	0	1 (1.2)
Upper respiratory tract infection	1 (1.9)	1 (1.7)	1 (1.2)
Urinary tract infection	0	0	1 (1.2)

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Table T.35.3.3.1.4.1
Summary of Grade 3/4/5 Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	 <=200 mg (N=58) n (%)	 All Doses (N=83) n (%)
Injury, poisoning and procedural complications	2 (3.8)	2 (3.4)	3 (3.6)
Anaemia postoperative	1 (1.9)	1 (1.7)	1 (1.2)
Femoral neck fracture	0	0	1 (1.2)
Subdural haematoma	1 (1.9)	1 (1.7)	1 (1.2)
Investigations	12 (23.1)	14 (24.1)	19 (22.9)
Platelet count decreased	5 (9.6)	6 (10.3)	6 (7.2)
White blood cell count decreased	4 (7.7)	5 (8.6)	6 (7.2)
Blood alkaline phosphatase increased	2 (3.8)	3 (5.2)	5 (6.0)
Neutrophil count decreased	3 (5.8)	3 (5.2)	3 (3.6)
Weight increased	1 (1.9)	1 (1.7)	2 (2.4)

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AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	 <=200 mg (N=58) n (%)	 All Doses (N=83) n (%)
Investigations (cont.)			
Blood bilirubin increased	0	0	1 (1.2)
Blood bilirubin unconjugated increased	1 (1.9)	1 (1.7)	1 (1.2)
Gamma-glutamyltransferase increased	1 (1.9)	1 (1.7)	1 (1.2)
Metabolism and nutrition disorders	2 (3.8)	2 (3.4)	9 (10.8)
Hypophosphataemia	0	0	3 (3.6)
Hypokalaemia	0	0	2 (2.4)
Decreased appetite	0	0	1 (1.2)
Hyperglycaemia	1 (1.9)	1 (1.7)	1 (1.2)
Hypernatraemia	0	0	1 (1.2)
Hypoalbuminaemia	0	0	1 (1.2)

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AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	 <=200 mg (N=58) n (%)	 All Doses (N=83) n (%)
Metabolism and nutrition disorders (cont.)			
Hypoglycaemia	0	0	1 (1.2)
Hyponatraemia	0	0	1 (1.2)
Tumour lysis syndrome	1 (1.9)	1 (1.7)	1 (1.2)
Musculoskeletal and connective tissue disorders	2 (3.8)	3 (5.2)	3 (3.6)
Arthralgia	1 (1.9)	2 (3.4)	2 (2.4)
Back pain	1 (1.9)	1 (1.7)	1 (1.2)
Muscular weakness	0	1 (1.7)	1 (1.2)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4 (7.7)	5 (8.6)	6 (7.2)
Acute myeloid leukaemia	1 (1.9)	1 (1.7)	1 (1.2)
Basal cell carcinoma	1 (1.9)	1 (1.7)	1 (1.2)

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System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	 <=200 mg (N=58) n (%)	 All Doses (N=83) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont.)			
Benign gastrointestinal neoplasm	1 (1.9)	1 (1.7)	1 (1.2)
Intraductal proliferative breast lesion	0	1 (1.7)	1 (1.2)
Intravascular papillary endothelial hyperplasia	0	0	1 (1.2)
Malignant melanoma	1 (1.9)	1 (1.7)	1 (1.2)
Myelodysplastic syndrome	1 (1.9)	1 (1.7)	1 (1.2)
Nervous system disorders	1 (1.9)	1 (1.7)	6 (7.2)
Encephalopathy	0	0	2 (2.4)
Haemorrhage intracranial	0	0	2 (2.4)
Cognitive disorder	0	0	1 (1.2)
Dizziness	0	0	1 (1.2)

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Summary of Grade 3/4/5 Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	 <=200 mg (N=58) n (%)	 All Doses (N=83) n (%)
Nervous system disorders (cont.)			
Headache	0	0	1 (1.2)
Myoclonus	1 (1.9)	1 (1.7)	1 (1.2)
Syncope	0	0	1 (1.2)
Psychiatric disorders	1 (1.9)	1 (1.7)	3 (3.6)
Insomnia	0	0	2 (2.4)
Delirium	1 (1.9)	1 (1.7)	1 (1.2)
Mental status changes	0	0	1 (1.2)
Renal and urinary disorders	2 (3.8)	2 (3.4)	4 (4.8)
Acute kidney injury	1 (1.9)	1 (1.7)	3 (3.6)
Nephrolithiasis	1 (1.9)	1 (1.7)	1 (1.2)

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AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	 <=200 mg (N=58) n (%)	 All Doses (N=83) n (%)
Renal and urinary disorders (cont.)			
Obstructive uropathy	1 (1.9)	1 (1.7)	1 (1.2)
Renal impairment	0	0	1 (1.2)
Respiratory, thoracic and mediastinal disorders	3 (5.8)	3 (5.2)	6 (7.2)
Pleural effusion	2 (3.8)	2 (3.4)	2 (2.4)
Acute respiratory failure	0	0	1 (1.2)
Bronchial haemorrhage	1 (1.9)	1 (1.7)	1 (1.2)
Chronic obstructive pulmonary disease	0	0	1 (1.2)
Haemothorax	1 (1.9)	1 (1.7)	1 (1.2)
Hypoxia	1 (1.9)	1 (1.7)	1 (1.2)
Laryngeal oedema	0	0	1 (1.2)

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Note 3: System Organ Classes are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'All Doses' column.
Program: ../BLU-285/ISS_BLU285/Final/Programs/Prod/Adhoc/German Request/t-35-3-3-1-4-1-g345-aesocpt.sas
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Table T.35.3.3.1.4.1
Summary of Grade 3/4/5 Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	 <=200 mg (N=58) n (%)	 All Doses (N=83) n (%)
Respiratory, thoracic and mediastinal disorders (cont.)			
Pulmonary hypertension	1 (1.9)	1 (1.7)	1 (1.2)
Skin and subcutaneous tissue disorders	0	0	1 (1.2)
Hair colour changes	0	0	1 (1.2)
Vascular disorders	3 (5.8)	3 (5.2)	6 (7.2)
Hypertension	0	0	3 (3.6)
Haemorrhage	1 (1.9)	1 (1.7)	1 (1.2)
Hypotension	1 (1.9)	1 (1.7)	1 (1.2)
Shock haemorrhagic	1 (1.9)	1 (1.7)	1 (1.2)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: System Organ Classes are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.3.3.1.6.1
Summary of Serious Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	BLU-285-2101 <=200 mg (N=16) n (%)	BLU-285-2101 All Doses (N=41) n (%)
Patients with at least one Event	5 (41.7)	7 (43.8)	27 (65.9)
Blood and lymphatic system disorders	1 (8.3)	1 (6.3)	3 (7.3)
Anaemia	1 (8.3)	1 (6.3)	3 (7.3)
Cardiac disorders	0	0	1 (2.4)
Acute myocardial infarction	0	0	1 (2.4)
Ear and labyrinth disorders	0	0	1 (2.4)
Tinnitus	0	0	1 (2.4)
Vertigo	0	0	1 (2.4)
Eye disorders	0	1 (6.3)	1 (2.4)
Uveitis	0	1 (6.3)	1 (2.4)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: System Organ Classes are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.3.3.1.6.1
Summary of Serious Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	 <=200 mg (N=16) n (%)	 All Doses (N=41) n (%)
Gastrointestinal disorders	2 (16.7)	2 (12.5)	9 (22.0)
Ascites	0	0	2 (4.9)
Abdominal pain	0	0	1 (2.4)
Gastric haemorrhage	0	0	1 (2.4)
Gastrointestinal haemorrhage	0	0	1 (2.4)
Gastrointestinal perforation	0	0	1 (2.4)
Incarcerated umbilical hernia	1 (8.3)	1 (6.3)	1 (2.4)
Large intestine perforation	1 (8.3)	1 (6.3)	1 (2.4)
Pancreatitis	0	0	1 (2.4)
Vomiting	0	0	1 (2.4)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: System Organ Classes are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.3.3.1.6.1
Summary of Serious Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	BLU-285-2101 <=200 mg (N=16) n (%)	BLU-285-2101 All Doses (N=41) n (%)
General disorders and administration site conditions	0	0	2 (4.9)
Pyrexia	0	0	2 (4.9)
Hepatobiliary disorders	0	0	1 (2.4)
Cholelithiasis	0	0	1 (2.4)
Immune system disorders	0	0	2 (4.9)
Anaphylactic reaction	0	0	1 (2.4)
Anaphylactic shock	0	0	1 (2.4)
Infections and infestations	2 (16.7)	2 (12.5)	9 (22.0)
Pneumonia	0	0	3 (7.3)
Clostridium difficile infection	0	0	1 (2.4)

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Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: System Organ Classes are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.3.3.1.6.1
Summary of Serious Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	<=200 mg (N=16) n (%)	All Doses (N=41) n (%)
Infections and infestations (cont.)			
Diverticulitis	1 (8.3)	1 (6.3)	1 (2.4)
Escherichia bacteraemia	0	0	1 (2.4)
Localised infection	1 (8.3)	1 (6.3)	1 (2.4)
Sepsis	0	0	1 (2.4)
Septic shock	0	0	1 (2.4)
Urinary tract infection	0	0	1 (2.4)
Injury, poisoning and procedural complications	2 (16.7)	2 (12.5)	5 (12.2)
Subdural haematoma	1 (8.3)	1 (6.3)	2 (4.9)
Femoral neck fracture	0	0	1 (2.4)
Fractured sacrum	1 (8.3)	1 (6.3)	1 (2.4)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
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Table T.35.3.3.1.6.1
Summary of Serious Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	 <=200 mg (N=16) n (%)	 All Doses (N=41) n (%)
Injury, poisoning and procedural complications (cont.)			
Lumbar vertebral fracture	1 (8.3)	1 (6.3)	1 (2.4)
Overdose	0	0	1 (2.4)
Metabolism and nutrition disorders	0	0	2 (4.9)
Hypoglycaemia	0	0	1 (2.4)
Hyponatraemia	0	0	1 (2.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (8.3)	2 (12.5)	4 (9.8)
Intraductal proliferative breast lesion	0	1 (6.3)	1 (2.4)
Intravascular papillary endothelial hyperplasia	0	0	1 (2.4)
Myelodysplastic syndrome	1 (8.3)	1 (6.3)	1 (2.4)
Transitional cell carcinoma	0	0	1 (2.4)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
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Table T.35.3.3.1.6.1
Summary of Serious Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	BLU-285-2101 <=200 mg (N=16) n (%)	BLU-285-2101 All Doses (N=41) n (%)
Nervous system disorders	1 (8.3)	1 (6.3)	5 (12.2)
Encephalopathy	0	0	2 (4.9)
Dementia	0	0	1 (2.4)
Haemorrhage intracranial	0	0	1 (2.4)
Myoclonus	1 (8.3)	1 (6.3)	1 (2.4)
Syncope	0	0	1 (2.4)
Psychiatric disorders	0	0	1 (2.4)
Mental status changes	0	0	1 (2.4)
Renal and urinary disorders	1 (8.3)	1 (6.3)	2 (4.9)
Acute kidney injury	1 (8.3)	1 (6.3)	2 (4.9)

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Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
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Table T.35.3.3.1.6.1
Summary of Serious Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	 <=200 mg (N=16) n (%)	 All Doses (N=41) n (%)
Respiratory, thoracic and mediastinal disorders	1 (8.3)	1 (6.3)	3 (7.3)
Acute respiratory failure	0	0	1 (2.4)
Chronic obstructive pulmonary disease	0	0	1 (2.4)
Pleural effusion	1 (8.3)	1 (6.3)	1 (2.4)
Pneumothorax	1 (8.3)	1 (6.3)	1 (2.4)

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Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
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Note 3: System Organ Classes are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.3.3.1.6.1
Summary of Serious Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 200 mg (N=40) n (%)	 <=200 mg (N=42) n (%)	 All Doses (N=42) n (%)
Patients with at least one Event	16 (40.0)	17 (40.5)	17 (40.5)
Blood and lymphatic system disorders	2 (5.0)	2 (4.8)	2 (4.8)
Haemorrhagic diathesis	1 (2.5)	1 (2.4)	1 (2.4)
Leukocytosis	1 (2.5)	1 (2.4)	1 (2.4)
Cardiac disorders	1 (2.5)	1 (2.4)	1 (2.4)
Cardiac failure	1 (2.5)	1 (2.4)	1 (2.4)
Gastrointestinal disorders	5 (12.5)	5 (11.9)	5 (11.9)
Ascites	1 (2.5)	1 (2.4)	1 (2.4)
Duodenal ulcer haemorrhage	1 (2.5)	1 (2.4)	1 (2.4)
Gastrointestinal haemorrhage	1 (2.5)	1 (2.4)	1 (2.4)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: System Organ Classes are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.3.3.1.6.1
Summary of Serious Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 200 mg (N=40) n (%)	 <=200 mg (N=42) n (%)	 All Doses (N=42) n (%)
Gastrointestinal disorders (cont.)			
Intra-abdominal haemorrhage	1 (2.5)	1 (2.4)	1 (2.4)
Lower gastrointestinal haemorrhage	1 (2.5)	1 (2.4)	1 (2.4)
General disorders and administration site conditions	1 (2.5)	1 (2.4)	1 (2.4)
Disease progression	1 (2.5)	1 (2.4)	1 (2.4)
Immune system disorders	1 (2.5)	1 (2.4)	1 (2.4)
Immune system disorder	1 (2.5)	1 (2.4)	1 (2.4)
Infections and infestations	6 (15.0)	7 (16.7)	7 (16.7)
Appendiceal abscess	1 (2.5)	1 (2.4)	1 (2.4)
Corona virus infection	1 (2.5)	1 (2.4)	1 (2.4)
Herpes zoster	0	1 (2.4)	1 (2.4)

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Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
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Table T.35.3.3.1.6.1
Summary of Serious Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 200 mg (N=40) n (%)	 <=200 mg (N=42) n (%)	 All Doses (N=42) n (%)
Infections and infestations (cont.)			
Necrotising fasciitis	1 (2.5)	1 (2.4)	1 (2.4)
Skin infection	1 (2.5)	1 (2.4)	1 (2.4)
Stoma site cellulitis	1 (2.5)	1 (2.4)	1 (2.4)
Wound infection	1 (2.5)	1 (2.4)	1 (2.4)
Injury, poisoning and procedural complications	1 (2.5)	1 (2.4)	1 (2.4)
Subdural haematoma	1 (2.5)	1 (2.4)	1 (2.4)
Investigations	1 (2.5)	1 (2.4)	1 (2.4)
Haemoglobin decreased	1 (2.5)	1 (2.4)	1 (2.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (7.5)	3 (7.1)	3 (7.1)
Acute myeloid leukaemia	1 (2.5)	1 (2.4)	1 (2.4)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: System Organ Classes are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.3.3.1.6.1
Summary of Serious Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 200 mg (N=40) n (%)	 <=200 mg (N=42) n (%)	 All Doses (N=42) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont.)			
Basal cell carcinoma	1 (2.5)	1 (2.4)	1 (2.4)
Benign gastrointestinal neoplasm	1 (2.5)	1 (2.4)	1 (2.4)
Malignant melanoma	1 (2.5)	1 (2.4)	1 (2.4)
Renal and urinary disorders	1 (2.5)	1 (2.4)	1 (2.4)
Nephrolithiasis	1 (2.5)	1 (2.4)	1 (2.4)
Obstructive uropathy	1 (2.5)	1 (2.4)	1 (2.4)
Respiratory, thoracic and mediastinal disorders	1 (2.5)	1 (2.4)	1 (2.4)
Bronchial haemorrhage	1 (2.5)	1 (2.4)	1 (2.4)
Haemothorax	1 (2.5)	1 (2.4)	1 (2.4)
Vascular disorders	3 (7.5)	3 (7.1)	3 (7.1)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: System Organ Classes are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.3.3.1.6.1
Summary of Serious Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 200 mg (N=40) n (%)	 <=200 mg (N=42) n (%)	 All Doses (N=42) n (%)
Vascular disorders (cont.)			
Haemorrhage	1 (2.5)	1 (2.4)	1 (2.4)
Hypotension	1 (2.5)	1 (2.4)	1 (2.4)
Shock haemorrhagic	1 (2.5)	1 (2.4)	1 (2.4)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: System Organ Classes are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.3.3.1.6.1
Summary of Serious Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	 <=200 mg (N=58) n (%)	 All Doses (N=83) n (%)
Patients with at least one Event	21 (40.4)	24 (41.4)	44 (53.0)
Blood and lymphatic system disorders	3 (5.8)	3 (5.2)	5 (6.0)
Anaemia	1 (1.9)	1 (1.7)	3 (3.6)
Haemorrhagic diathesis	1 (1.9)	1 (1.7)	1 (1.2)
Leukocytosis	1 (1.9)	1 (1.7)	1 (1.2)
Cardiac disorders	1 (1.9)	1 (1.7)	2 (2.4)
Acute myocardial infarction	0	0	1 (1.2)
Cardiac failure	1 (1.9)	1 (1.7)	1 (1.2)
Ear and labyrinth disorders	0	0	1 (1.2)
Tinnitus	0	0	1 (1.2)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
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Table T.35.3.3.1.6.1
Summary of Serious Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	 <=200 mg (N=58) n (%)	 All Doses (N=83) n (%)
Ear and labyrinth disorders (cont.)			
Vertigo	0	0	1 (1.2)
Eye disorders	0	1 (1.7)	1 (1.2)
Uveitis	0	1 (1.7)	1 (1.2)
Gastrointestinal disorders	7 (13.5)	7 (12.1)	14 (16.9)
Ascites	1 (1.9)	1 (1.7)	3 (3.6)
Gastrointestinal haemorrhage	1 (1.9)	1 (1.7)	2 (2.4)
Abdominal pain	0	0	1 (1.2)
Duodenal ulcer haemorrhage	1 (1.9)	1 (1.7)	1 (1.2)
Gastric haemorrhage	0	0	1 (1.2)
Gastrointestinal perforation	0	0	1 (1.2)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: System Organ Classes are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.3.3.1.6.1
Summary of Serious Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	 <=200 mg (N=58) n (%)	 All Doses (N=83) n (%)
Gastrointestinal disorders (cont.)			
Incarcerated umbilical hernia	1 (1.9)	1 (1.7)	1 (1.2)
Intra-abdominal haemorrhage	1 (1.9)	1 (1.7)	1 (1.2)
Large intestine perforation	1 (1.9)	1 (1.7)	1 (1.2)
Lower gastrointestinal haemorrhage	1 (1.9)	1 (1.7)	1 (1.2)
Pancreatitis	0	0	1 (1.2)
Vomiting	0	0	1 (1.2)
General disorders and administration site conditions	1 (1.9)	1 (1.7)	3 (3.6)
Pyrexia	0	0	2 (2.4)
Disease progression	1 (1.9)	1 (1.7)	1 (1.2)
Hepatobiliary disorders	0	0	1 (1.2)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
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Table T.35.3.3.1.6.1
Summary of Serious Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	 <=200 mg (N=58) n (%)	 All Doses (N=83) n (%)
Hepatobiliary disorders (cont.)			
Cholelithiasis	0	0	1 (1.2)
Immune system disorders	1 (1.9)	1 (1.7)	3 (3.6)
Anaphylactic reaction	0	0	1 (1.2)
Anaphylactic shock	0	0	1 (1.2)
Immune system disorder	1 (1.9)	1 (1.7)	1 (1.2)
Infections and infestations	8 (15.4)	9 (15.5)	16 (19.3)
Pneumonia	0	0	3 (3.6)
Appendiceal abscess	1 (1.9)	1 (1.7)	1 (1.2)
Clostridium difficile infection	0	0	1 (1.2)
Corona virus infection	1 (1.9)	1 (1.7)	1 (1.2)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: System Organ Classes are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.3.3.1.6.1
Summary of Serious Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	 <=200 mg (N=58) n (%)	 All Doses (N=83) n (%)
Infections and infestations (cont.)			
Diverticulitis	1 (1.9)	1 (1.7)	1 (1.2)
Escherichia bacteraemia	0	0	1 (1.2)
Herpes zoster	0	1 (1.7)	1 (1.2)
Localised infection	1 (1.9)	1 (1.7)	1 (1.2)
Necrotising fasciitis	1 (1.9)	1 (1.7)	1 (1.2)
Sepsis	0	0	1 (1.2)
Septic shock	0	0	1 (1.2)
Skin infection	1 (1.9)	1 (1.7)	1 (1.2)
Stoma site cellulitis	1 (1.9)	1 (1.7)	1 (1.2)
Urinary tract infection	0	0	1 (1.2)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: System Organ Classes are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.3.3.1.6.1
Summary of Serious Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	 <=200 mg (N=58) n (%)	 All Doses (N=83) n (%)
Infections and infestations (cont.)			
Wound infection	1 (1.9)	1 (1.7)	1 (1.2)
Injury, poisoning and procedural complications	3 (5.8)	3 (5.2)	6 (7.2)
Subdural haematoma	2 (3.8)	2 (3.4)	3 (3.6)
Femoral neck fracture	0	0	1 (1.2)
Fractured sacrum	1 (1.9)	1 (1.7)	1 (1.2)
Lumbar vertebral fracture	1 (1.9)	1 (1.7)	1 (1.2)
Overdose	0	0	1 (1.2)
Investigations	1 (1.9)	1 (1.7)	1 (1.2)
Haemoglobin decreased	1 (1.9)	1 (1.7)	1 (1.2)
Metabolism and nutrition disorders	0	0	2 (2.4)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: System Organ Classes are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.3.3.1.6.1
Summary of Serious Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	 <=200 mg (N=58) n (%)	 All Doses (N=83) n (%)
Metabolism and nutrition disorders (cont.)			
Hypoglycaemia	0	0	1 (1.2)
Hyponatraemia	0	0	1 (1.2)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4 (7.7)	5 (8.6)	7 (8.4)
Acute myeloid leukaemia	1 (1.9)	1 (1.7)	1 (1.2)
Basal cell carcinoma	1 (1.9)	1 (1.7)	1 (1.2)
Benign gastrointestinal neoplasm	1 (1.9)	1 (1.7)	1 (1.2)
Intraductal proliferative breast lesion	0	1 (1.7)	1 (1.2)
Intravascular papillary endothelial hyperplasia	0	0	1 (1.2)
Malignant melanoma	1 (1.9)	1 (1.7)	1 (1.2)
Myelodysplastic syndrome	1 (1.9)	1 (1.7)	1 (1.2)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: System Organ Classes are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.3.3.1.6.1
Summary of Serious Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	 <=200 mg (N=58) n (%)	 All Doses (N=83) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont.)			
Transitional cell carcinoma	0	0	1 (1.2)
Nervous system disorders	1 (1.9)	1 (1.7)	5 (6.0)
Encephalopathy	0	0	2 (2.4)
Dementia	0	0	1 (1.2)
Haemorrhage intracranial	0	0	1 (1.2)
Myoclonus	1 (1.9)	1 (1.7)	1 (1.2)
Syncope	0	0	1 (1.2)
Psychiatric disorders	0	0	1 (1.2)
Mental status changes	0	0	1 (1.2)
Renal and urinary disorders	2 (3.8)	2 (3.4)	3 (3.6)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: System Organ Classes are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.3.3.1.6.1
Summary of Serious Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	 <=200 mg (N=58) n (%)	 All Doses (N=83) n (%)
Renal and urinary disorders (cont.)			
Acute kidney injury	1 (1.9)	1 (1.7)	2 (2.4)
Nephrolithiasis	1 (1.9)	1 (1.7)	1 (1.2)
Obstructive uropathy	1 (1.9)	1 (1.7)	1 (1.2)
Respiratory, thoracic and mediastinal disorders	2 (3.8)	2 (3.4)	4 (4.8)
Acute respiratory failure	0	0	1 (1.2)
Bronchial haemorrhage	1 (1.9)	1 (1.7)	1 (1.2)
Chronic obstructive pulmonary disease	0	0	1 (1.2)
Haemothorax	1 (1.9)	1 (1.7)	1 (1.2)
Pleural effusion	1 (1.9)	1 (1.7)	1 (1.2)
Pneumothorax	1 (1.9)	1 (1.7)	1 (1.2)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: System Organ Classes are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.3.3.1.6.1
Summary of Serious Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	 <=200 mg (N=58) n (%)	 All Doses (N=83) n (%)
Vascular disorders	3 (5.8)	3 (5.2)	3 (3.6)
Haemorrhage	1 (1.9)	1 (1.7)	1 (1.2)
Hypotension	1 (1.9)	1 (1.7)	1 (1.2)
Shock haemorrhagic	1 (1.9)	1 (1.7)	1 (1.2)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: System Organ Classes are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.3.3.1.8.1
Summary of Fatal Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

	BLU-285-2101		
System Organ Class Preferred Term	200 mg (N=12) n (%)	<=200 mg (N=16) n (%)	All Doses (N=41) n (%)
Patients with at least one Event	0	0	2 (4.9)
Infections and infestations	0	0	1 (2.4)
Septic shock	0	0	1 (2.4)
Nervous system disorders	0	0	1 (2.4)
Haemorrhage intracranial	0	0	1 (2.4)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: System Organ Classes are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.3.3.1.8.1
Summary of Fatal Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2202 200 mg (N=40) n (%)	BLU-285-2202 <=200 mg (N=42) n (%)	BLU-285-2202 All Doses (N=42) n (%)
Patients with at least one Event	3 (7.5)	3 (7.1)	3 (7.1)
General disorders and administration site conditions	1 (2.5)	1 (2.4)	1 (2.4)
Disease progression	1 (2.5)	1 (2.4)	1 (2.4)
Infections and infestations	1 (2.5)	1 (2.4)	1 (2.4)
Necrotising fasciitis	1 (2.5)	1 (2.4)	1 (2.4)
Vascular disorders	1 (2.5)	1 (2.4)	1 (2.4)
Shock haemorrhagic	1 (2.5)	1 (2.4)	1 (2.4)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: System Organ Classes are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.3.3.1.8.1
Summary of Fatal Adverse Events by System Organ Class and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

System Organ Class Preferred Term	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	 <=200 mg (N=58) n (%)	 All Doses (N=83) n (%)
Patients with at least one Event	3 (5.8)	3 (5.2)	5 (6.0)
General disorders and administration site conditions	1 (1.9)	1 (1.7)	1 (1.2)
Disease progression	1 (1.9)	1 (1.7)	1 (1.2)
Infections and infestations	1 (1.9)	1 (1.7)	2 (2.4)
Necrotising fasciitis	1 (1.9)	1 (1.7)	1 (1.2)
Septic shock	0	0	1 (1.2)
Nervous system disorders	0	0	1 (1.2)
Haemorrhage intracranial	0	0	1 (1.2)
Vascular disorders	1 (1.9)	1 (1.7)	1 (1.2)
Shock haemorrhagic	1 (1.9)	1 (1.7)	1 (1.2)

Abbreviations: AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experiences more than 1 event within a given System Organ Class or Preferred Term, that patient is counted only once under that System Organ Class or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: System Organ Classes are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.3.3.2.1.2
Summary of Adverse Events of Special Interest by Category, Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

AESI Category Preferred Term	BLU-285-2101 & 200 mg Dose Group (N=12) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Patients with at least one Event	3 (25.0)	0	0	0	0	3 (25.0)
Cognitive effects	2 (16.7)	0	0	0	0	2 (16.7)
Cognitive disorder	1 (8.3)	0	0	0	0	1 (8.3)
Memory impairment	1 (8.3)	0	0	0	0	1 (8.3)
Agitation	0	0	0	0	0	0
Amnesia	0	0	0	0	0	0
Confusional state	0	0	0	0	0	0
Delirium	0	0	0	0	0	0
Dementia	0	0	0	0	0	0
Disorientation	0	0	0	0	0	0
Encephalopathy	0	0	0	0	0	0
Hallucination	0	0	0	0	0	0

Abbreviations: AESI=Adverse Event of Special Interest; AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
Note 1: In each treatment group, if a patient experiences more than 1 event within a given AESI category or Preferred Term, that patient is counted only once at the highest grade under that AESI category or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column and treatment group.
Note 3: AESI Categories are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'Any Grade' column.
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Table T.35.3.3.2.1.2
Summary of Adverse Events of Special Interest by Category, Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

AESI Category Preferred Term	BLU-285-2101 & 200 mg Dose Group (N=12) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Cognitive effects (cont.)						
Mental impairment	0	0	0	0	0	0
Mental status changes	0	0	0	0	0	0
Mood altered	0	0	0	0	0	0
Personality change	0	0	0	0	0	0
Psychotic disorder	0	0	0	0	0	0
Somnolence	0	0	0	0	0	0
Speech disorder	0	0	0	0	0	0
Intracranial bleeding	1 (8.3)	0	0	0	0	1 (8.3)
Subdural haematoma	1 (8.3)	0	0	0	0	1 (8.3)
Cerebral haemorrhage	0	0	0	0	0	0
Haemorrhage intracranial	0	0	0	0	0	0

Abbreviations: AESI=Adverse Event of Special Interest; AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
Note 1: In each treatment group, if a patient experiences more than 1 event within a given AESI category or Preferred Term, that patient is counted only once at the highest grade under that AESI category or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column and treatment group.
Note 3: AESI Categories are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'Any Grade' column.
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Table T.35.3.3.2.1.2
Summary of Adverse Events of Special Interest by Category, Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

AESI Category Preferred Term	BLU-285-2101 & <=200 mg Dose Group (N=16) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Patients with at least one Event	3 (18.8)	0	0	0	0	3 (18.8)
Cognitive effects	2 (12.5)	0	0	0	0	2 (12.5)
Cognitive disorder	1 (6.3)	0	0	0	0	1 (6.3)
Memory impairment	1 (6.3)	0	0	0	0	1 (6.3)
Agitation	0	0	0	0	0	0
Amnesia	0	0	0	0	0	0
Confusional state	0	0	0	0	0	0
Delirium	0	0	0	0	0	0
Dementia	0	0	0	0	0	0
Disorientation	0	0	0	0	0	0
Encephalopathy	0	0	0	0	0	0
Hallucination	0	0	0	0	0	0

Abbreviations: AESI=Adverse Event of Special Interest; AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
Note 1: In each treatment group, if a patient experiences more than 1 event within a given AESI category or Preferred Term, that patient is counted only once at the highest grade under that AESI category or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column and treatment group.
Note 3: AESI Categories are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'Any Grade' column.
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Table T.35.3.3.2.1.2
Summary of Adverse Events of Special Interest by Category, Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

AESI Category Preferred Term	BLU-285-2101 & <=200 mg Dose Group (N=16) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Cognitive effects (cont.)						
Mental impairment	0	0	0	0	0	0
Mental status changes	0	0	0	0	0	0
Mood altered	0	0	0	0	0	0
Personality change	0	0	0	0	0	0
Psychotic disorder	0	0	0	0	0	0
Somnolence	0	0	0	0	0	0
Speech disorder	0	0	0	0	0	0
Intracranial bleeding	1 (6.3)	0	0	0	0	1 (6.3)
Subdural haematoma	1 (6.3)	0	0	0	0	1 (6.3)
Cerebral haemorrhage	0	0	0	0	0	0
Haemorrhage intracranial	0	0	0	0	0	0

Abbreviations: AESI=Adverse Event of Special Interest; AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
Note 1: In each treatment group, if a patient experiences more than 1 event within a given AESI category or Preferred Term, that patient is counted only once at the highest grade under that AESI category or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column and treatment group.
Note 3: AESI Categories are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'Any Grade' column.
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Table T.35.3.3.2.1.2
Summary of Adverse Events of Special Interest by Category, Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

AESI Category Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Patients with at least one Event	9 (22.0)	4 (9.8)	3 (7.3)	0	1 (2.4)	17 (41.5)
Cognitive effects	9 (22.0)	4 (9.8)	2 (4.9)	0	0	15 (36.6)
Memory impairment	7 (17.1)	2 (4.9)	0	0	0	9 (22.0)
Cognitive disorder	2 (4.9)	2 (4.9)	1 (2.4)	0	0	5 (12.2)
Confusional state	0	2 (4.9)	0	0	0	2 (4.9)
Encephalopathy	0	0	2 (4.9)	0	0	2 (4.9)
Dementia	0	1 (2.4)	0	0	0	1 (2.4)
Mental status changes	0	0	1 (2.4)	0	0	1 (2.4)
Somnolence	1 (2.4)	0	0	0	0	1 (2.4)
Agitation	0	0	0	0	0	0
Amnesia	0	0	0	0	0	0
Delirium	0	0	0	0	0	0

Abbreviations: AESI=Adverse Event of Special Interest; AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
Note 1: In each treatment group, if a patient experiences more than 1 event within a given AESI category or Preferred Term, that patient is counted only once at the highest grade under that AESI category or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column and treatment group.
Note 3: AESI Categories are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'Any Grade' column.
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Table T.35.3.3.2.1.2
Summary of Adverse Events of Special Interest by Category, Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

AESI Category Preferred Term	BLU-285-2101 & All Dose Group (N=41) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Cognitive effects (cont.)						
Disorientation	0	0	0	0	0	0
Hallucination	0	0	0	0	0	0
Mental impairment	0	0	0	0	0	0
Mood altered	0	0	0	0	0	0
Personality change	0	0	0	0	0	0
Psychotic disorder	0	0	0	0	0	0
Speech disorder	0	0	0	0	0	0
Intracranial bleeding	2 (4.9)	0	1 (2.4)	0	1 (2.4)	4 (9.8)
Haemorrhage intracranial	0	0	1 (2.4)	0	1 (2.4)	2 (4.9)
Subdural haematoma	2 (4.9)	0	0	0	0	2 (4.9)
Cerebral haemorrhage	0	0	0	0	0	0

Abbreviations: AESI=Adverse Event of Special Interest; AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
Note 1: In each treatment group, if a patient experiences more than 1 event within a given AESI category or Preferred Term, that patient is counted only once at the highest grade under that AESI category or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column and treatment group.
Note 3: AESI Categories are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'Any Grade' column.
Program: ../BLU-285/ISS_BLU285/Final/Programs/Prod/Adhoc/German Request/t-35-3-3-2-1-2-aesigr.sas
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Table T.35.3.3.2.1.2
Summary of Adverse Events of Special Interest by Category, Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

AESI Category Preferred Term	BLU-285-2202 & 200 mg Dose Group (N=40) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Patients with at least one Event	4 (10.0)	1 (2.5)	1 (2.5)	1 (2.5)	0	7 (17.5)
Cognitive effects	5 (12.5)	1 (2.5)	1 (2.5)	0	0	7 (17.5)
Cognitive disorder	1 (2.5)	1 (2.5)	0	0	0	2 (5.0)
Memory impairment	2 (5.0)	0	0	0	0	2 (5.0)
Confusional state	1 (2.5)	0	0	0	0	1 (2.5)
Delirium	0	0	1 (2.5)	0	0	1 (2.5)
Disorientation	1 (2.5)	0	0	0	0	1 (2.5)
Agitation	0	0	0	0	0	0
Amnesia	0	0	0	0	0	0
Dementia	0	0	0	0	0	0
Encephalopathy	0	0	0	0	0	0
Hallucination	0	0	0	0	0	0

Abbreviations: AESI=Adverse Event of Special Interest; AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
Note 1: In each treatment group, if a patient experiences more than 1 event within a given AESI category or Preferred Term, that patient is counted only once at the highest grade under that AESI category or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column and treatment group.
Note 3: AESI Categories are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'Any Grade' column.
Program: ../BLU-285/ISS_BLU285/Final/Programs/Prod/Adhoc/German Request/t-35-3-3-2-1-2-aesigr.sas
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Table T.35.3.3.2.1.2
Summary of Adverse Events of Special Interest by Category, Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

AESI Category Preferred Term	BLU-285-2202 & 200 mg Dose Group (N=40) Grade 1 n (%)	 Grade 2 n (%)	 Grade 3 n (%)	 Grade 4 n (%)	 Grade 5 n (%)	 Any Grade n (%)
Cognitive effects (cont.)						
Mental impairment	0	0	0	0	0	0
Mental status changes	0	0	0	0	0	0
Mood altered	0	0	0	0	0	0
Personality change	0	0	0	0	0	0
Psychotic disorder	0	0	0	0	0	0
Somnolence	0	0	0	0	0	0
Speech disorder	0	0	0	0	0	0
Intracranial bleeding	0	0	0	1 (2.5)	0	1 (2.5)
Subdural haematoma	0	0	0	1 (2.5)	0	1 (2.5)
Cerebral haemorrhage	0	0	0	0	0	0
Haemorrhage intracranial	0	0	0	0	0	0

Abbreviations: AESI=Adverse Event of Special Interest; AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
Note 1: In each treatment group, if a patient experiences more than 1 event within a given AESI category or Preferred Term, that patient is counted only once at the highest grade under that AESI category or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column and treatment group.
Note 3: AESI Categories are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'Any Grade' column.
Program: ../BLU-285/ISS_BLU285/Final/Programs/Prod/Adhoc/German Request/t-35-3-3-2-1-2-aesigr.sas
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Table T.35.3.3.2.1.2
Summary of Adverse Events of Special Interest by Category, Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

AESI Category Preferred Term	BLU-285-2202 & <=200 mg Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Patients with at least one Event	4 (9.5)	1 (2.4)	1 (2.4)	1 (2.4)	0	7 (16.7)
Cognitive effects	5 (11.9)	1 (2.4)	1 (2.4)	0	0	7 (16.7)
Cognitive disorder	1 (2.4)	1 (2.4)	0	0	0	2 (4.8)
Memory impairment	2 (4.8)	0	0	0	0	2 (4.8)
Confusional state	1 (2.4)	0	0	0	0	1 (2.4)
Delirium	0	0	1 (2.4)	0	0	1 (2.4)
Disorientation	1 (2.4)	0	0	0	0	1 (2.4)
Agitation	0	0	0	0	0	0
Amnesia	0	0	0	0	0	0
Dementia	0	0	0	0	0	0
Encephalopathy	0	0	0	0	0	0
Hallucination	0	0	0	0	0	0

Abbreviations: AESI=Adverse Event of Special Interest; AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
Note 1: In each treatment group, if a patient experiences more than 1 event within a given AESI category or Preferred Term, that patient is counted only once at the highest grade under that AESI category or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column and treatment group.
Note 3: AESI Categories are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'Any Grade' column.
Program: ../BLU-285/ISS_BLU285/Final/Programs/Prod/Adhoc/German Request/t-35-3-3-2-1-2-aesigr.sas
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Table T.35.3.3.2.1.2
Summary of Adverse Events of Special Interest by Category, Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

AESI Category Preferred Term	BLU-285-2202 & <=200 mg Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Cognitive effects (cont.)						
Mental impairment	0	0	0	0	0	0
Mental status changes	0	0	0	0	0	0
Mood altered	0	0	0	0	0	0
Personality change	0	0	0	0	0	0
Psychotic disorder	0	0	0	0	0	0
Somnolence	0	0	0	0	0	0
Speech disorder	0	0	0	0	0	0
Intracranial bleeding	0	0	0	1 (2.4)	0	1 (2.4)
Subdural haematoma	0	0	0	1 (2.4)	0	1 (2.4)
Cerebral haemorrhage	0	0	0	0	0	0
Haemorrhage intracranial	0	0	0	0	0	0

Abbreviations: AESI=Adverse Event of Special Interest; AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
Note 1: In each treatment group, if a patient experiences more than 1 event within a given AESI category or Preferred Term, that patient is counted only once at the highest grade under that AESI category or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column and treatment group.
Note 3: AESI Categories are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'Any Grade' column.
Program: ../BLU-285/ISS_BLU285/Final/Programs/Prod/Adhoc/German Request/t-35-3-3-2-1-2-aesigr.sas
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Table T.35.3.3.2.1.2
Summary of Adverse Events of Special Interest by Category, Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

AESI Category Preferred Term	BLU-285-2202 & All Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Patients with at least one Event	4 (9.5)	1 (2.4)	1 (2.4)	1 (2.4)	0	7 (16.7)
Cognitive effects	5 (11.9)	1 (2.4)	1 (2.4)	0	0	7 (16.7)
Cognitive disorder	1 (2.4)	1 (2.4)	0	0	0	2 (4.8)
Memory impairment	2 (4.8)	0	0	0	0	2 (4.8)
Confusional state	1 (2.4)	0	0	0	0	1 (2.4)
Delirium	0	0	1 (2.4)	0	0	1 (2.4)
Disorientation	1 (2.4)	0	0	0	0	1 (2.4)
Agitation	0	0	0	0	0	0
Amnesia	0	0	0	0	0	0
Dementia	0	0	0	0	0	0
Encephalopathy	0	0	0	0	0	0
Hallucination	0	0	0	0	0	0

Abbreviations: AESI=Adverse Event of Special Interest; AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
Note 1: In each treatment group, if a patient experiences more than 1 event within a given AESI category or Preferred Term, that patient is counted only once at the highest grade under that AESI category or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column and treatment group.
Note 3: AESI Categories are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'Any Grade' column.
Program: ../BLU-285/ISS_BLU285/Final/Programs/Prod/Adhoc/German Request/t-35-3-3-2-1-2-aesigr.sas
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Table T.35.3.3.2.1.2
Summary of Adverse Events of Special Interest by Category, Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

AESI Category Preferred Term	BLU-285-2202 & All Dose Group (N=42) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Cognitive effects (cont.)						
Mental impairment	0	0	0	0	0	0
Mental status changes	0	0	0	0	0	0
Mood altered	0	0	0	0	0	0
Personality change	0	0	0	0	0	0
Psychotic disorder	0	0	0	0	0	0
Somnolence	0	0	0	0	0	0
Speech disorder	0	0	0	0	0	0
Intracranial bleeding	0	0	0	1 (2.4)	0	1 (2.4)
Subdural haematoma	0	0	0	1 (2.4)	0	1 (2.4)
Cerebral haemorrhage	0	0	0	0	0	0
Haemorrhage intracranial	0	0	0	0	0	0

Abbreviations: AESI=Adverse Event of Special Interest; AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
Note 1: In each treatment group, if a patient experiences more than 1 event within a given AESI category or Preferred Term, that patient is counted only once at the highest grade under that AESI category or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column and treatment group.
Note 3: AESI Categories are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'Any Grade' column.
Program: ../BLU-285/ISS_BLU285/Final/Programs/Prod/Adhoc/German Request/t-35-3-3-2-1-2-aesigr.sas
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Table T.35.3.3.2.1.2
Summary of Adverse Events of Special Interest by Category, Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

AESI Category Preferred Term	BLU-285-2101 + BLU-285-2202 & 200 mg Dose Group (N=52) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Patients with at least one Event	7 (13.5)	1 (1.9)	1 (1.9)	1 (1.9)	0	10 (19.2)
Cognitive effects	7 (13.5)	1 (1.9)	1 (1.9)	0	0	9 (17.3)
Cognitive disorder	2 (3.8)	1 (1.9)	0	0	0	3 (5.8)
Memory impairment	3 (5.8)	0	0	0	0	3 (5.8)
Confusional state	1 (1.9)	0	0	0	0	1 (1.9)
Delirium	0	0	1 (1.9)	0	0	1 (1.9)
Disorientation	1 (1.9)	0	0	0	0	1 (1.9)
Agitation	0	0	0	0	0	0
Amnesia	0	0	0	0	0	0
Dementia	0	0	0	0	0	0
Encephalopathy	0	0	0	0	0	0
Hallucination	0	0	0	0	0	0

Abbreviations: AESI=Adverse Event of Special Interest; AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
Note 1: In each treatment group, if a patient experiences more than 1 event within a given AESI category or Preferred Term, that patient is counted only once at the highest grade under that AESI category or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column and treatment group.
Note 3: AESI Categories are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'Any Grade' column.
Program: ../BLU-285/ISS_BLU285/Final/Programs/Prod/Adhoc/German Request/t-35-3-3-2-1-2-aesigr.sas
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Table T.35.3.3.2.1.2
Summary of Adverse Events of Special Interest by Category, Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

AESI Category Preferred Term	BLU-285-2101 + BLU-285-2202 & 200 mg Dose Group (N=52) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Cognitive effects (cont.)						
Mental impairment	0	0	0	0	0	0
Mental status changes	0	0	0	0	0	0
Mood altered	0	0	0	0	0	0
Personality change	0	0	0	0	0	0
Psychotic disorder	0	0	0	0	0	0
Somnolence	0	0	0	0	0	0
Speech disorder	0	0	0	0	0	0
Intracranial bleeding	1 (1.9)	0	0	1 (1.9)	0	2 (3.8)
Subdural haematoma	1 (1.9)	0	0	1 (1.9)	0	2 (3.8)
Cerebral haemorrhage	0	0	0	0	0	0
Haemorrhage intracranial	0	0	0	0	0	0

Abbreviations: AESI=Adverse Event of Special Interest; AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
Note 1: In each treatment group, if a patient experiences more than 1 event within a given AESI category or Preferred Term, that patient is counted only once at the highest grade under that AESI category or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column and treatment group.
Note 3: AESI Categories are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'Any Grade' column.
Program: ../BLU-285/ISS_BLU285/Final/Programs/Prod/Adhoc/German Request/t-35-3-3-2-1-2-aesigr.sas
Date: 16:32/17SEP2021

Table T.35.3.3.2.1.2
Summary of Adverse Events of Special Interest by Category, Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

AESI Category Preferred Term	BLU-285-2101 + BLU-285-2202 & <=200 mg Dose Group (N=58) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Patients with at least one Event	7 (12.1)	1 (1.7)	1 (1.7)	1 (1.7)	0	10 (17.2)
Cognitive effects	7 (12.1)	1 (1.7)	1 (1.7)	0	0	9 (15.5)
Cognitive disorder	2 (3.4)	1 (1.7)	0	0	0	3 (5.2)
Memory impairment	3 (5.2)	0	0	0	0	3 (5.2)
Confusional state	1 (1.7)	0	0	0	0	1 (1.7)
Delirium	0	0	1 (1.7)	0	0	1 (1.7)
Disorientation	1 (1.7)	0	0	0	0	1 (1.7)
Agitation	0	0	0	0	0	0
Amnesia	0	0	0	0	0	0
Dementia	0	0	0	0	0	0
Encephalopathy	0	0	0	0	0	0
Hallucination	0	0	0	0	0	0

Abbreviations: AESI=Adverse Event of Special Interest; AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
Note 1: In each treatment group, if a patient experiences more than 1 event within a given AESI category or Preferred Term, that patient is counted only once at the highest grade under that AESI category or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column and treatment group.
Note 3: AESI Categories are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'Any Grade' column.
Program: ../BLU-285/ISS_BLU285/Final/Programs/Prod/Adhoc/German Request/t-35-3-3-2-1-2-aesigr.sas
Date: 16:32/17SEP2021

Table T.35.3.3.2.1.2
Summary of Adverse Events of Special Interest by Category, Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

AESI Category Preferred Term	BLU-285-2101 + BLU-285-2202 & <=200 mg Dose Group (N=58) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Cognitive effects (cont.)						
Mental impairment	0	0	0	0	0	0
Mental status changes	0	0	0	0	0	0
Mood altered	0	0	0	0	0	0
Personality change	0	0	0	0	0	0
Psychotic disorder	0	0	0	0	0	0
Somnolence	0	0	0	0	0	0
Speech disorder	0	0	0	0	0	0
Intracranial bleeding	1 (1.7)	0	0	1 (1.7)	0	2 (3.4)
Subdural haematoma	1 (1.7)	0	0	1 (1.7)	0	2 (3.4)
Cerebral haemorrhage	0	0	0	0	0	0
Haemorrhage intracranial	0	0	0	0	0	0

Abbreviations: AESI=Adverse Event of Special Interest; AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
Note 1: In each treatment group, if a patient experiences more than 1 event within a given AESI category or Preferred Term, that patient is counted only once at the highest grade under that AESI category or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column and treatment group.
Note 3: AESI Categories are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'Any Grade' column.
Program: ../BLU-285/ISS_BLU285/Final/Programs/Prod/Adhoc/German Request/t-35-3-3-2-1-2-aesigr.sas
Date: 16:32/17SEP2021

Table T.35.3.3.2.1.2
Summary of Adverse Events of Special Interest by Category, Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

AESI Category Preferred Term	BLU-285-2101 + BLU-285-2202 & All Dose Group (N=83) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Patients with at least one Event	13 (15.7)	5 (6.0)	4 (4.8)	1 (1.2)	1 (1.2)	24 (28.9)
Cognitive effects	14 (16.9)	5 (6.0)	3 (3.6)	0	0	22 (26.5)
Memory impairment	9 (10.8)	2 (2.4)	0	0	0	11 (13.3)
Cognitive disorder	3 (3.6)	3 (3.6)	1 (1.2)	0	0	7 (8.4)
Confusional state	1 (1.2)	2 (2.4)	0	0	0	3 (3.6)
Encephalopathy	0	0	2 (2.4)	0	0	2 (2.4)
Delirium	0	0	1 (1.2)	0	0	1 (1.2)
Dementia	0	1 (1.2)	0	0	0	1 (1.2)
Disorientation	1 (1.2)	0	0	0	0	1 (1.2)
Mental status changes	0	0	1 (1.2)	0	0	1 (1.2)
Somnolence	1 (1.2)	0	0	0	0	1 (1.2)
Agitation	0	0	0	0	0	0

Abbreviations: AESI=Adverse Event of Special Interest; AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
Note 1: In each treatment group, if a patient experiences more than 1 event within a given AESI category or Preferred Term, that patient is counted only once at the highest grade under that AESI category or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column and treatment group.
Note 3: AESI Categories are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'Any Grade' column.
Program: ../BLU-285/ISS_BLU285/Final/Programs/Prod/Adhoc/German Request/t-35-3-3-2-1-2-aesigr.sas
Date: 16:32/17SEP2021

Table T.35.3.3.2.1.2
Summary of Adverse Events of Special Interest by Category, Preferred Term, and NCI CTCAE Grade
AdvSM Population & Prior Neoplastic Therapy = Yes

AESI Category Preferred Term	BLU-285-2101 + BLU-285-2202 & All Dose Group (N=83) Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Any Grade n (%)
Cognitive effects (cont.)						
Amnesia	0	0	0	0	0	0
Hallucination	0	0	0	0	0	0
Mental impairment	0	0	0	0	0	0
Mood altered	0	0	0	0	0	0
Personality change	0	0	0	0	0	0
Psychotic disorder	0	0	0	0	0	0
Speech disorder	0	0	0	0	0	0
Intracranial bleeding	2 (2.4)	0	1 (1.2)	1 (1.2)	1 (1.2)	5 (6.0)
Subdural haematoma	2 (2.4)	0	0	1 (1.2)	0	3 (3.6)
Haemorrhage intracranial	0	0	1 (1.2)	0	1 (1.2)	2 (2.4)
Cerebral haemorrhage	0	0	0	0	0	0

Abbreviations: AESI=Adverse Event of Special Interest; AdvSM = Advanced Systemic Mastocytosis; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events
Note 1: In each treatment group, if a patient experiences more than 1 event within a given AESI category or Preferred Term, that patient is counted only once at the highest grade under that AESI category or Preferred Term, respectively.
Note 2: Percentages are based on the number of patients in the Safety Population in each column and treatment group.
Note 3: AESI Categories are sorted alphabetically and Preferred Terms are subsequently sorted in decreasing order of frequency using the 'Any Grade' column.
Program: ../BLU-285/ISS_BLU285/Final/Programs/Prod/Adhoc/German Request/t-35-3-3-2-1-2-aesigr.sas
Date: 16:32/17SEP2021

Table T.35.2.1.1
Grade <=2 Adverse Events of Special Interest (AESI) by AESI Category and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

AESI Category Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	 <=200 mg (N=16) n (%)	 All Doses (N=41) n (%)
Patients with at least one Event	3 (25.0)	3 (18.8)	15 (36.6)
Cognitive effects	2 (16.7)	2 (12.5)	13 (31.7)
Memory impairment	1 (8.3)	1 (6.3)	9 (22.0)
Cognitive disorder	1 (8.3)	1 (6.3)	4 (9.8)
Confusional state	0	0	2 (4.9)
Dementia	0	0	1 (2.4)
Somnolence	0	0	1 (2.4)
Agitation	0	0	0
Amnesia	0	0	0
Delirium	0	0	0
Disorientation	0	0	0
Encephalopathy	0	0	0

Abbreviations: AESI = Adverse Event of Special Interest; AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experienced more than 1 event in a given AESI category, that patient is counted once for the category. If a patient experienced more than 1 event within a given preferred term, that patient is counted only once for that term.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: AESI Categories are sorted alphabetically and Preferred Terms are sorted in decreasing order of frequency using the 'All Doses' column.
Program: ../BLU-285/ISS_BLU285/Final/Programs/Prod/Adhoc/German Request/t-35-2-1-1-aesi-g2-high.sas
Date: 11:31/25JAN2022

Table T.35.2.1.1
Grade <=2 Adverse Events of Special Interest (AESI) by AESI Category and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

AESI Category Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	 <=200 mg (N=16) n (%)	 All Doses (N=41) n (%)
Cognitive effects (cont.)			
Hallucination	0	0	0
Mental impairment	0	0	0
Mental status changes	0	0	0
Mood altered	0	0	0
Personality change	0	0	0
Psychotic disorder	0	0	0
Speech disorder	0	0	0
Intracranial bleeding	1 (8.3)	1 (6.3)	2 (4.9)
Subdural haematoma	1 (8.3)	1 (6.3)	2 (4.9)
Cerebral haemorrhage	0	0	0
Haemorrhage intracranial	0	0	0

Abbreviations: AESI = Adverse Event of Special Interest; AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experienced more than 1 event in a given AESI category, that patient is counted once for the category. If a patient experienced more than 1 event within a given preferred term, that patient is counted only once for that term.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: AESI Categories are sorted alphabetically and Preferred Terms are sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.2.1.1
Grade <=2 Adverse Events of Special Interest (AESI) by AESI Category and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

AESI Category Preferred Term	BLU-285-2202 200 mg (N=40) n (%)	 <=200 mg (N=42) n (%)	 All Doses (N=42) n (%)
Patients with at least one Event	6 (15.0)	6 (14.3)	6 (14.3)
Cognitive effects	6 (15.0)	6 (14.3)	6 (14.3)
Cognitive disorder	2 (5.0)	2 (4.8)	2 (4.8)
Memory impairment	2 (5.0)	2 (4.8)	2 (4.8)
Confusional state	1 (2.5)	1 (2.4)	1 (2.4)
Disorientation	1 (2.5)	1 (2.4)	1 (2.4)
Agitation	0	0	0
Amnesia	0	0	0
Delirium	0	0	0
Dementia	0	0	0
Encephalopathy	0	0	0
Hallucination	0	0	0

Abbreviations: AESI = Adverse Event of Special Interest; AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experienced more than 1 event in a given AESI category, that patient is counted once for the category. If a patient experienced more than 1 event within a given preferred term, that patient is counted only once for that term.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: AESI Categories are sorted alphabetically and Preferred Terms are sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.2.1.1
Grade <=2 Adverse Events of Special Interest (AESI) by AESI Category and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

AESI Category Preferred Term	BLU-285-2202 200 mg (N=40) n (%)	 <=200 mg (N=42) n (%)	 All Doses (N=42) n (%)
Cognitive effects (cont.)			
Mental impairment	0	0	0
Mental status changes	0	0	0
Mood altered	0	0	0
Personality change	0	0	0
Psychotic disorder	0	0	0
Somnolence	0	0	0
Speech disorder	0	0	0
Intracranial bleeding	0	0	0
Cerebral haemorrhage	0	0	0
Haemorrhage intracranial	0	0	0
Subdural haematoma	0	0	0

Abbreviations: AESI = Adverse Event of Special Interest; AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experienced more than 1 event in a given AESI category, that patient is counted once for the category. If a patient experienced more than 1 event within a given preferred term, that patient is counted only once for that term.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: AESI Categories are sorted alphabetically and Preferred Terms are sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.2.1.1
Grade <=2 Adverse Events of Special Interest (AESI) by AESI Category and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

AESI Category Preferred Term	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	 <=200 mg (N=58) n (%)	 All Doses (N=83) n (%)
Patients with at least one Event	9 (17.3)	9 (15.5)	21 (25.3)
Cognitive effects	8 (15.4)	8 (13.8)	19 (22.9)
Memory impairment	3 (5.8)	3 (5.2)	11 (13.3)
Cognitive disorder	3 (5.8)	3 (5.2)	6 (7.2)
Confusional state	1 (1.9)	1 (1.7)	3 (3.6)
Dementia	0	0	1 (1.2)
Disorientation	1 (1.9)	1 (1.7)	1 (1.2)
Somnolence	0	0	1 (1.2)
Agitation	0	0	0
Amnesia	0	0	0
Delirium	0	0	0
Encephalopathy	0	0	0

Abbreviations: AESI = Adverse Event of Special Interest; AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experienced more than 1 event in a given AESI category, that patient is counted once for the category. If a patient experienced more than 1 event within a given preferred term, that patient is counted only once for that term.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: AESI Categories are sorted alphabetically and Preferred Terms are sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.2.1.1
Grade <=2 Adverse Events of Special Interest (AESI) by AESI Category and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

AESI Category Preferred Term	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	 <=200 mg (N=58) n (%)	 All Doses (N=83) n (%)
Cognitive effects (cont.)			
Hallucination	0	0	0
Mental impairment	0	0	0
Mental status changes	0	0	0
Mood altered	0	0	0
Personality change	0	0	0
Psychotic disorder	0	0	0
Speech disorder	0	0	0
Intracranial bleeding	1 (1.9)	1 (1.7)	2 (2.4)
Subdural haematoma	1 (1.9)	1 (1.7)	2 (2.4)
Cerebral haemorrhage	0	0	0
Haemorrhage intracranial	0	0	0

Abbreviations: AESI = Adverse Event of Special Interest; AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experienced more than 1 event in a given AESI category, that patient is counted once for the category. If a patient experienced more than 1 event within a given preferred term, that patient is counted only once for that term.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: AESI Categories are sorted alphabetically and Preferred Terms are sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.2.1.2
Grade >= 3 Adverse Events of Special Interest (AESI) by AESI Category and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

	BLU-285-2101		
AESI Category Preferred Term	200 mg (N=12) n (%)	<=200 mg (N=16) n (%)	All Doses (N=41) n (%)
Patients with at least one Event	0	0	4 (9.8)
Cognitive effects	0	0	2 (4.9)
Encephalopathy	0	0	2 (4.9)
Cognitive disorder	0	0	1 (2.4)
Mental status changes	0	0	1 (2.4)
Agitation	0	0	0
Amnesia	0	0	0
Confusional state	0	0	0
Delirium	0	0	0
Dementia	0	0	0
Disorientation	0	0	0
Hallucination	0	0	0

Abbreviations: AESI = Adverse Event of Special Interest; AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experienced more than 1 event in a given AESI category, that patient is counted once for the category. If a patient experienced more than 1 event within a given preferred term, that patient is counted only once for that term.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: AESI Categories are sorted alphabetically and Preferred Terms are sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.2.1.2
Grade >= 3 Adverse Events of Special Interest (AESI) by AESI Category and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

AESI Category Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	 <=200 mg (N=16) n (%)	 All Doses (N=41) n (%)
Cognitive effects (cont.)			
Memory impairment	0	0	0
Mental impairment	0	0	0
Mood altered	0	0	0
Personality change	0	0	0
Psychotic disorder	0	0	0
Somnolence	0	0	0
Speech disorder	0	0	0
Intracranial bleeding	0	0	2 (4.9)
Haemorrhage intracranial	0	0	2 (4.9)
Cerebral haemorrhage	0	0	0
Subdural haematoma	0	0	0

Abbreviations: AESI = Adverse Event of Special Interest; AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experienced more than 1 event in a given AESI category, that patient is counted once for the category. If a patient experienced more than 1 event within a given preferred term, that patient is counted only once for that term.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: AESI Categories are sorted alphabetically and Preferred Terms are sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.2.1.2
Grade >= 3 Adverse Events of Special Interest (AESI) by AESI Category and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

AESI Category Preferred Term	BLU-285-2202 200 mg (N=40) n (%)	 <=200 mg (N=42) n (%)	 All Doses (N=42) n (%)
Patients with at least one Event	2 (5.0)	2 (4.8)	2 (4.8)
Cognitive effects	1 (2.5)	1 (2.4)	1 (2.4)
Delirium	1 (2.5)	1 (2.4)	1 (2.4)
Agitation	0	0	0
Amnesia	0	0	0
Cognitive disorder	0	0	0
Confusional state	0	0	0
Dementia	0	0	0
Disorientation	0	0	0
Encephalopathy	0	0	0
Hallucination	0	0	0
Memory impairment	0	0	0

Abbreviations: AESI = Adverse Event of Special Interest; AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experienced more than 1 event in a given AESI category, that patient is counted once for the category. If a patient experienced more than 1 event within a given preferred term, that patient is counted only once for that term.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: AESI Categories are sorted alphabetically and Preferred Terms are sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.2.1.2
Grade >= 3 Adverse Events of Special Interest (AESI) by AESI Category and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

AESI Category Preferred Term	BLU-285-2202 200 mg (N=40) n (%)	 <=200 mg (N=42) n (%)	 All Doses (N=42) n (%)
Cognitive effects (cont.)			
Mental impairment	0	0	0
Mental status changes	0	0	0
Mood altered	0	0	0
Personality change	0	0	0
Psychotic disorder	0	0	0
Somnolence	0	0	0
Speech disorder	0	0	0
Intracranial bleeding	1 (2.5)	1 (2.4)	1 (2.4)
Subdural haematoma	1 (2.5)	1 (2.4)	1 (2.4)
Cerebral haemorrhage	0	0	0
Haemorrhage intracranial	0	0	0

Abbreviations: AESI = Adverse Event of Special Interest; AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experienced more than 1 event in a given AESI category, that patient is counted once for the category. If a patient experienced more than 1 event within a given preferred term, that patient is counted only once for that term.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: AESI Categories are sorted alphabetically and Preferred Terms are sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.2.1.2
Grade >= 3 Adverse Events of Special Interest (AESI) by AESI Category and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

AESI Category Preferred Term	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	 <=200 mg (N=58) n (%)	 All Doses (N=83) n (%)
Patients with at least one Event	2 (3.8)	2 (3.4)	6 (7.2)
Cognitive effects	1 (1.9)	1 (1.7)	3 (3.6)
Encephalopathy	0	0	2 (2.4)
Cognitive disorder	0	0	1 (1.2)
Delirium	1 (1.9)	1 (1.7)	1 (1.2)
Mental status changes	0	0	1 (1.2)
Agitation	0	0	0
Amnesia	0	0	0
Confusional state	0	0	0
Dementia	0	0	0
Disorientation	0	0	0
Hallucination	0	0	0

Abbreviations: AESI = Adverse Event of Special Interest; AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experienced more than 1 event in a given AESI category, that patient is counted once for the category. If a patient experienced more than 1 event within a given preferred term, that patient is counted only once for that term.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: AESI Categories are sorted alphabetically and Preferred Terms are sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.2.1.2
Grade >= 3 Adverse Events of Special Interest (AESI) by AESI Category and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

AESI Category Preferred Term	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	 <=200 mg (N=58) n (%)	 All Doses (N=83) n (%)
Cognitive effects (cont.)			
Memory impairment	0	0	0
Mental impairment	0	0	0
Mood altered	0	0	0
Personality change	0	0	0
Psychotic disorder	0	0	0
Somnolence	0	0	0
Speech disorder	0	0	0
Intracranial bleeding	1 (1.9)	1 (1.7)	3 (3.6)
Haemorrhage intracranial	0	0	2 (2.4)
Subdural haematoma	1 (1.9)	1 (1.7)	1 (1.2)
Cerebral haemorrhage	0	0	0

Abbreviations: AESI = Adverse Event of Special Interest; AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experienced more than 1 event in a given AESI category, that patient is counted once for the category. If a patient experienced more than 1 event within a given preferred term, that patient is counted only once for that term.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: AESI Categories are sorted alphabetically and Preferred Terms are sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.3.3.2.2.1
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

AESI Category Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	 <=200 mg (N=16) n (%)	 All Doses (N=41) n (%)
Patients with at least one Event	1 (8.3)	1 (6.3)	6 (14.6)
Cognitive effects	0	0	3 (7.3)
Encephalopathy	0	0	2 (4.9)
Dementia	0	0	1 (2.4)
Mental status changes	0	0	1 (2.4)
Agitation	0	0	0
Amnesia	0	0	0
Cognitive disorder	0	0	0
Confusional state	0	0	0
Delirium	0	0	0
Disorientation	0	0	0
Hallucination	0	0	0

Abbreviations: AESI = Adverse Event of Special Interest; AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experienced more than 1 event in a given AESI category, that patient is counted once for the category. If a patient experienced more than 1 event within a given preferred term, that patient is counted only once for that term.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: AESI Categories are sorted alphabetically and Preferred Terms are sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.3.3.2.2.1
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

AESI Category Preferred Term	BLU-285-2101 200 mg (N=12) n (%)	 <=200 mg (N=16) n (%)	 All Doses (N=41) n (%)
Cognitive effects (cont.)			
Memory impairment	0	0	0
Mental impairment	0	0	0
Mood altered	0	0	0
Personality change	0	0	0
Psychotic disorder	0	0	0
Somnolence	0	0	0
Speech disorder	0	0	0
Intracranial bleeding	1 (8.3)	1 (6.3)	3 (7.3)
Subdural haematoma	1 (8.3)	1 (6.3)	2 (4.9)
Haemorrhage intracranial	0	0	1 (2.4)
Cerebral haemorrhage	0	0	0

Abbreviations: AESI = Adverse Event of Special Interest; AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experienced more than 1 event in a given AESI category, that patient is counted once for the category. If a patient experienced more than 1 event within a given preferred term, that patient is counted only once for that term.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: AESI Categories are sorted alphabetically and Preferred Terms are sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.3.3.2.2.1
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

AESI Category Preferred Term	BLU-285-2202 200 mg (N=40) n (%)	 <=200 mg (N=42) n (%)	 All Doses (N=42) n (%)
Patients with at least one Event	1 (2.5)	1 (2.4)	1 (2.4)
Cognitive effects	0	0	0
Agitation	0	0	0
Amnesia	0	0	0
Cognitive disorder	0	0	0
Confusional state	0	0	0
Delirium	0	0	0
Dementia	0	0	0
Disorientation	0	0	0
Encephalopathy	0	0	0
Hallucination	0	0	0
Memory impairment	0	0	0

Abbreviations: AESI = Adverse Event of Special Interest; AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experienced more than 1 event in a given AESI category, that patient is counted once for the category. If a patient experienced more than 1 event within a given preferred term, that patient is counted only once for that term.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: AESI Categories are sorted alphabetically and Preferred Terms are sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.3.3.2.2.1
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

AESI Category Preferred Term	BLU-285-2202 200 mg (N=40) n (%)	 <=200 mg (N=42) n (%)	 All Doses (N=42) n (%)
Cognitive effects (cont.)			
Mental impairment	0	0	0
Mental status changes	0	0	0
Mood altered	0	0	0
Personality change	0	0	0
Psychotic disorder	0	0	0
Somnolence	0	0	0
Speech disorder	0	0	0
Intracranial bleeding	1 (2.5)	1 (2.4)	1 (2.4)
Subdural haematoma	1 (2.5)	1 (2.4)	1 (2.4)
Cerebral haemorrhage	0	0	0
Haemorrhage intracranial	0	0	0

Abbreviations: AESI = Adverse Event of Special Interest; AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experienced more than 1 event in a given AESI category, that patient is counted once for the category. If a patient experienced more than 1 event within a given preferred term, that patient is counted only once for that term.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
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Table T.35.3.3.2.2.1
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

AESI Category Preferred Term	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	 <=200 mg (N=58) n (%)	 All Doses (N=83) n (%)
Patients with at least one Event	2 (3.8)	2 (3.4)	7 (8.4)
Cognitive effects	0	0	3 (3.6)
Encephalopathy	0	0	2 (2.4)
Dementia	0	0	1 (1.2)
Mental status changes	0	0	1 (1.2)
Agitation	0	0	0
Amnesia	0	0	0
Cognitive disorder	0	0	0
Confusional state	0	0	0
Delirium	0	0	0
Disorientation	0	0	0
Hallucination	0	0	0

Abbreviations: AESI = Adverse Event of Special Interest; AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experienced more than 1 event in a given AESI category, that patient is counted once for the category. If a patient experienced more than 1 event within a given preferred term, that patient is counted only once for that term.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: AESI Categories are sorted alphabetically and Preferred Terms are sorted in decreasing order of frequency using the 'All Doses' column.
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Table T.35.3.3.2.2.1
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
AdvSM Population & Prior Neoplastic Therapy = Yes

AESI Category Preferred Term	BLU-285-2101 + BLU-285-2202 200 mg (N=52) n (%)	 <=200 mg (N=58) n (%)	 All Doses (N=83) n (%)
Cognitive effects (cont.)			
Memory impairment	0	0	0
Mental impairment	0	0	0
Mood altered	0	0	0
Personality change	0	0	0
Psychotic disorder	0	0	0
Somnolence	0	0	0
Speech disorder	0	0	0
Intracranial bleeding	2 (3.8)	2 (3.4)	4 (4.8)
Subdural haematoma	2 (3.8)	2 (3.4)	3 (3.6)
Haemorrhage intracranial	0	0	1 (1.2)
Cerebral haemorrhage	0	0	0

Abbreviations: AESI = Adverse Event of Special Interest; AdvSM = Advanced Systemic Mastocytosis
Note 1: If a patient experienced more than 1 event in a given AESI category, that patient is counted once for the category. If a patient experienced more than 1 event within a given preferred term, that patient is counted only once for that term.
Note 2: Percentages are based on the number of patients in the Safety Population in each column.
Note 3: AESI Categories are sorted alphabetically and Preferred Terms are sorted in decreasing order of frequency using the 'All Doses' column.
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Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Starting Dose: Overall & Prior Antineoplastic Therapy = Yes

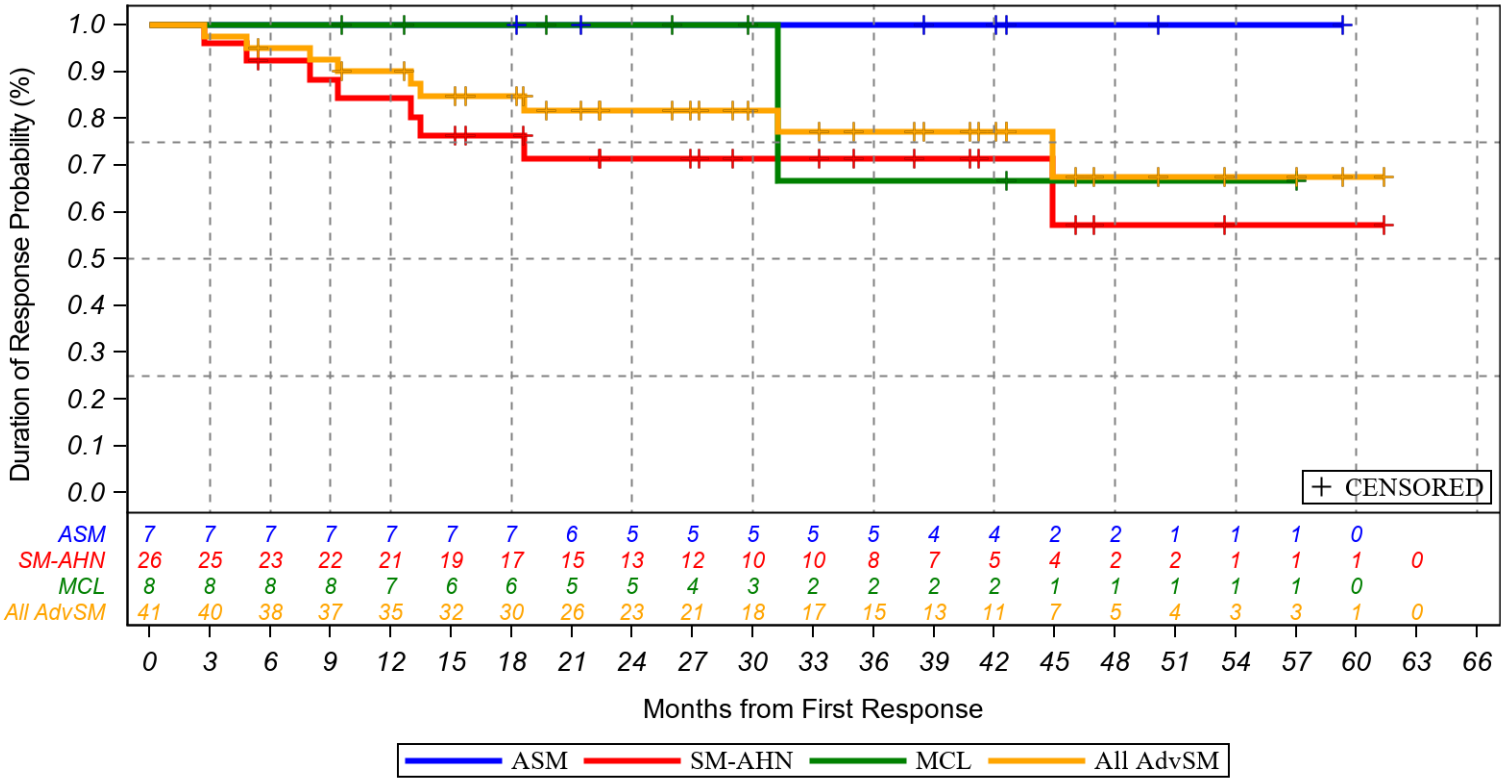

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Starting Dose: Overall & Prior Antineoplastic Therapy = No

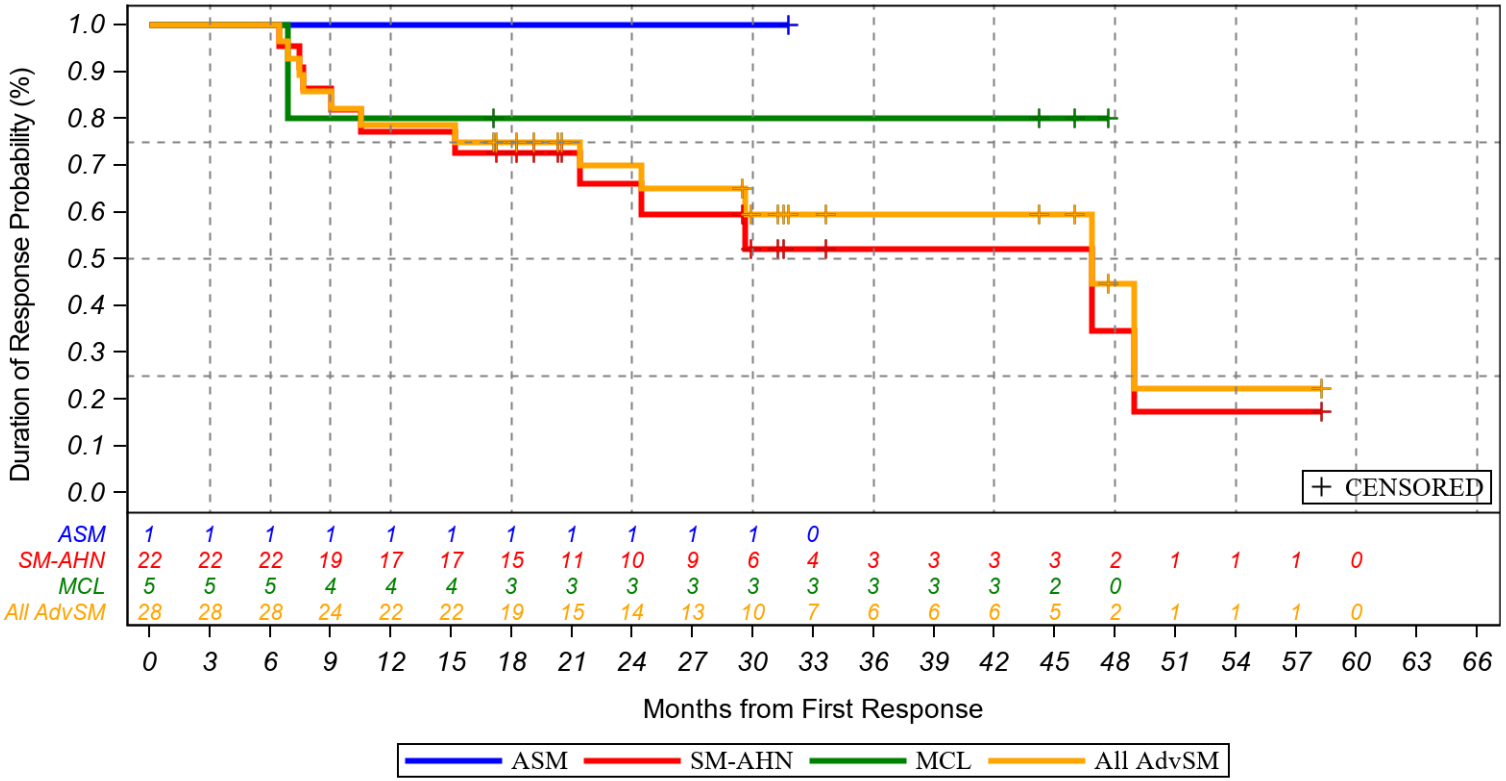

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Starting Dose: < 200 mg & Prior Antineoplastic Therapy = Yes

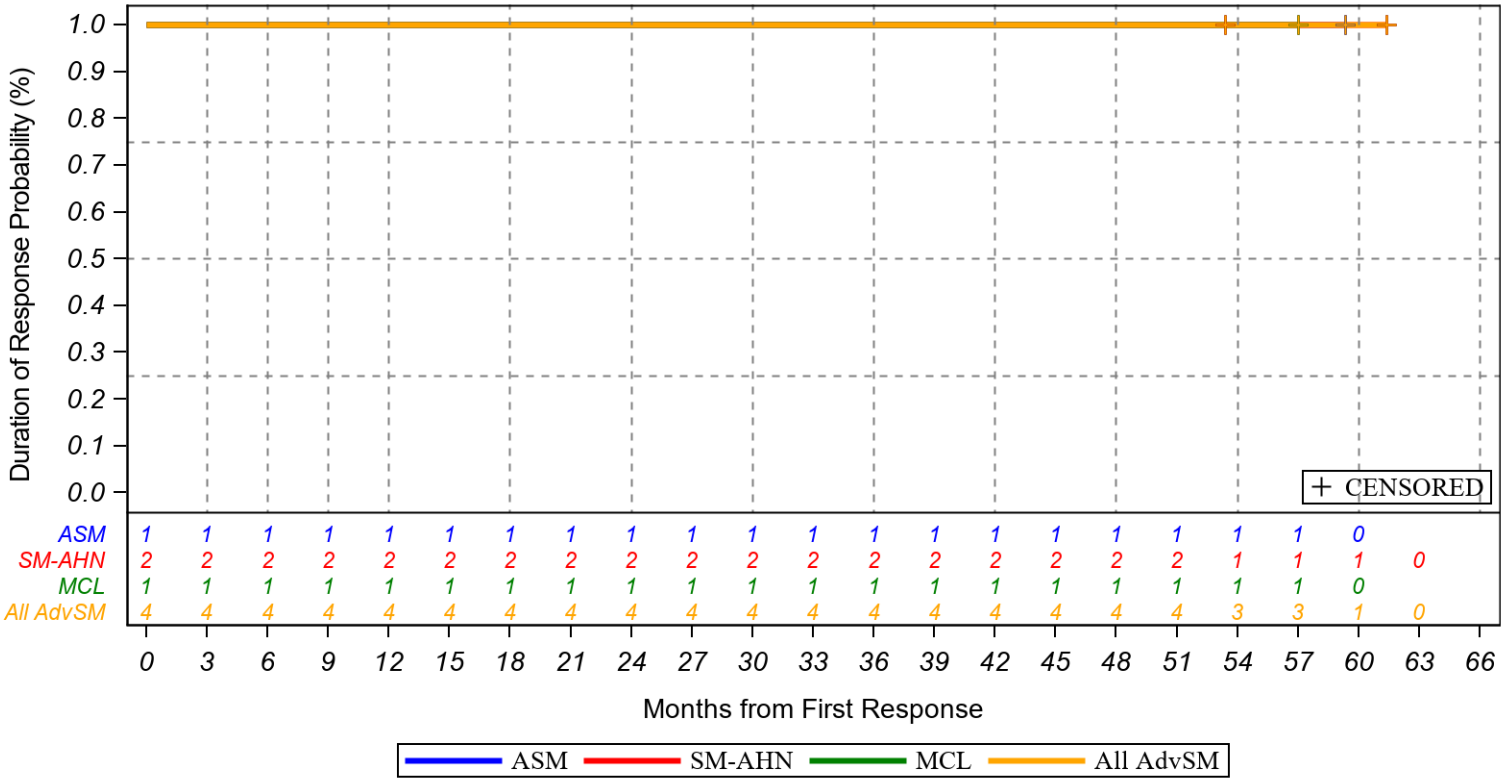

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Starting Dose: < 200 mg & Prior Antineoplastic Therapy = No

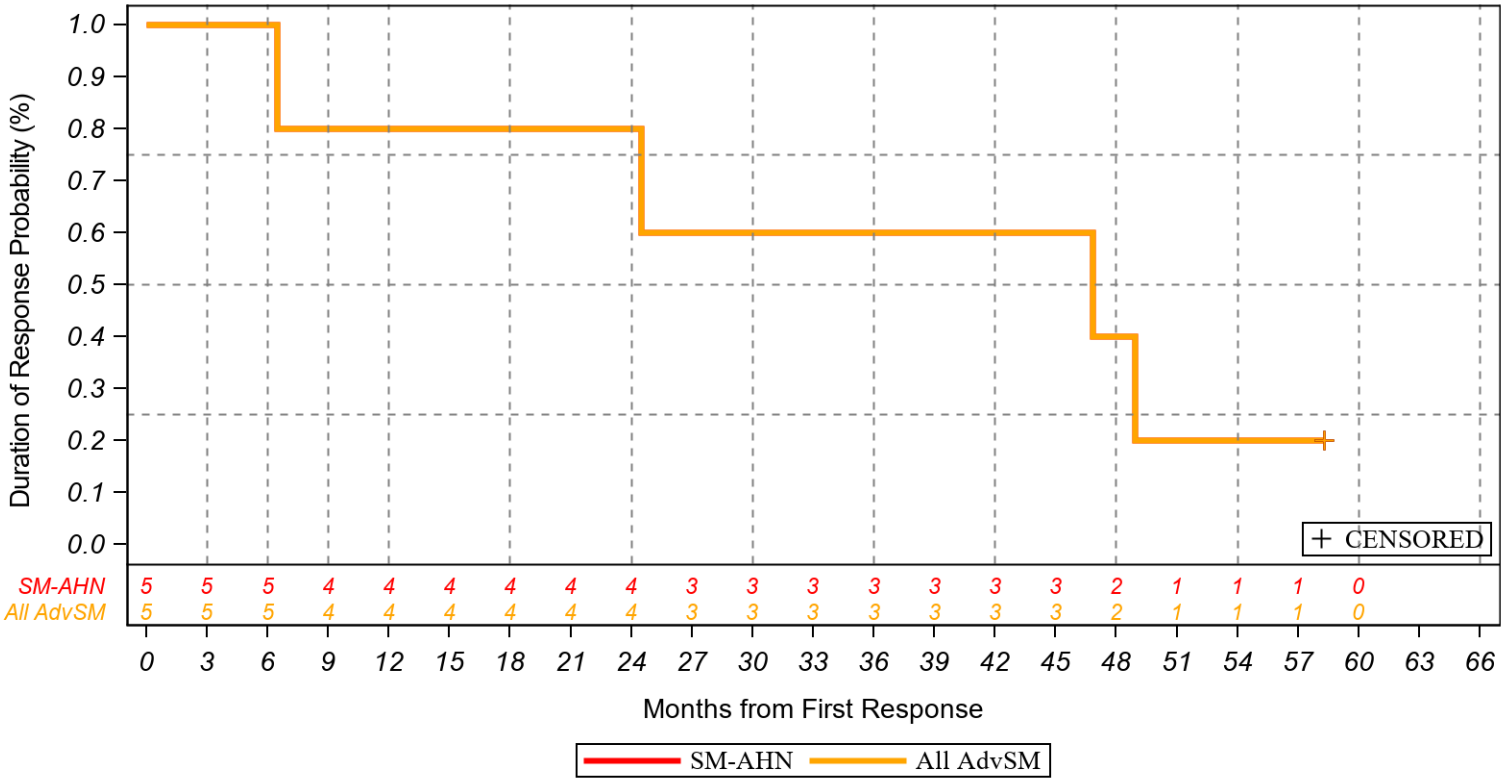

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Starting Dose: < 300 mg & Prior Antineoplastic Therapy = Yes

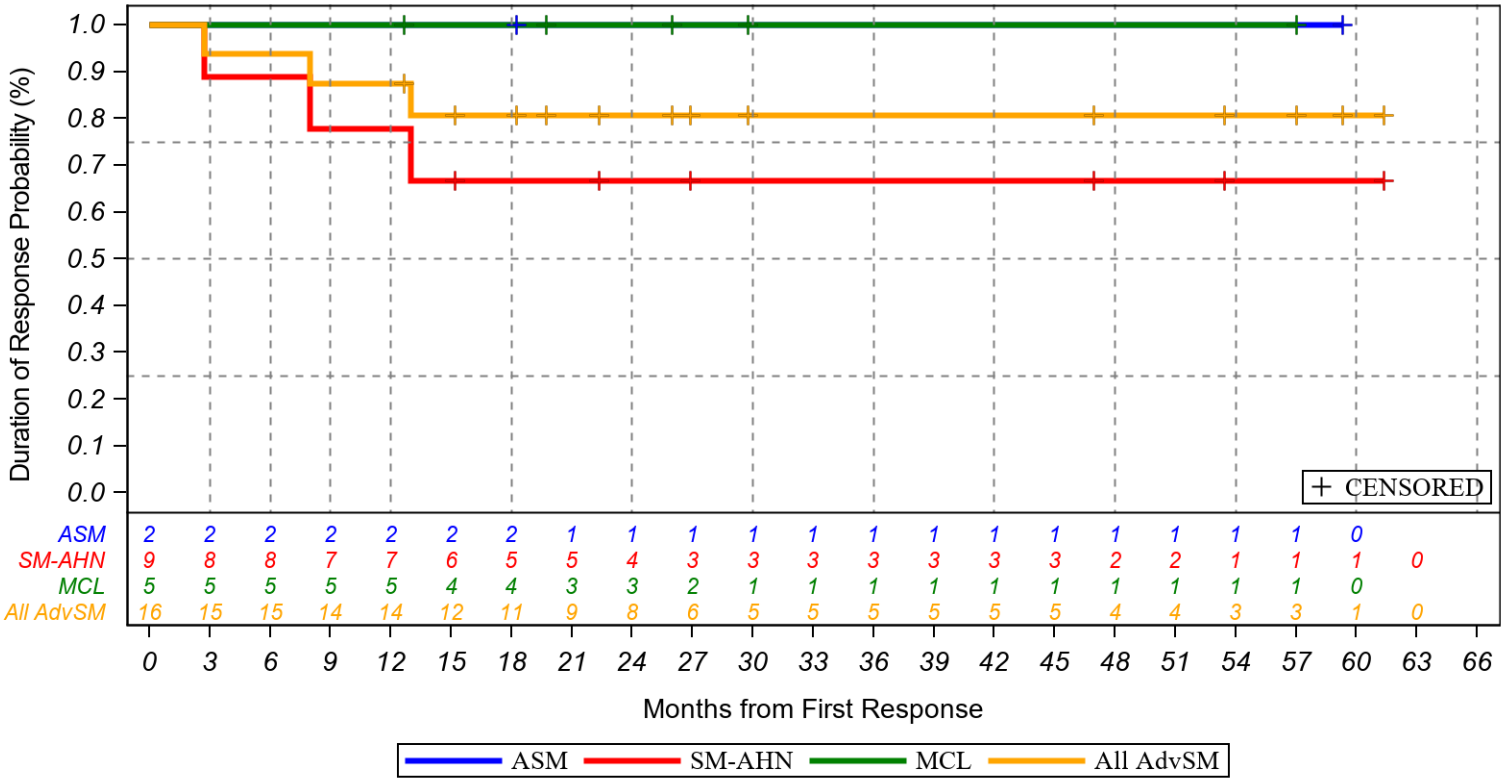

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Starting Dose: < 300 mg & Prior Antineoplastic Therapy = No

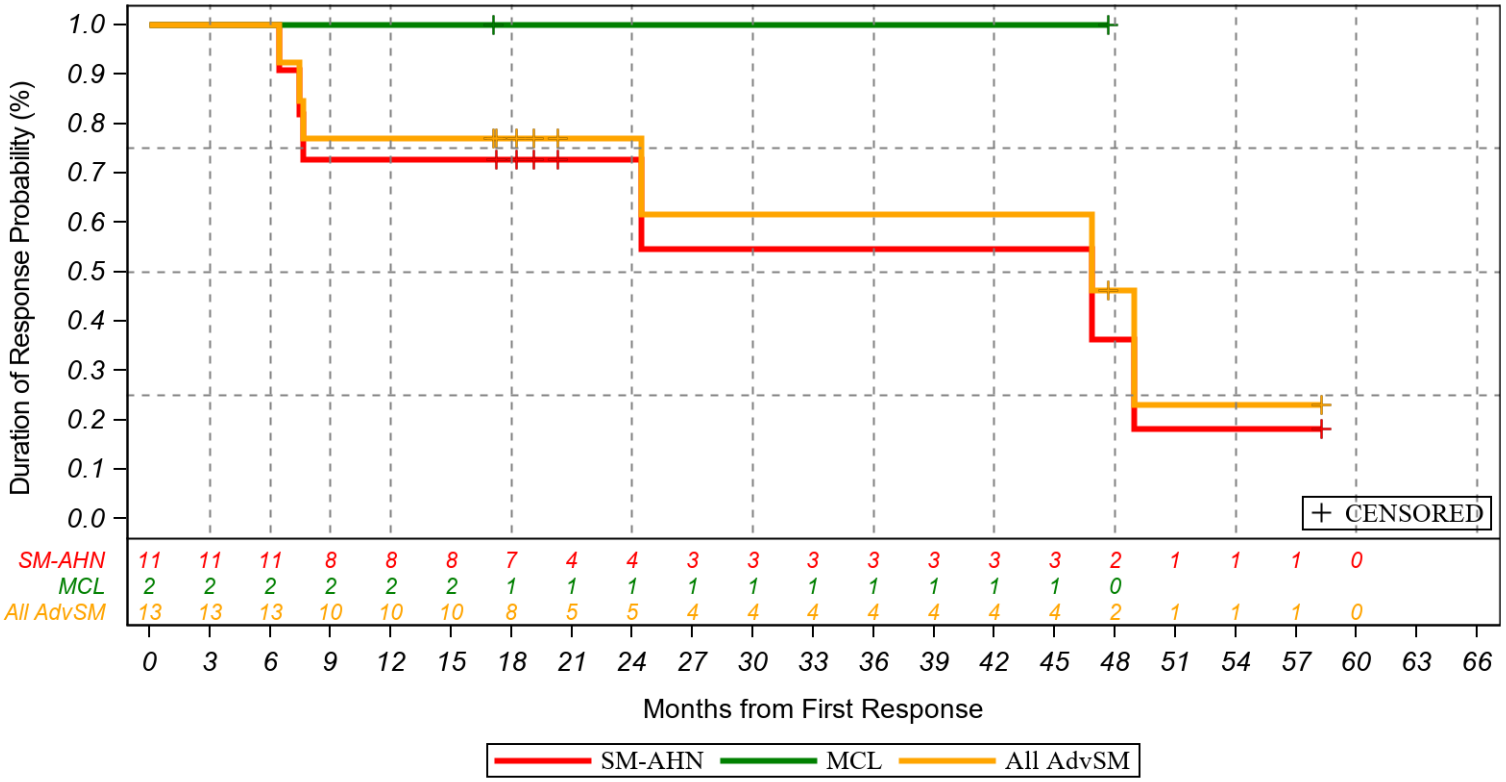

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Starting Dose: 200 mg & Prior Antineoplastic Therapy = Yes

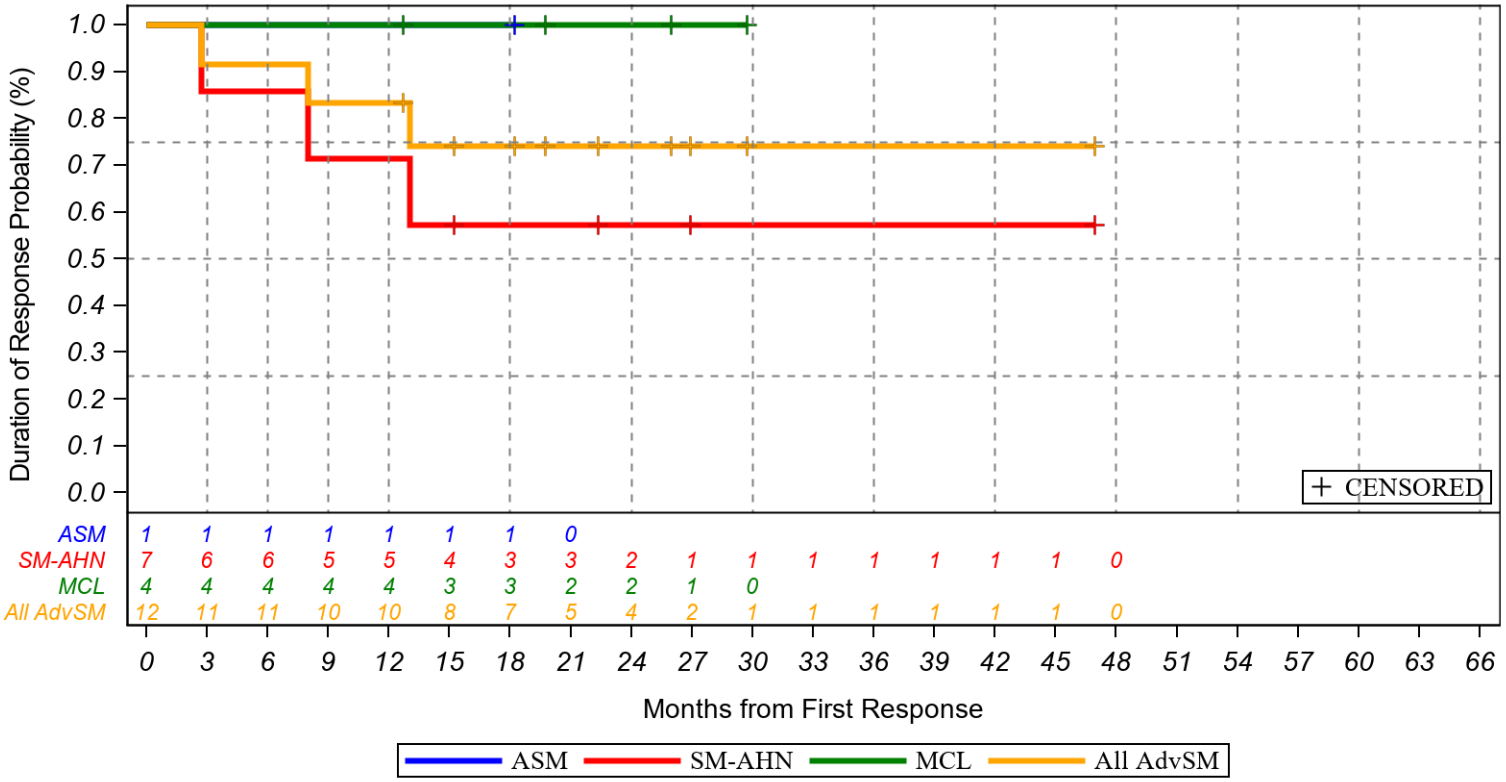

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Starting Dose: 200 mg & Prior Antineoplastic Therapy = No

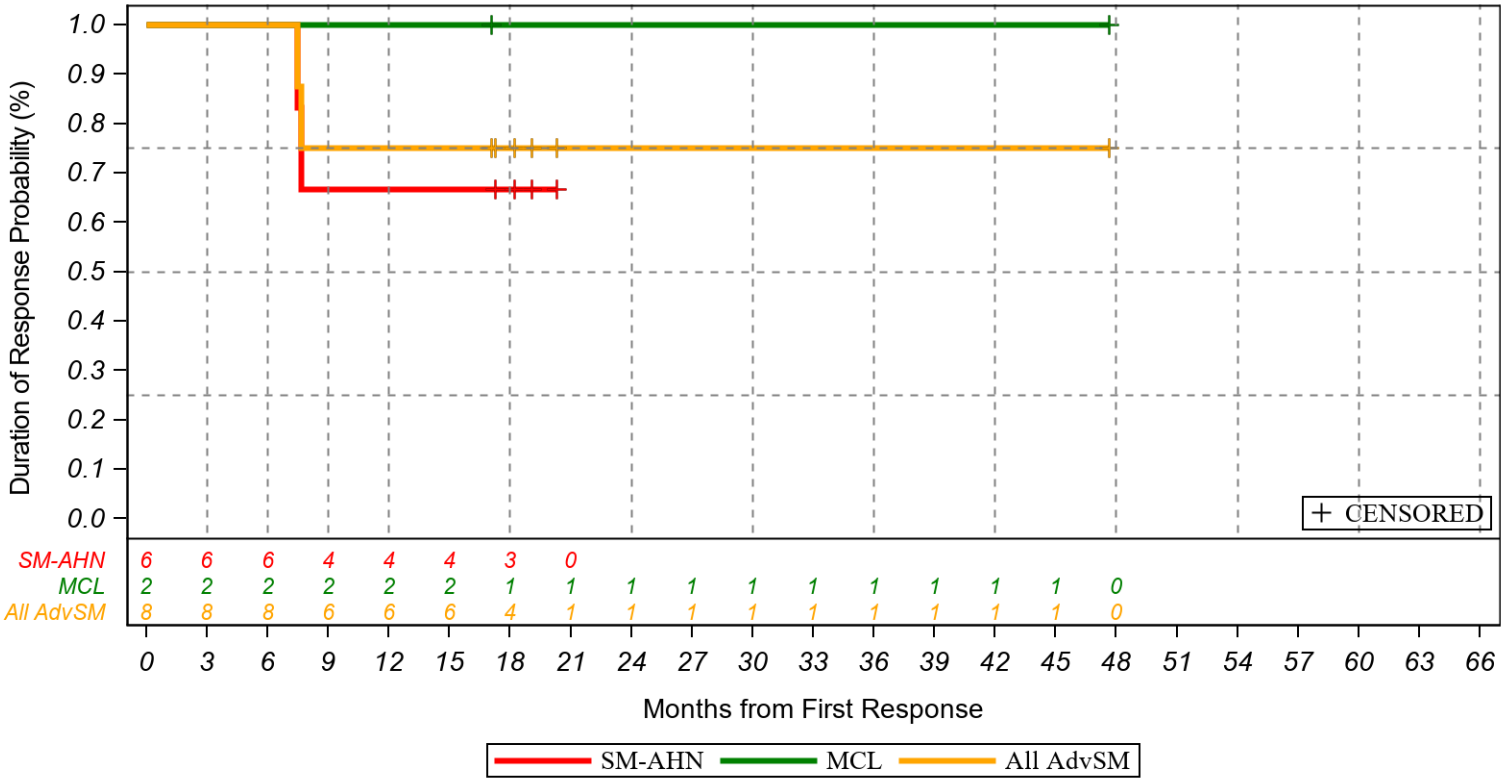

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Starting Dose: 300 mg & Prior Antineoplastic Therapy = Yes

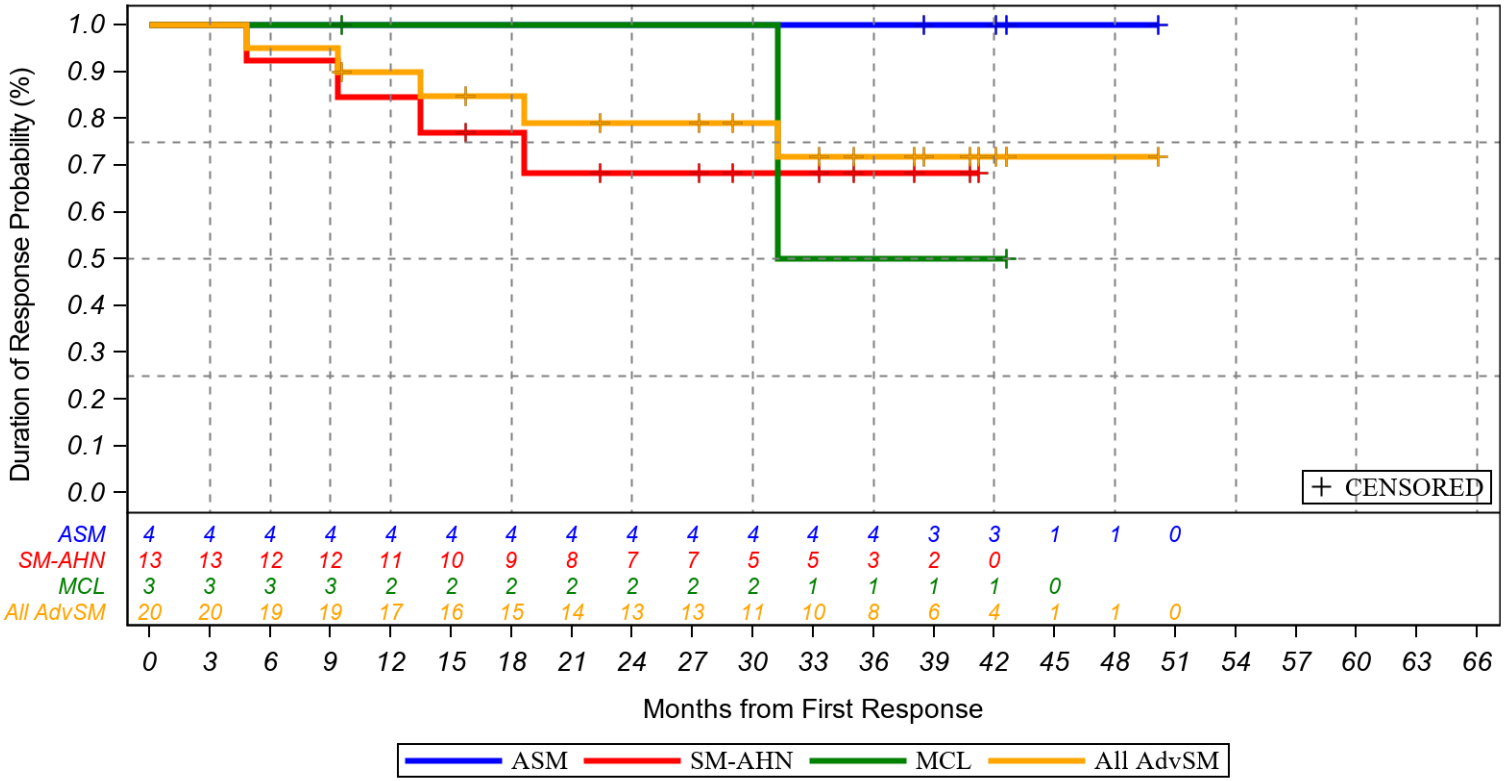

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Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Starting Dose: 300 mg & Prior Antineoplastic Therapy = No

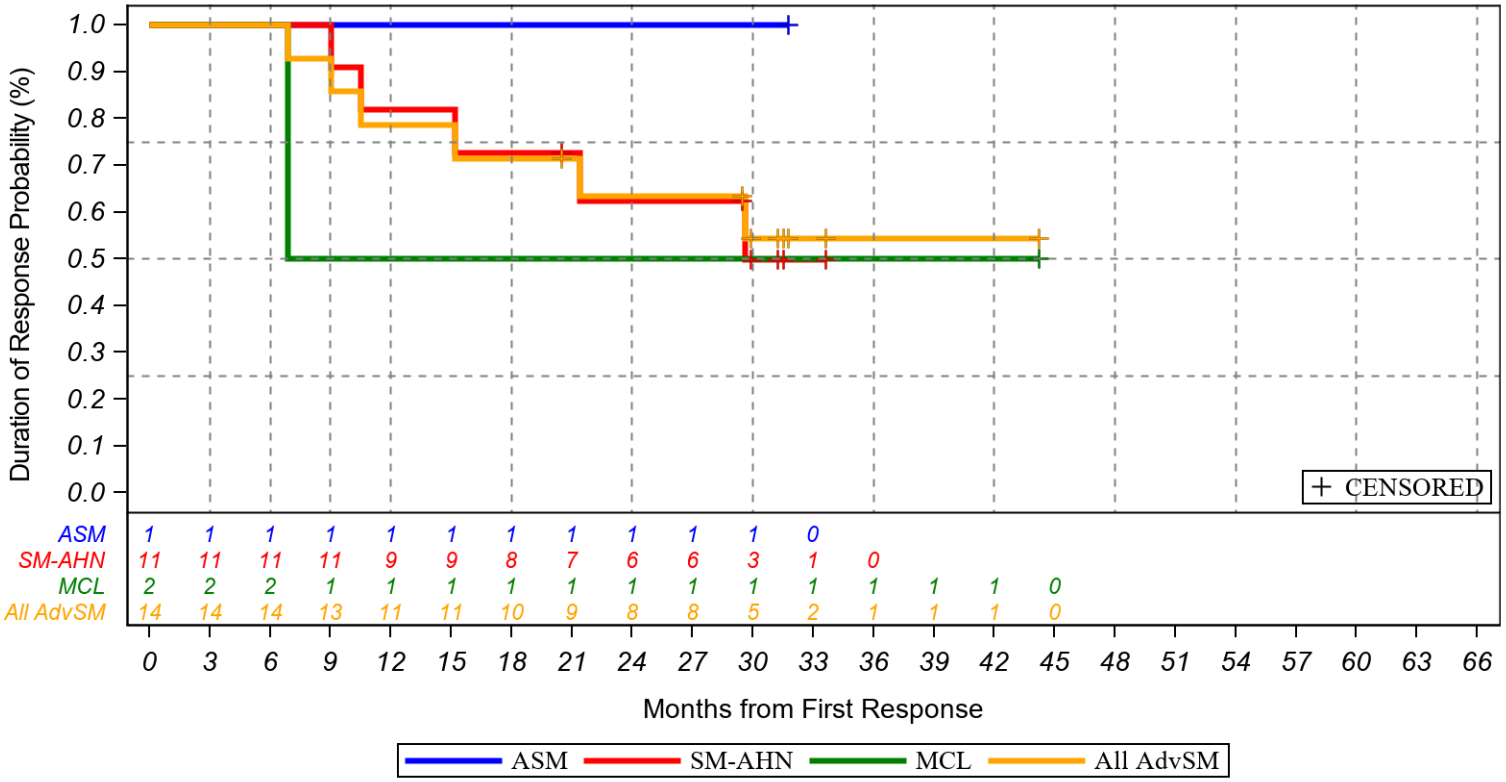

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Starting Dose: 200 mg and 300 mg & Prior Antineoplastic Therapy = Yes

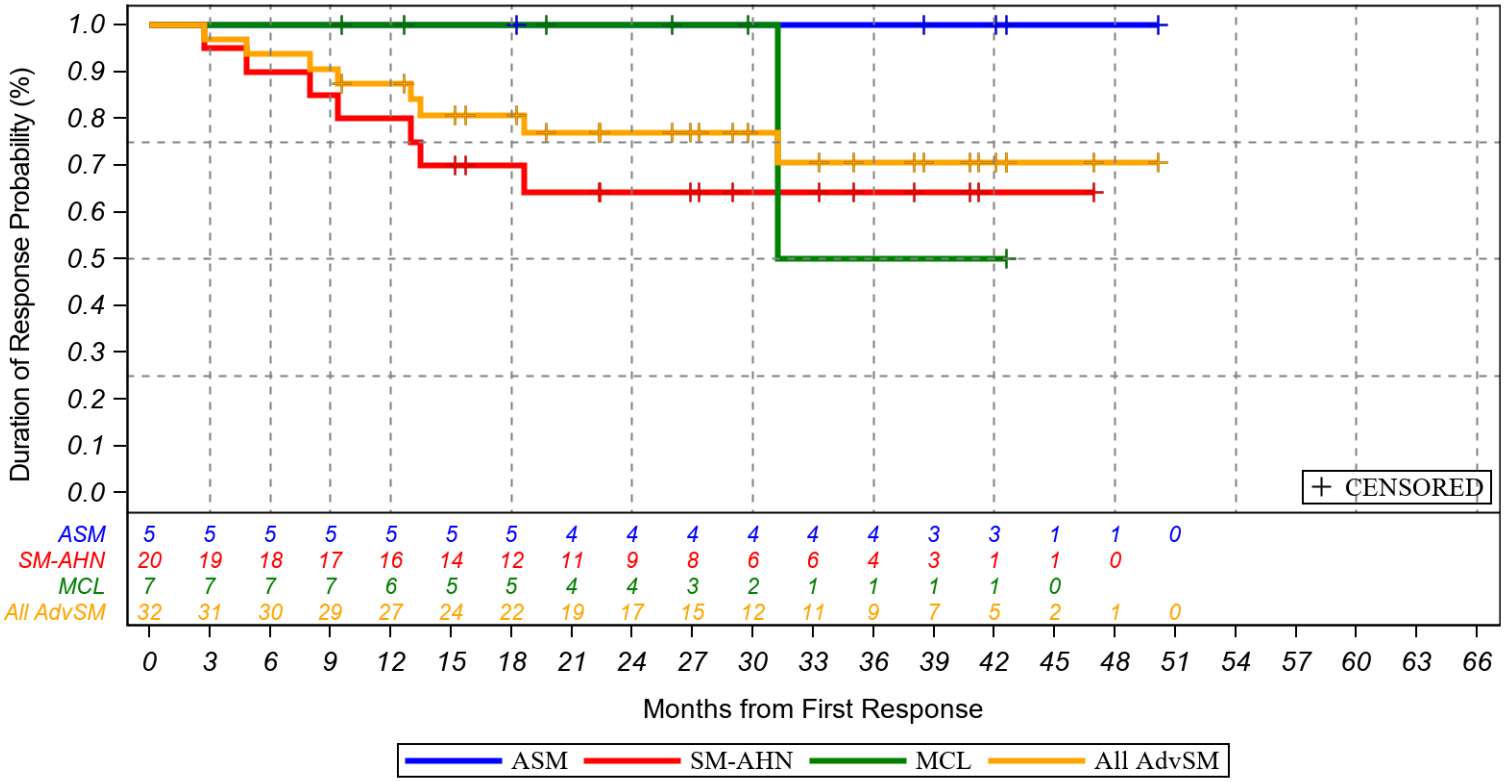

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Starting Dose: 200 mg and 300 mg & Prior Antineoplastic Therapy = No

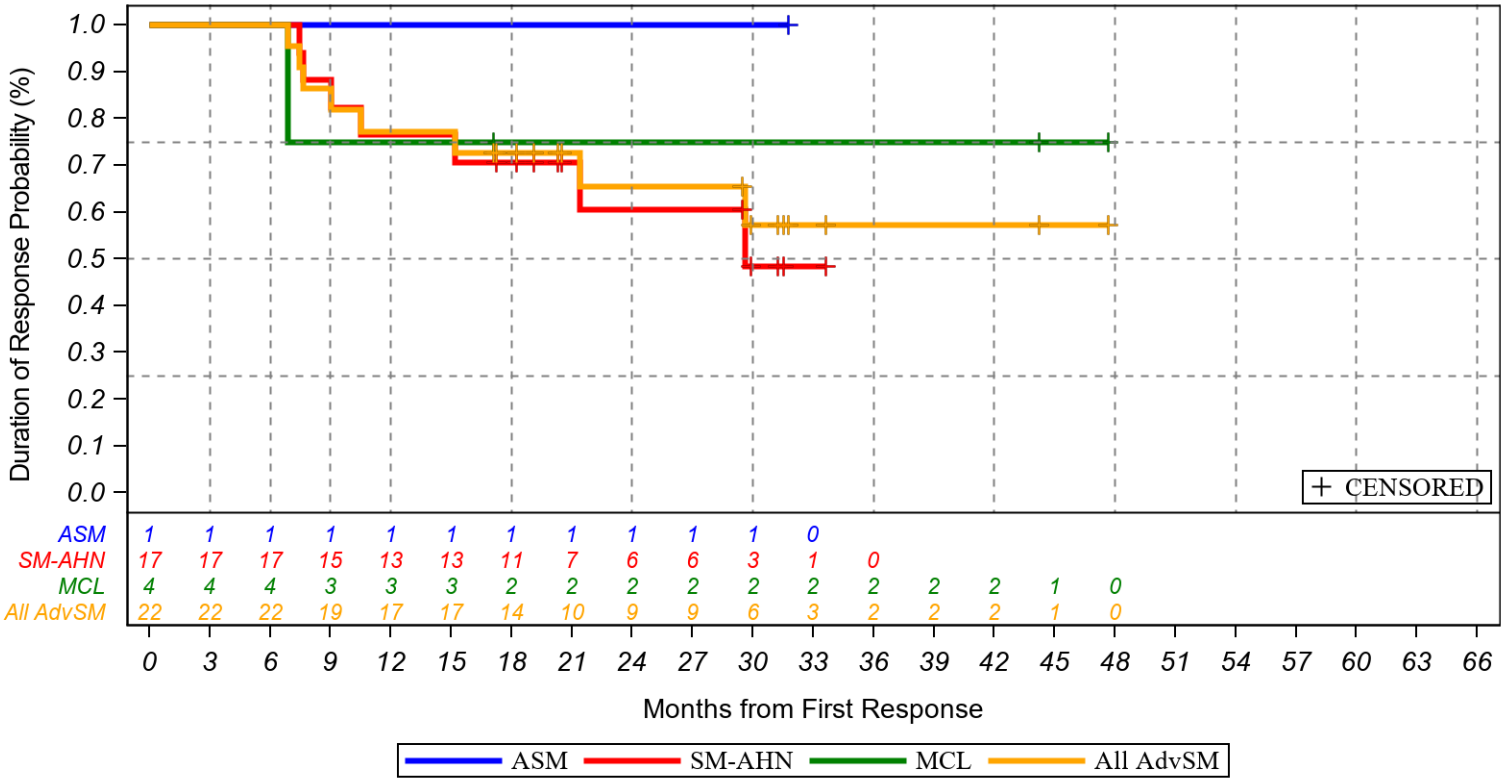

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Starting Dose: 400 mg & Prior Antineoplastic Therapy = Yes

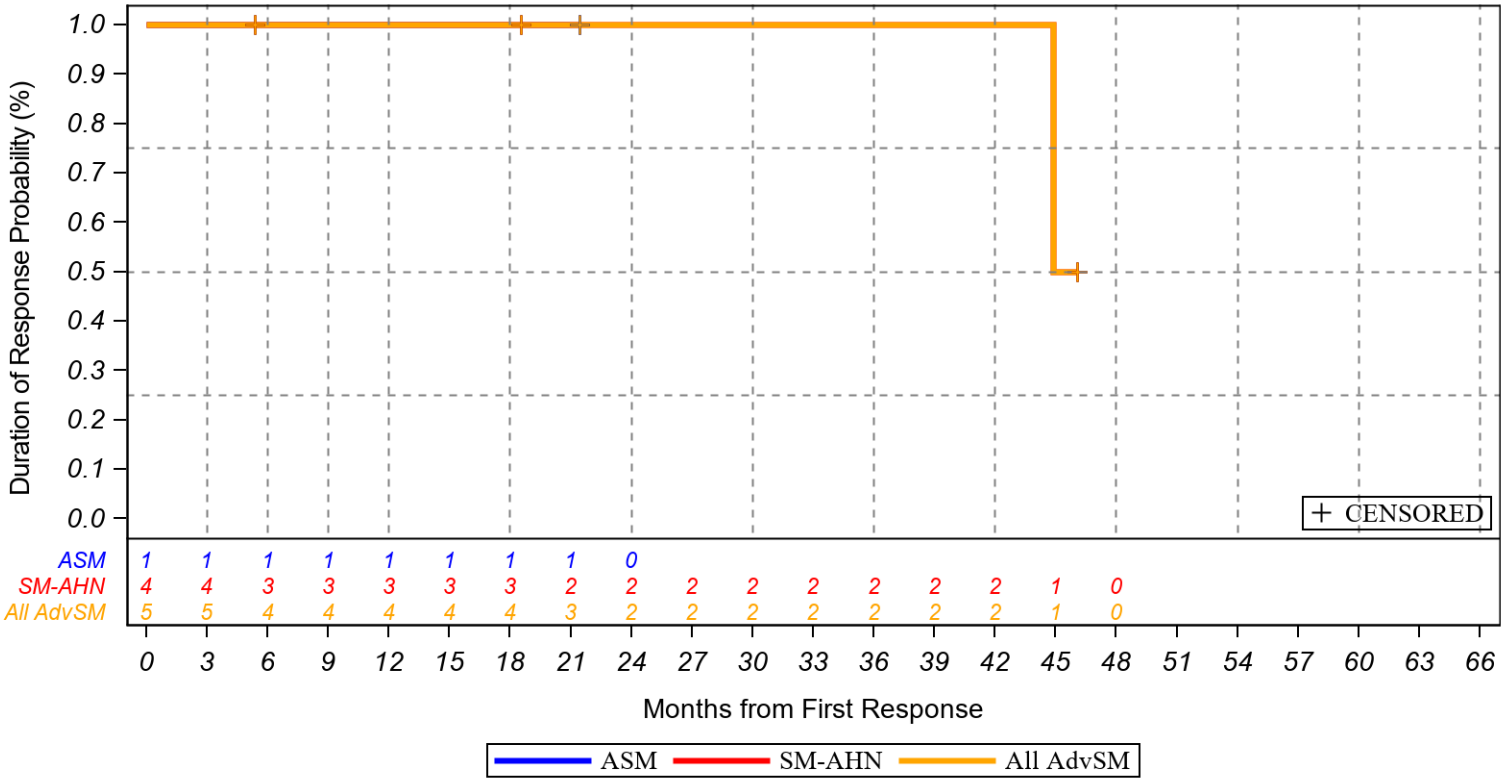

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101
Starting Dose: 400 mg & Prior Antineoplastic Therapy = No

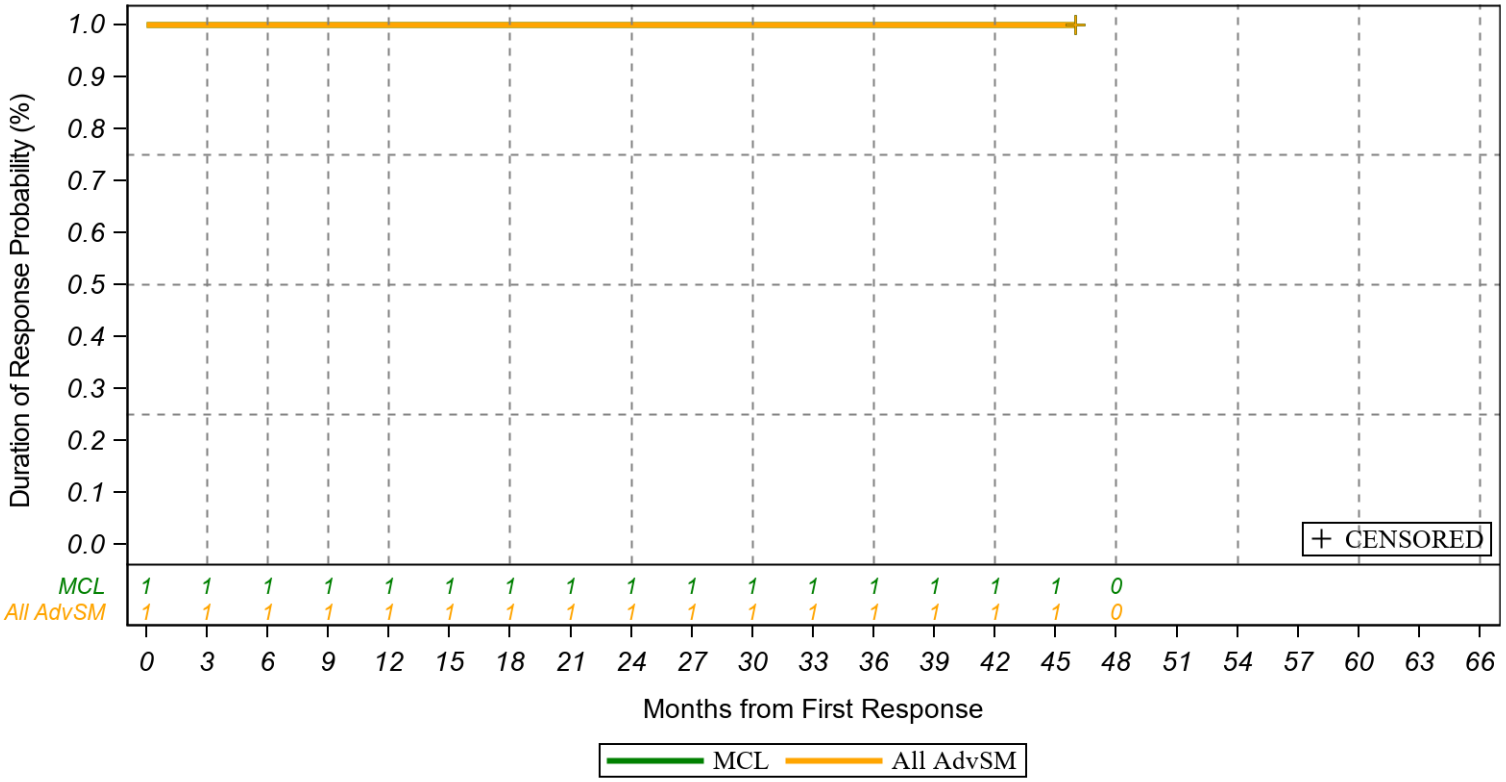

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2202
Starting Dose: Overall & Prior Antineoplastic Therapy = Yes

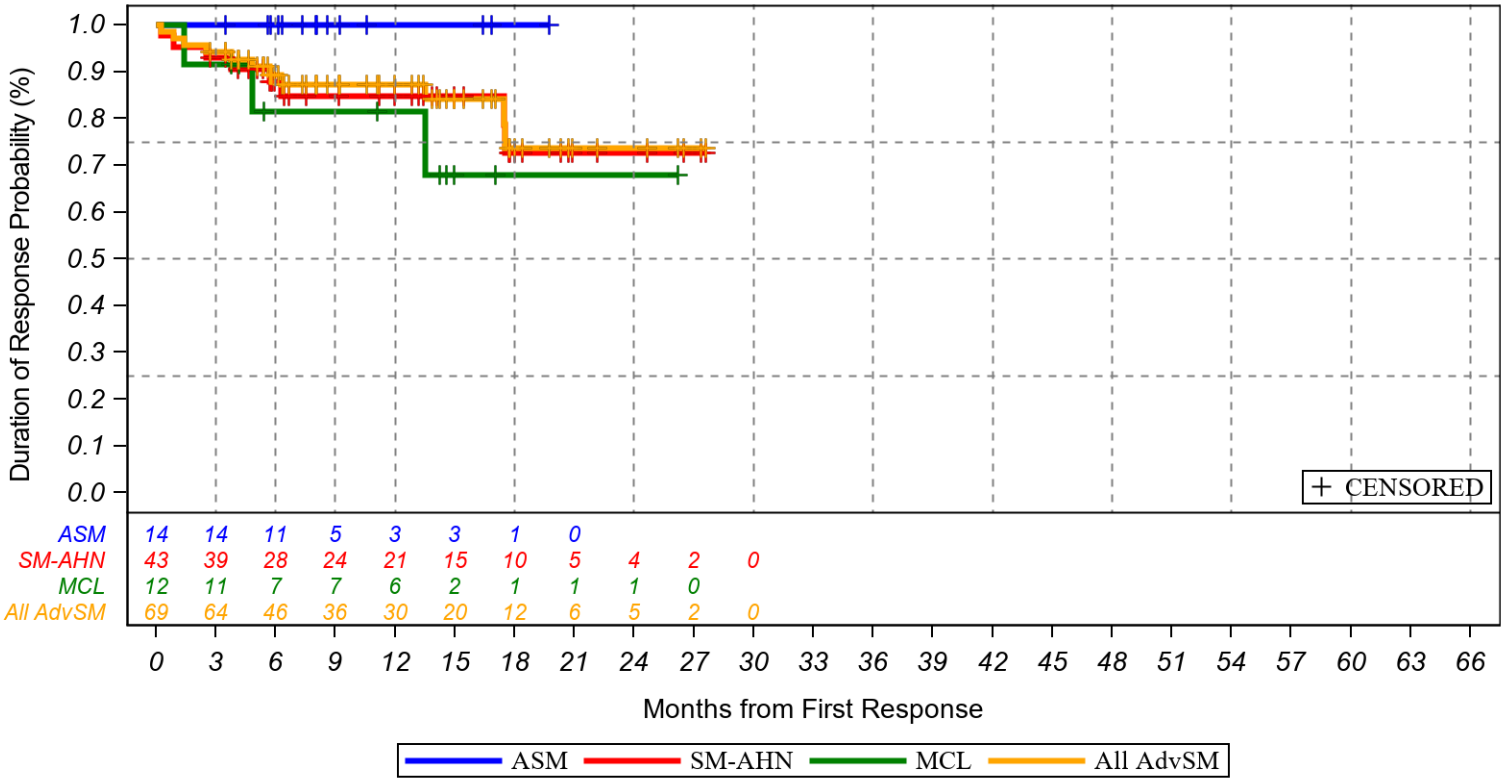

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2202
Starting Dose: Overall & Prior Antineoplastic Therapy = No

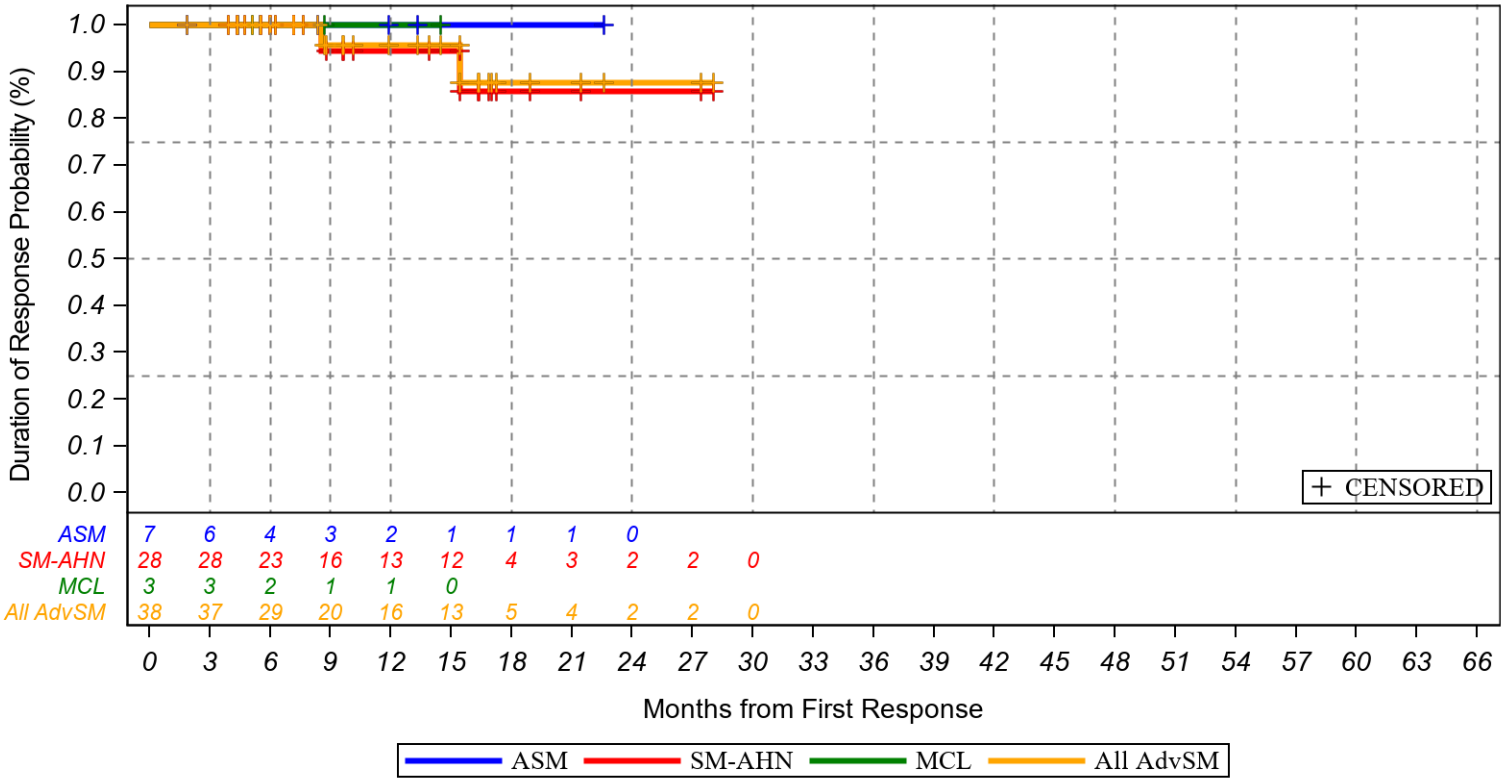

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2202
Starting Dose: 200 mg & Prior Antineoplastic Therapy = Yes

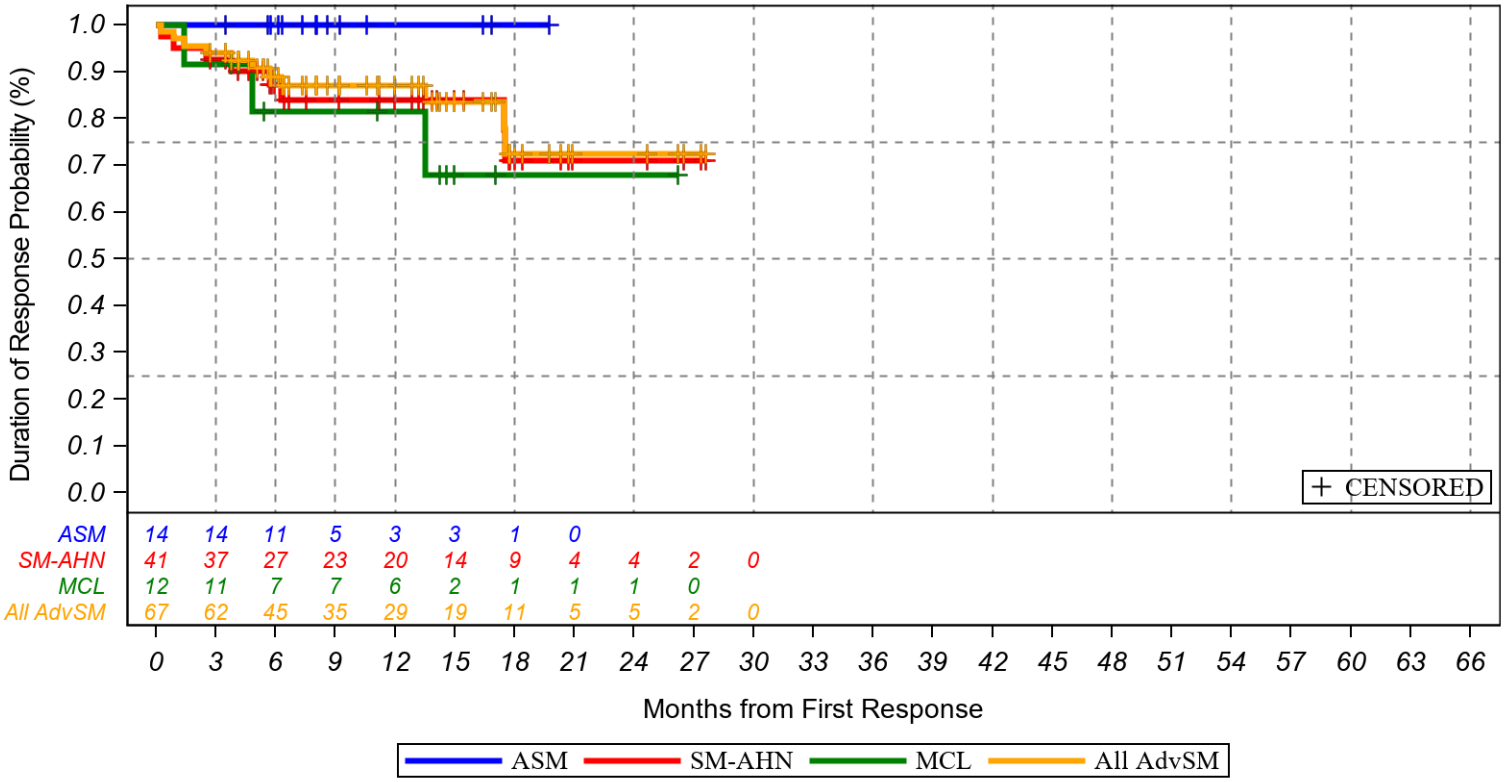

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Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2202
Starting Dose: 200 mg & Prior Antineoplastic Therapy = No

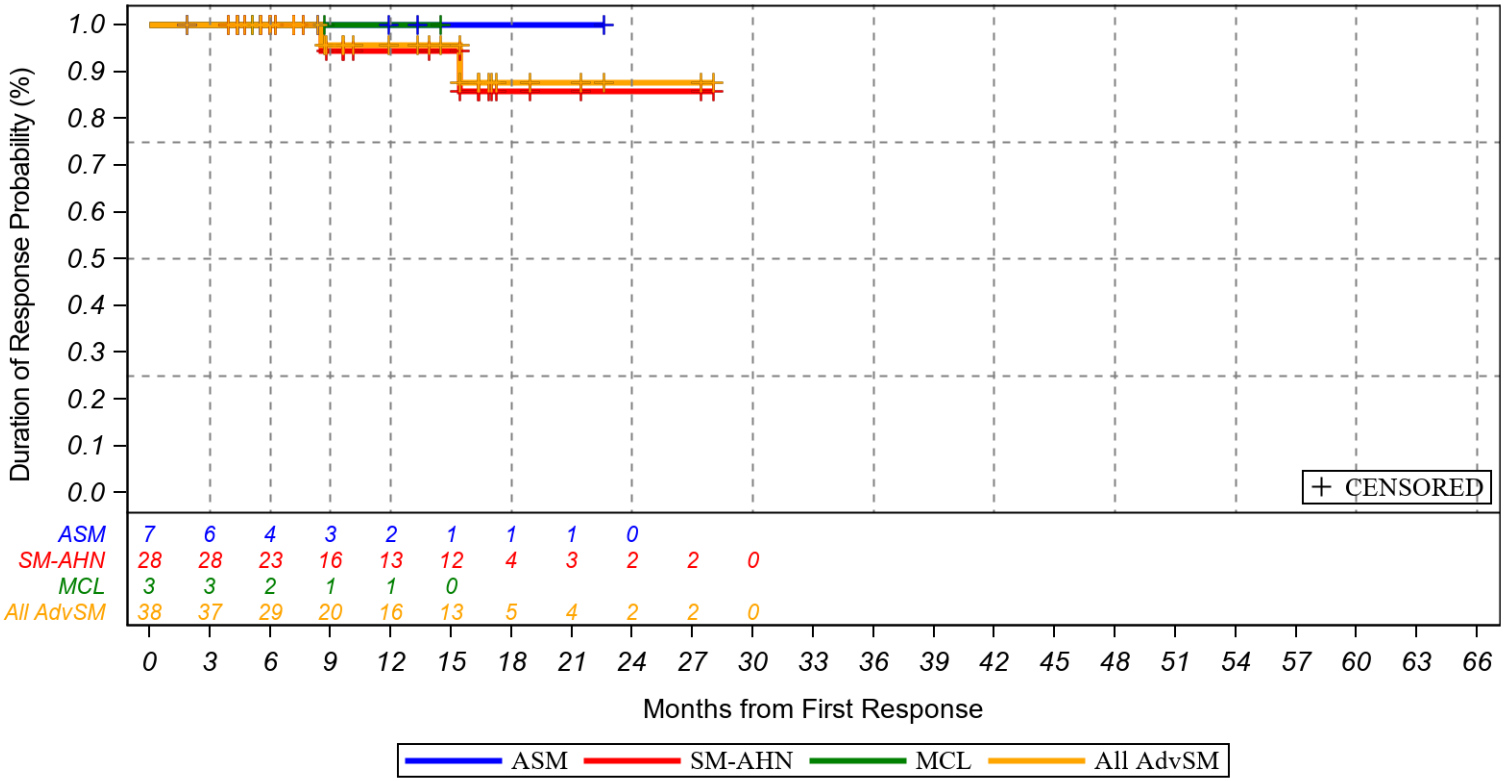

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall & Prior Antineoplastic Therapy = Yes

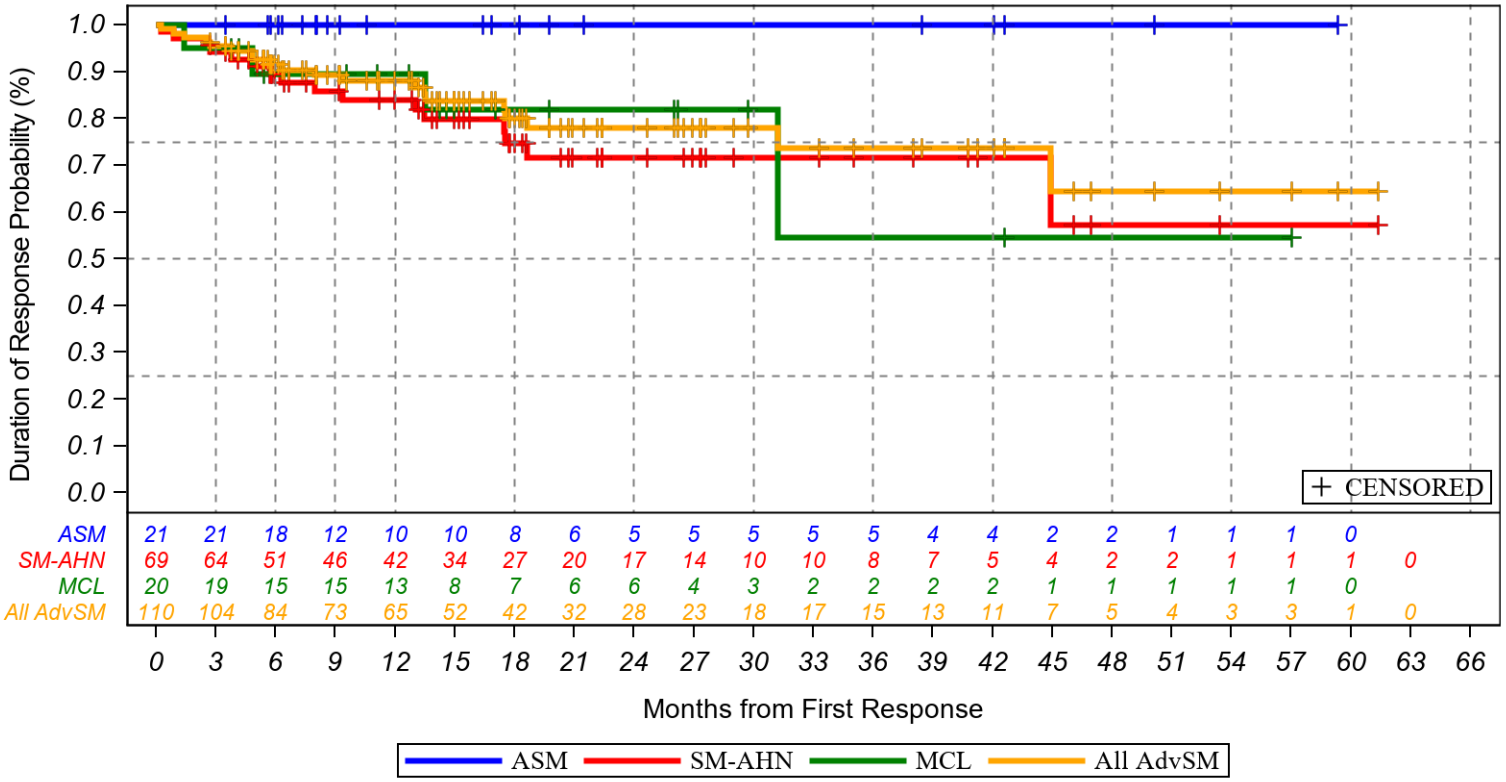

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall & Prior Antineoplastic Therapy = No

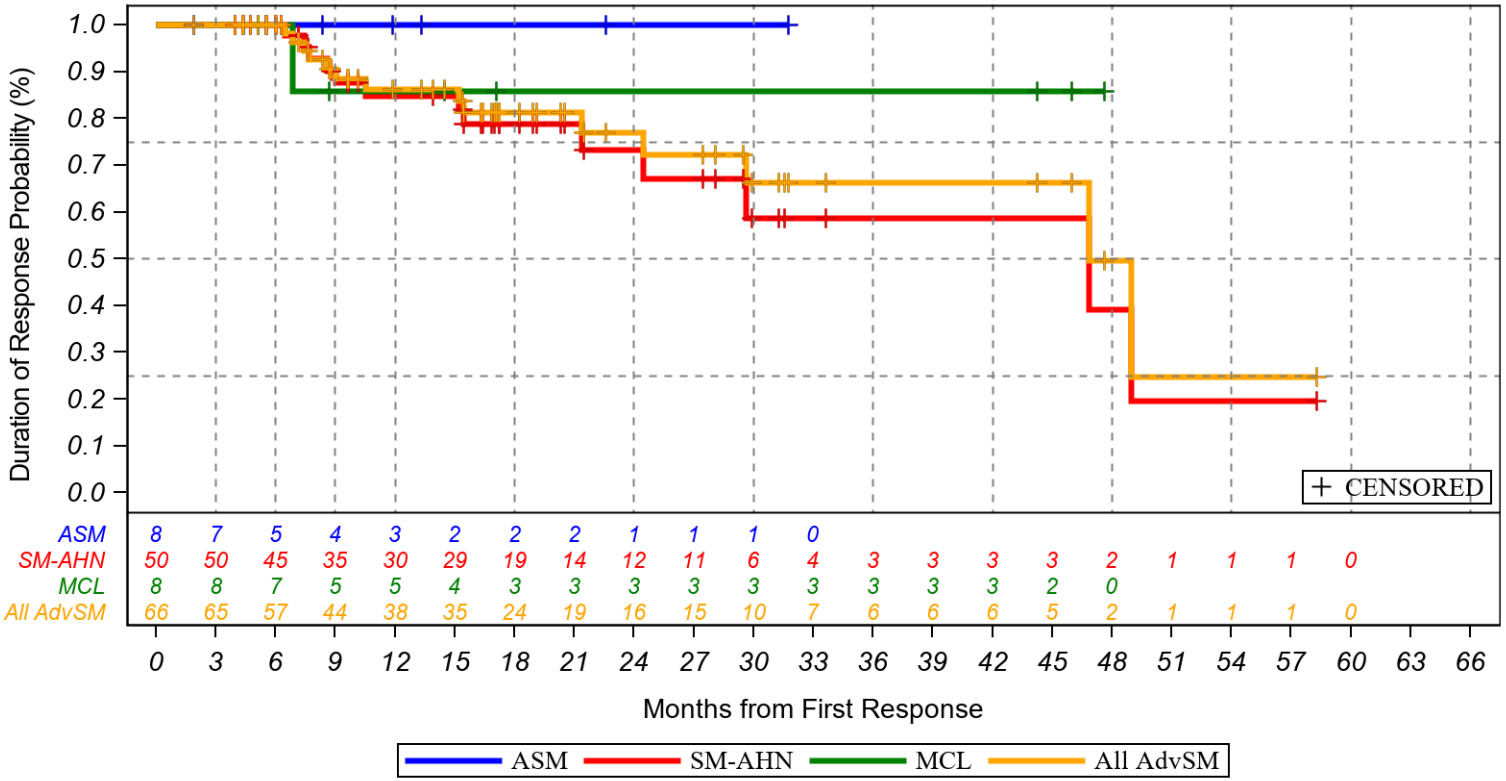

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg & Prior Antineoplastic Therapy = Yes

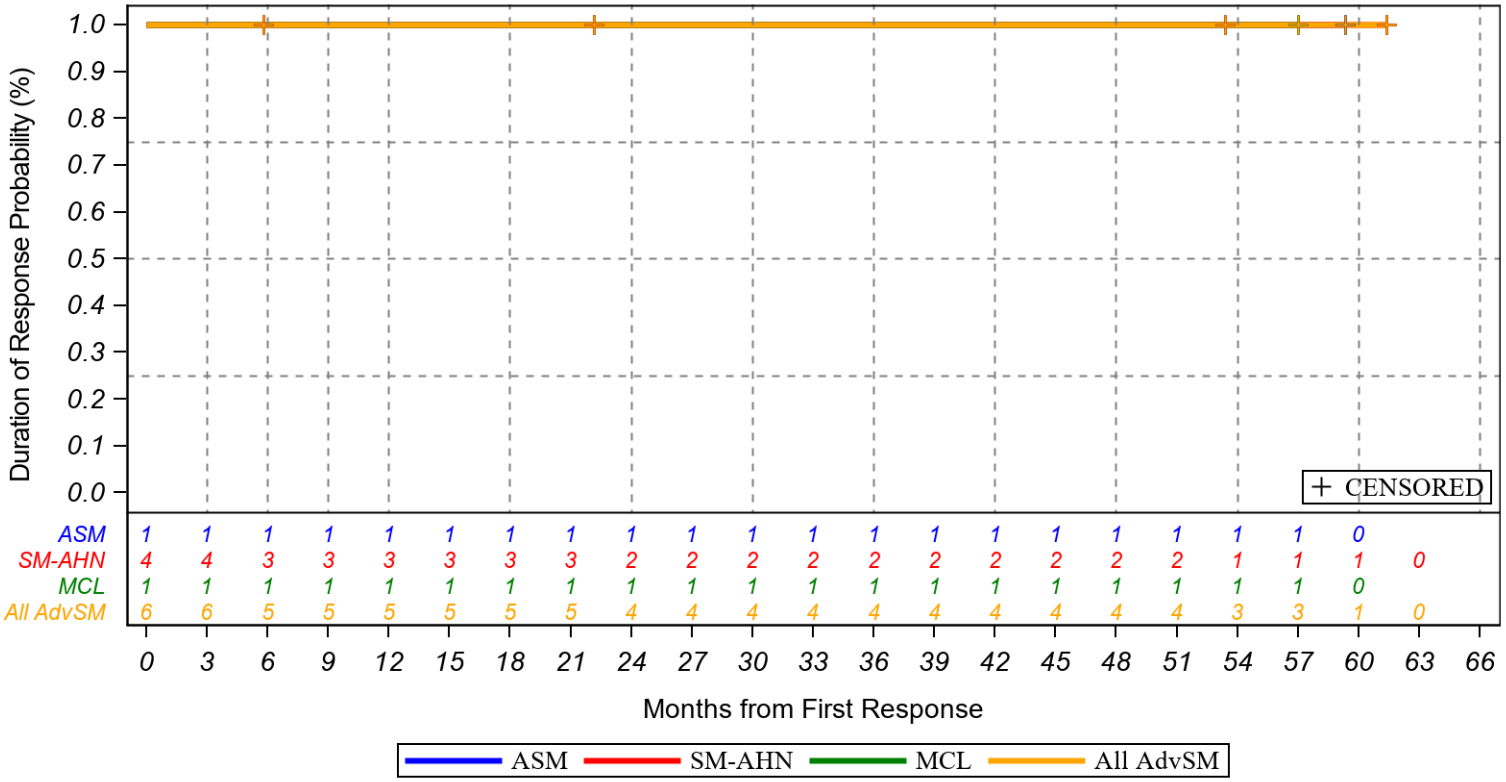

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg & Prior Antineoplastic Therapy = No

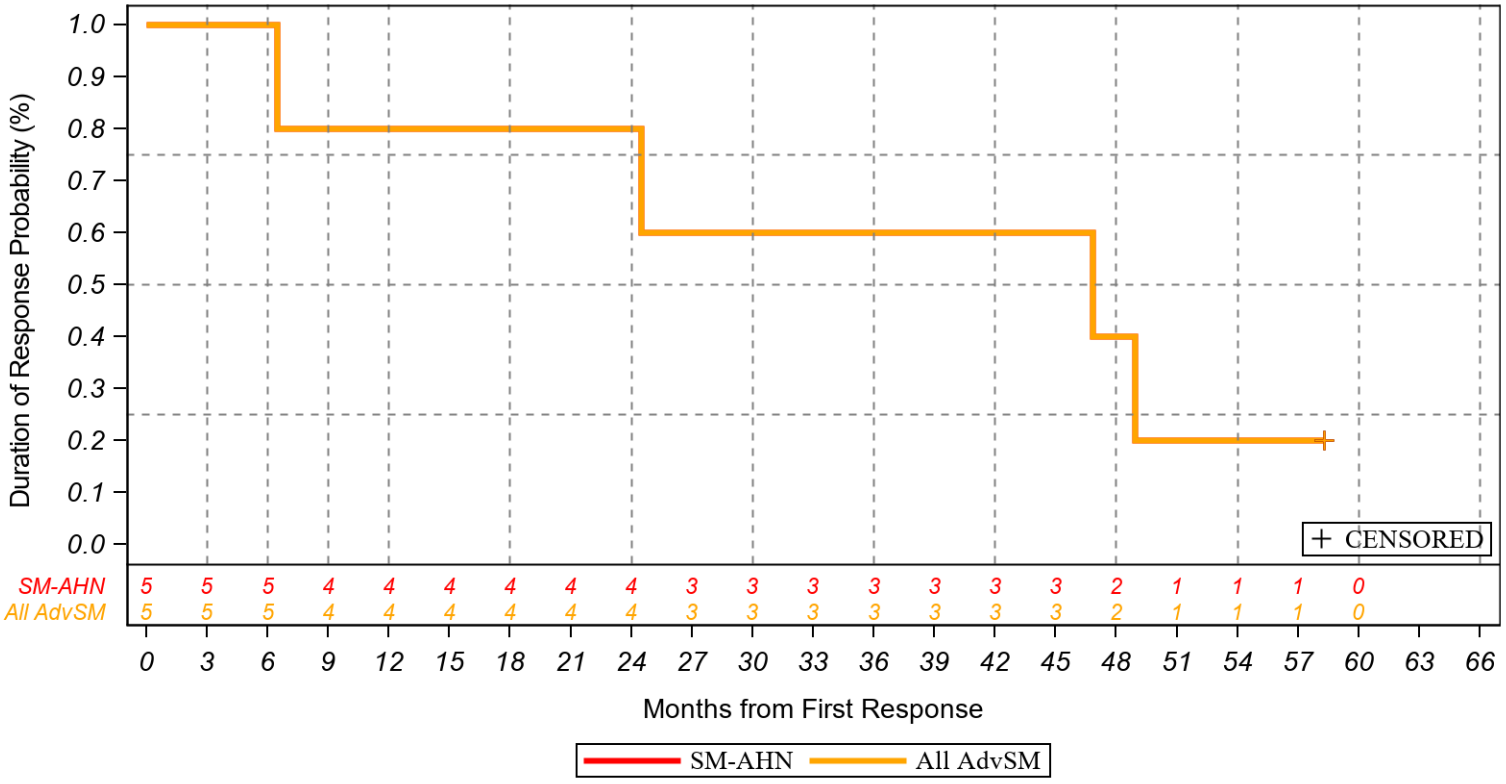

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg & Prior Antineoplastic Therapy = Yes

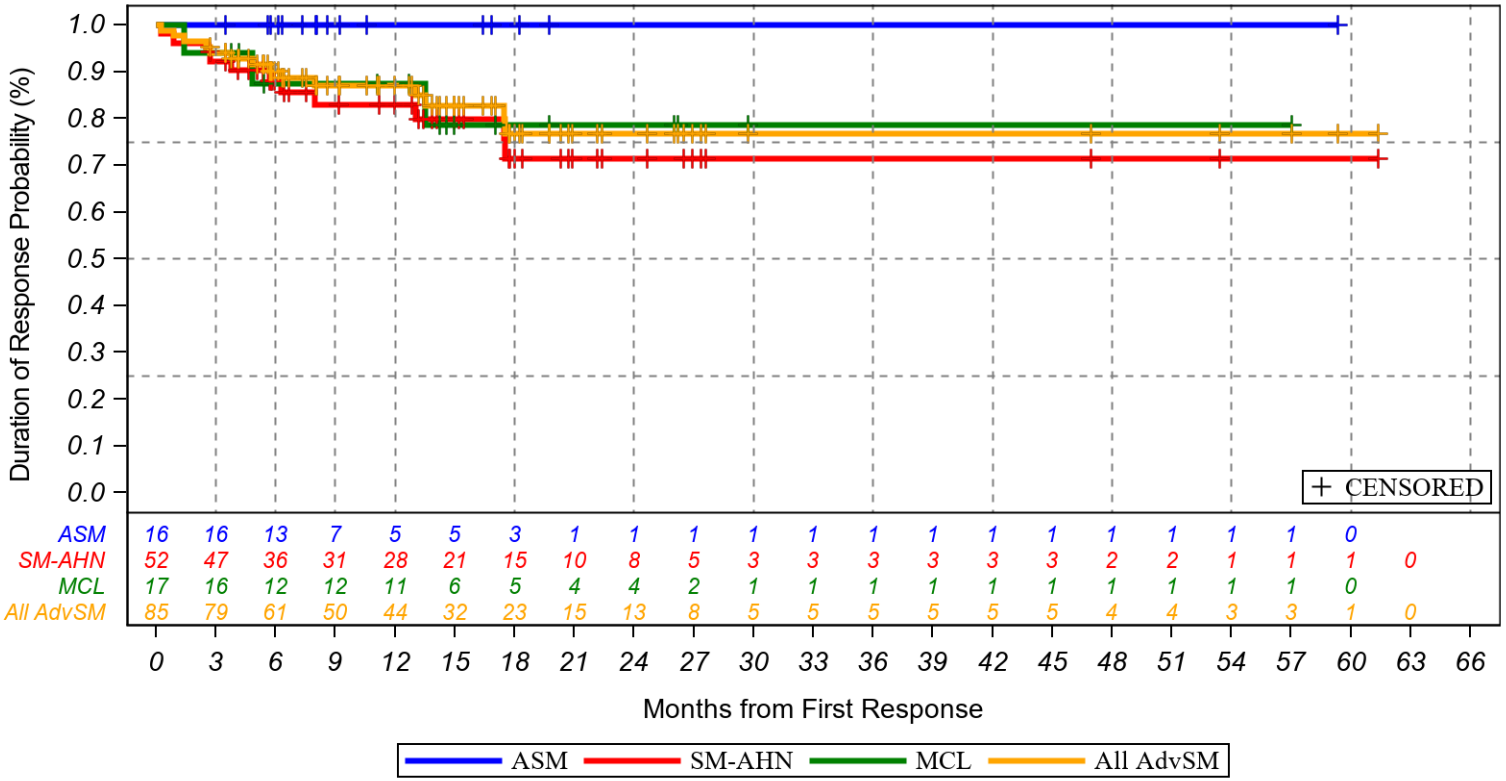

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg & Prior Antineoplastic Therapy = No

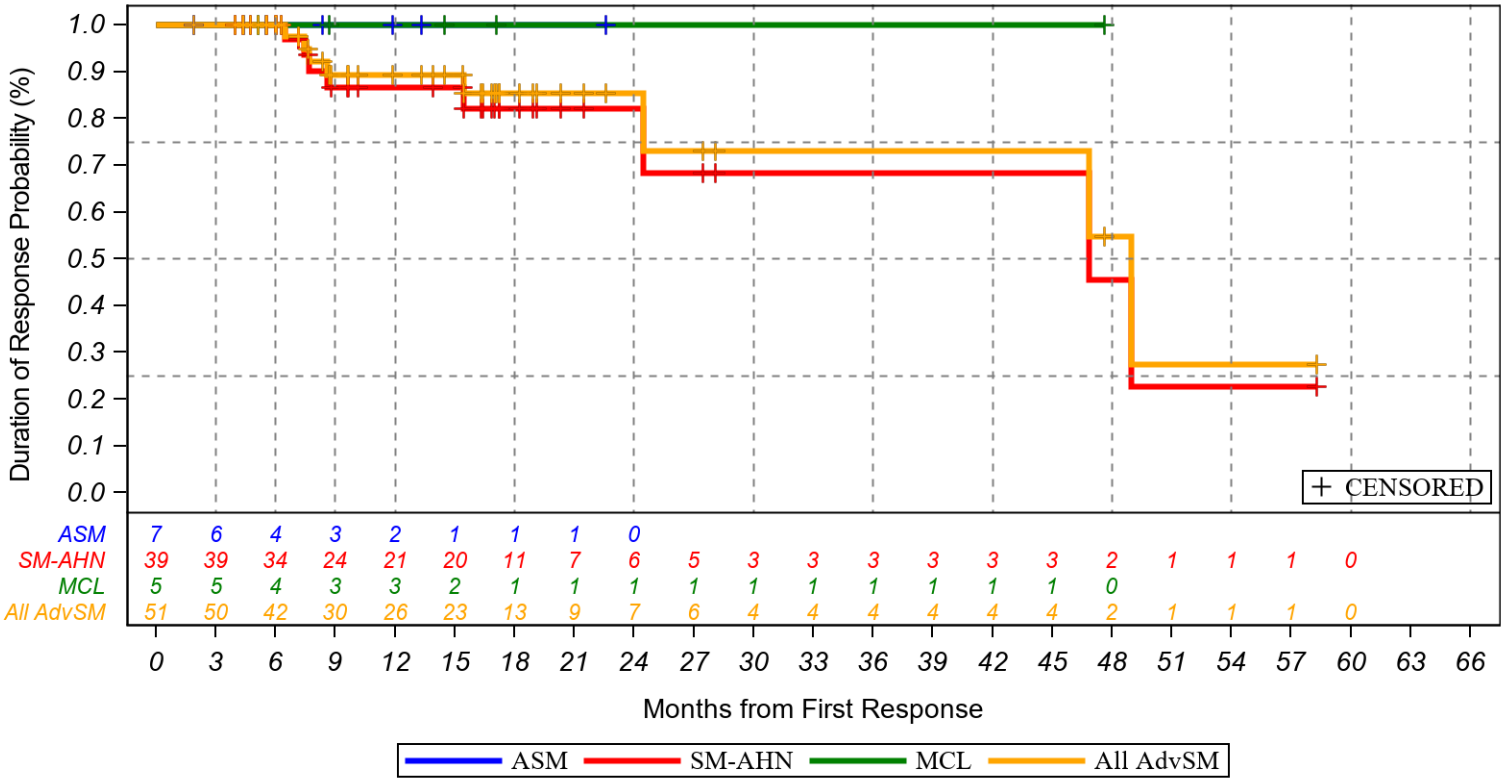

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg & Prior Antineoplastic Therapy = Yes

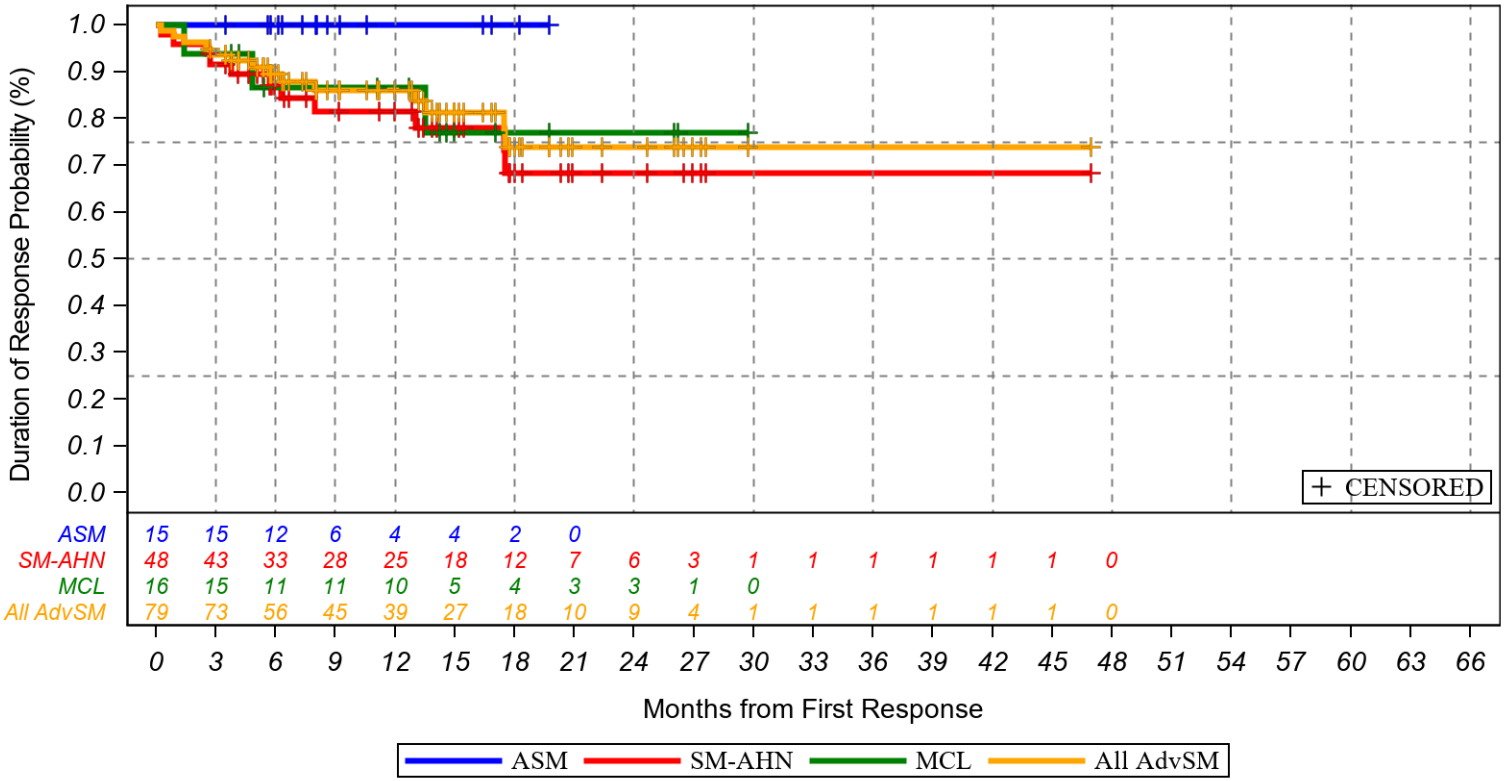

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg & Prior Antineoplastic Therapy = No

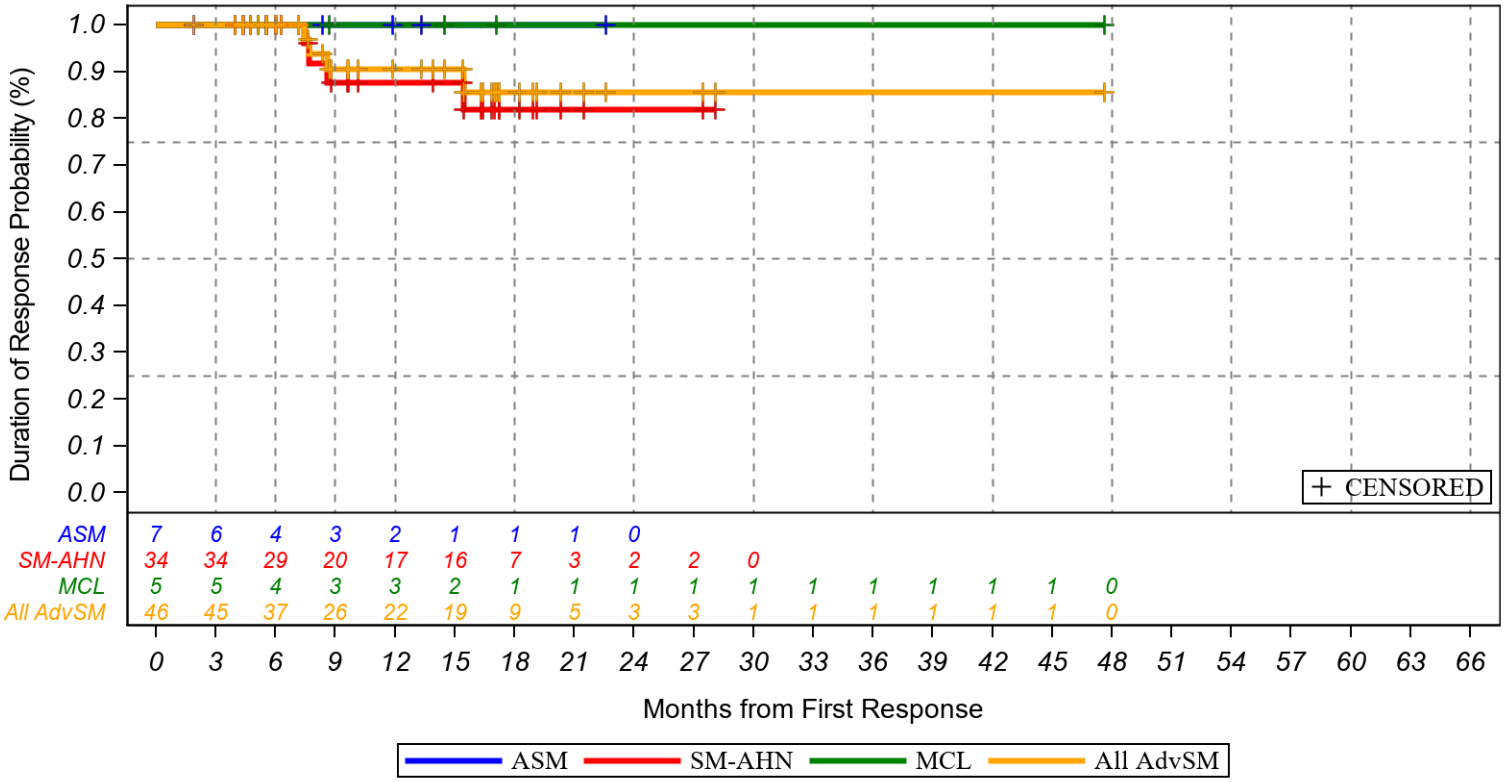

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg & Prior Antineoplastic Therapy = Yes

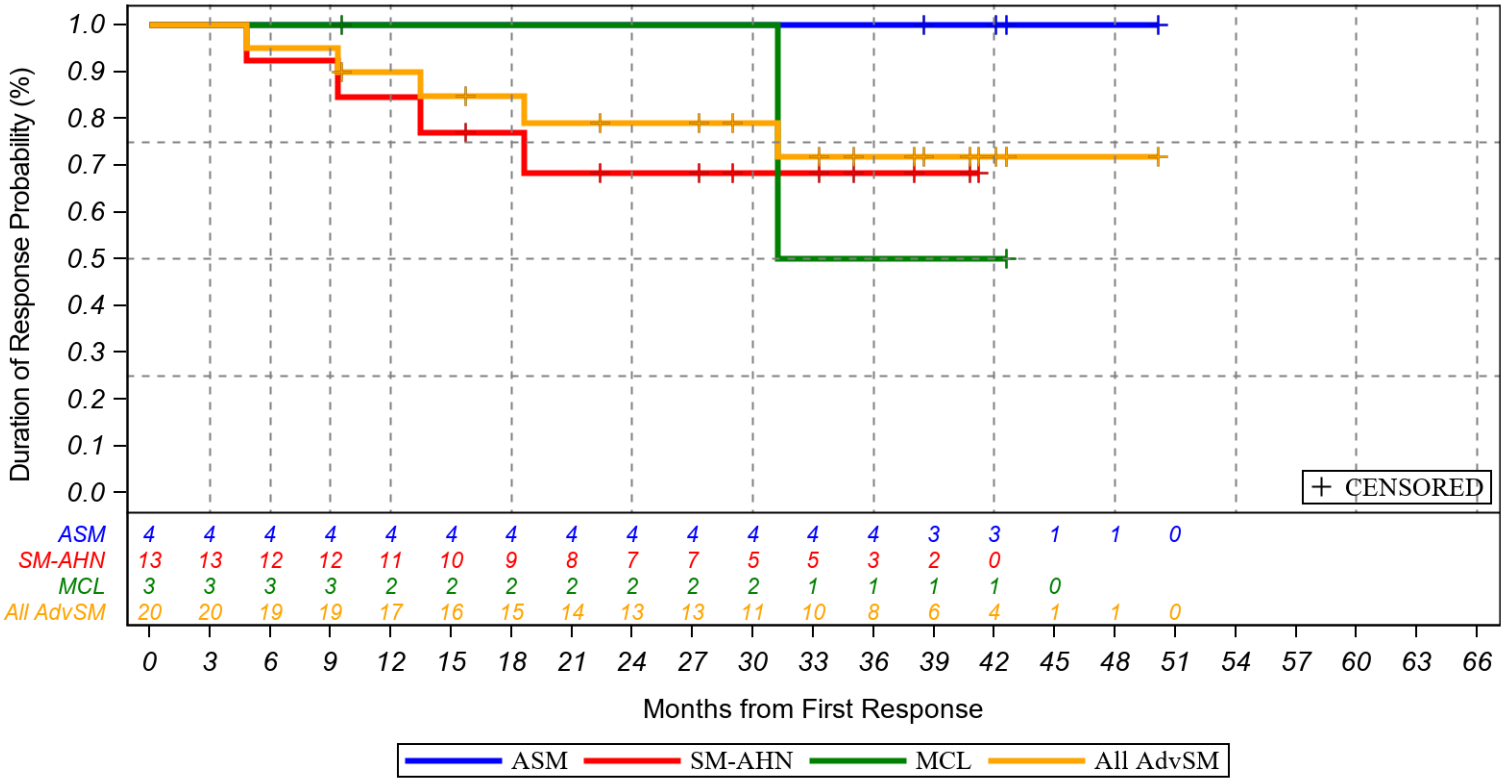

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Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg & Prior Antineoplastic Therapy = No

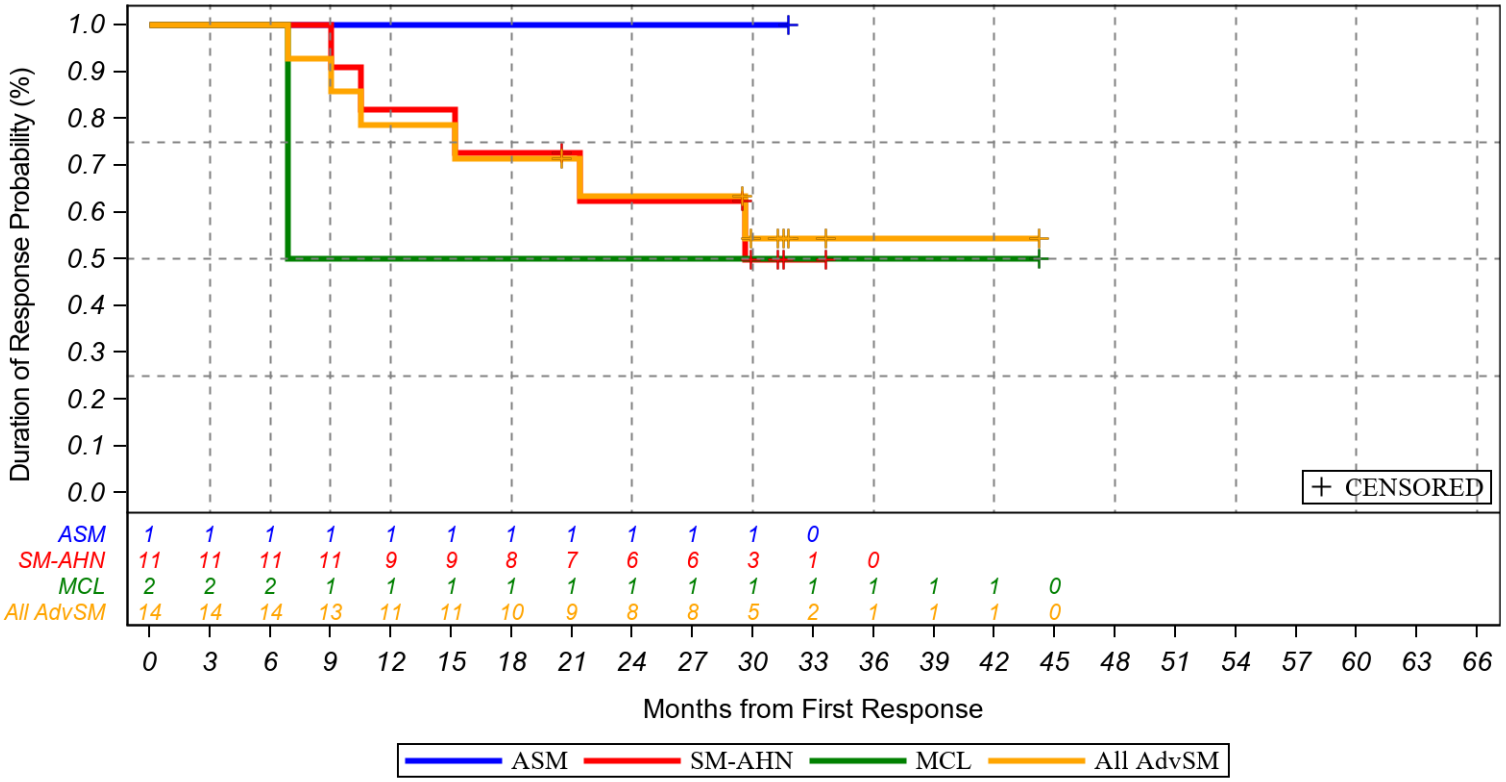

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg & Prior Antineoplastic Therapy = Yes

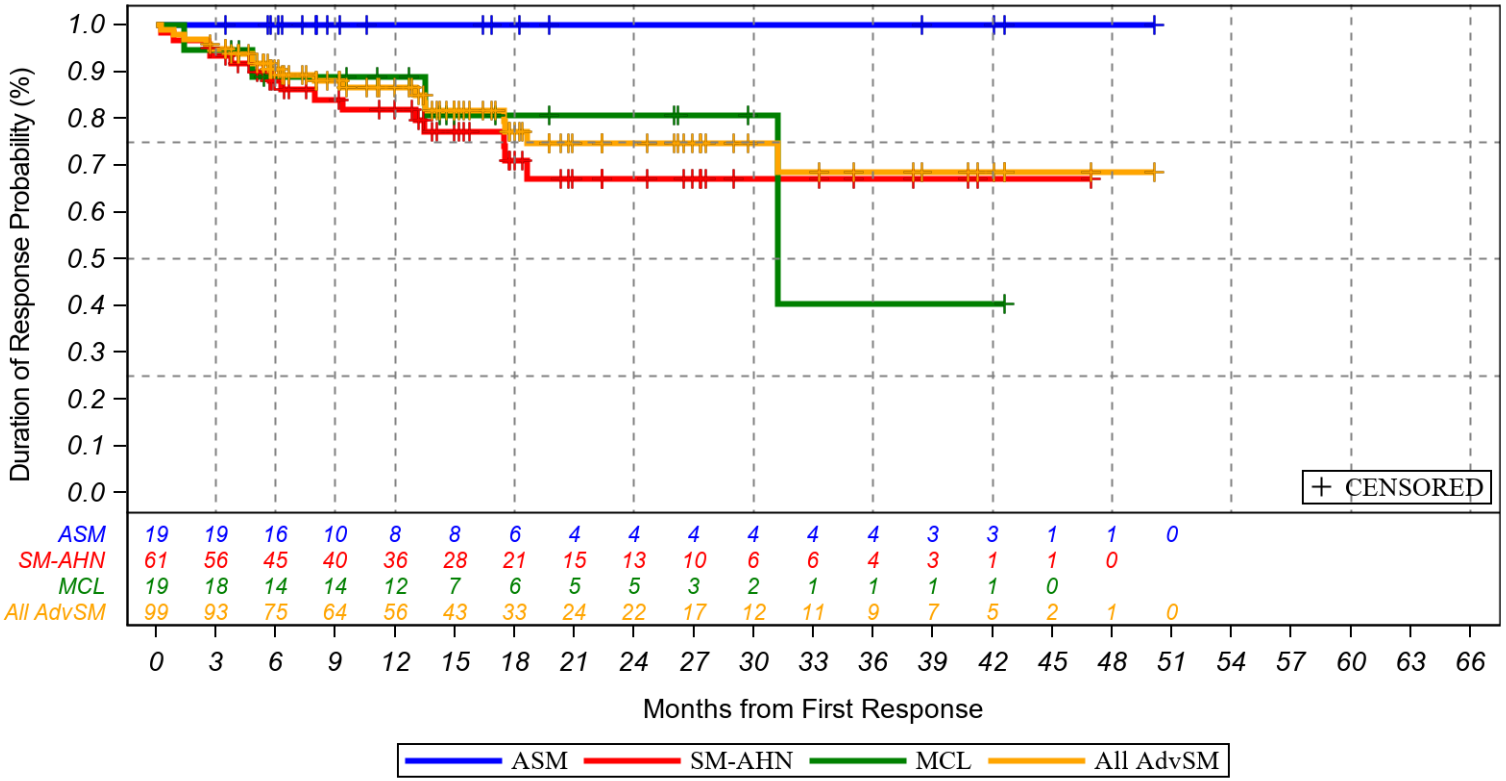

Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg & Prior Antineoplastic Therapy = No

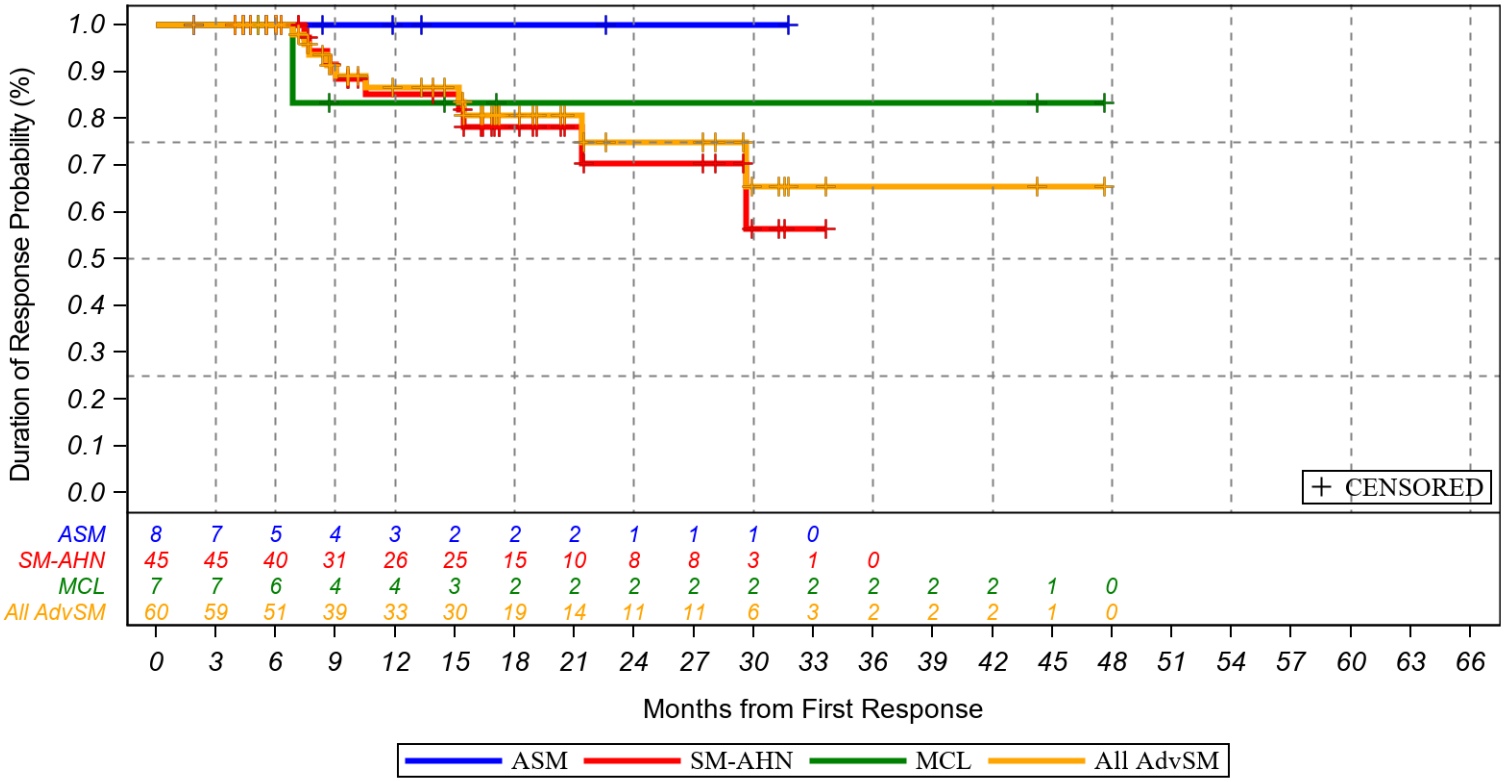

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Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg & Prior Antineoplastic Therapy = Yes

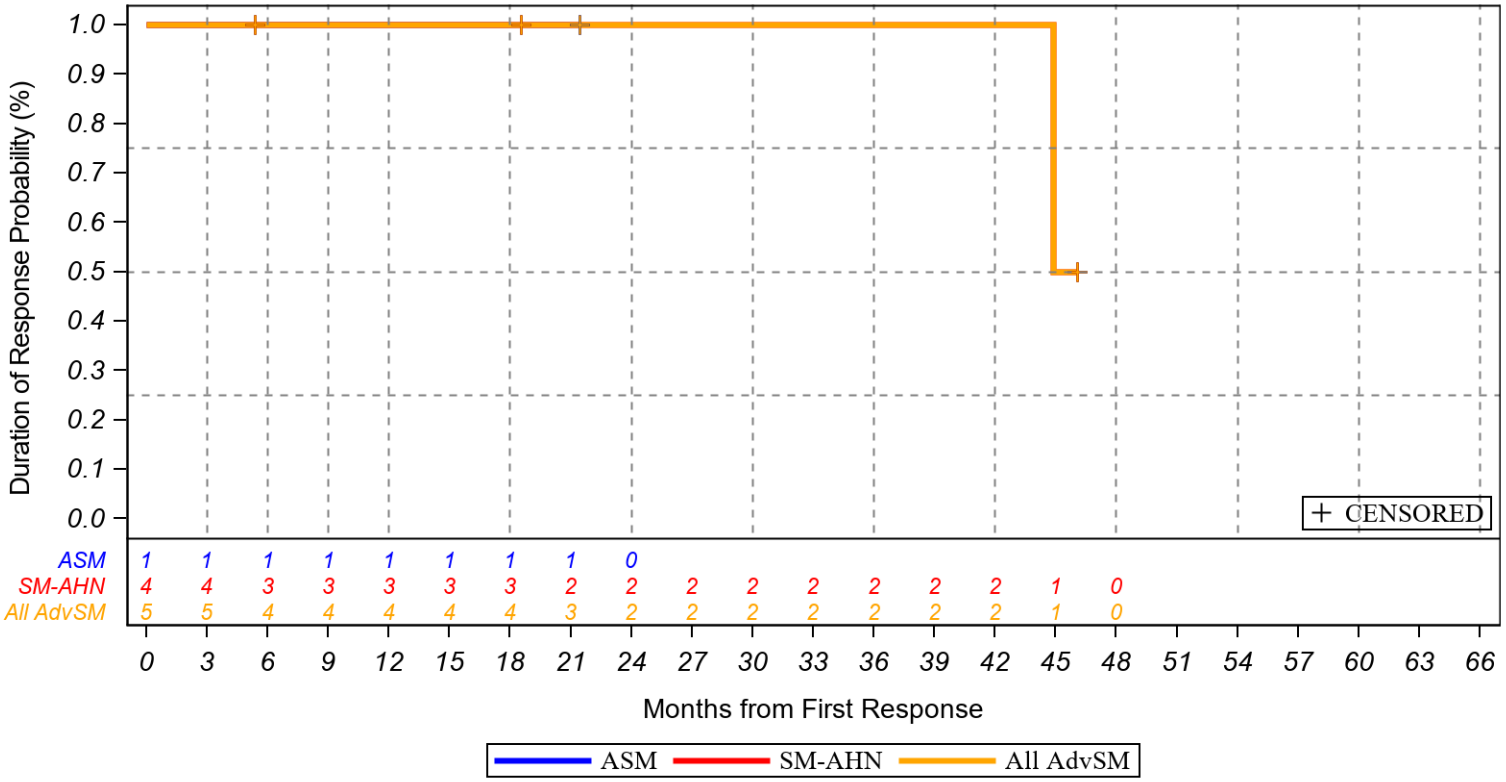
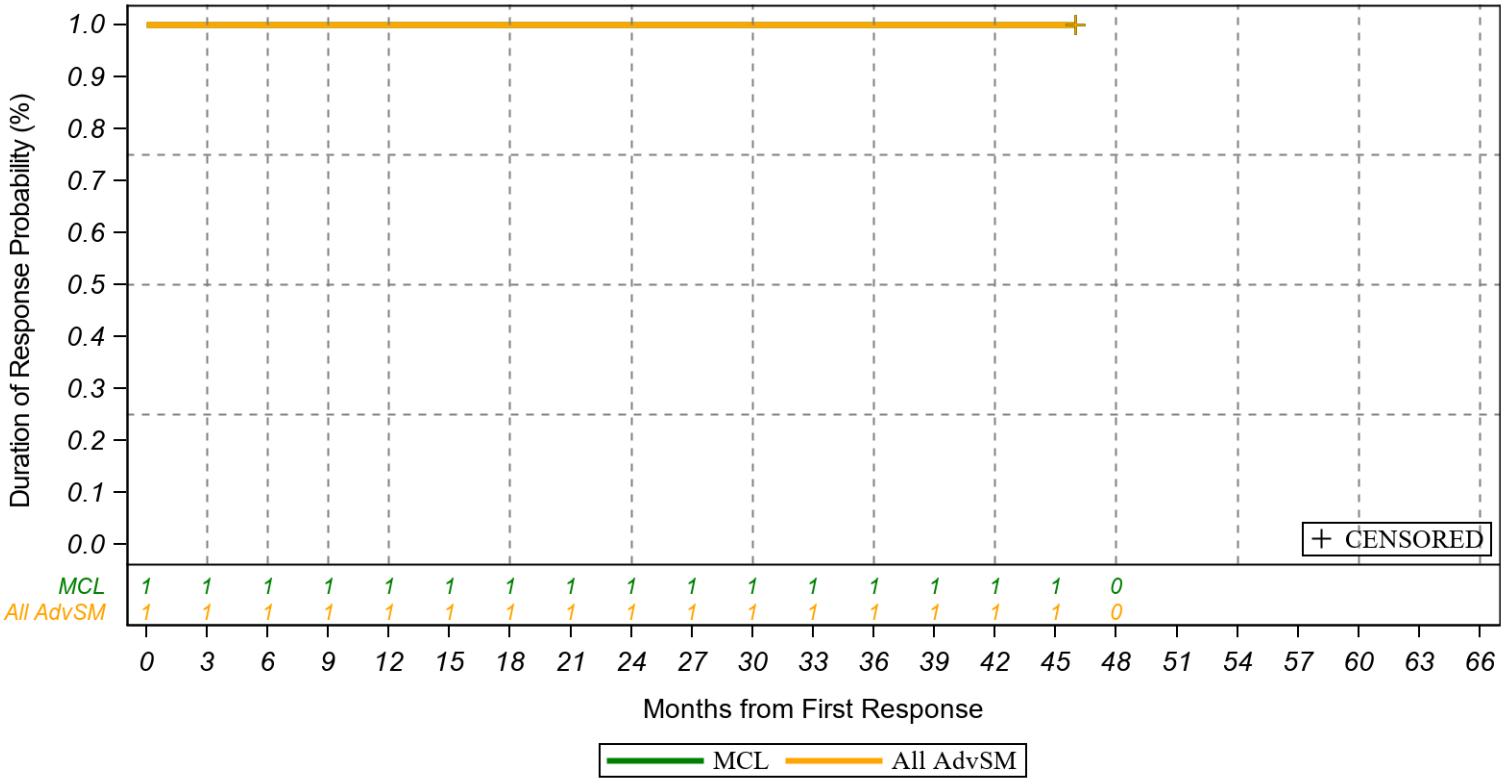


Figure 15.2.4.1c
Kaplan-Meier Curves of Overall Survival by Prior Antineoplastic Therapy
AdvSM Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg & Prior Antineoplastic Therapy = No



Blueprint Medicines
Page 1 of 64
Avapritinib Systemic Mastocytosis Integrated Summary of Efficacy
Data Cutoff Date: 20 April 2021

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: Overall
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR+CI)

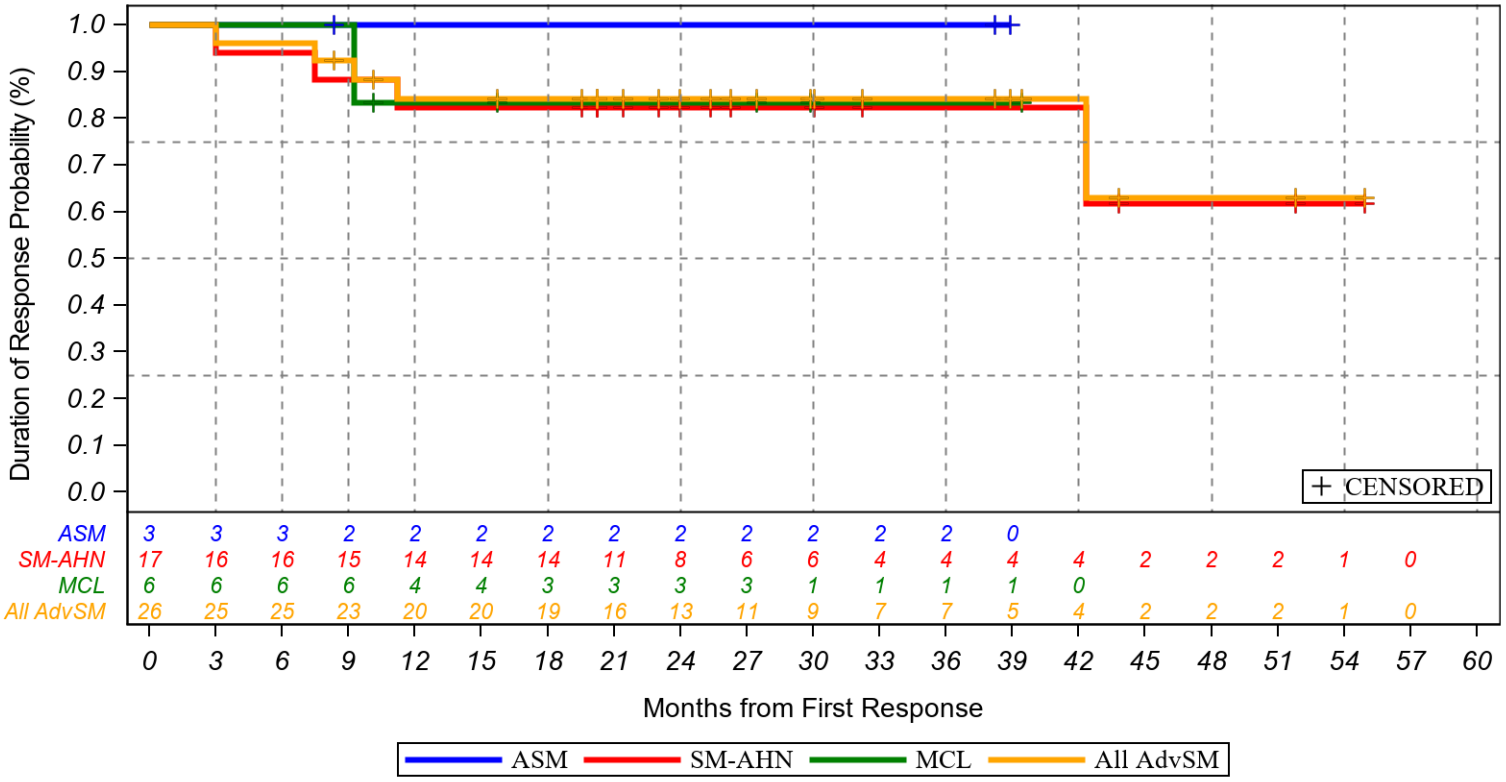


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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: Overall
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR)

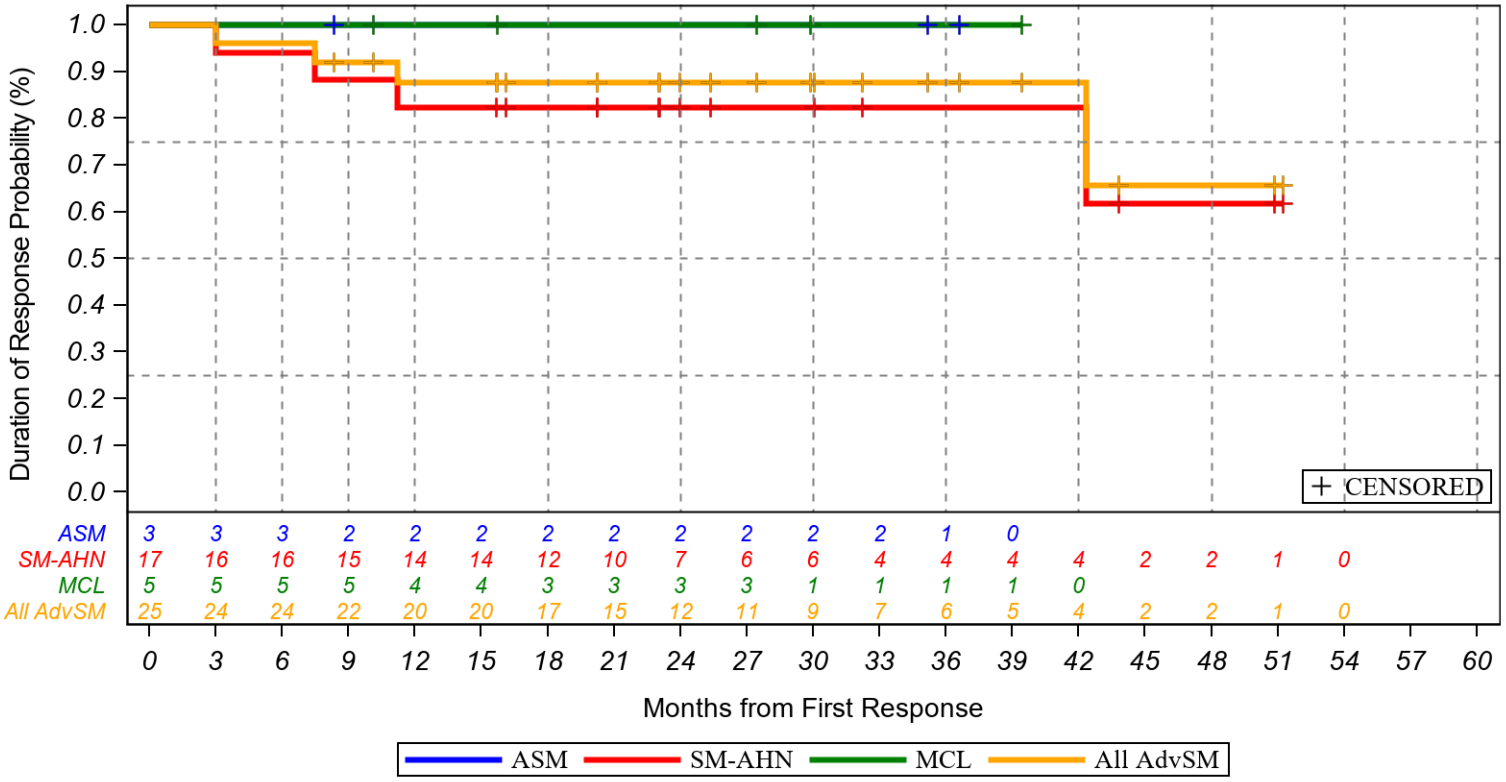

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: Overall
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR+CI)

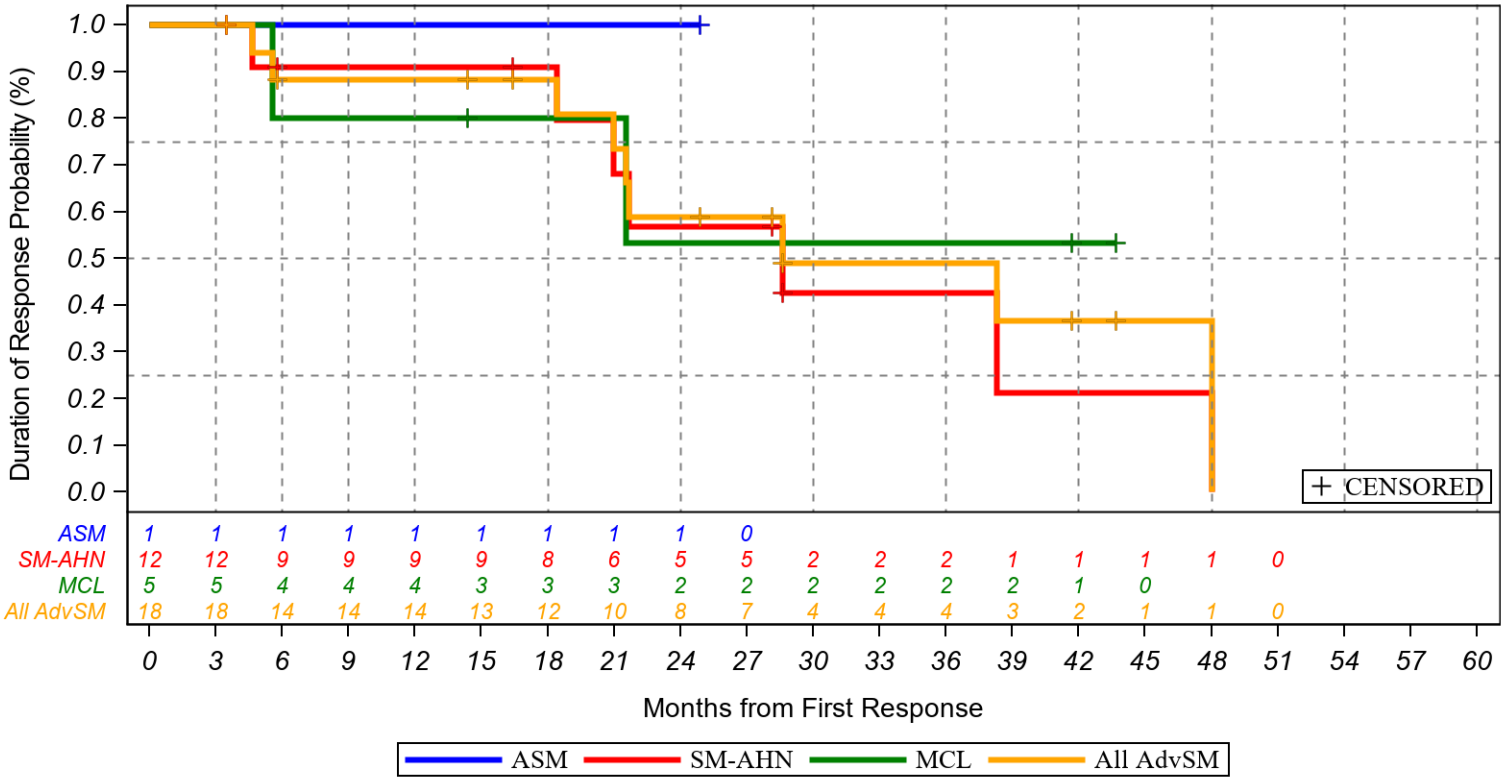

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: Overall
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR)

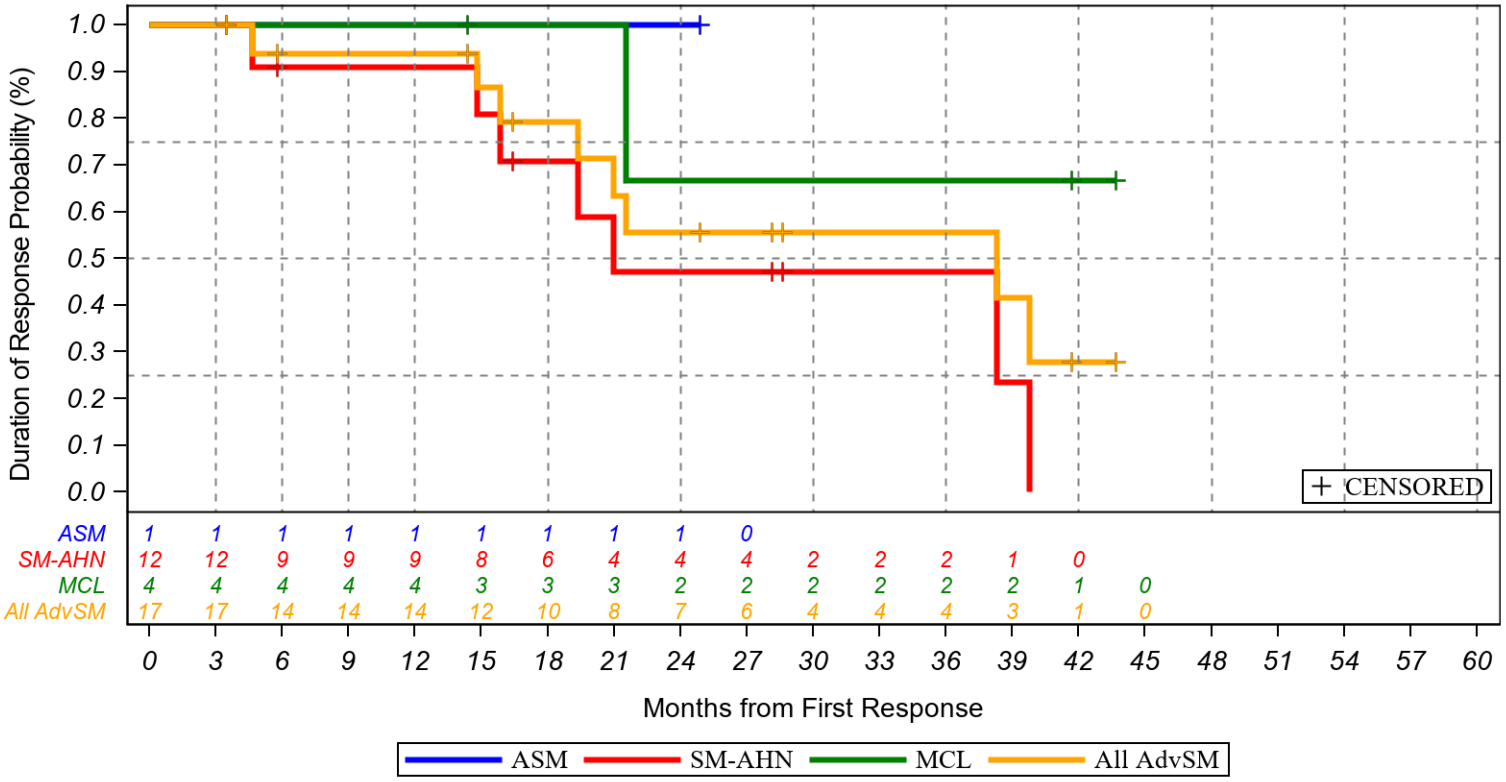

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: < 200 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR+CI)

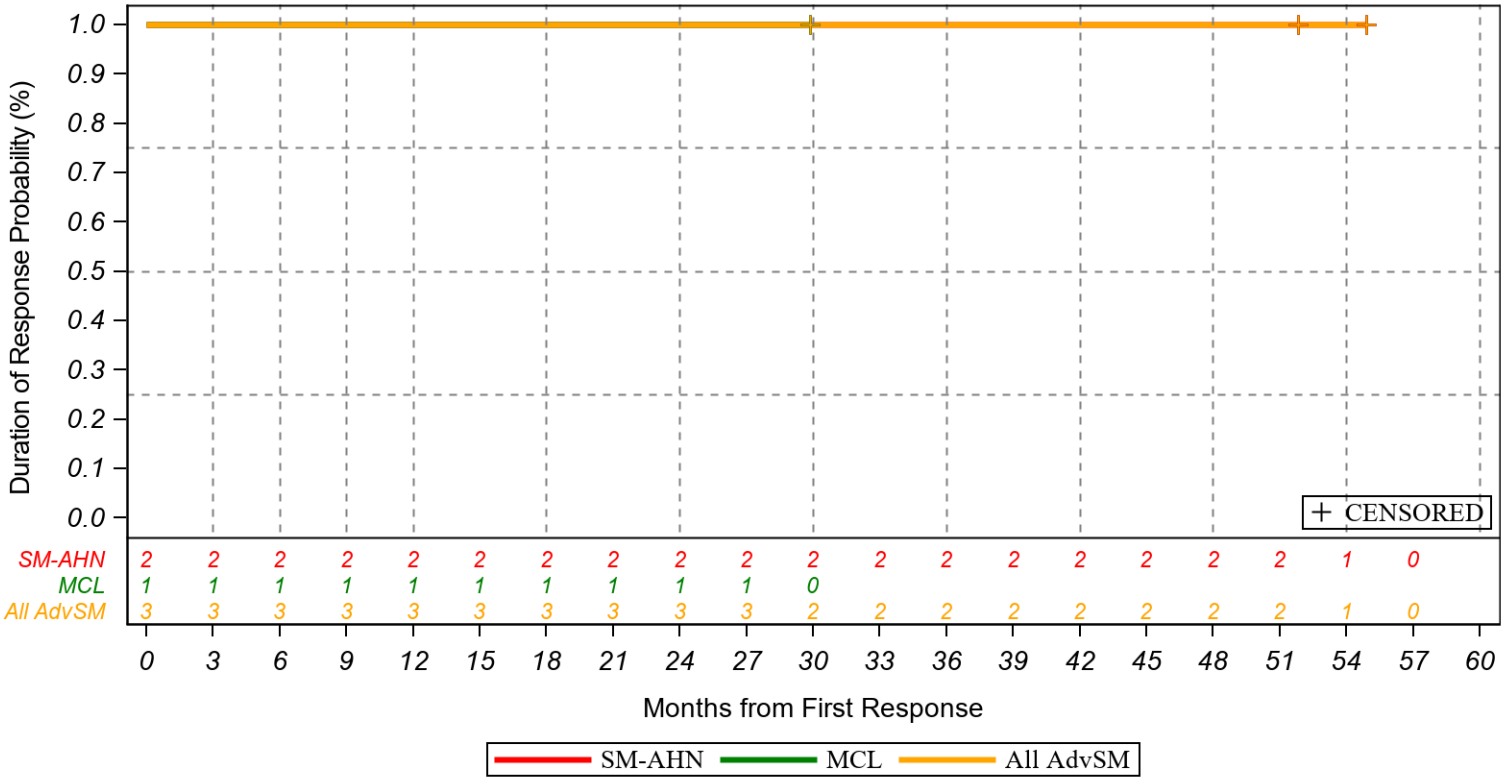

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: < 200 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR)

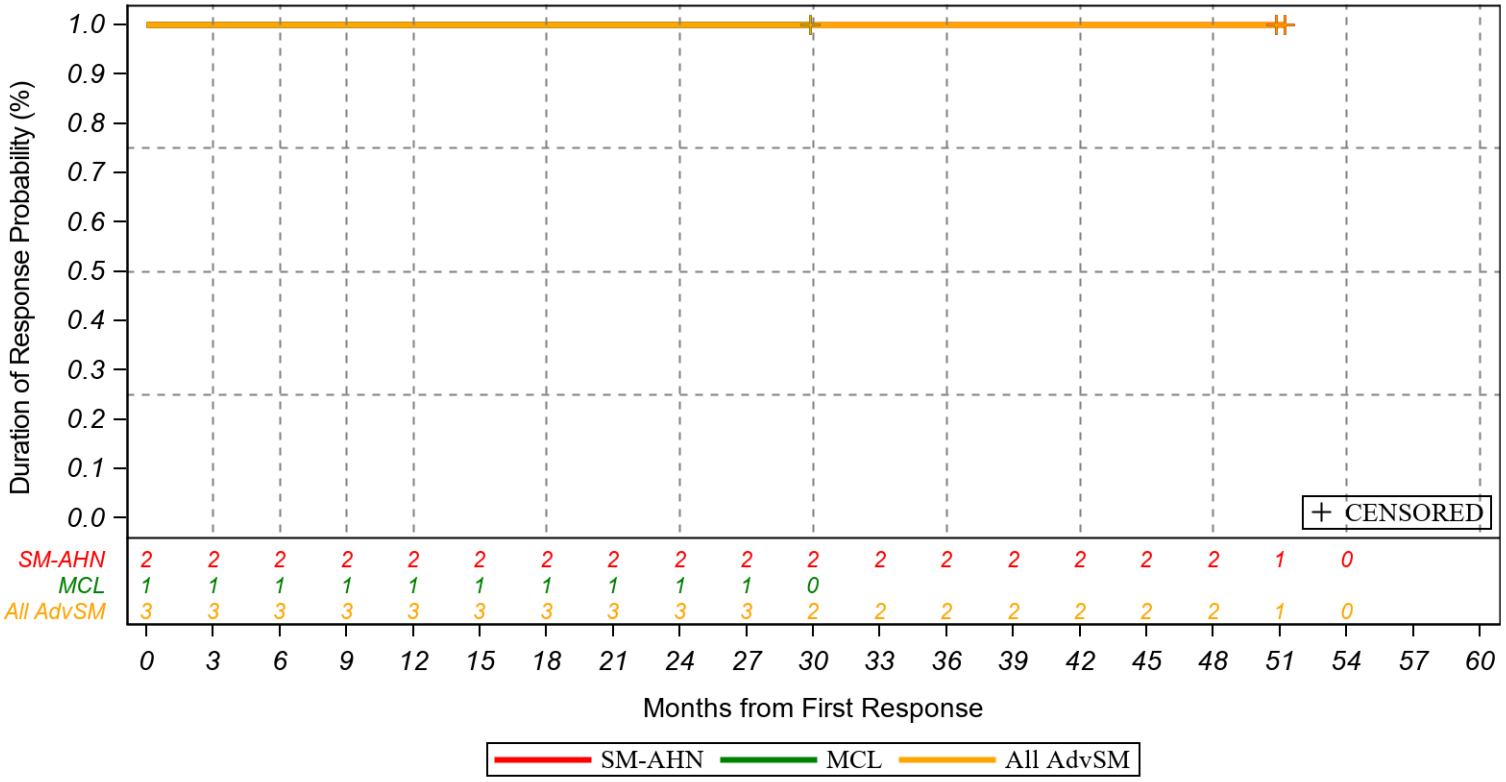

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: < 200 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR+CI)

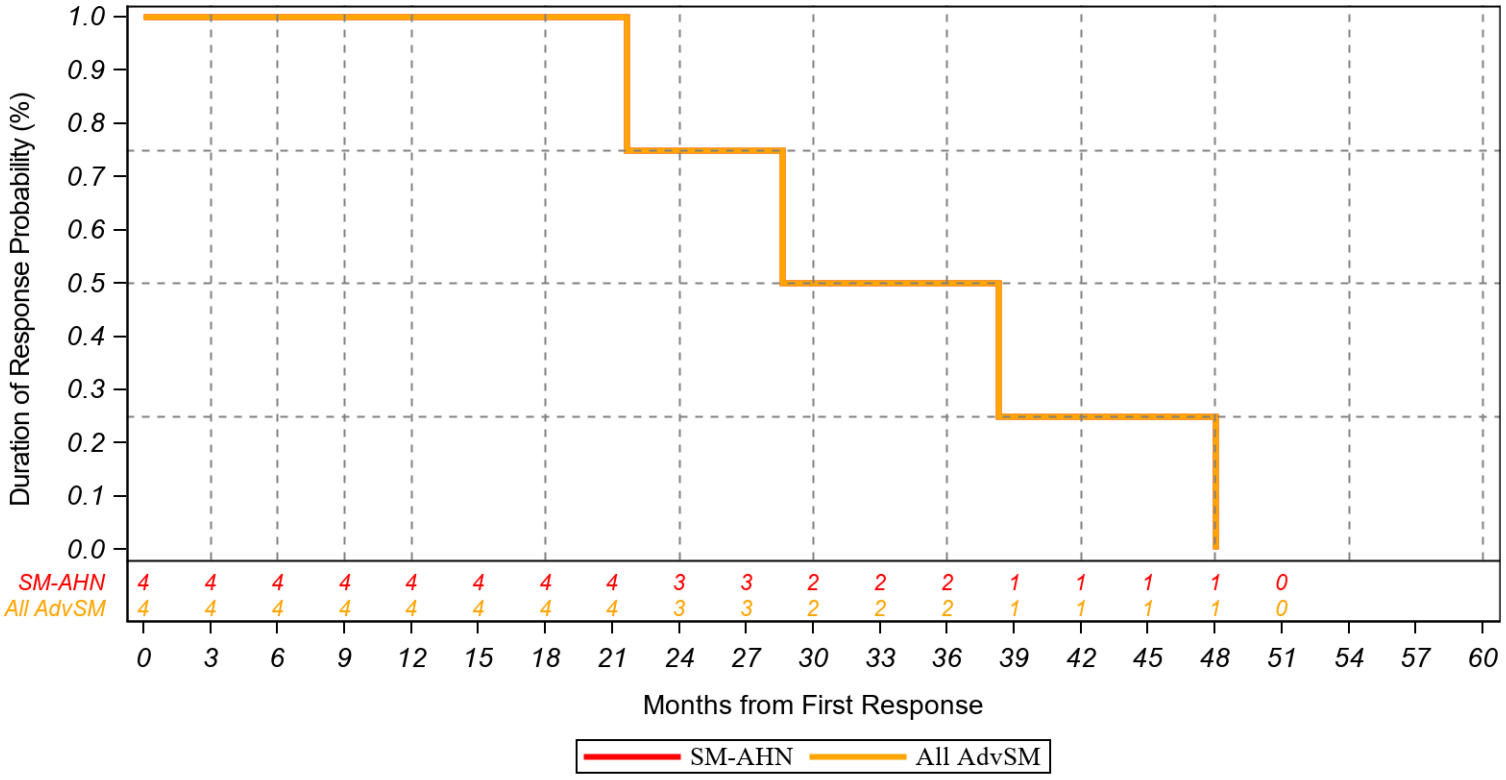

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: < 200 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR)

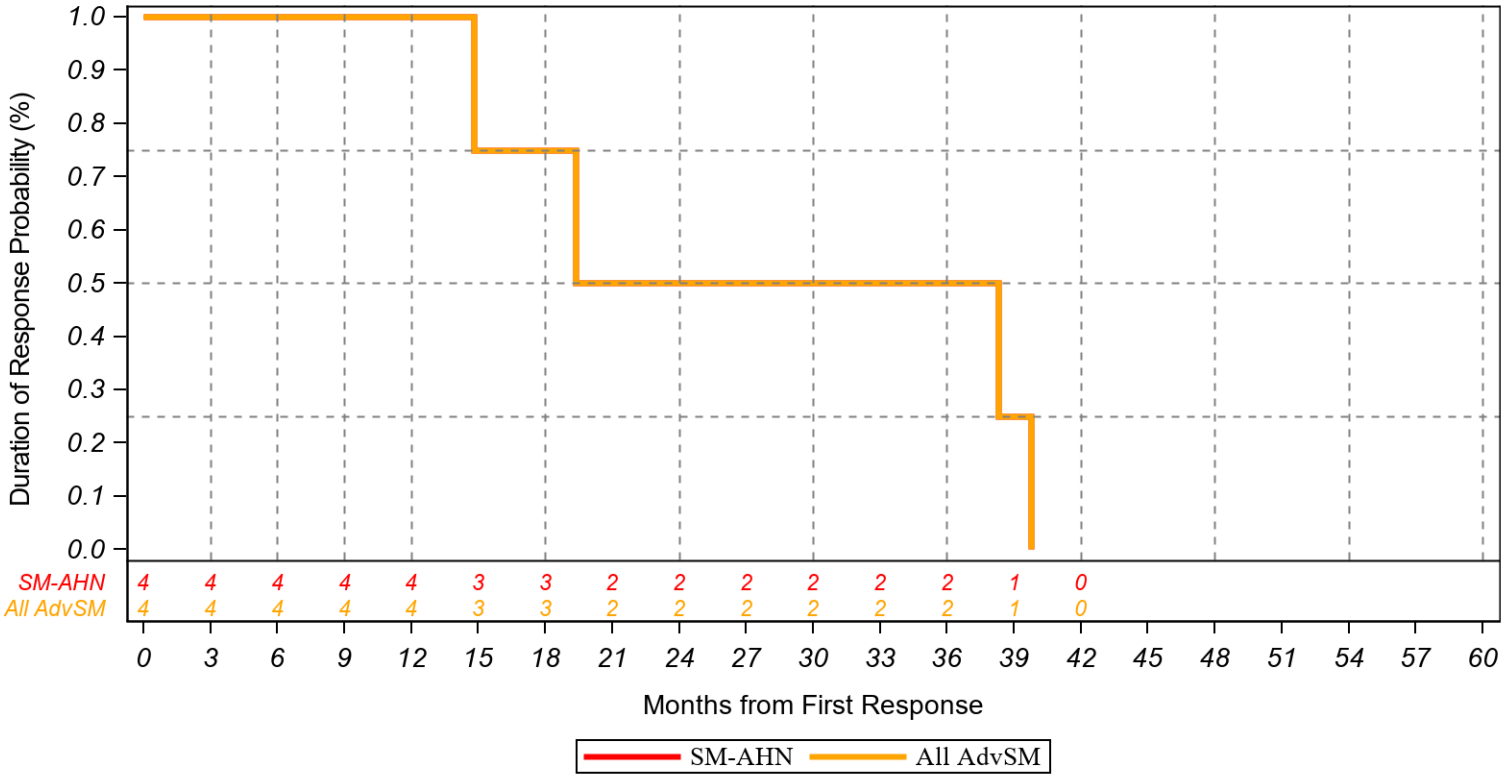

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: < 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR+CI)

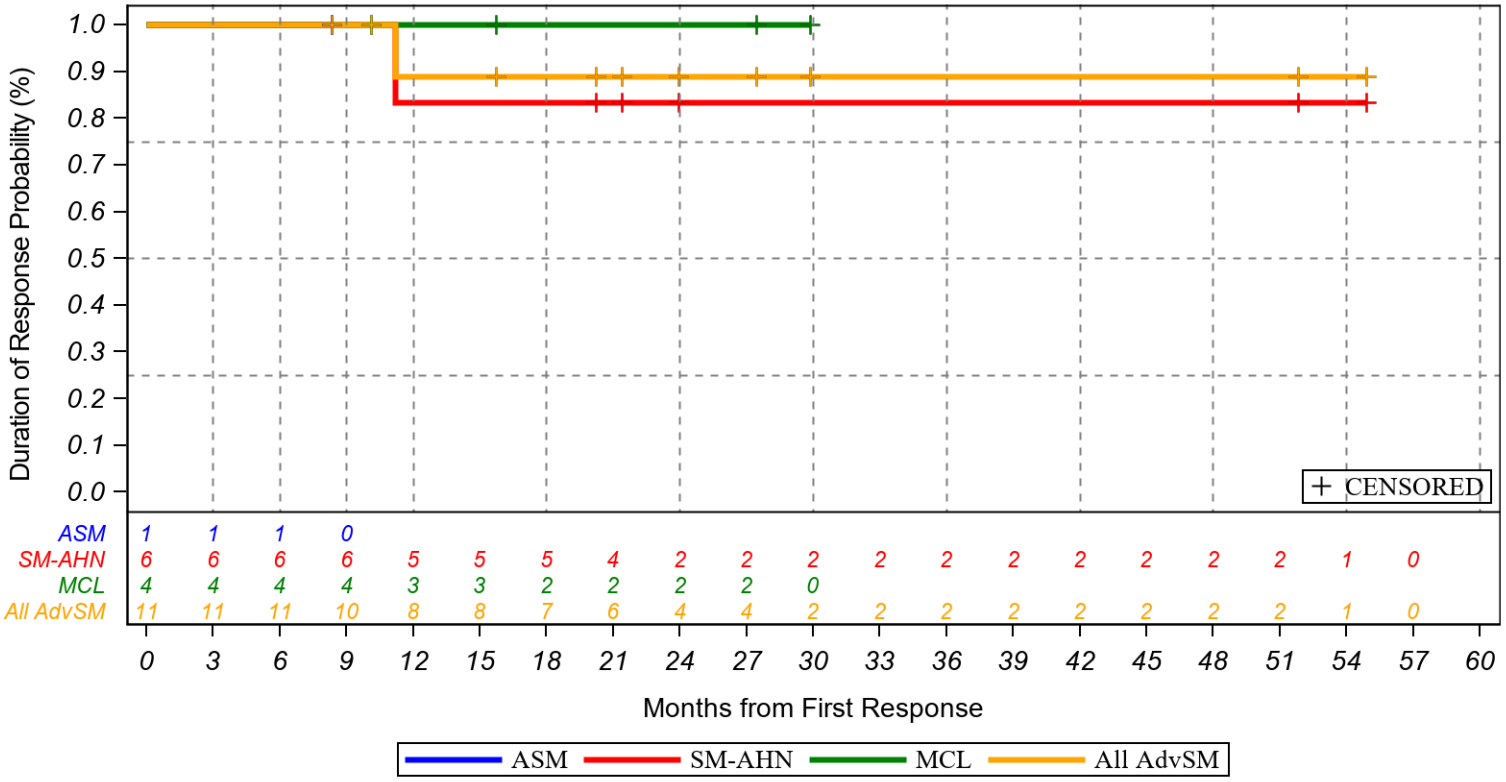

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: < 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR)

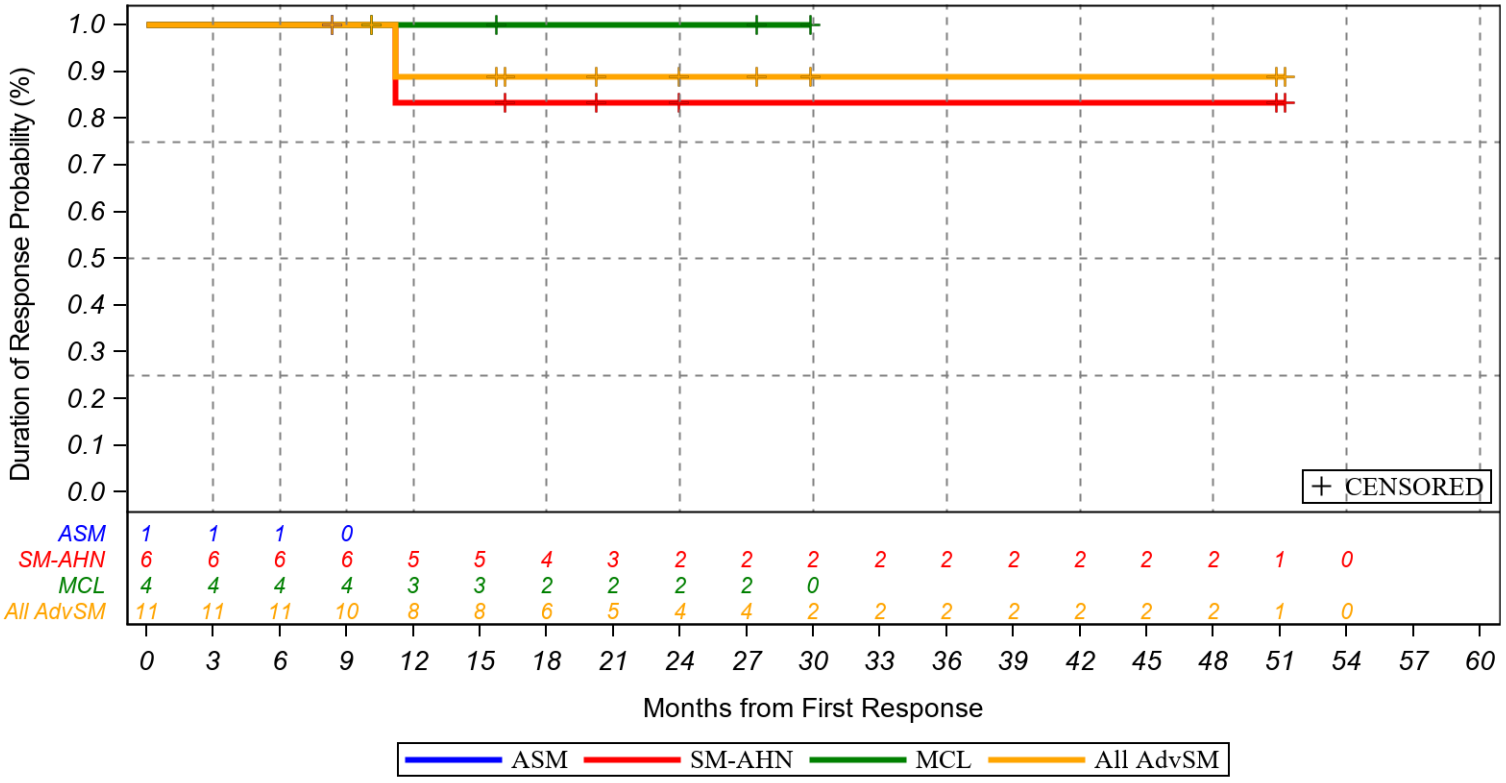

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: < 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR+CI)

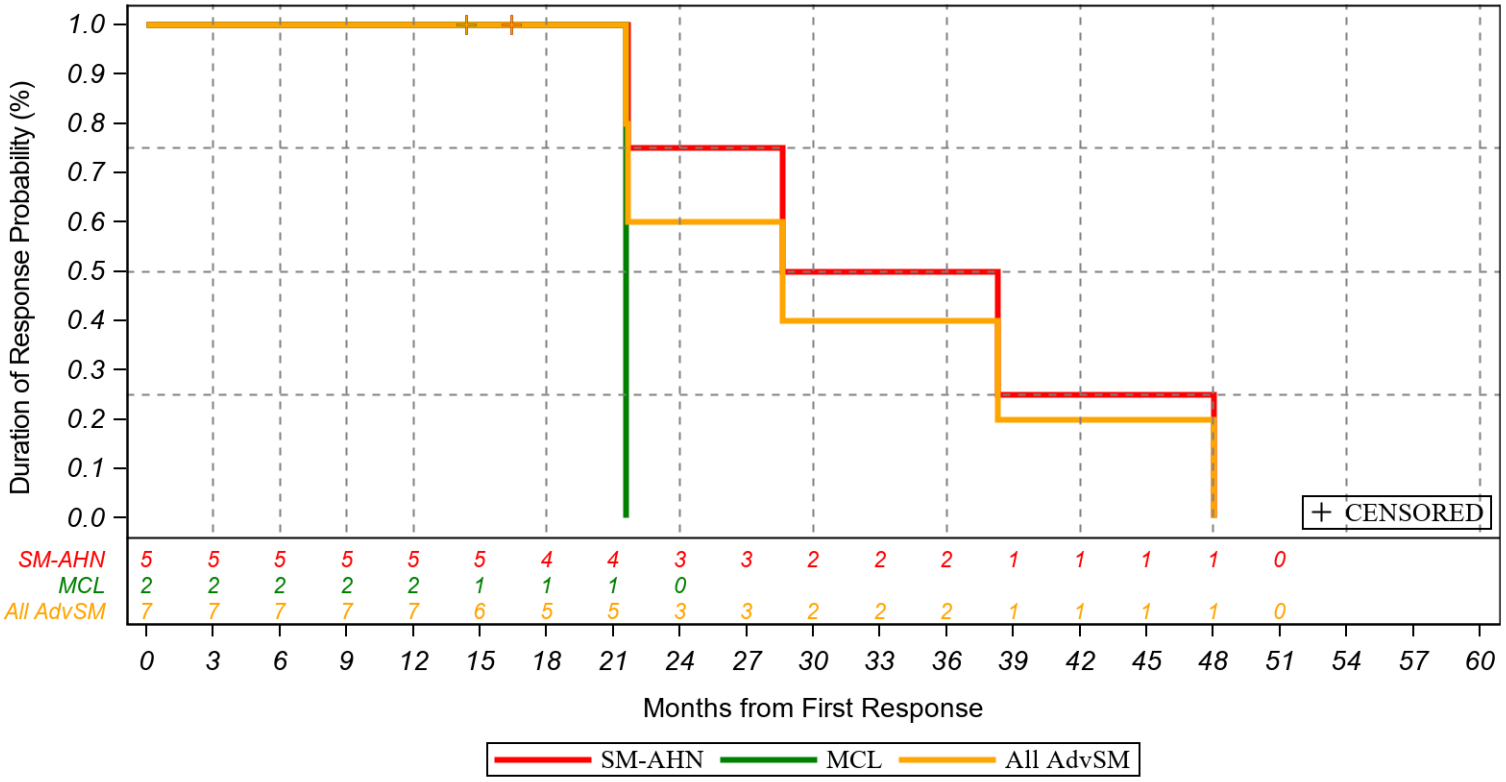

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: < 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR)

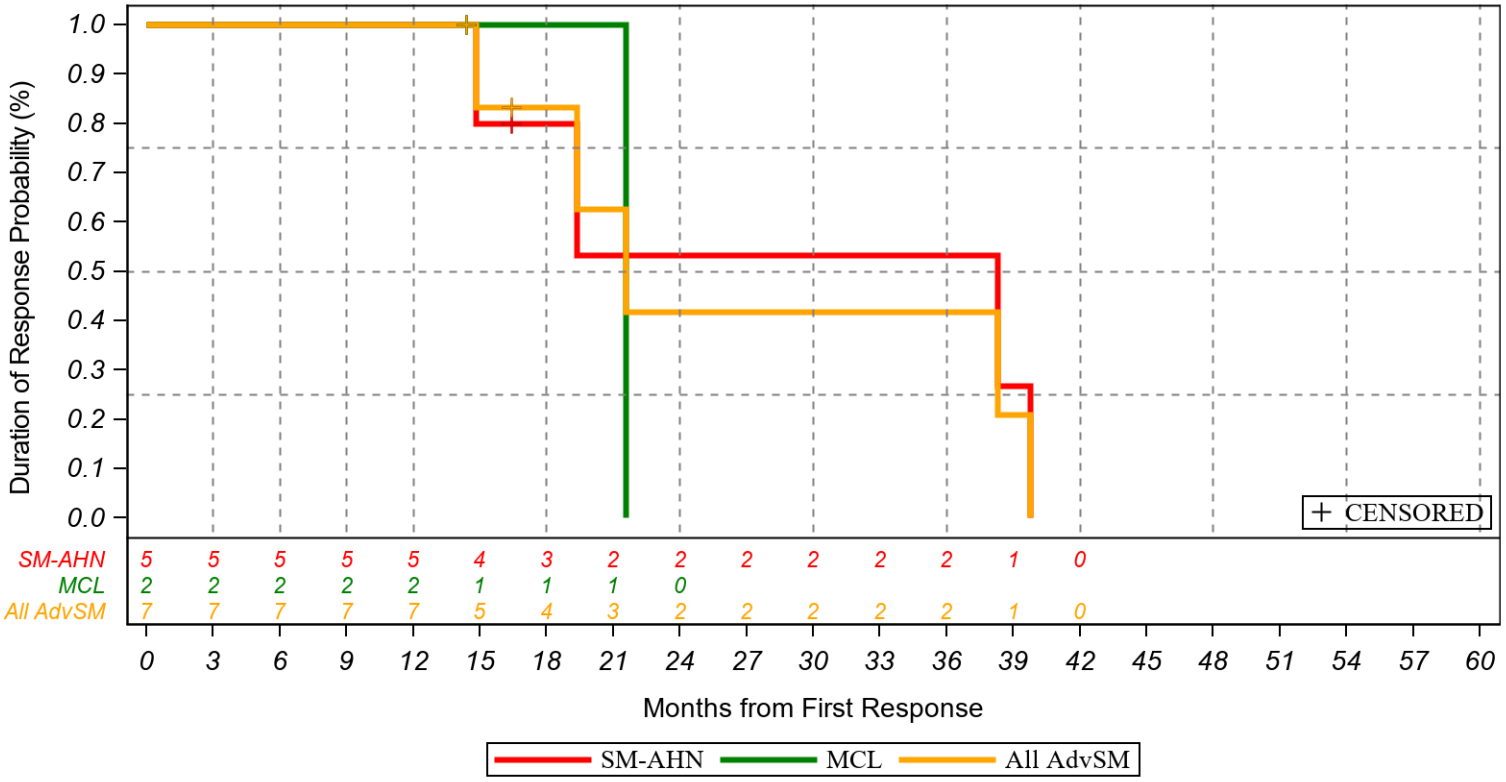

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: 200 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR+CI)

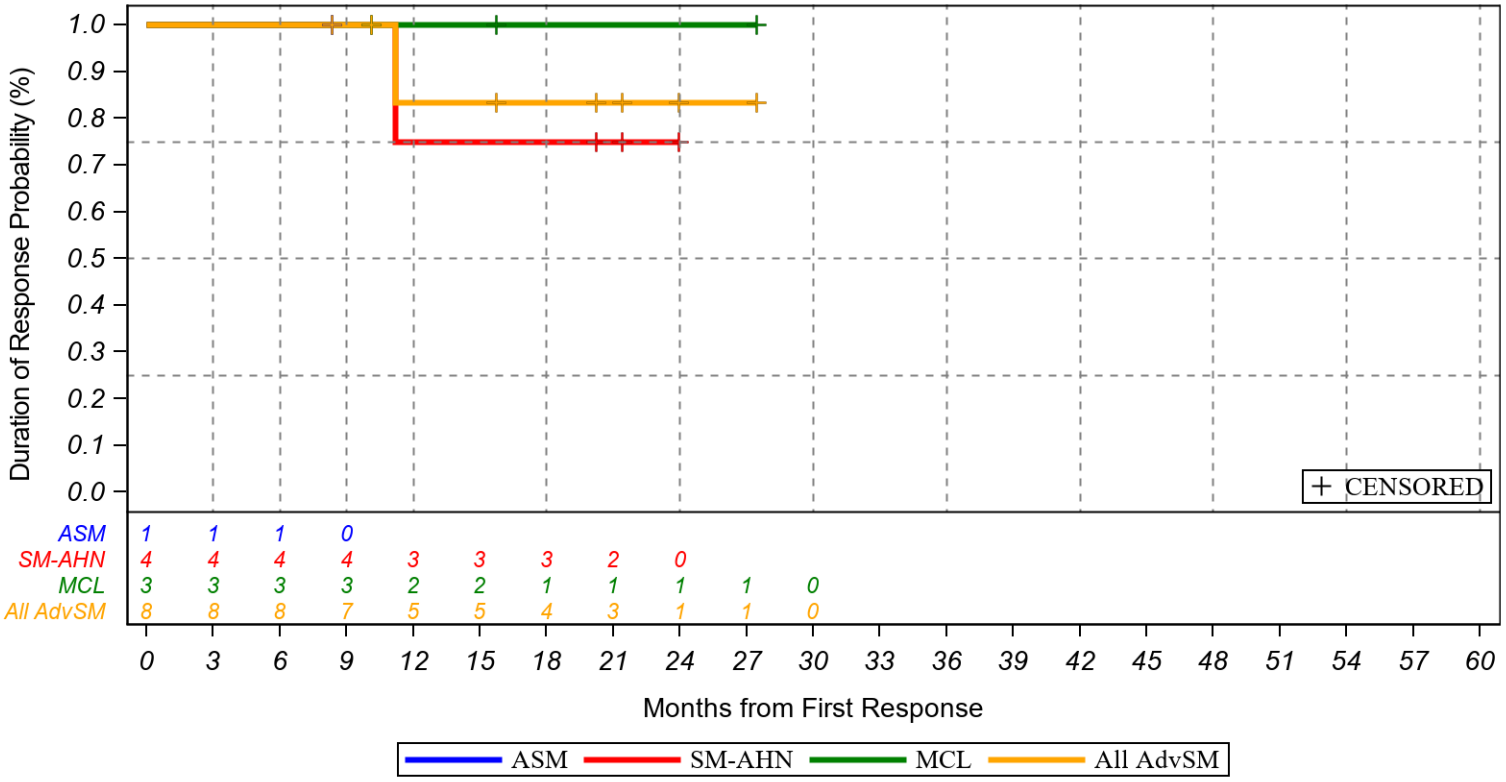

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: 200 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR)

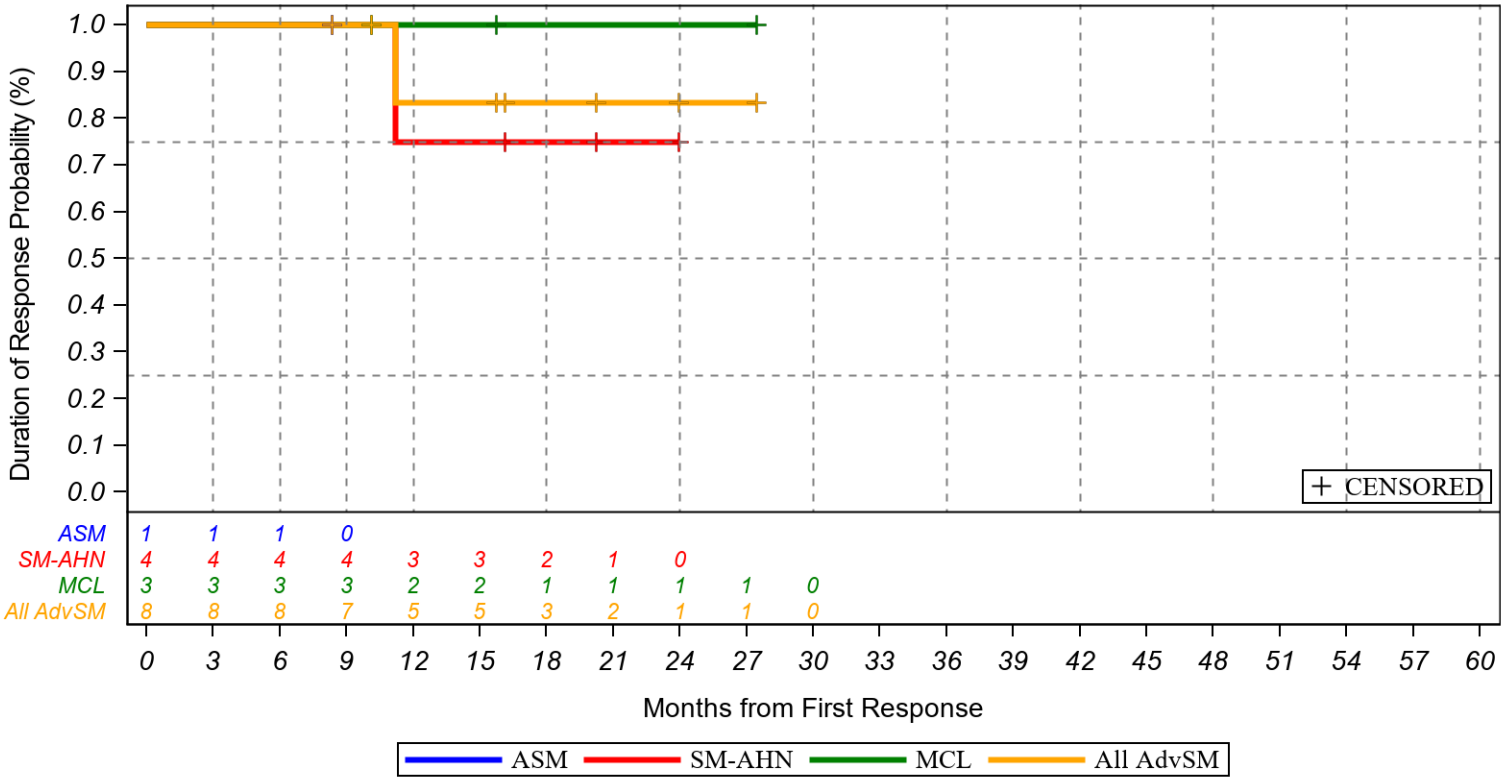

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: 200 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR+CI)

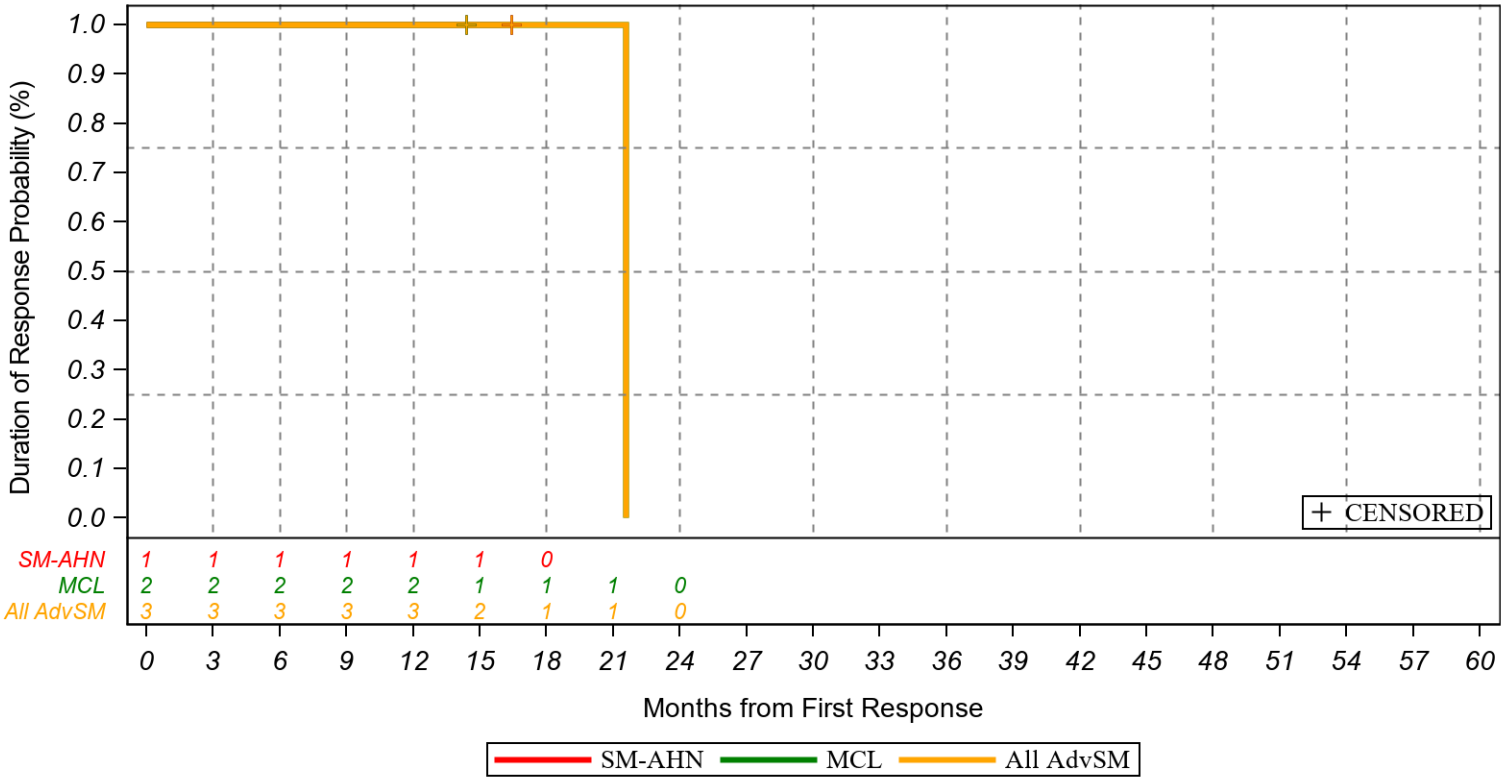

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: 200 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR)

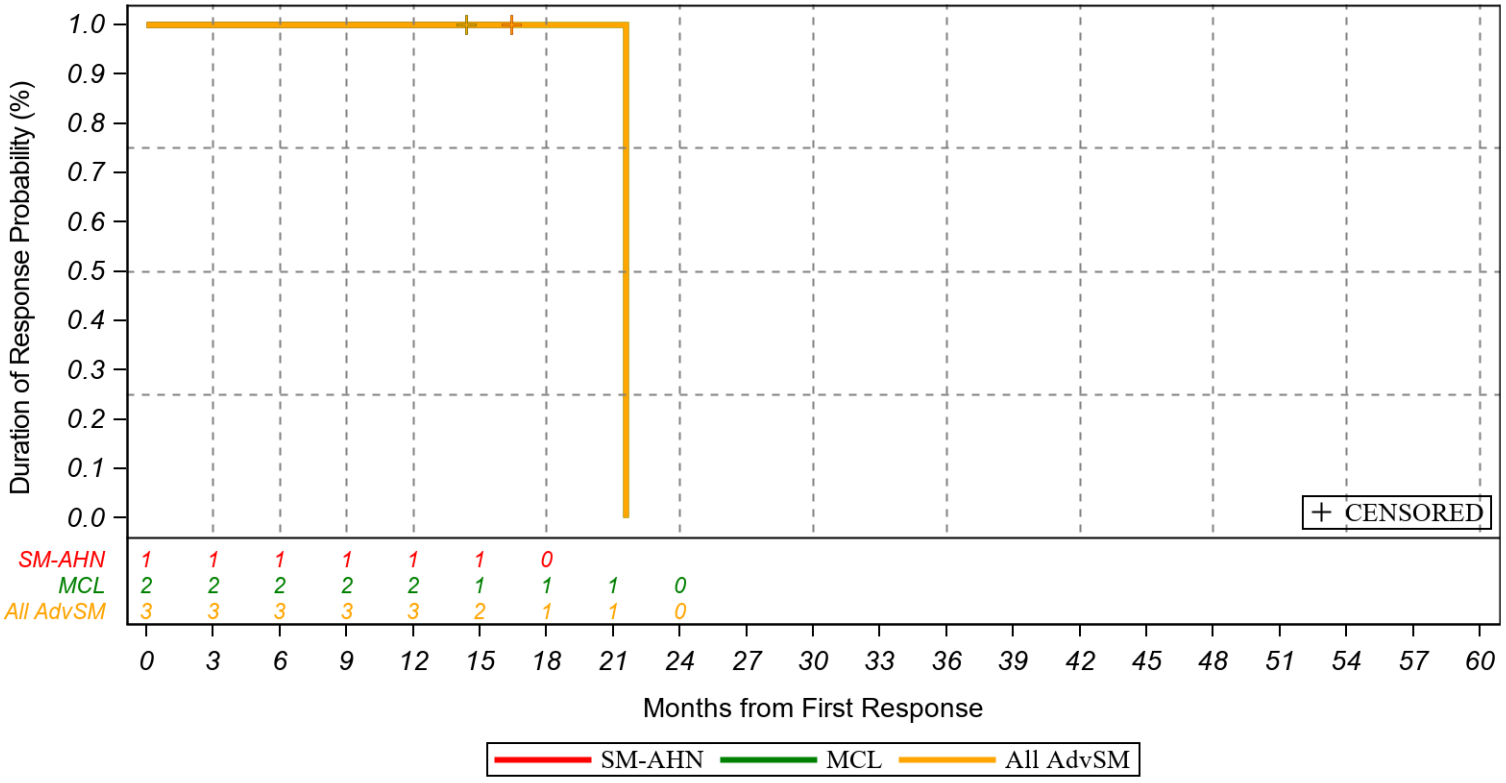

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR+CI)

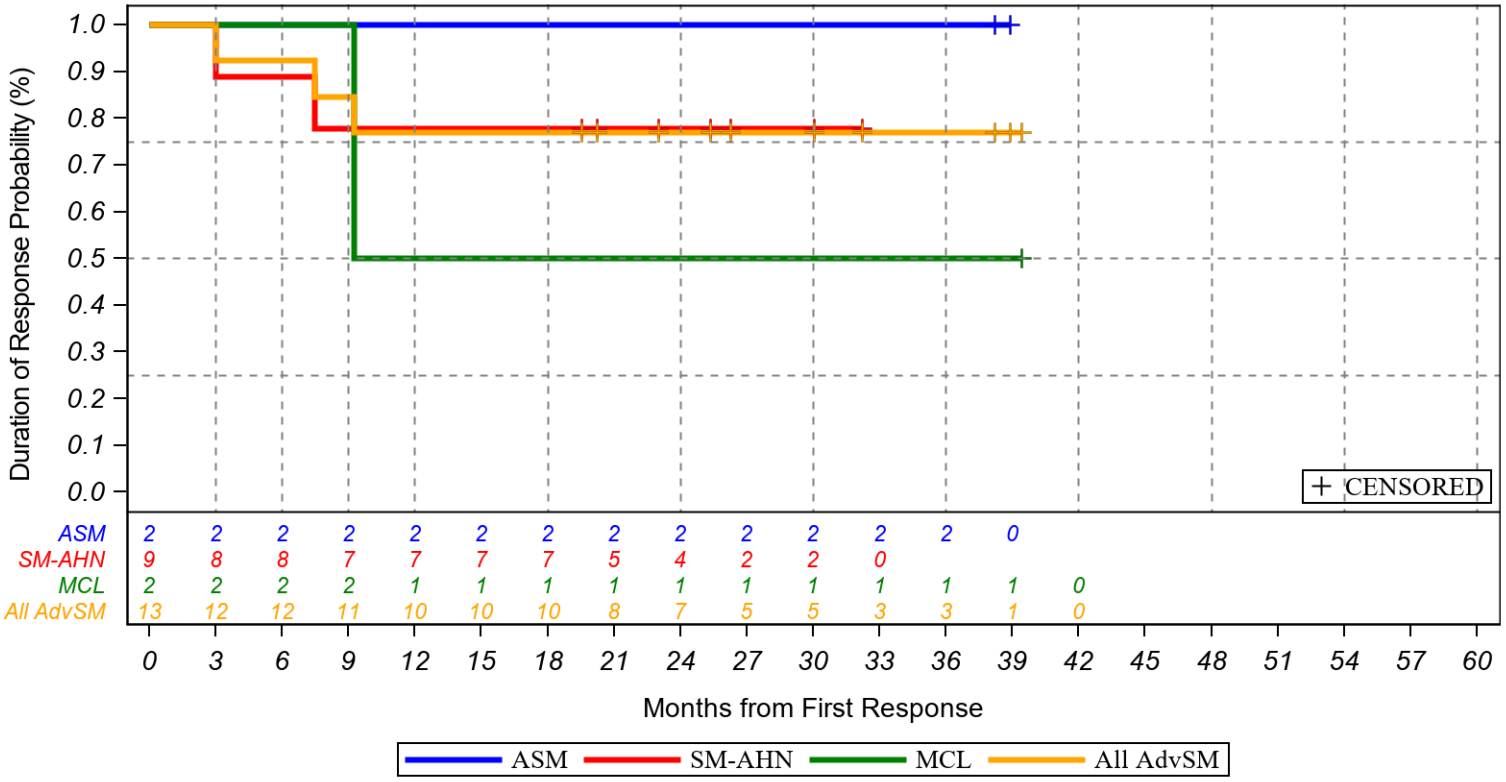

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR)

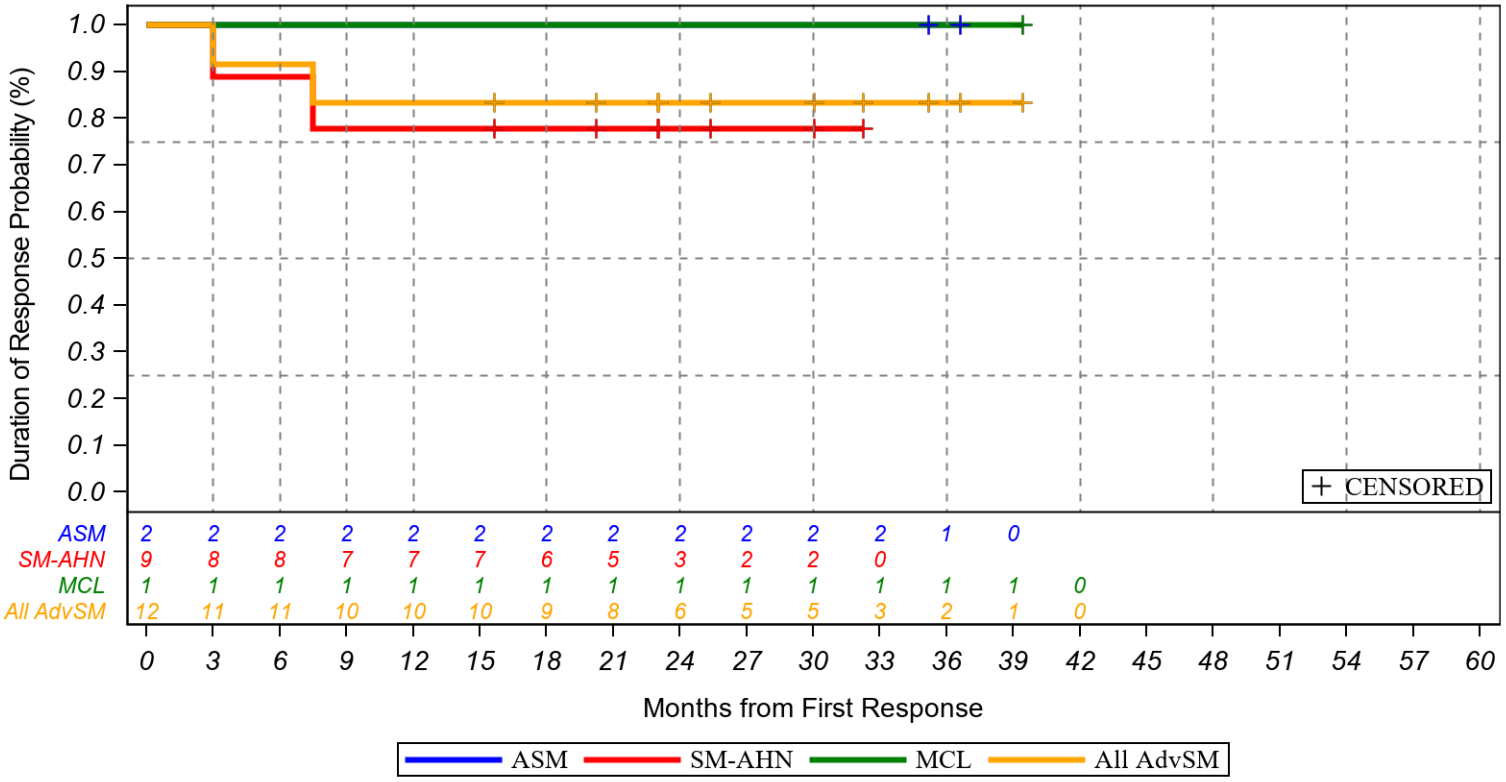

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR+CI)

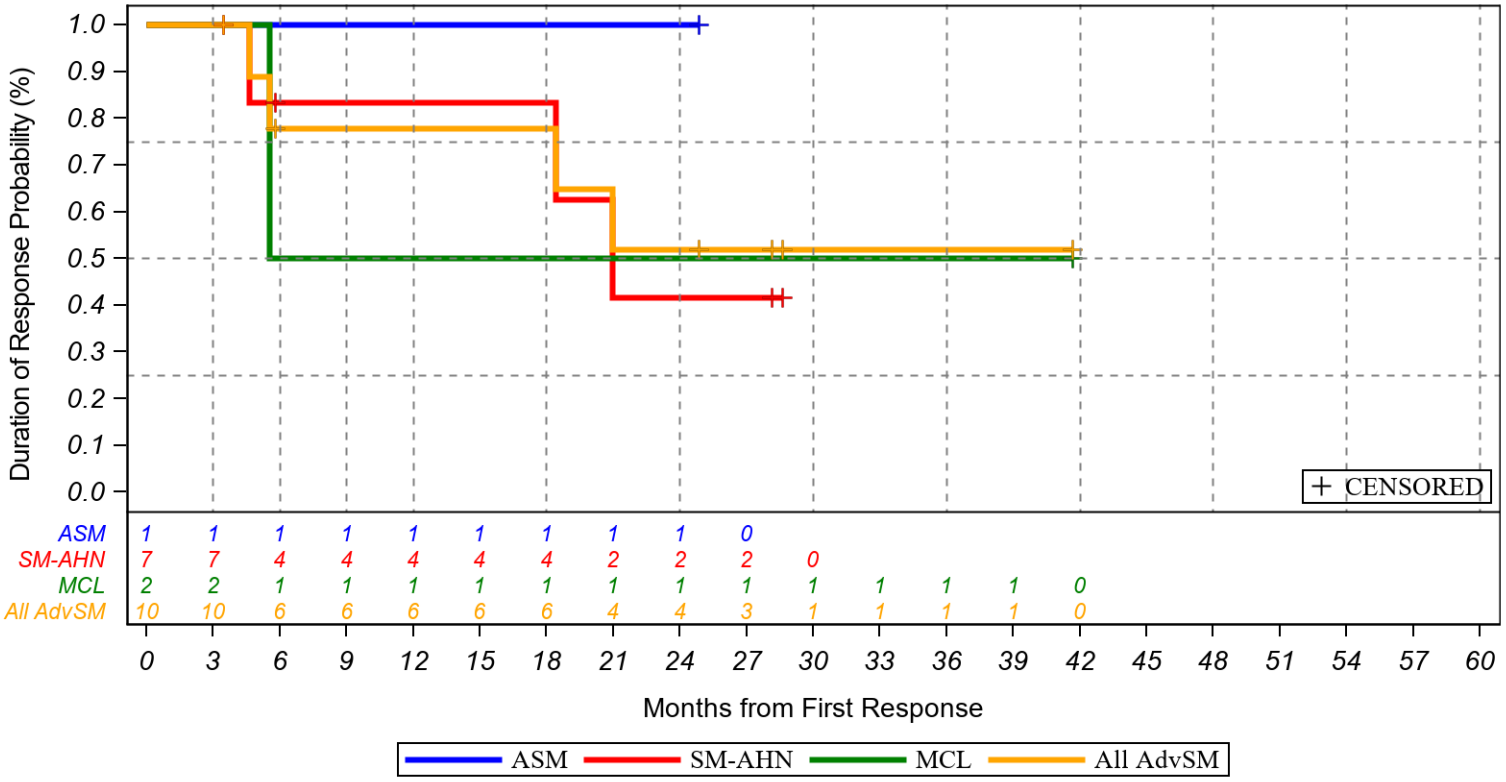

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR)

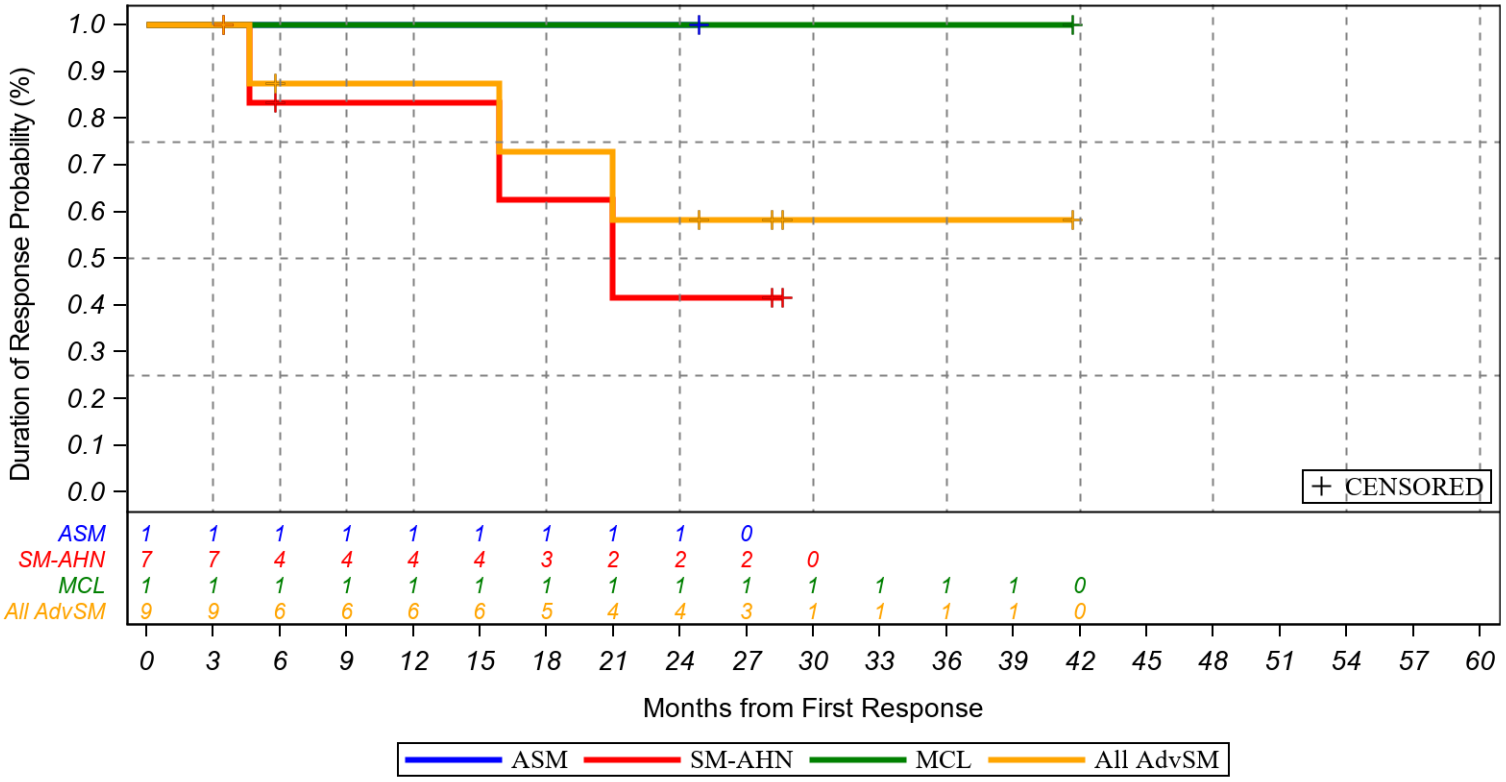

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: 200 mg and 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR+CI)

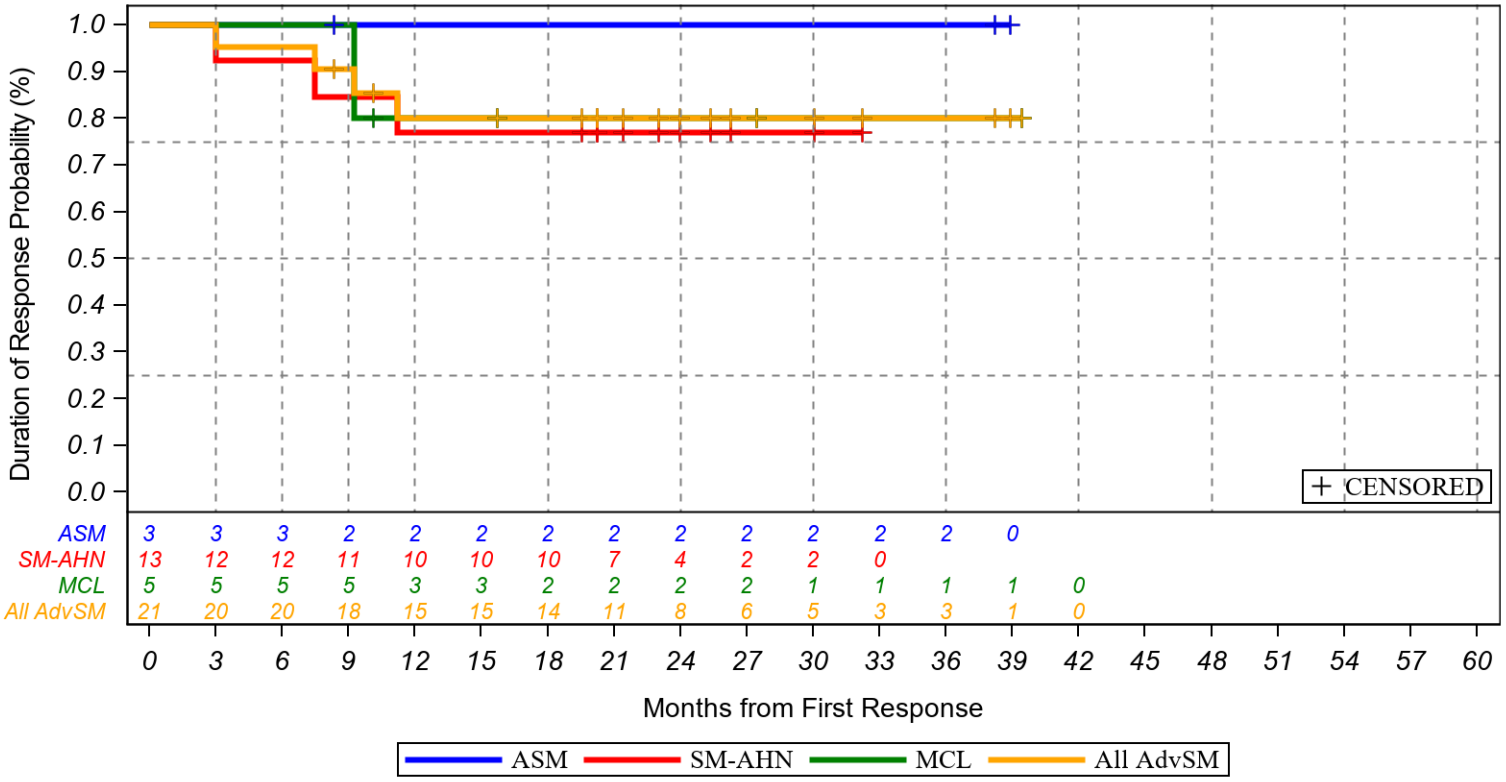

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: 200 mg and 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR)

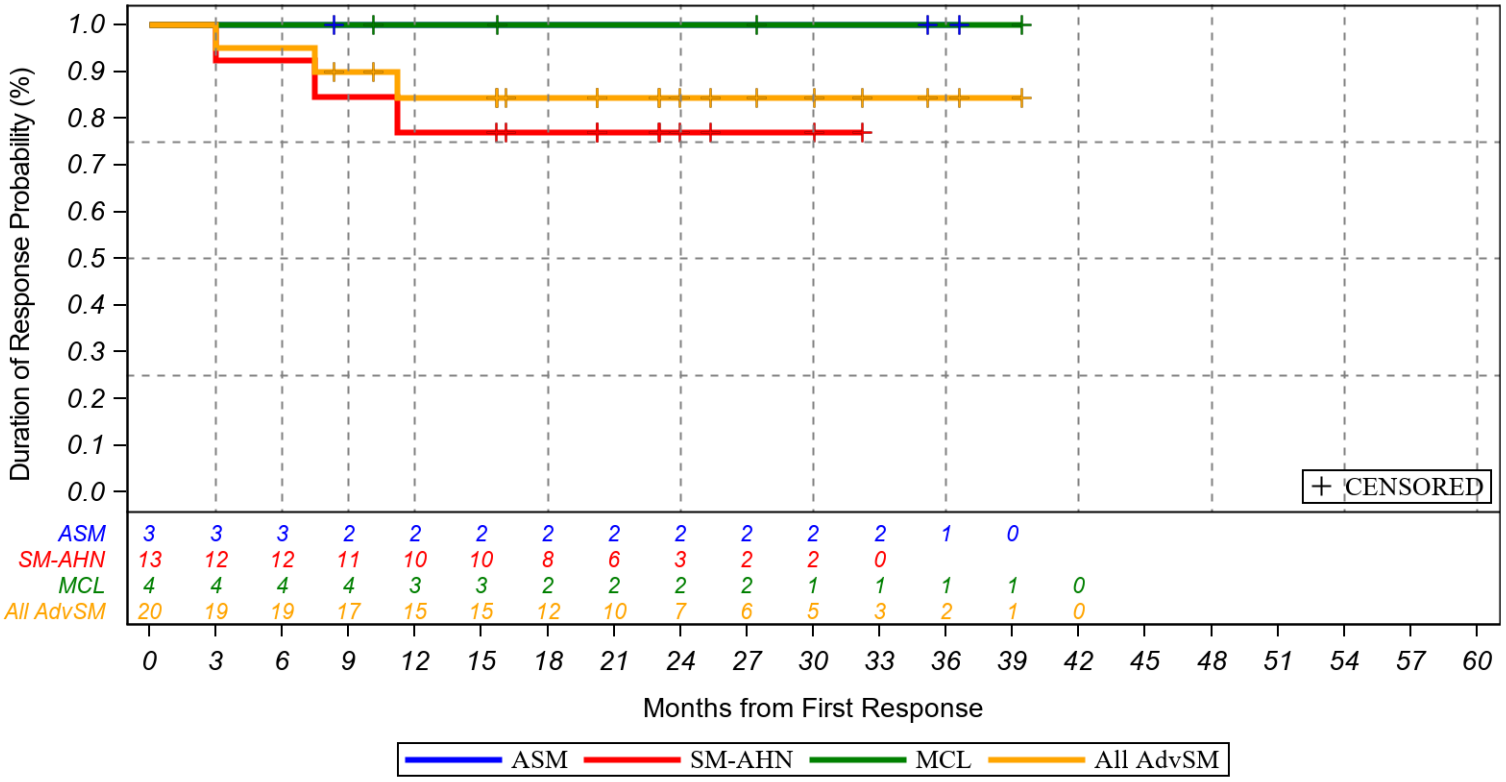

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: 200 mg and 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR+CI)

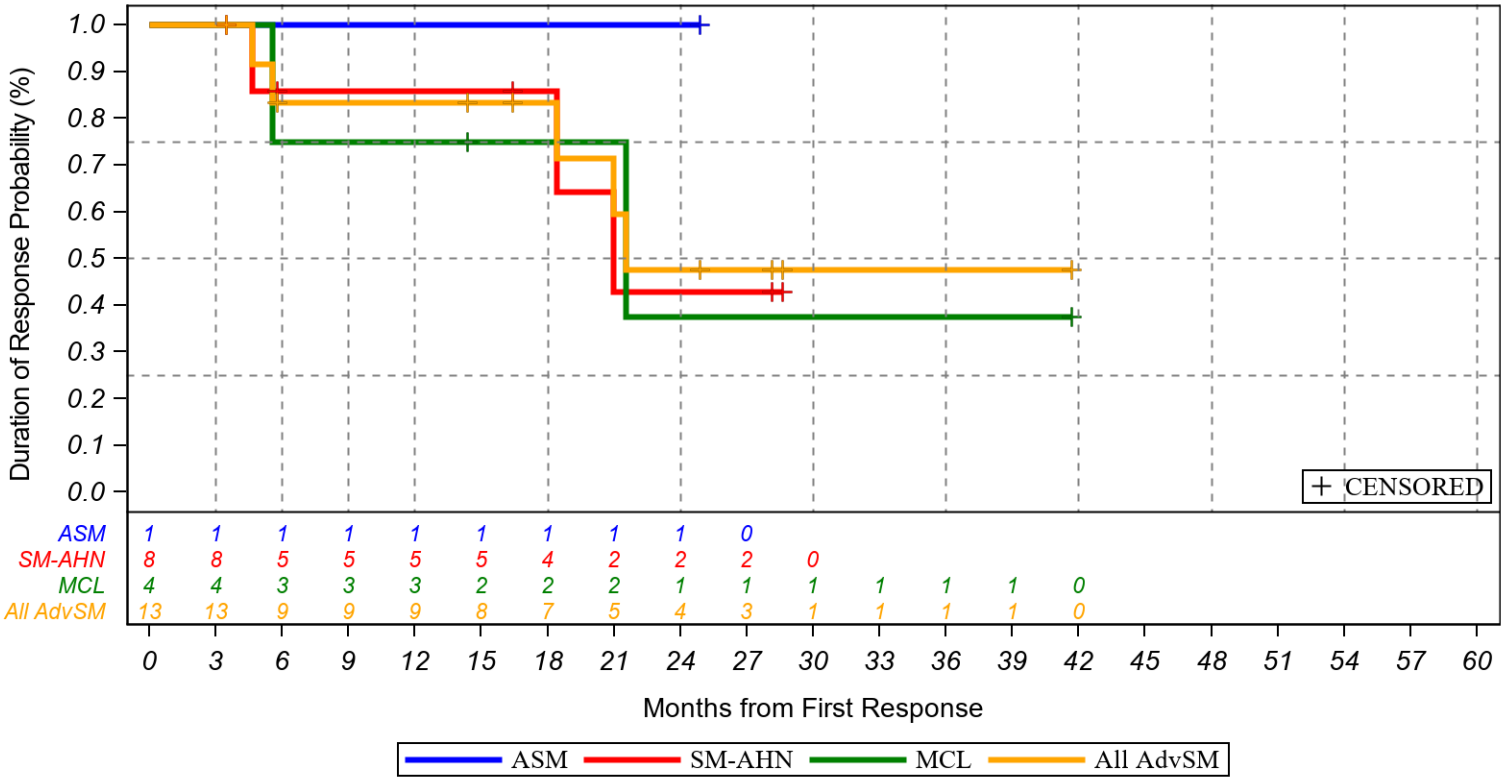

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: 200 mg and 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR)

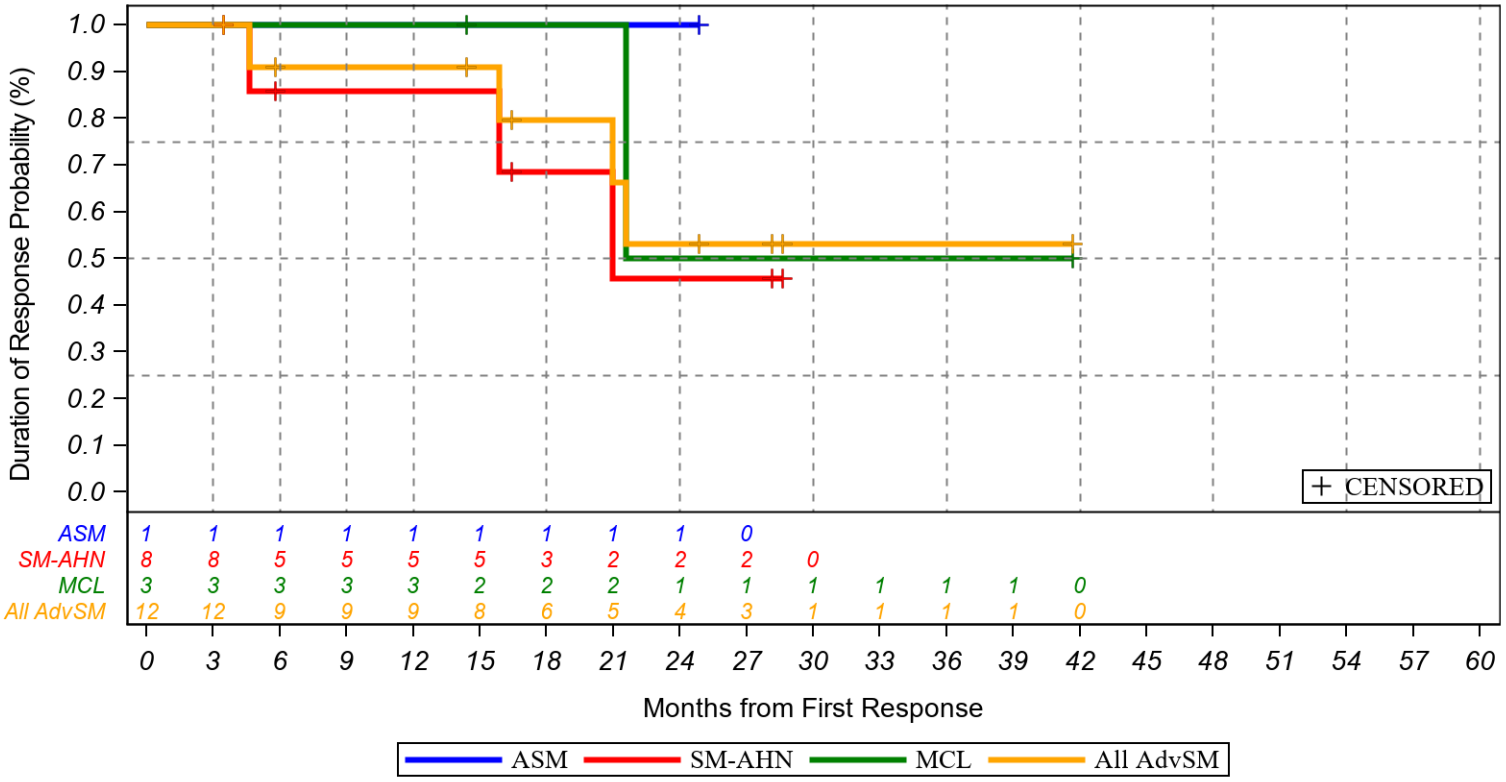

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: 400 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR+CI)

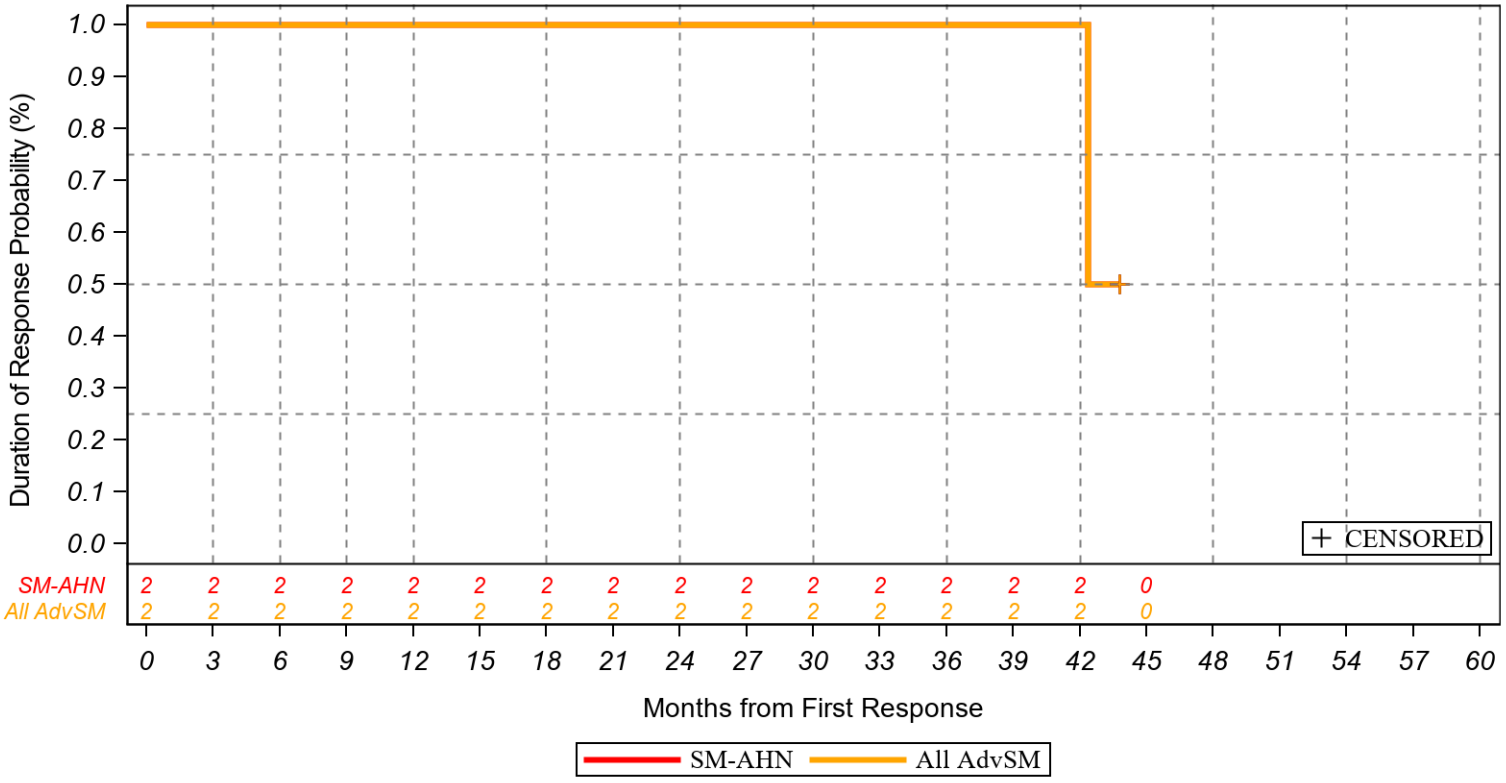

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: 400 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR)

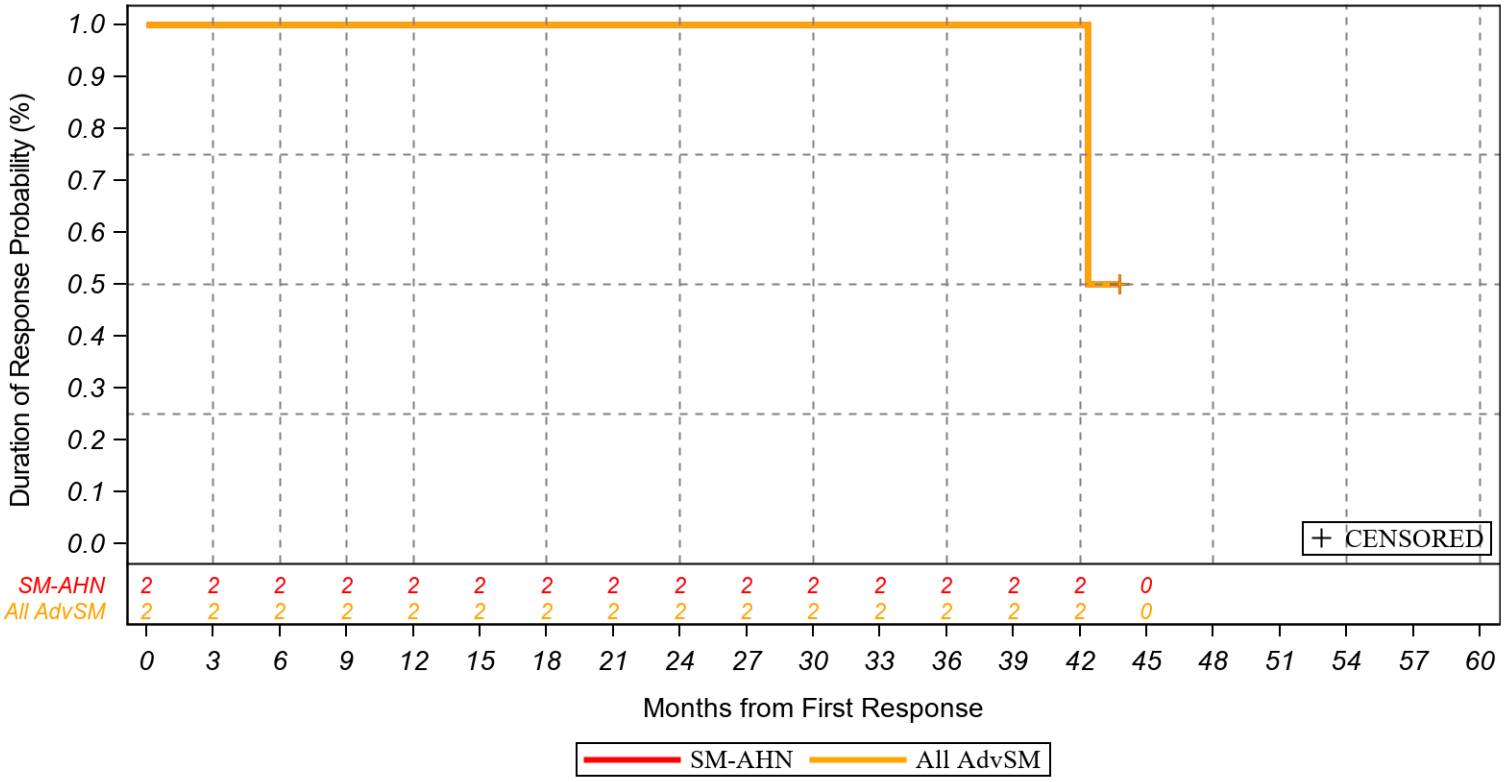

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: 400 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR+CI)

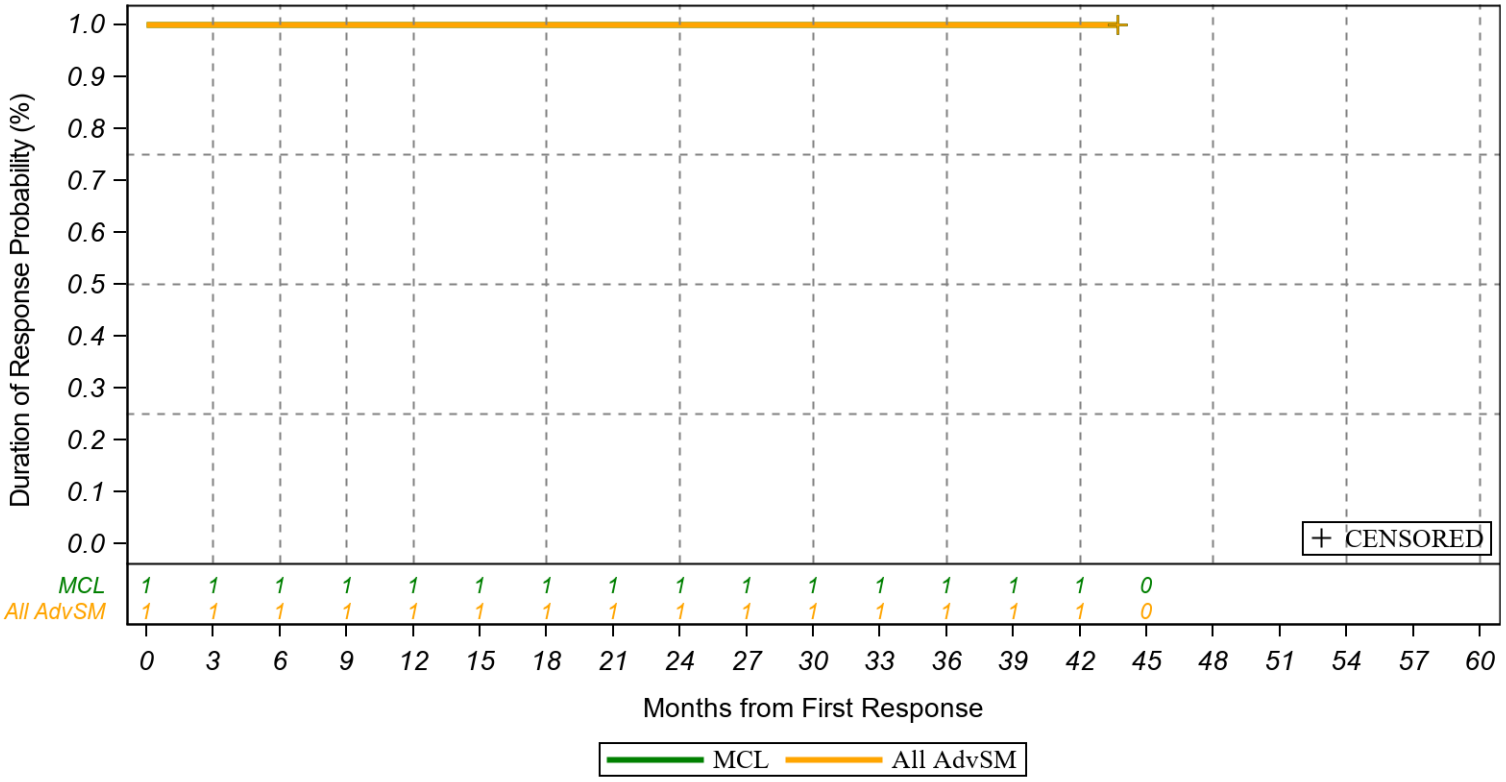

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101
Starting Dose: 400 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR)

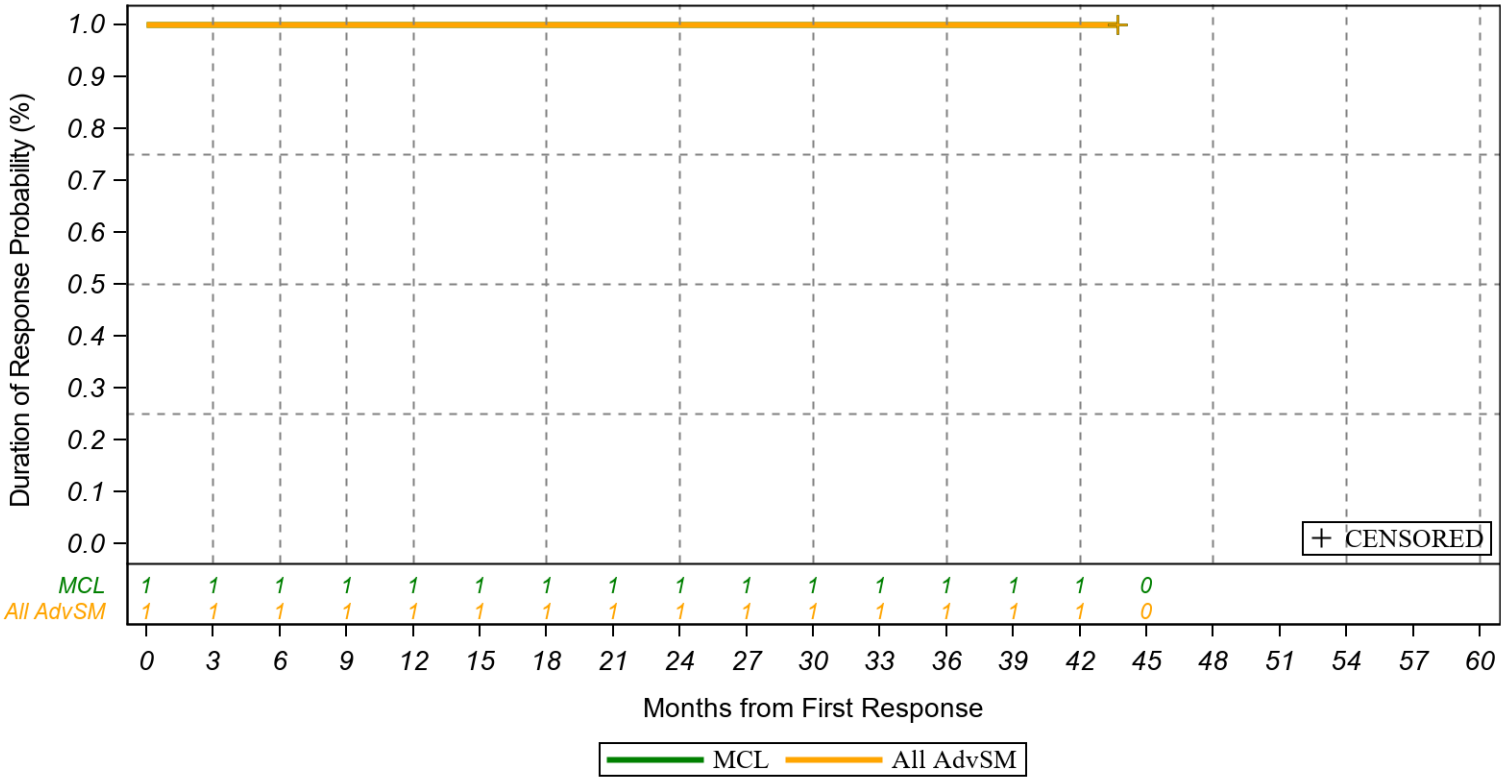

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2202
Starting Dose: Overall
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR+CI)

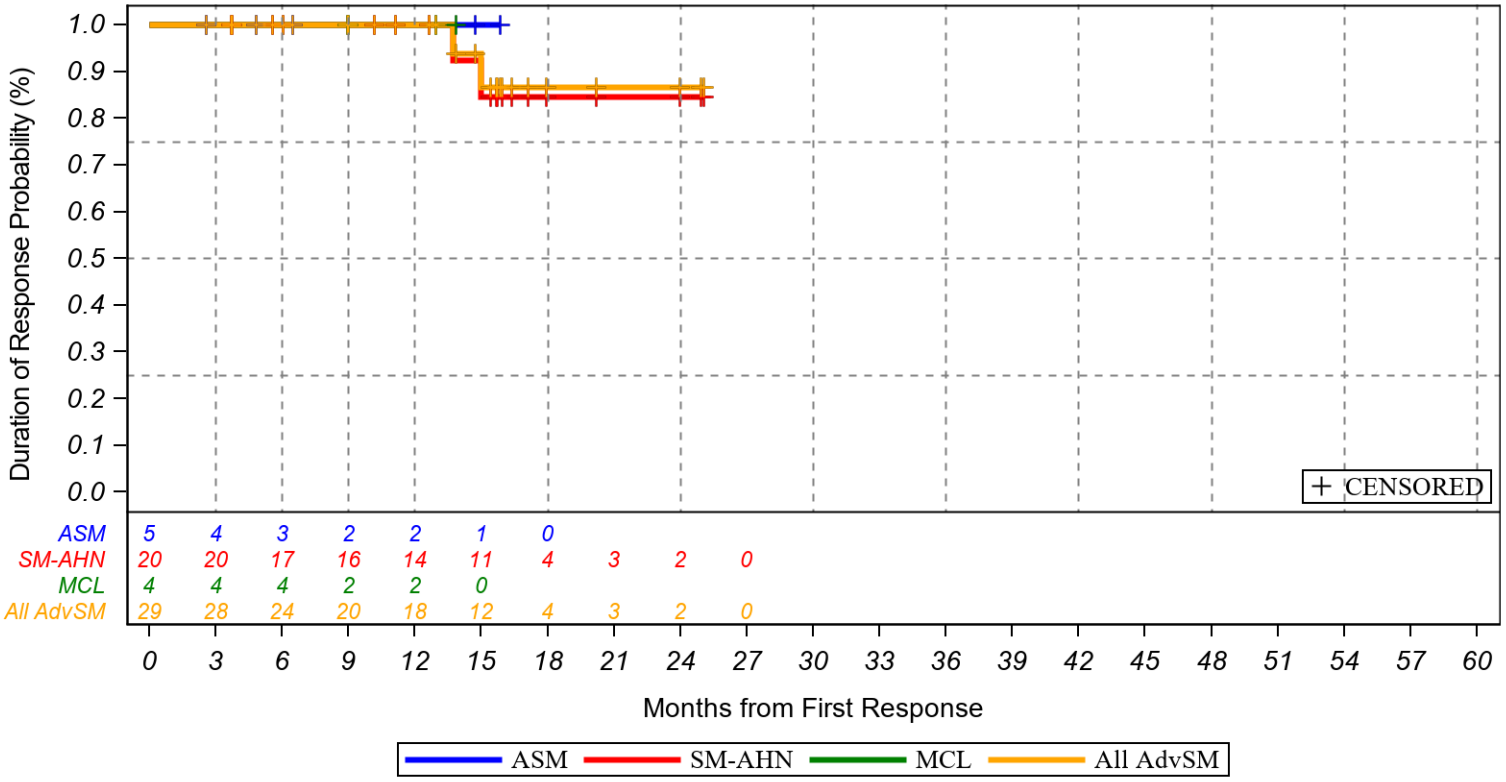

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2202
Starting Dose: Overall
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR)

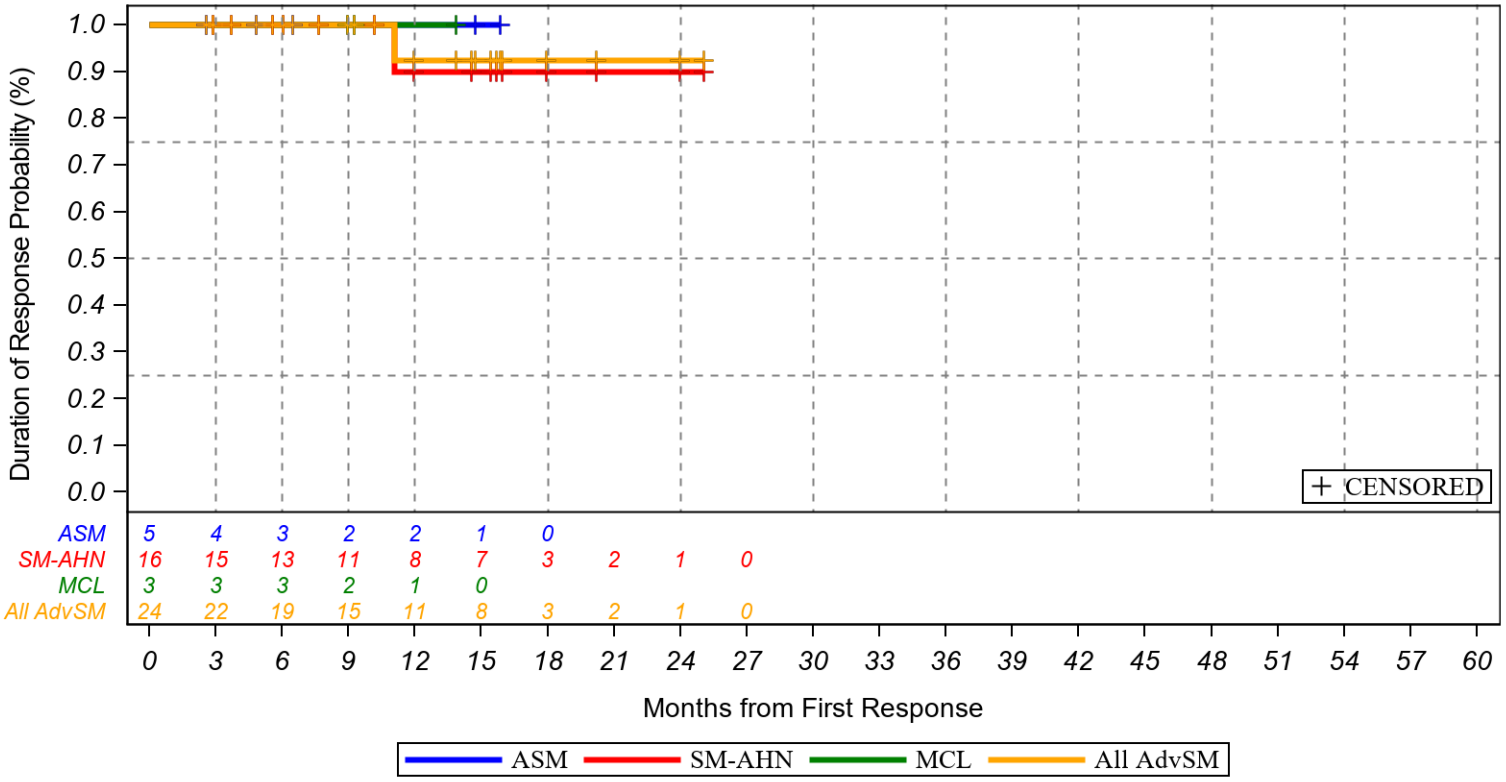

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2202
Starting Dose: Overall
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR+CI)

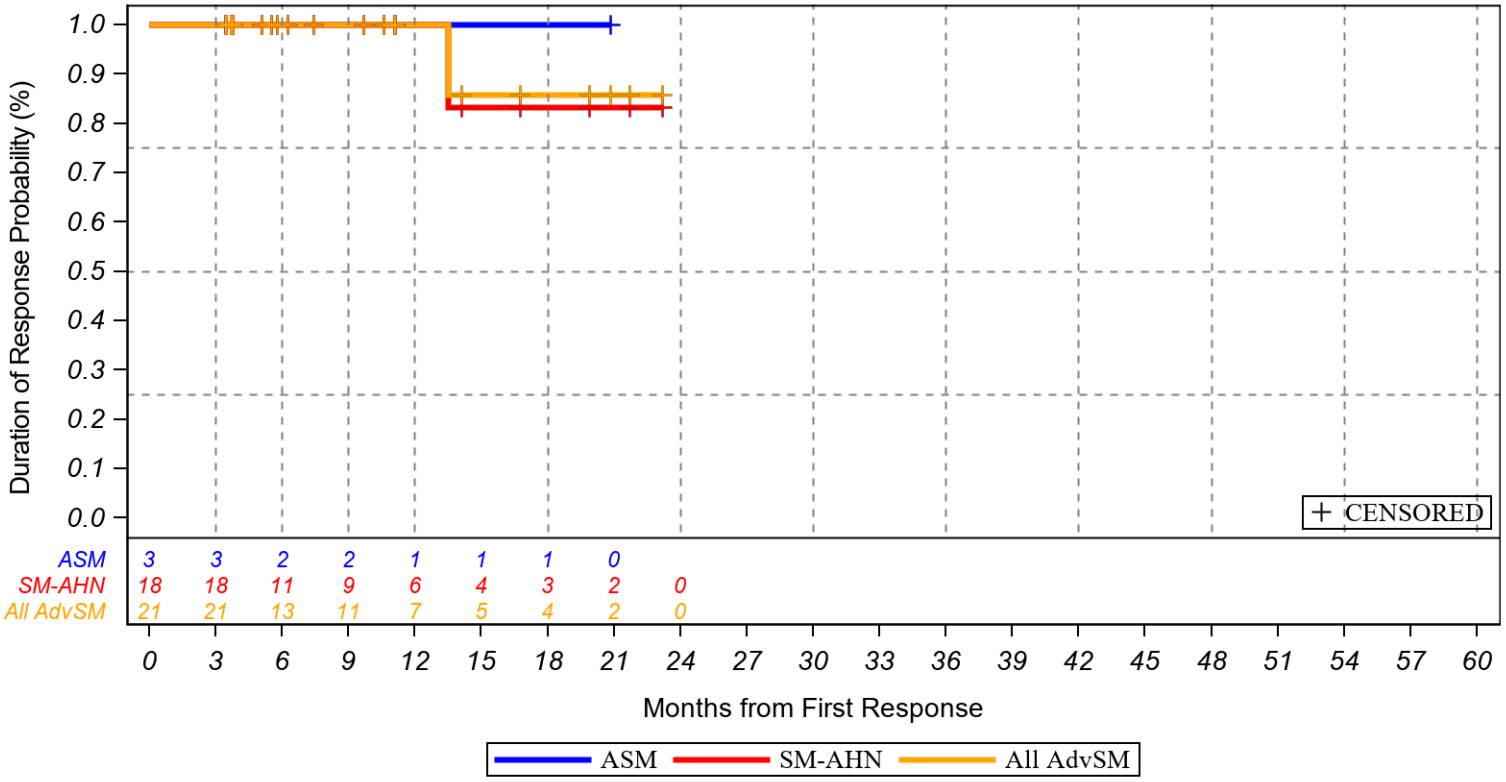

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2202
Starting Dose: Overall
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR)

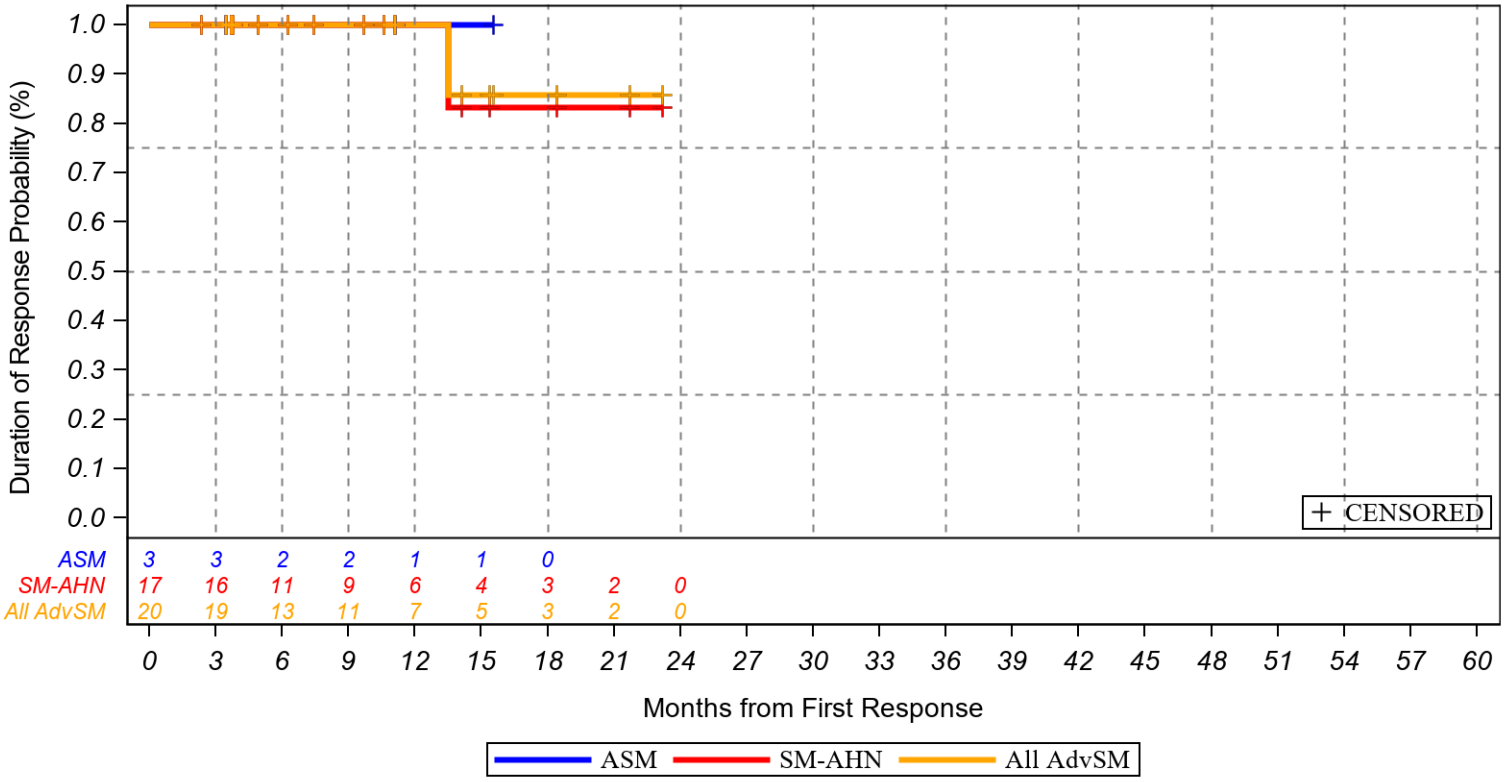

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2202
Starting Dose: 200 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR+CI)

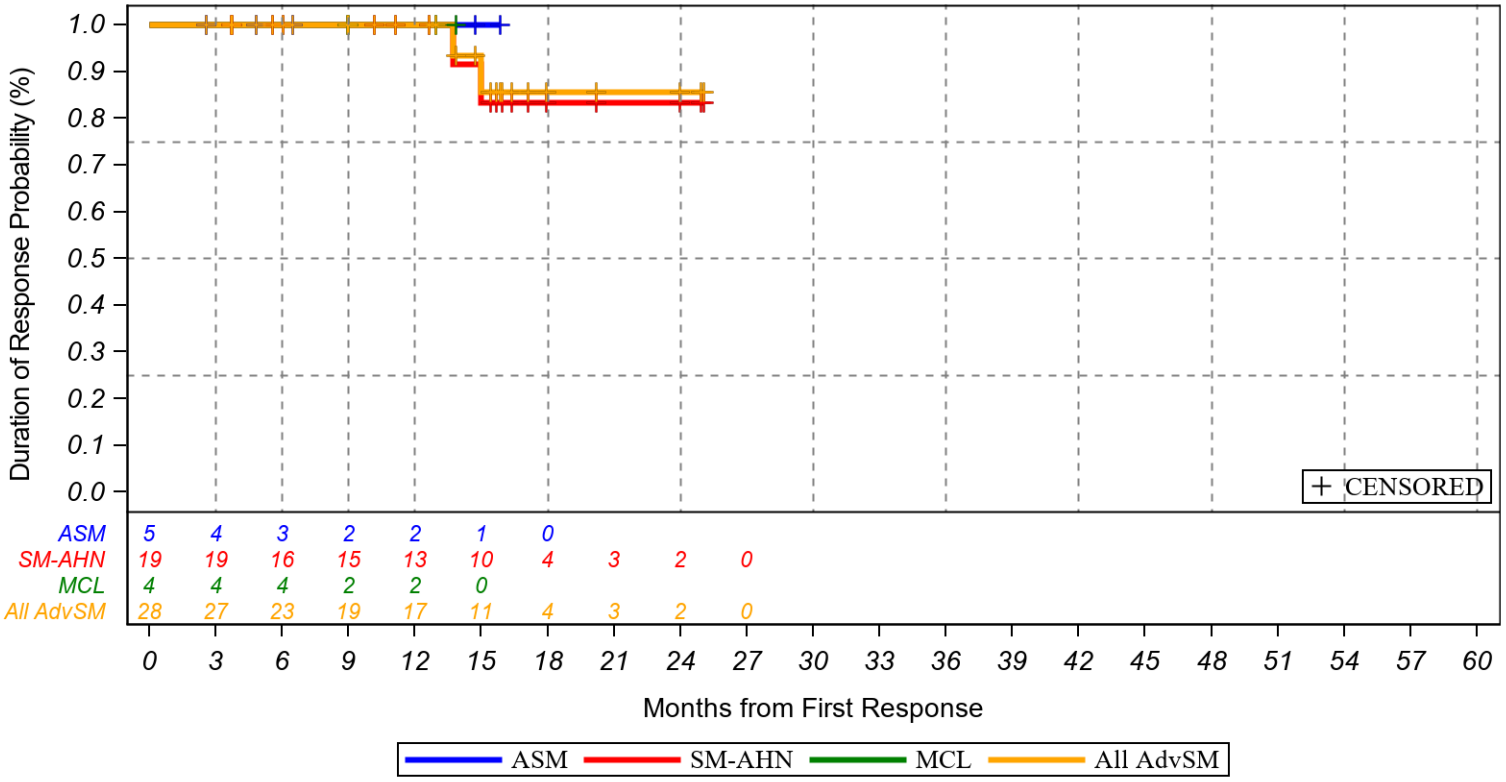

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2202
Starting Dose: 200 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR)

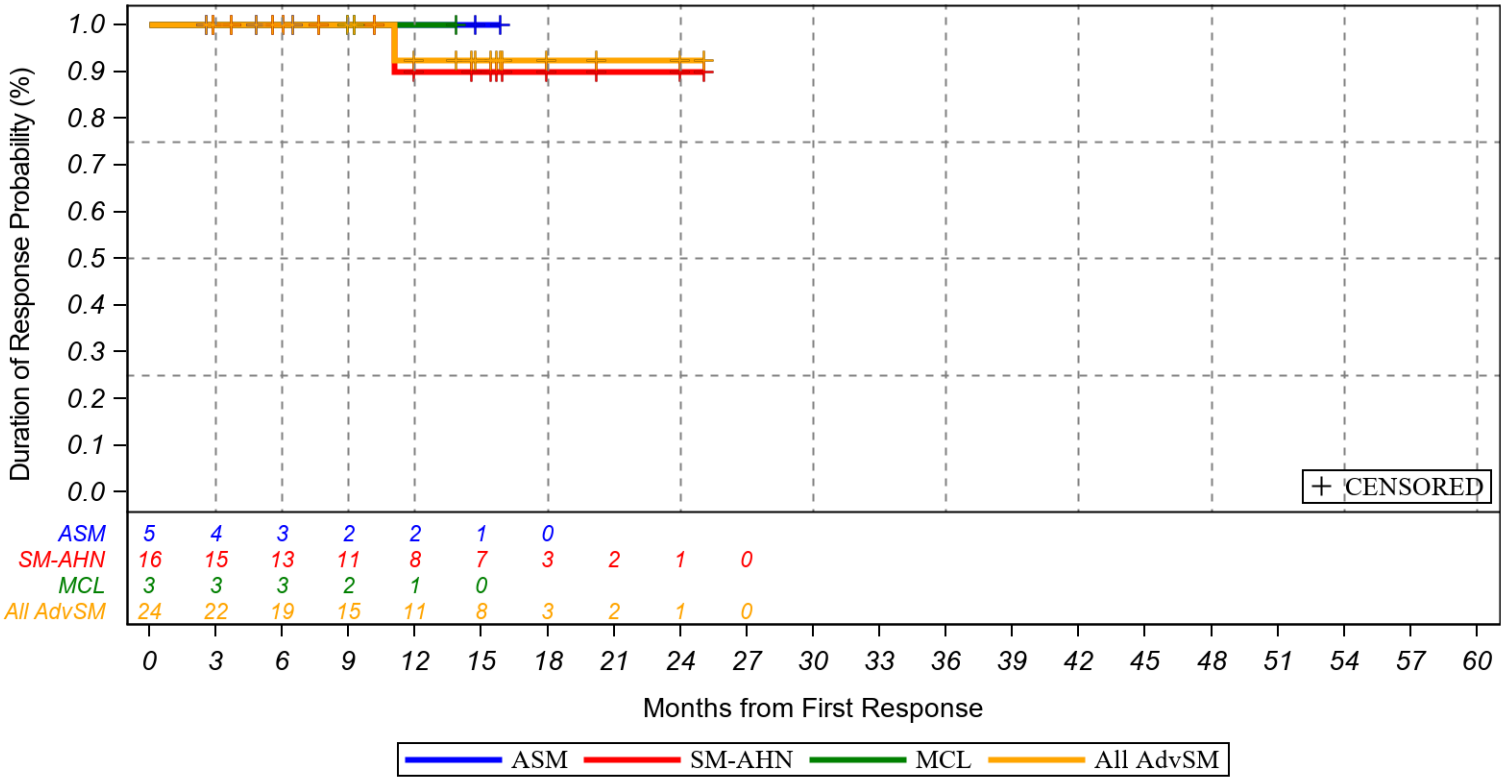

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2202
Starting Dose: 200 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR+CI)

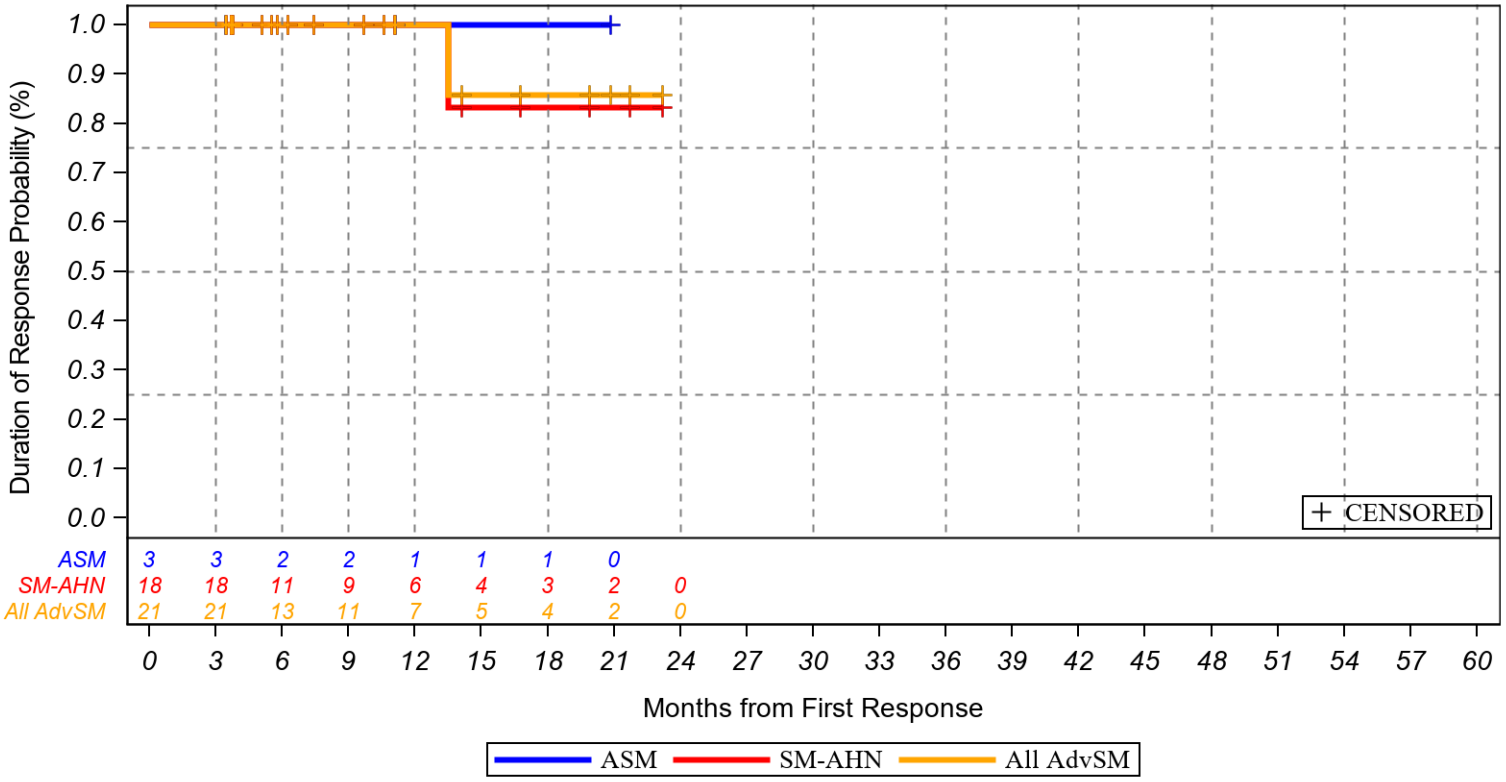

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2202
Starting Dose: 200 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR)

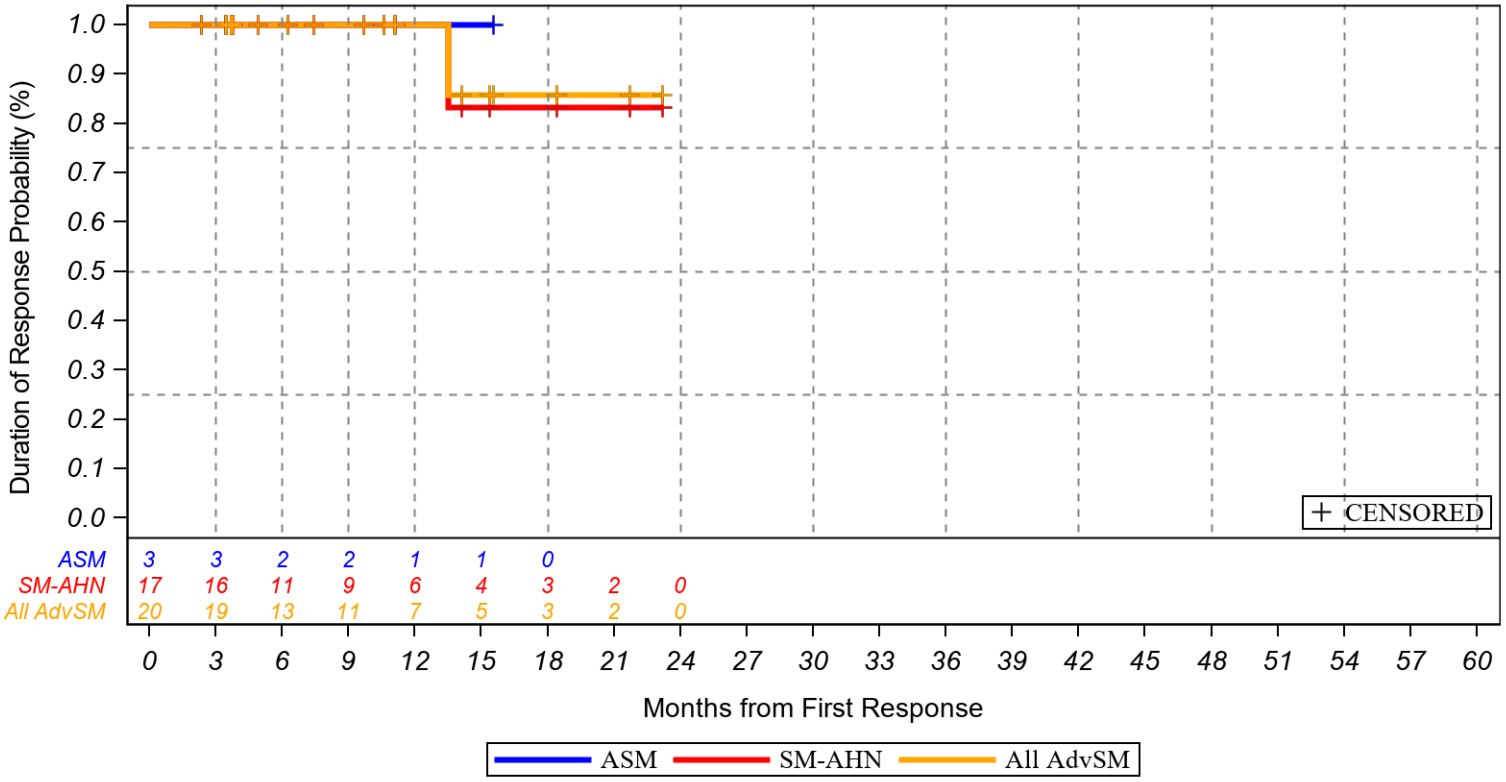

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR+CI)

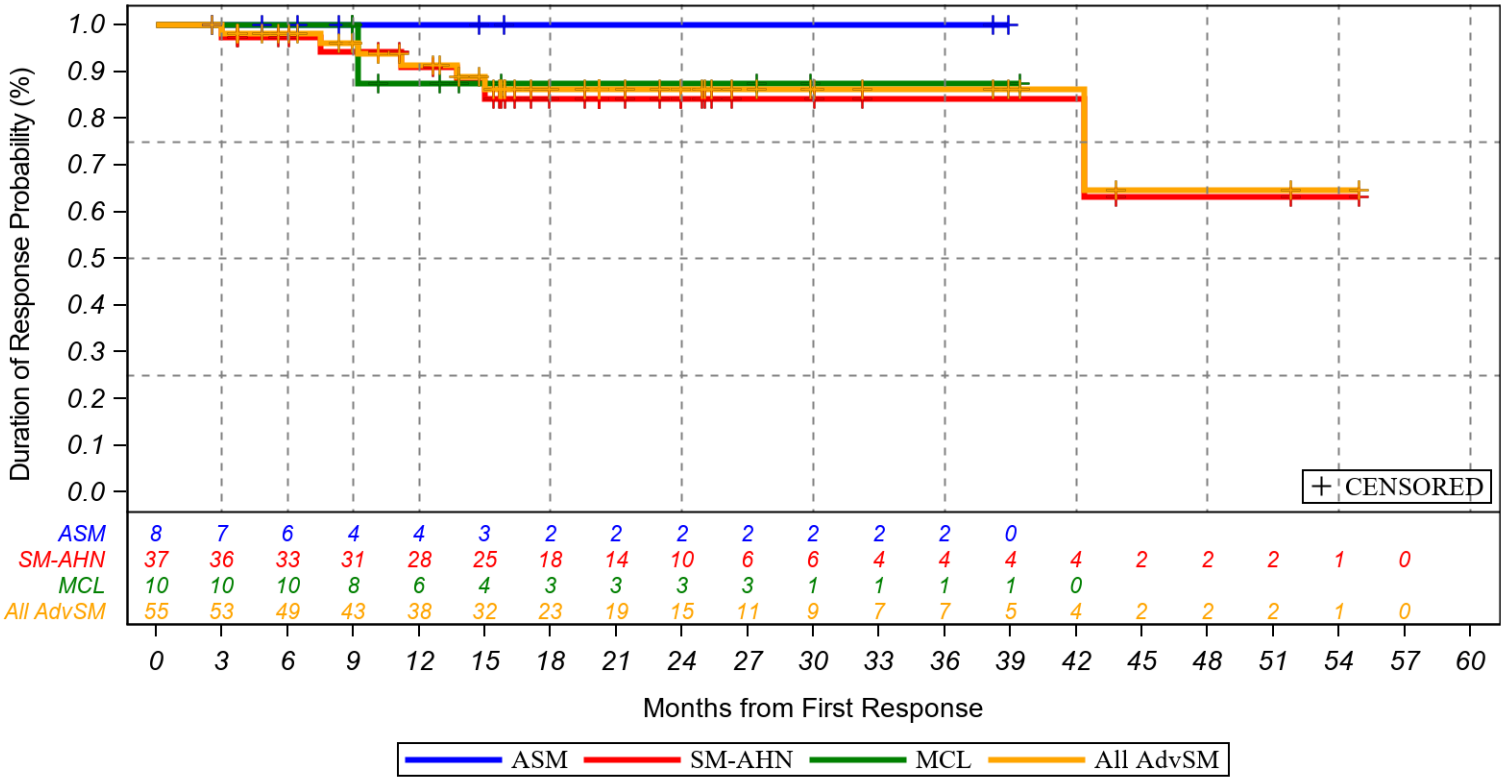

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR)

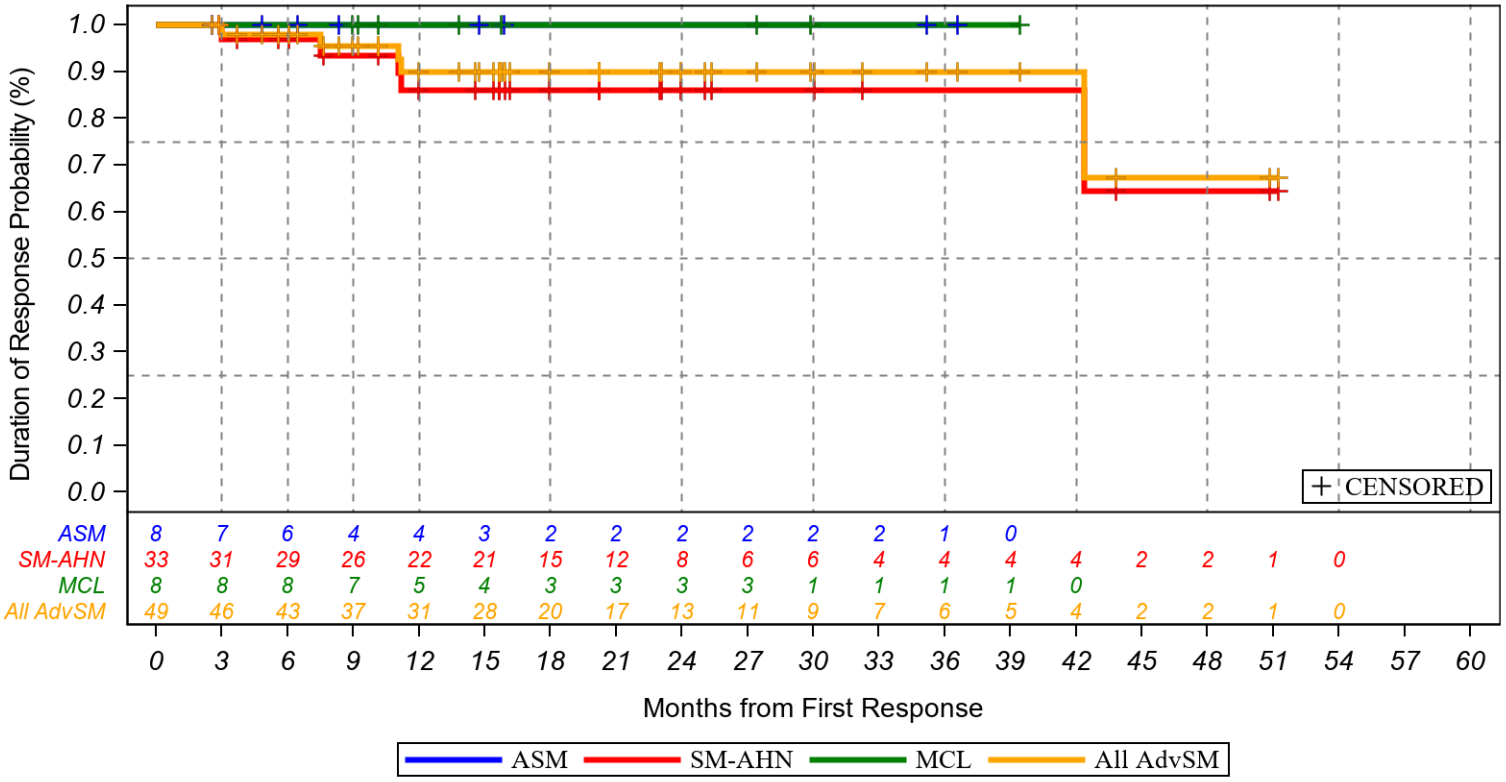

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR+CI)

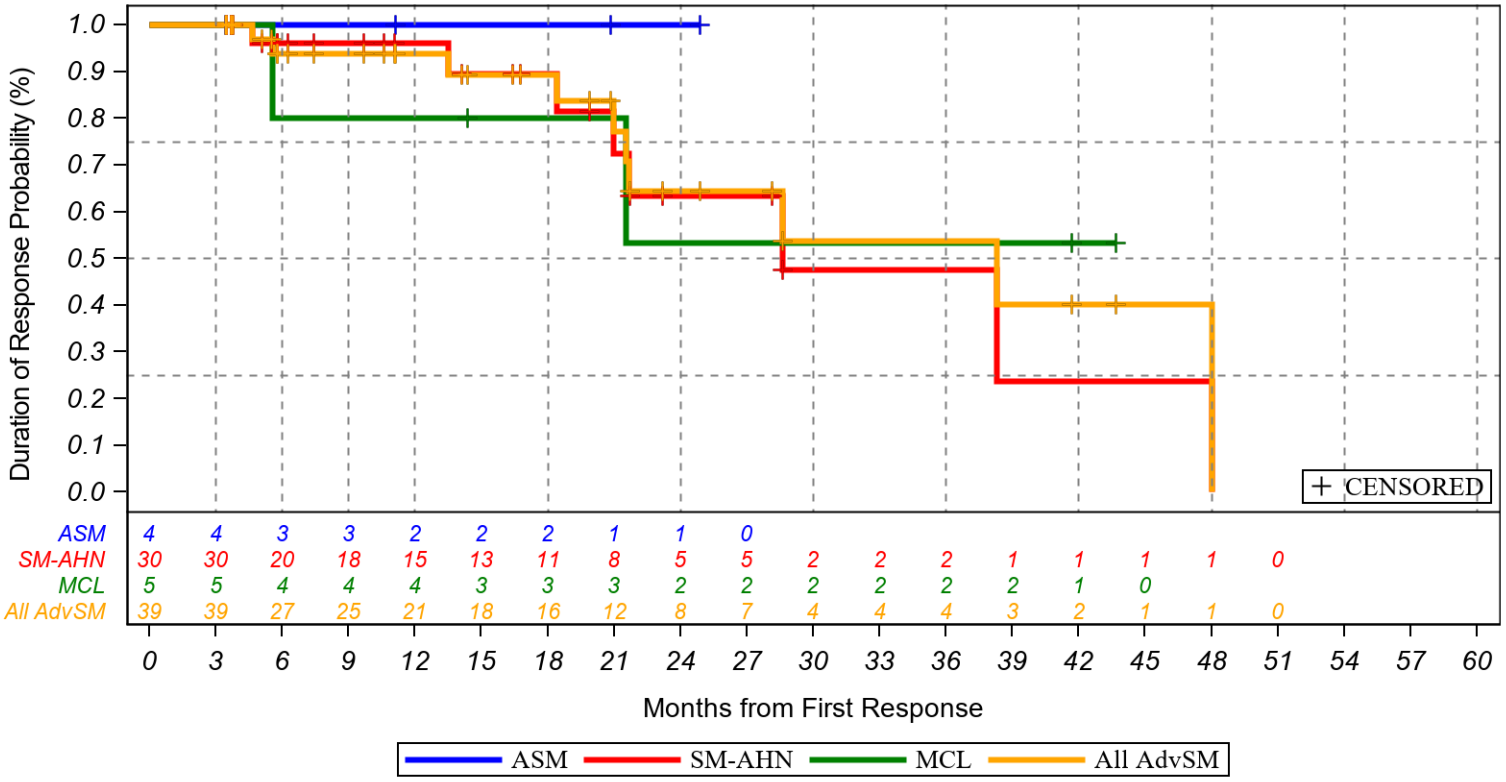

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR)

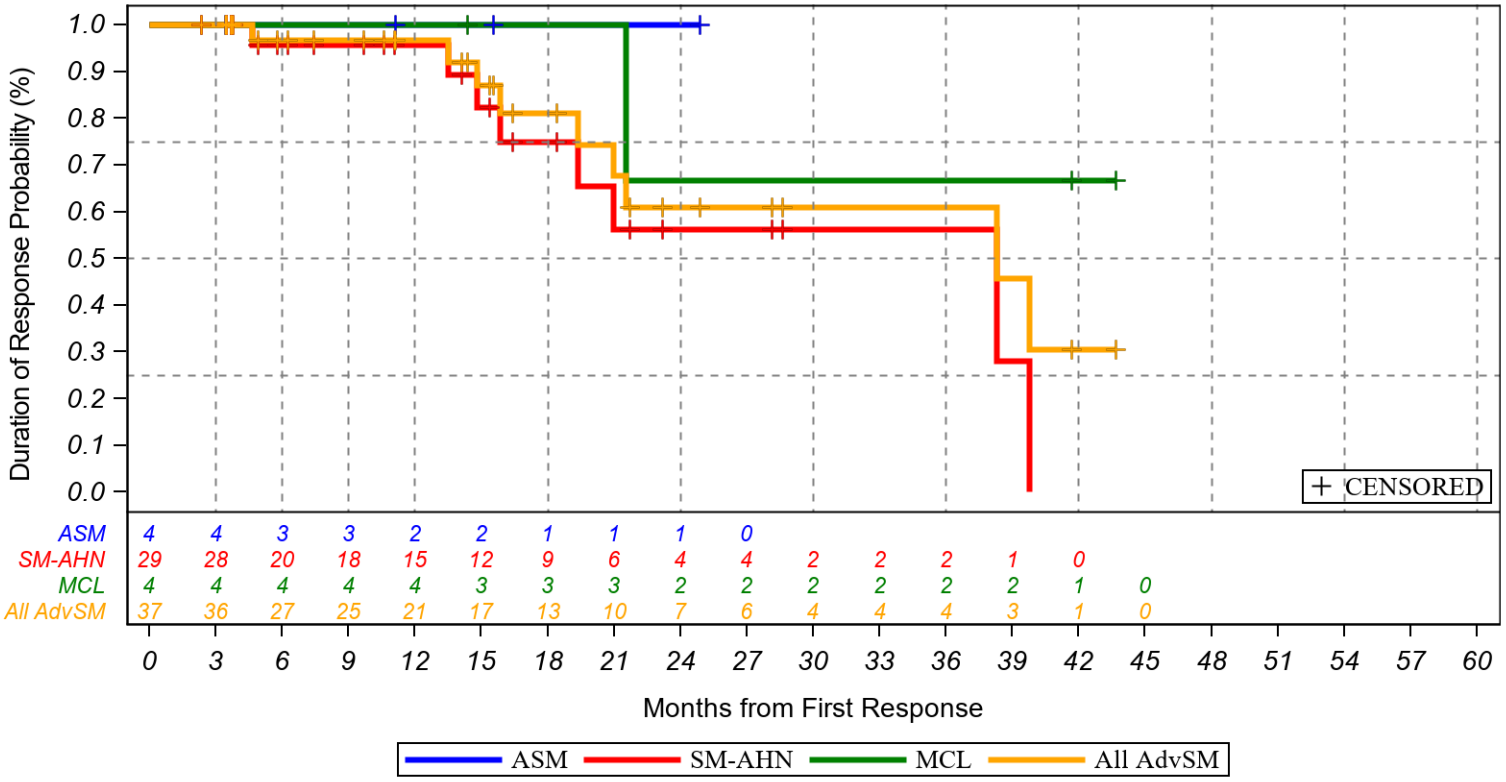

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR+CI)

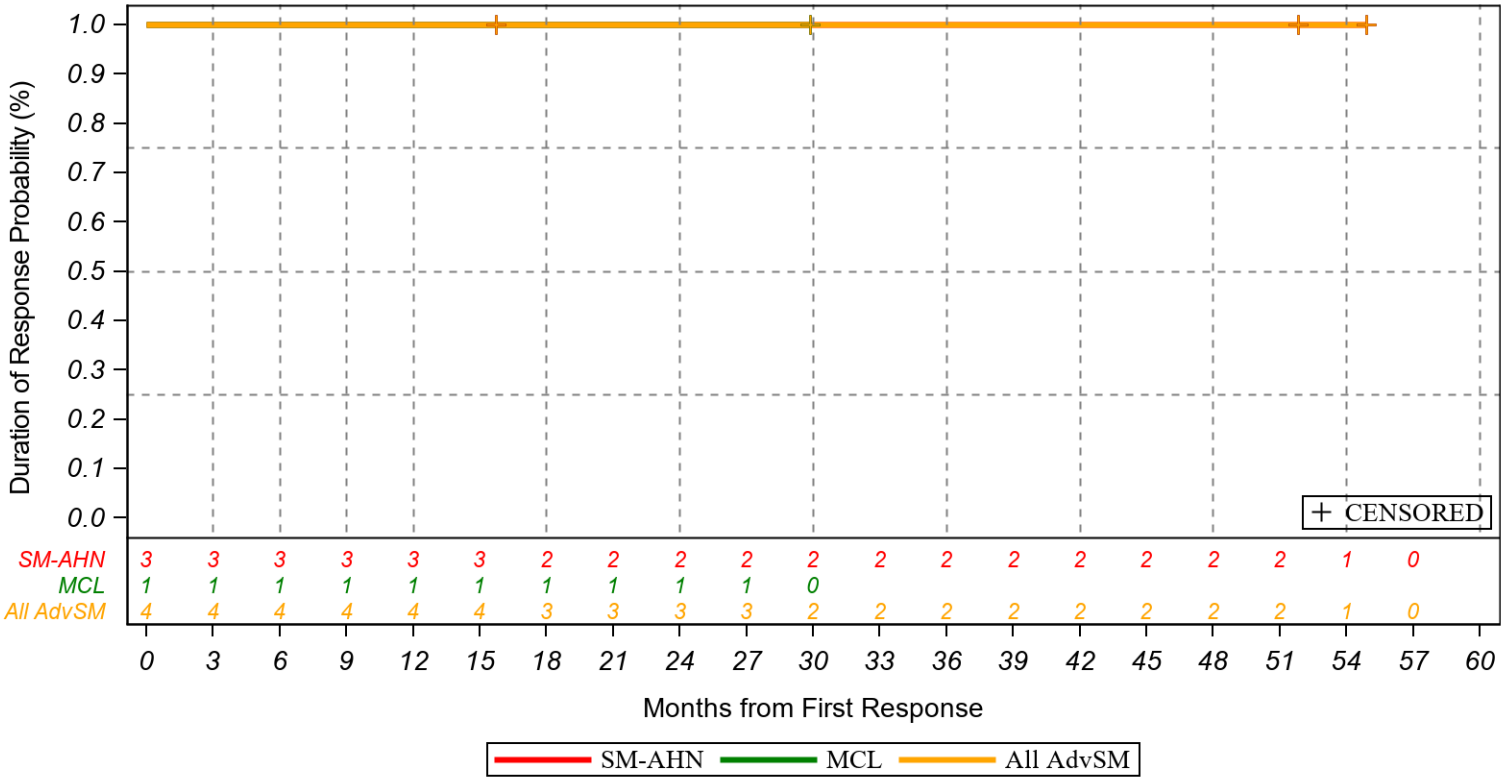

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR)

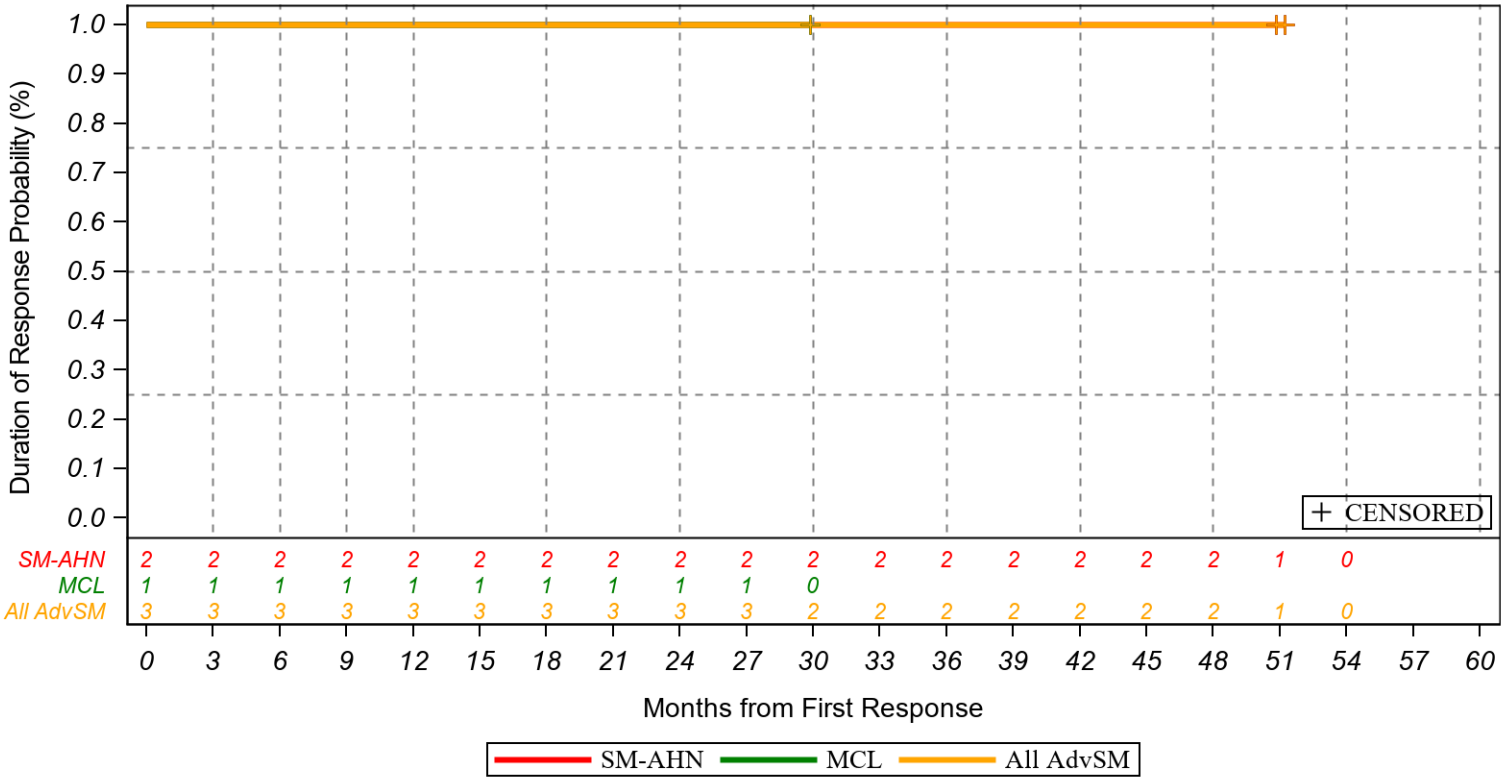

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR+CI)

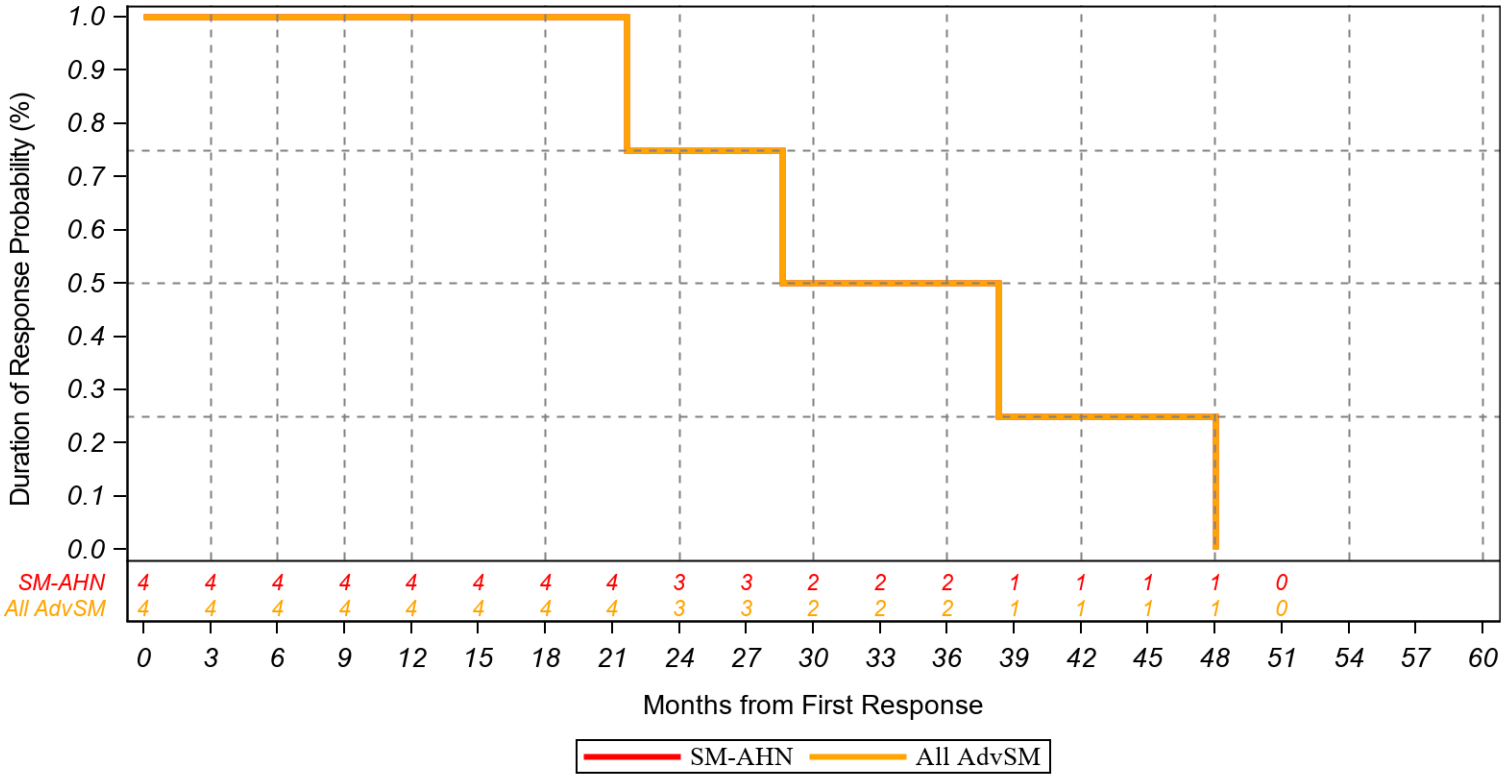

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR)

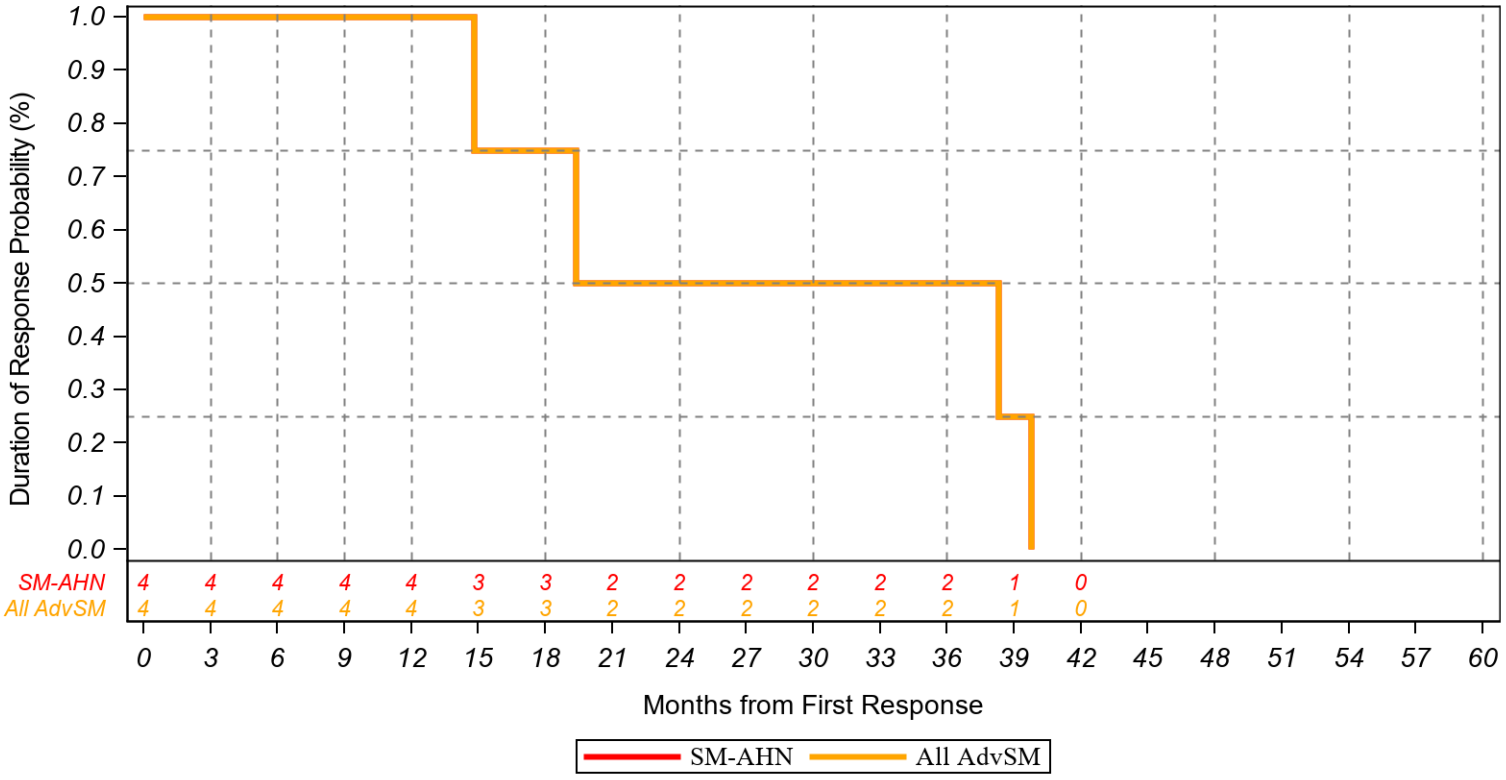

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR+CI)

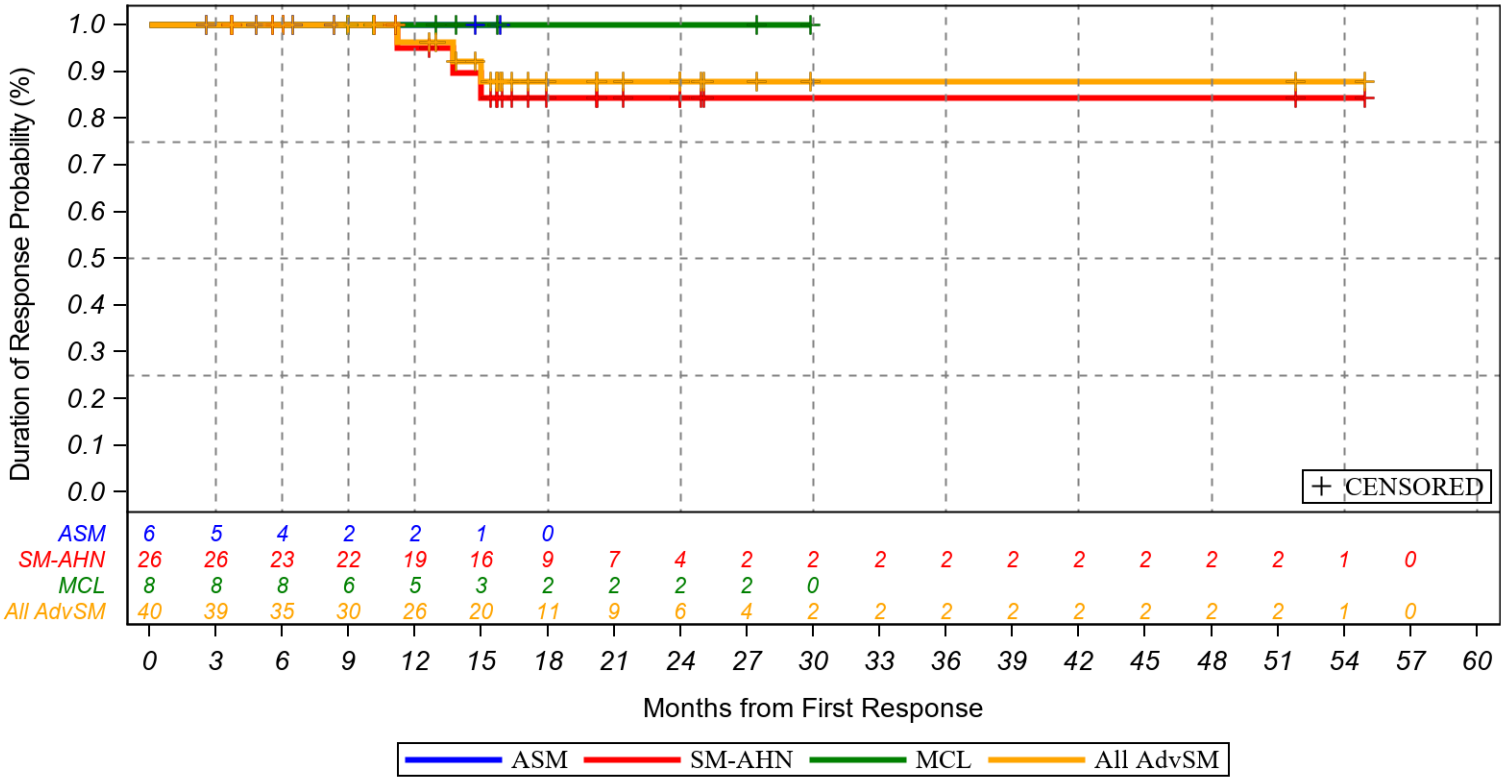

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR)

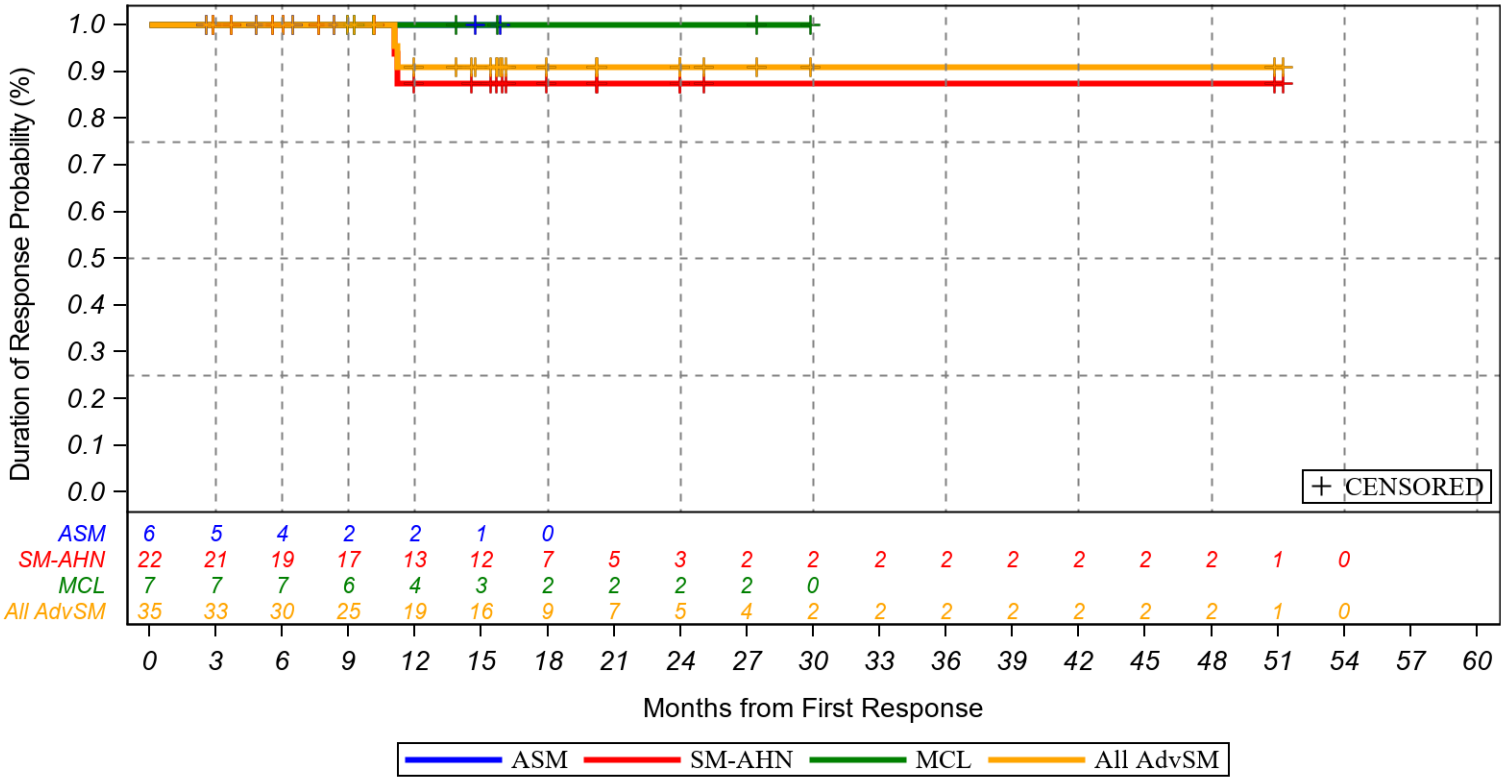

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR+CI)

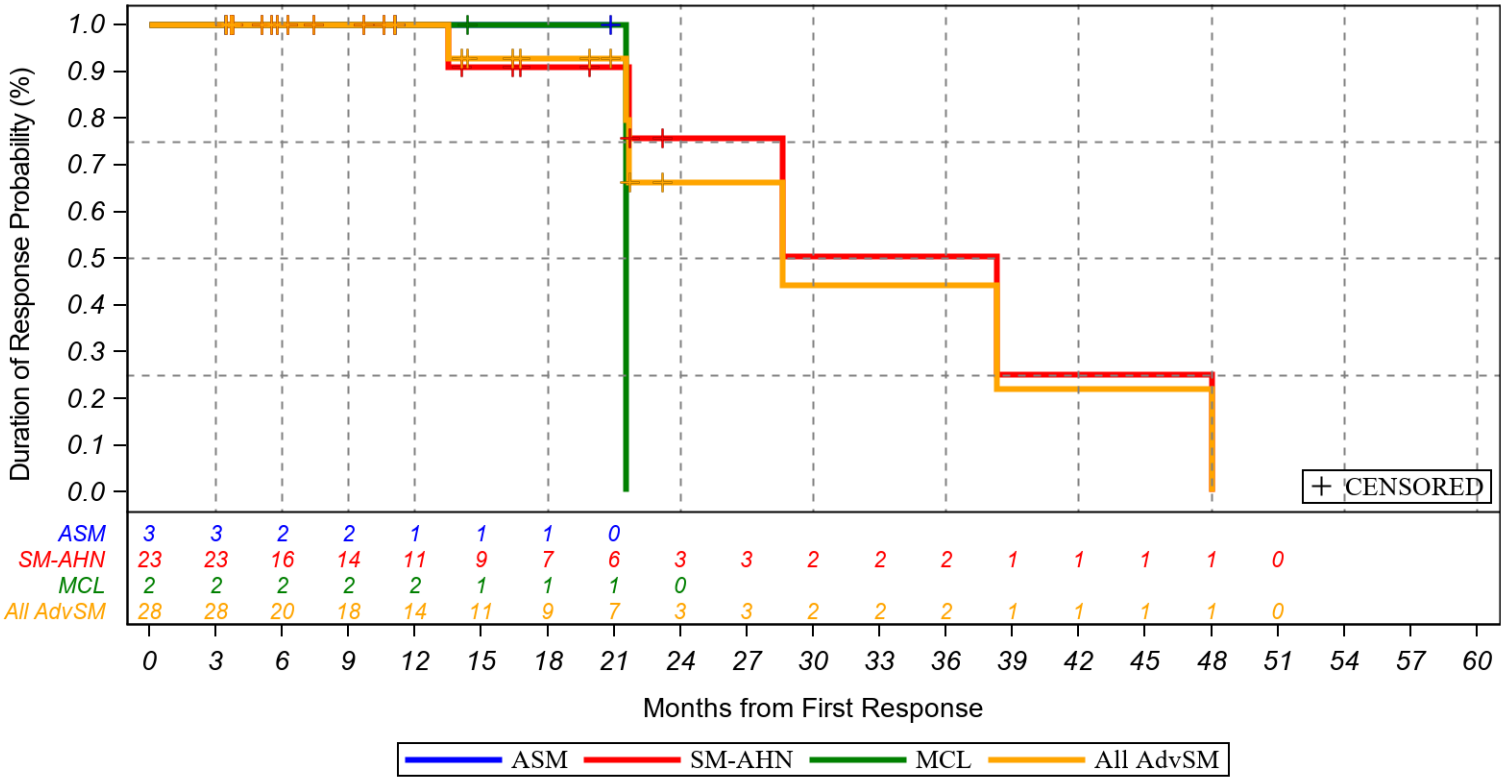

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR)

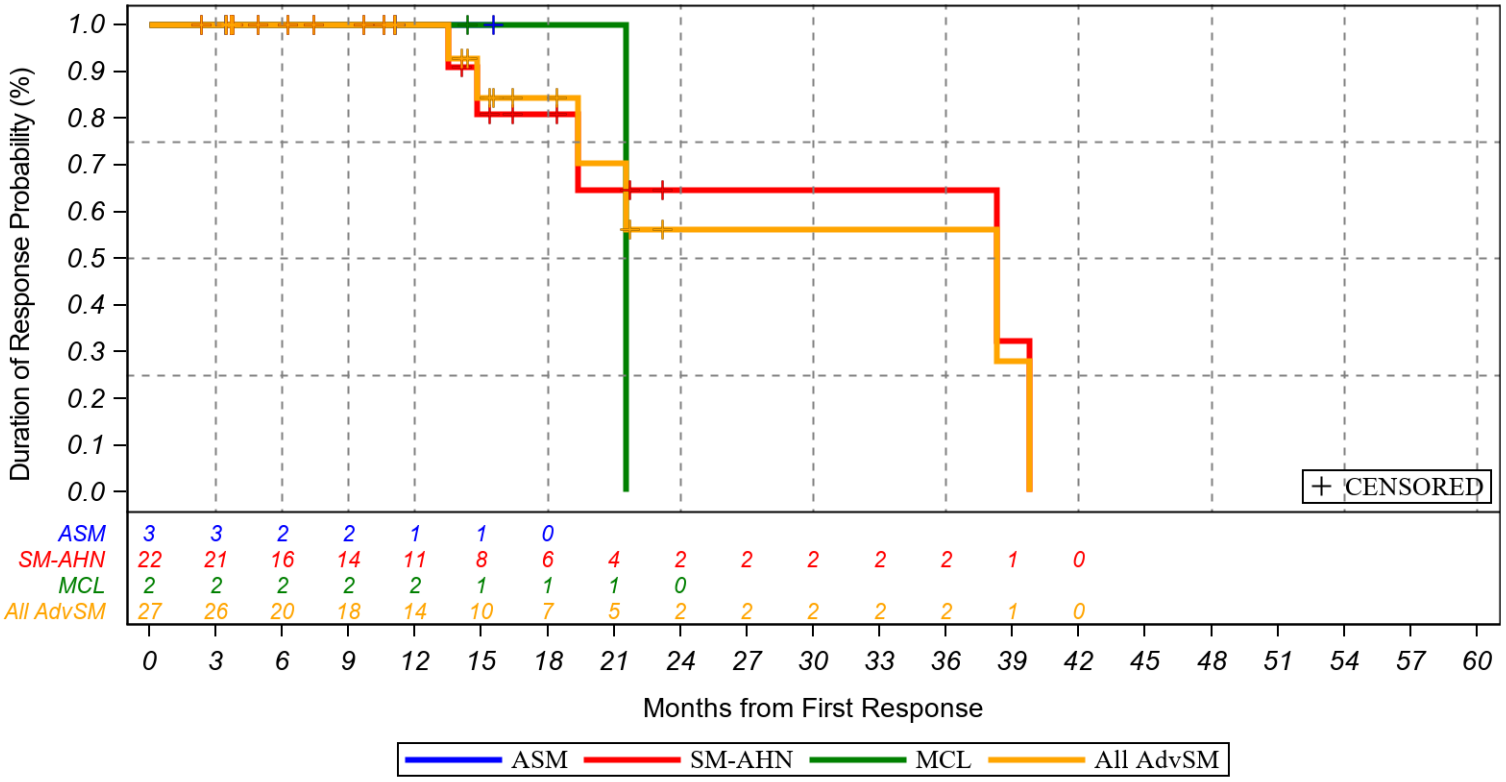

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR+CI)

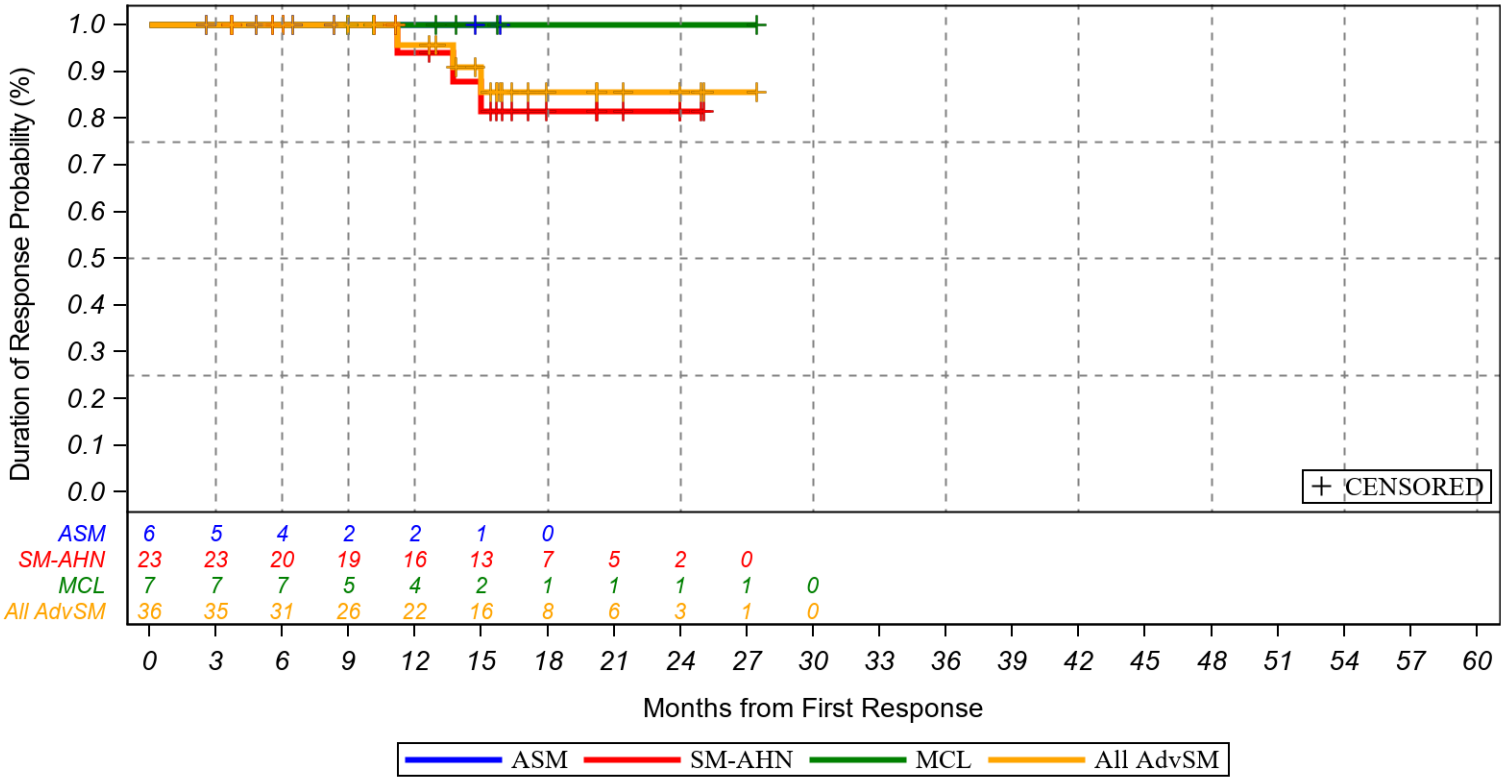

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR)

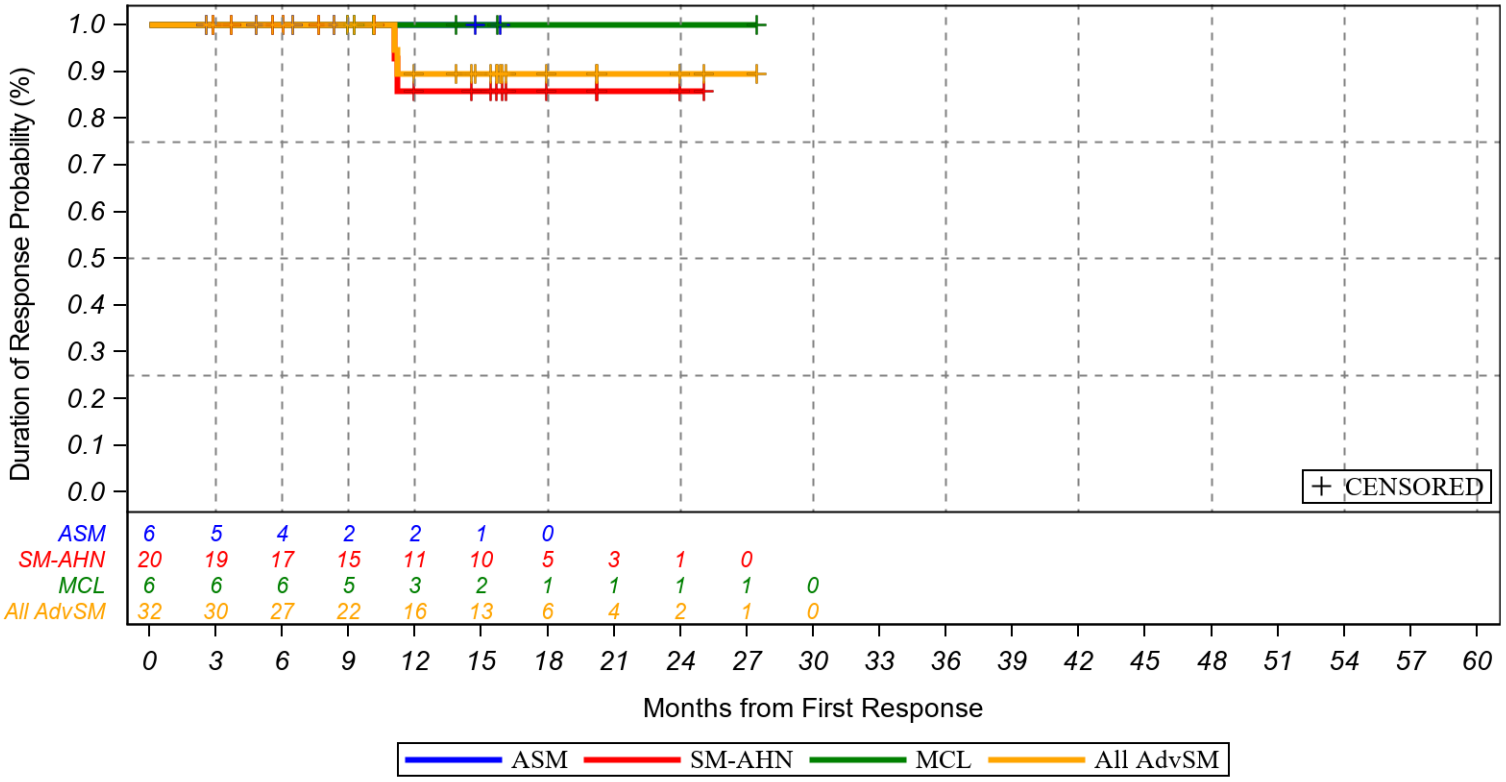

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR+CI)

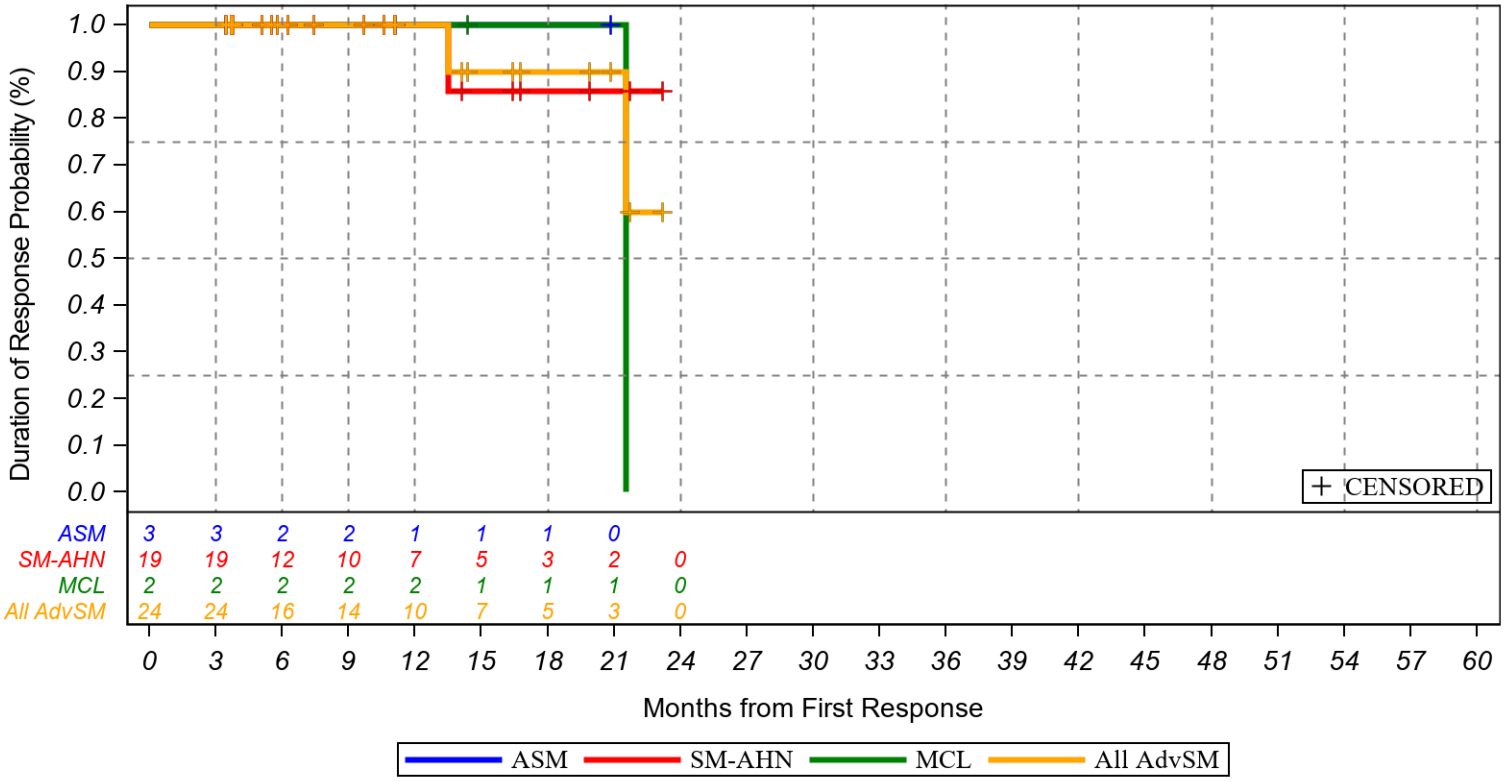

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR)

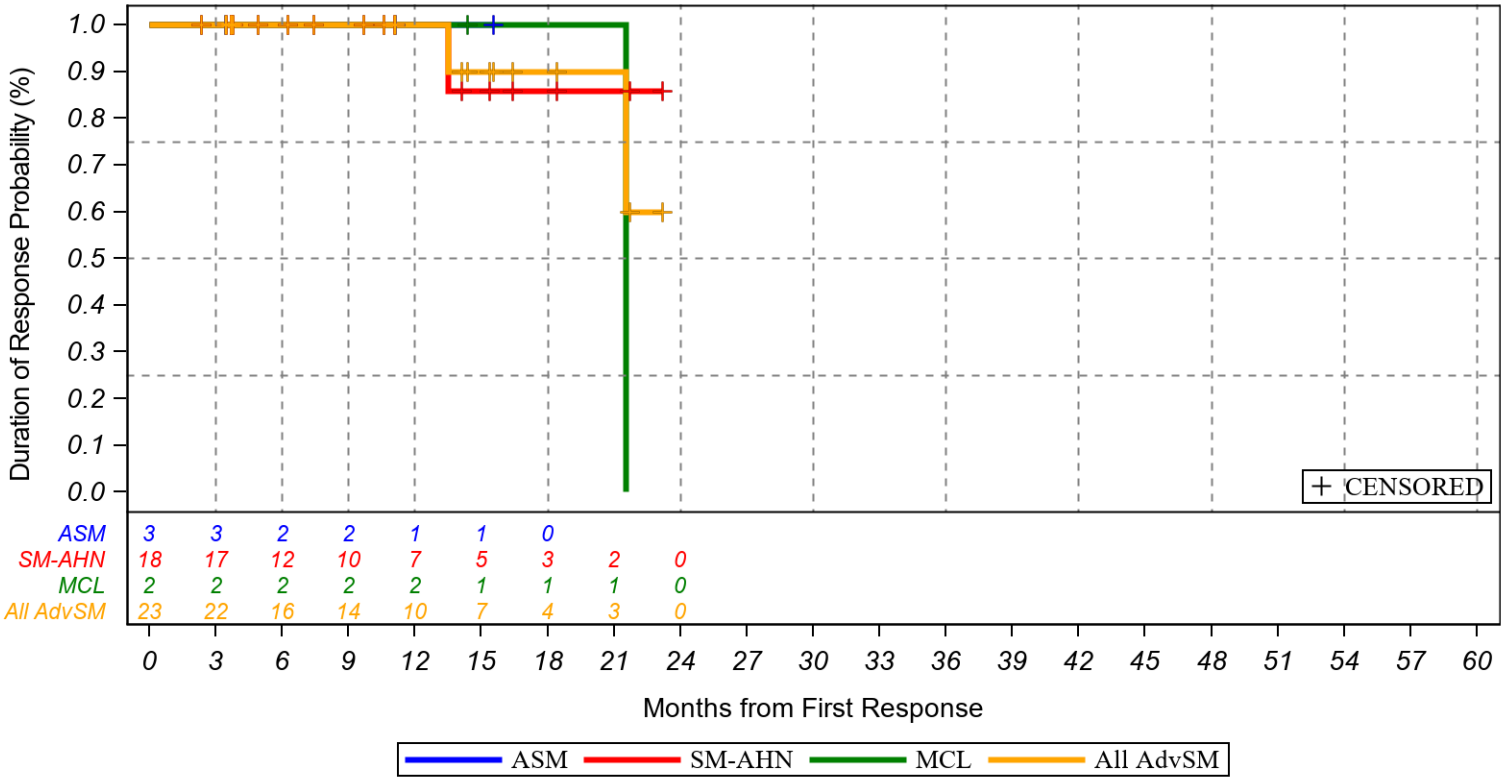

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR+CI)

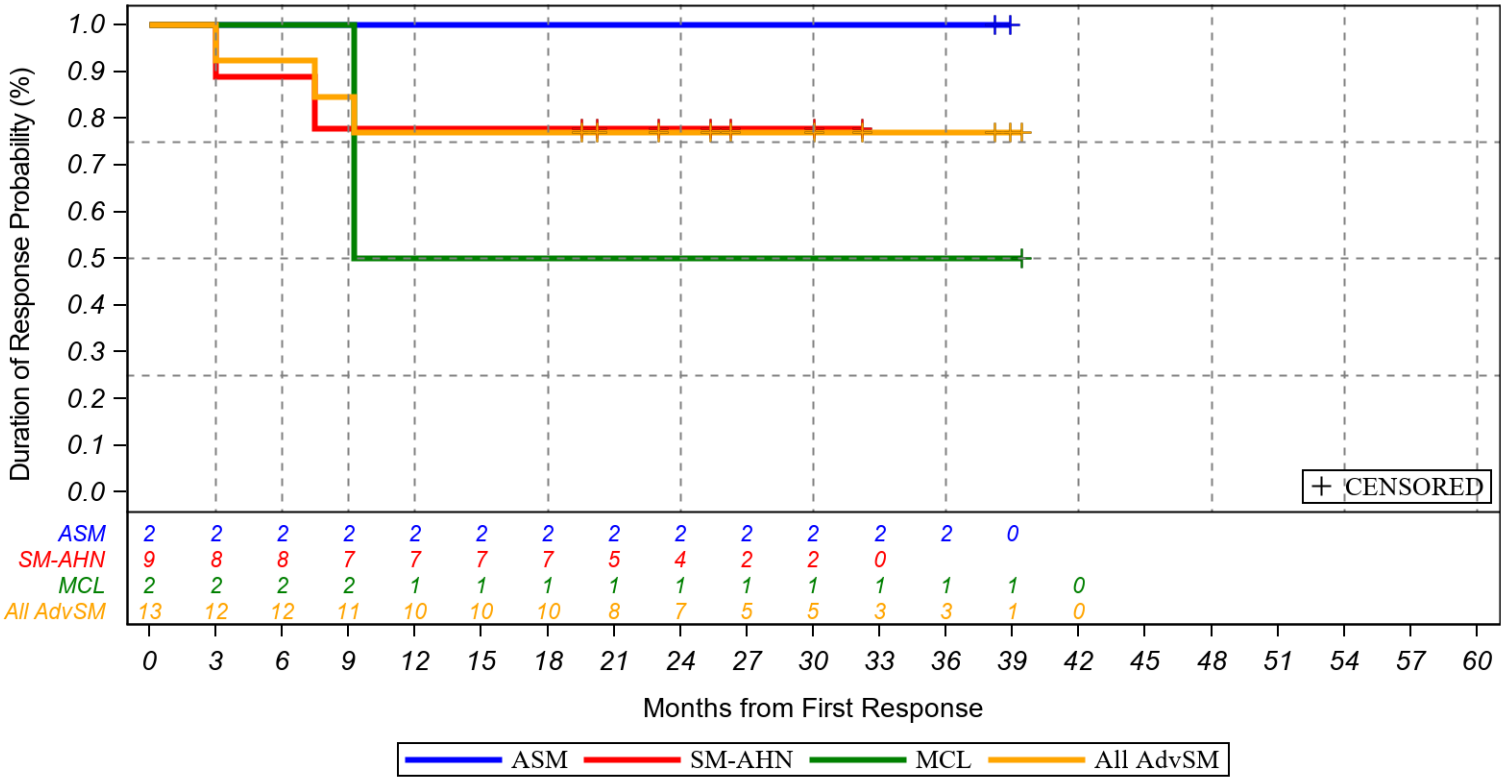

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR)

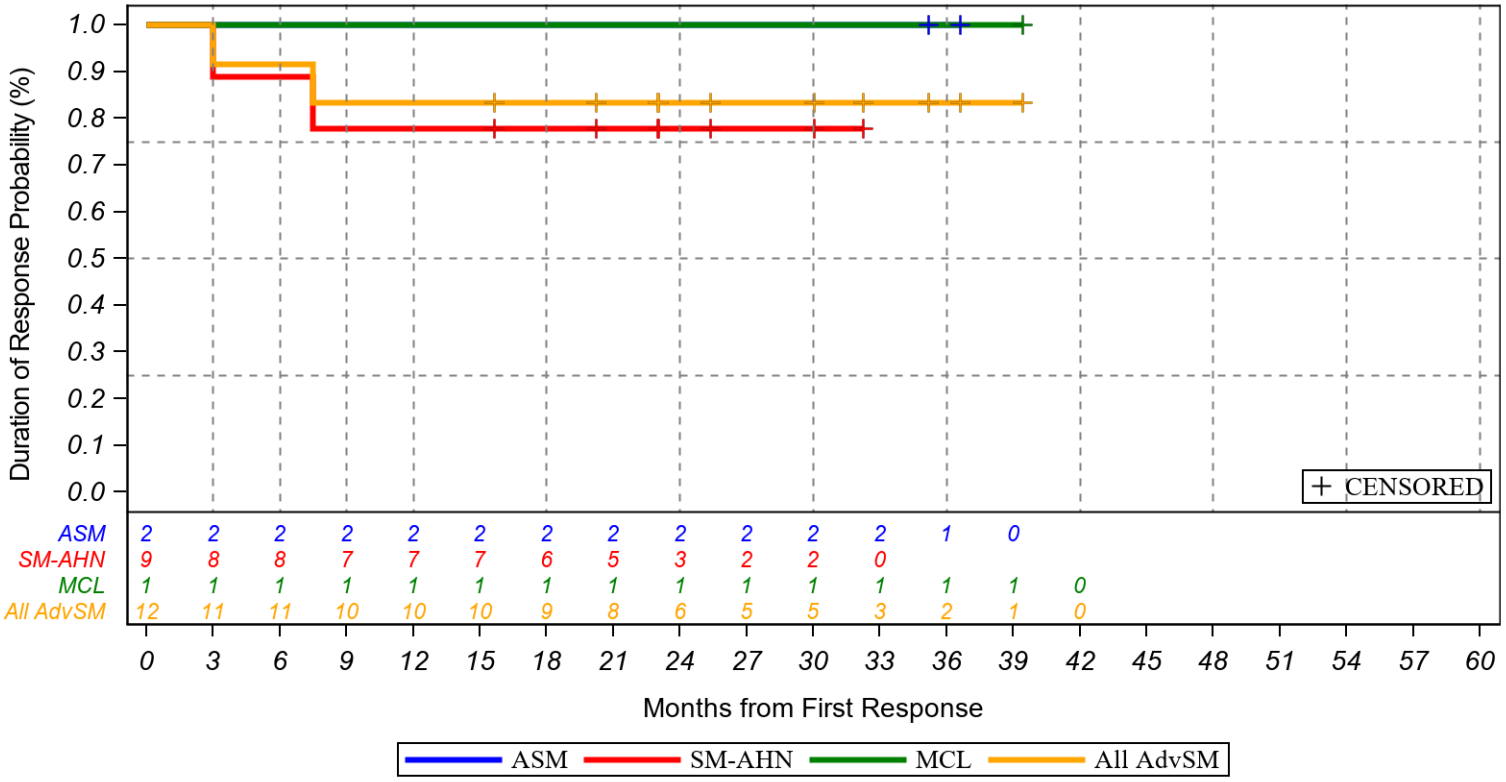

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR+CI)

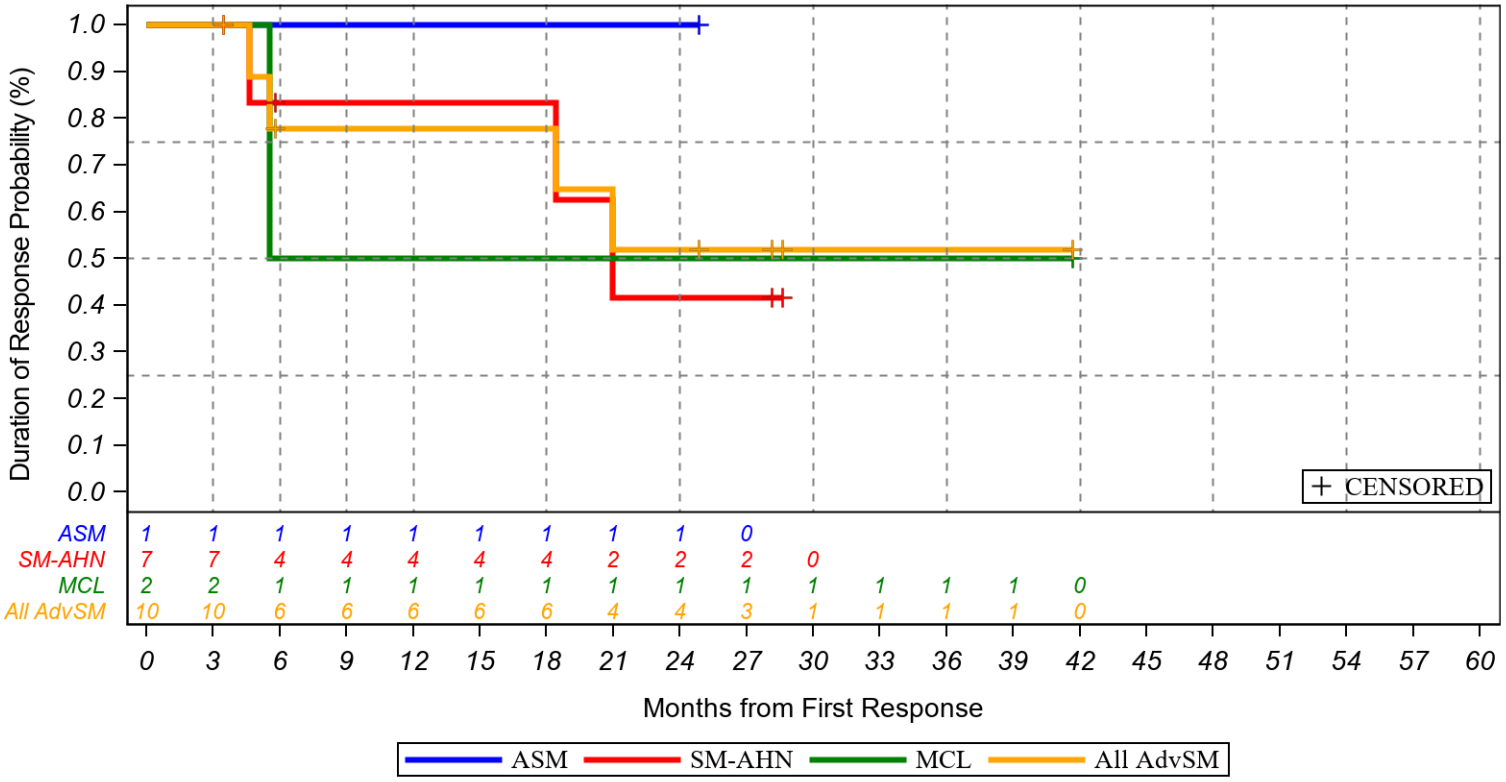

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR)

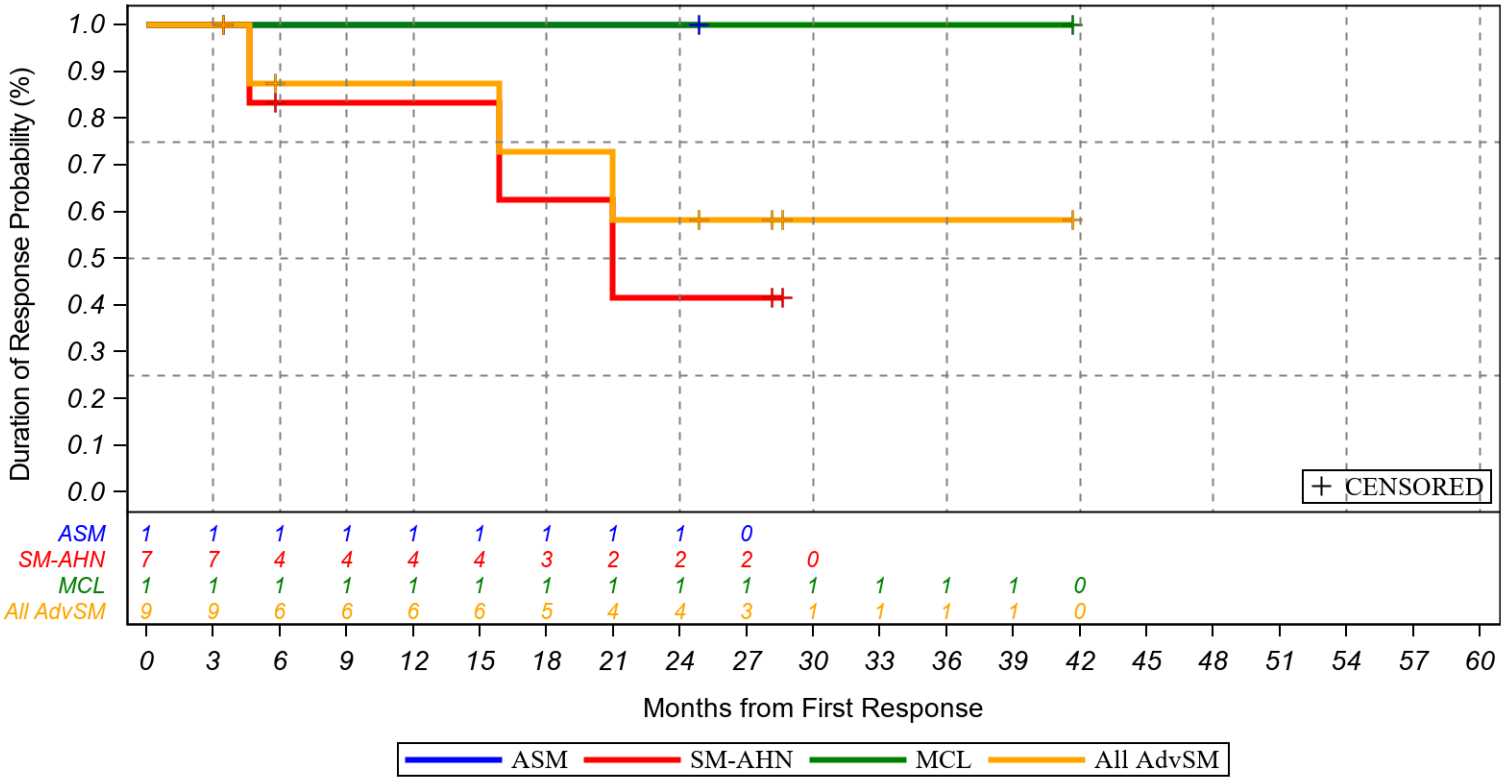

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
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Starting Dose: 200 mg and 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR+CI)

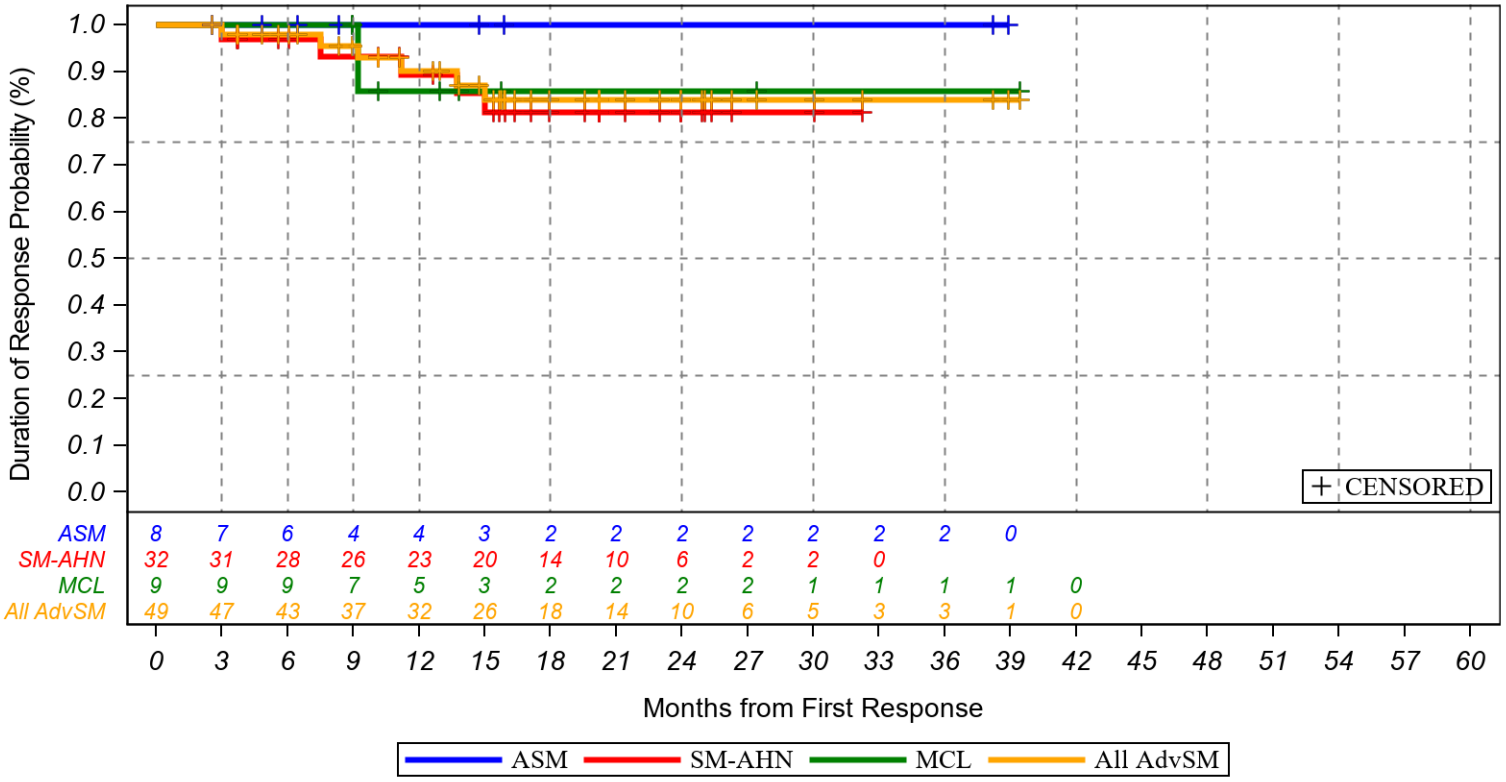

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR)

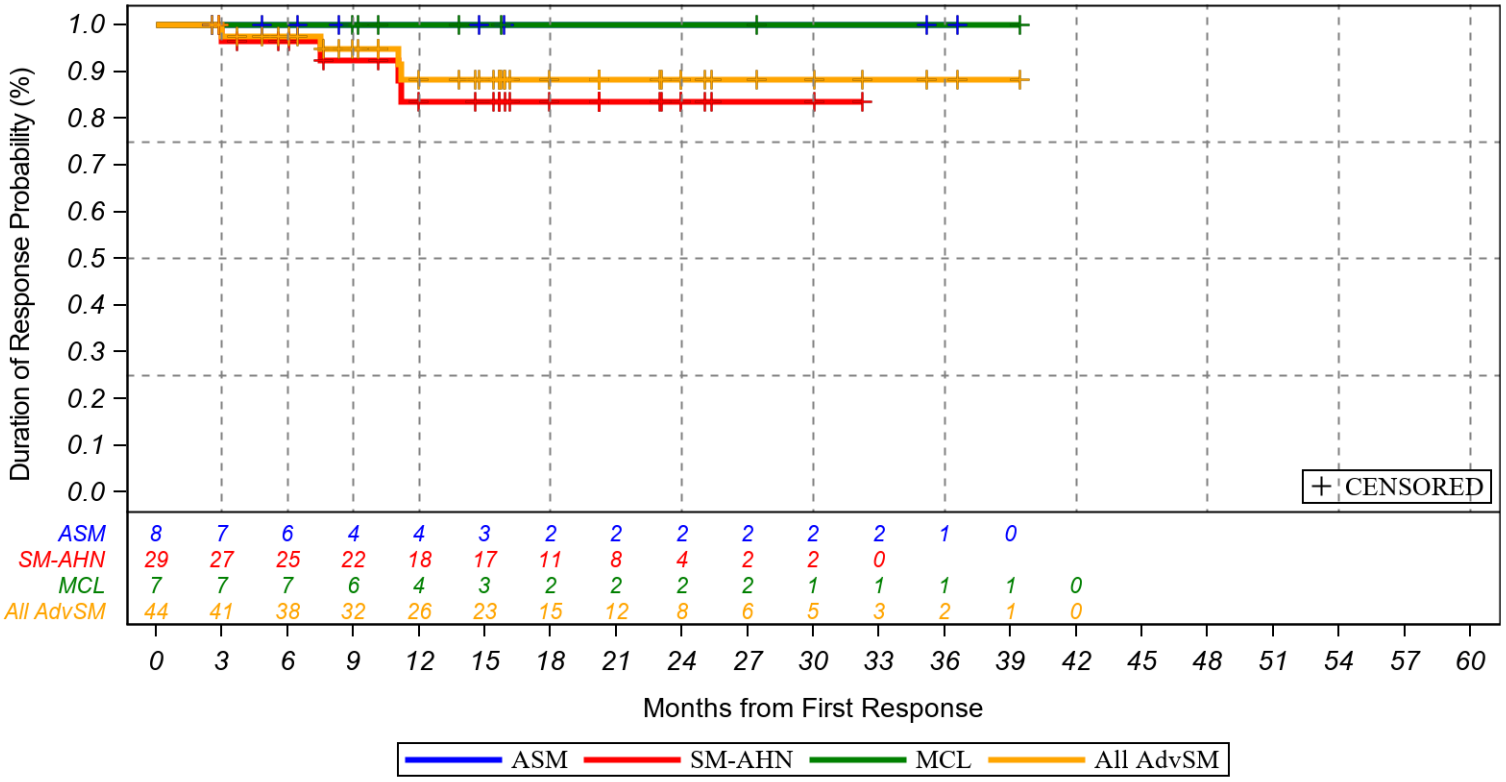

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR+CI)

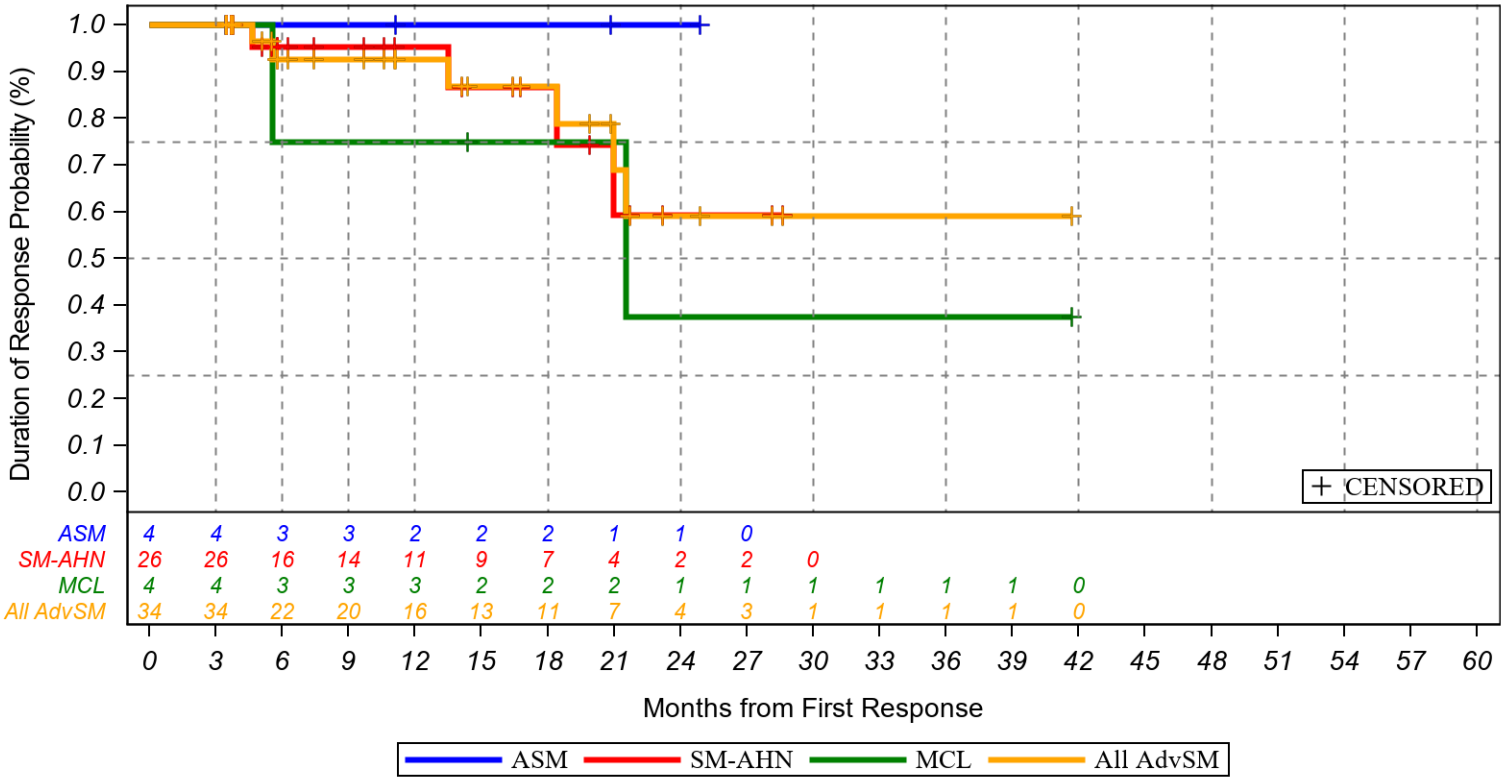

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR)

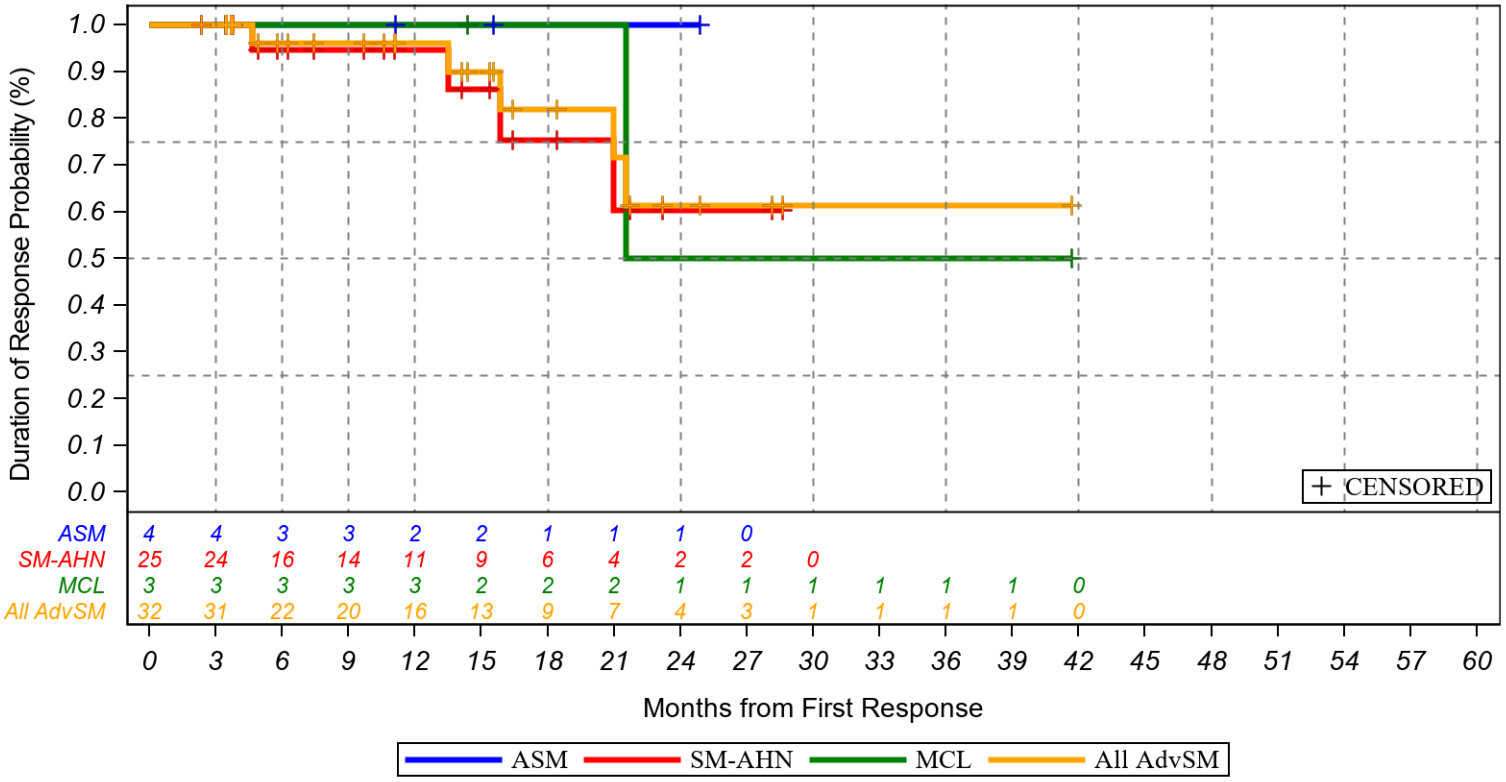

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Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
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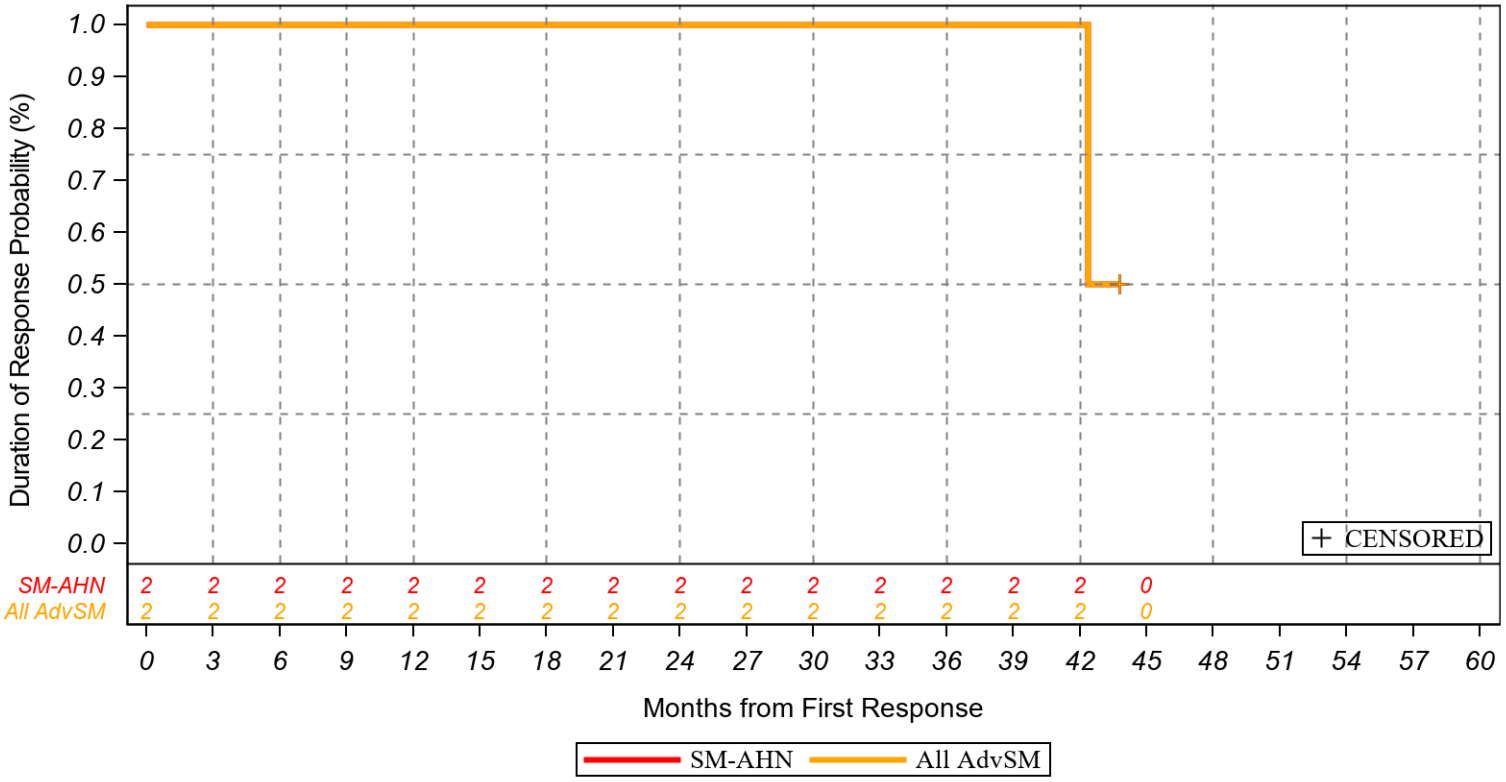
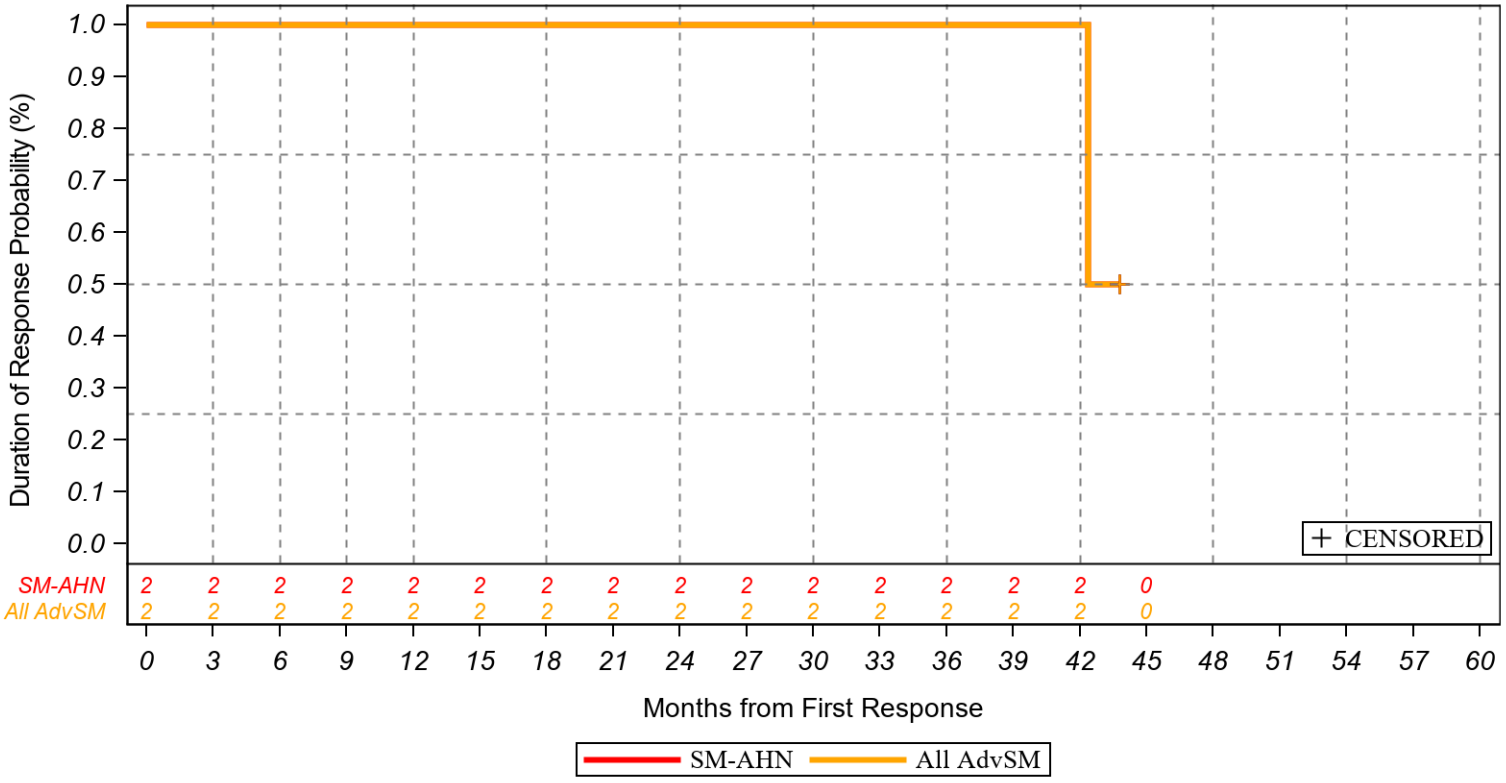
Starting Dose: 400 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR+CI)



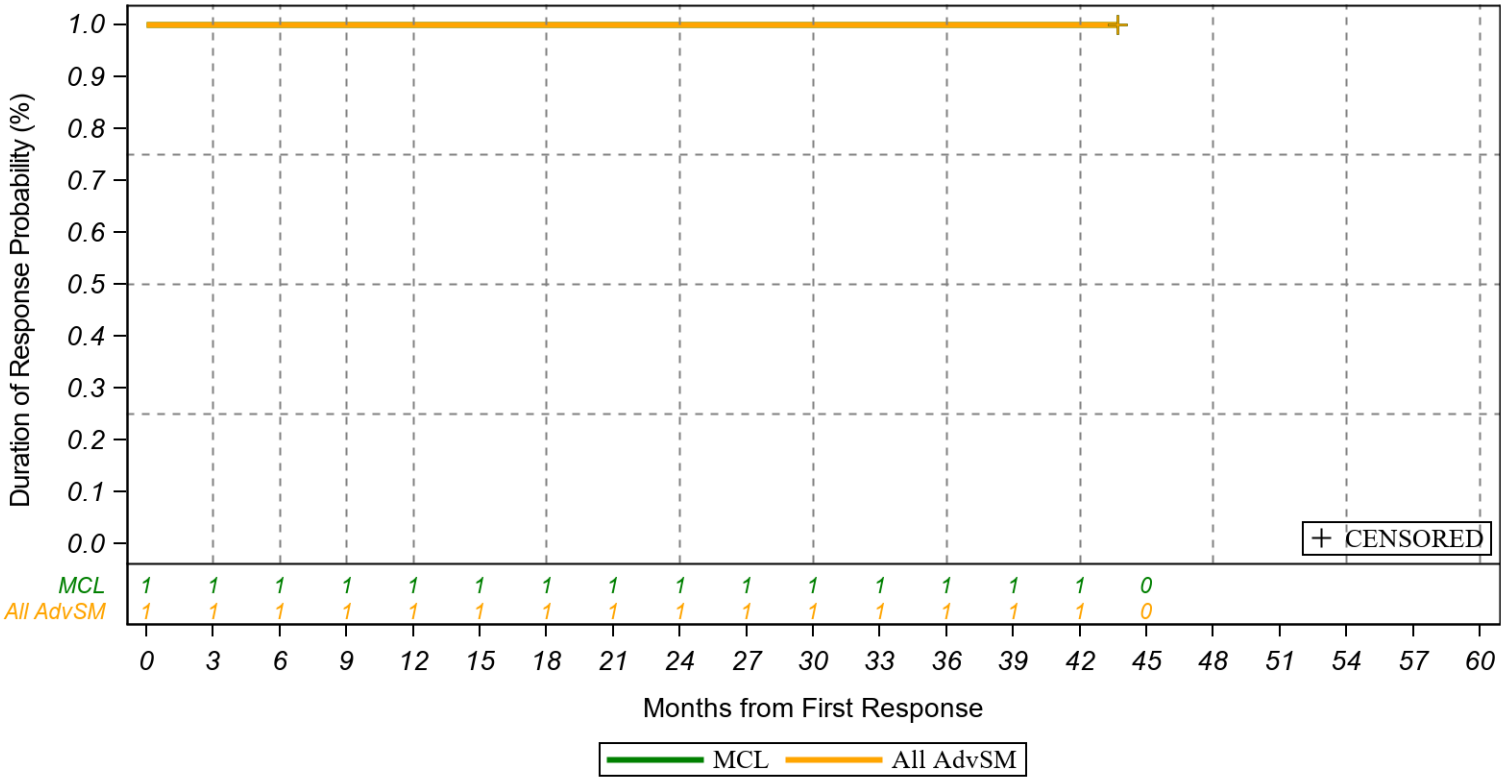
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_EUD120/Final/Programs/prod/figures/f-adj-m-dur-rac-tpy.sas Date: 18:07/22JUL2021

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+CRh+PR)



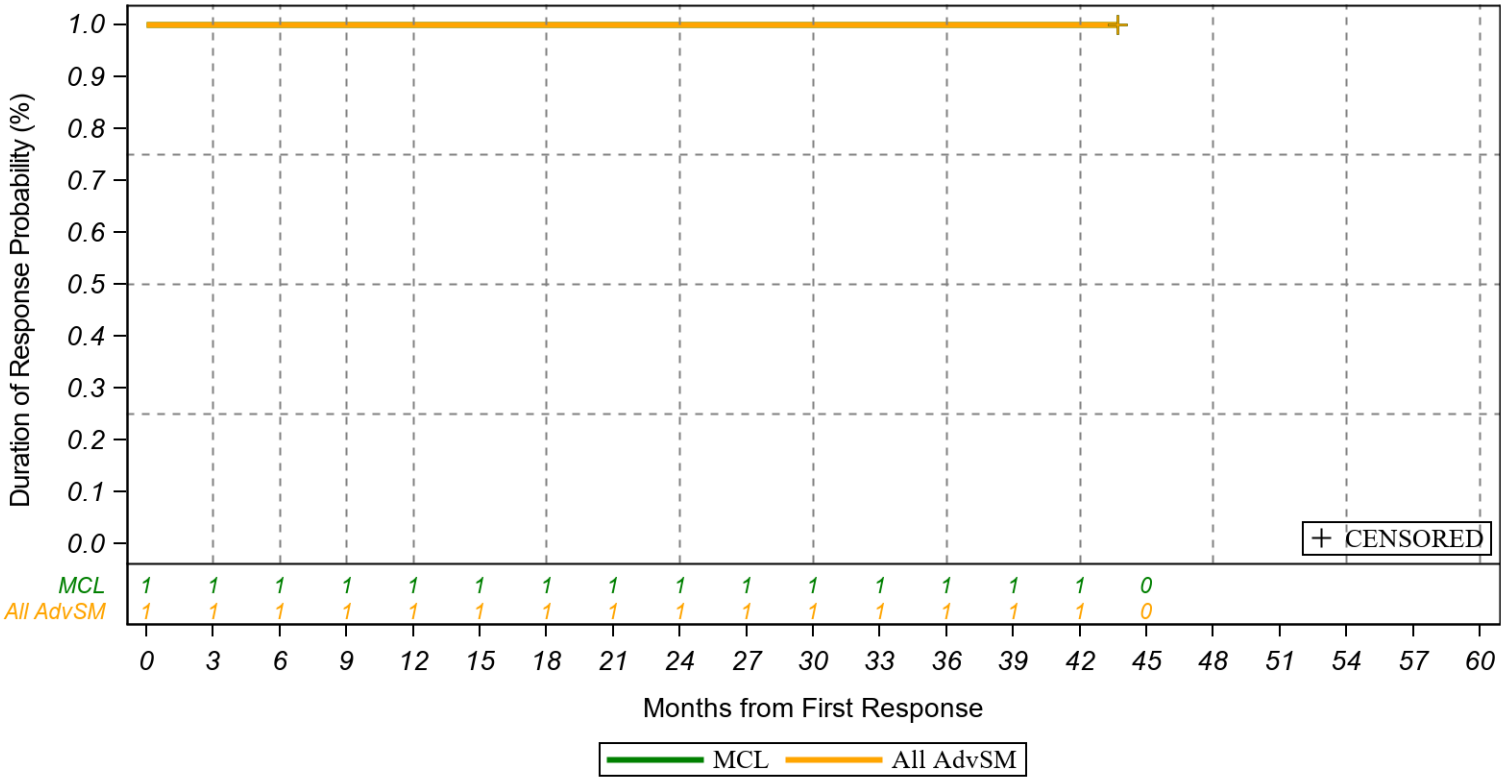
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_EUD120/Final/Programs/prod/figures/f-adj-m-dur-rac-tpy.sas Date: 18:07/22JUL2021

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR+CI)



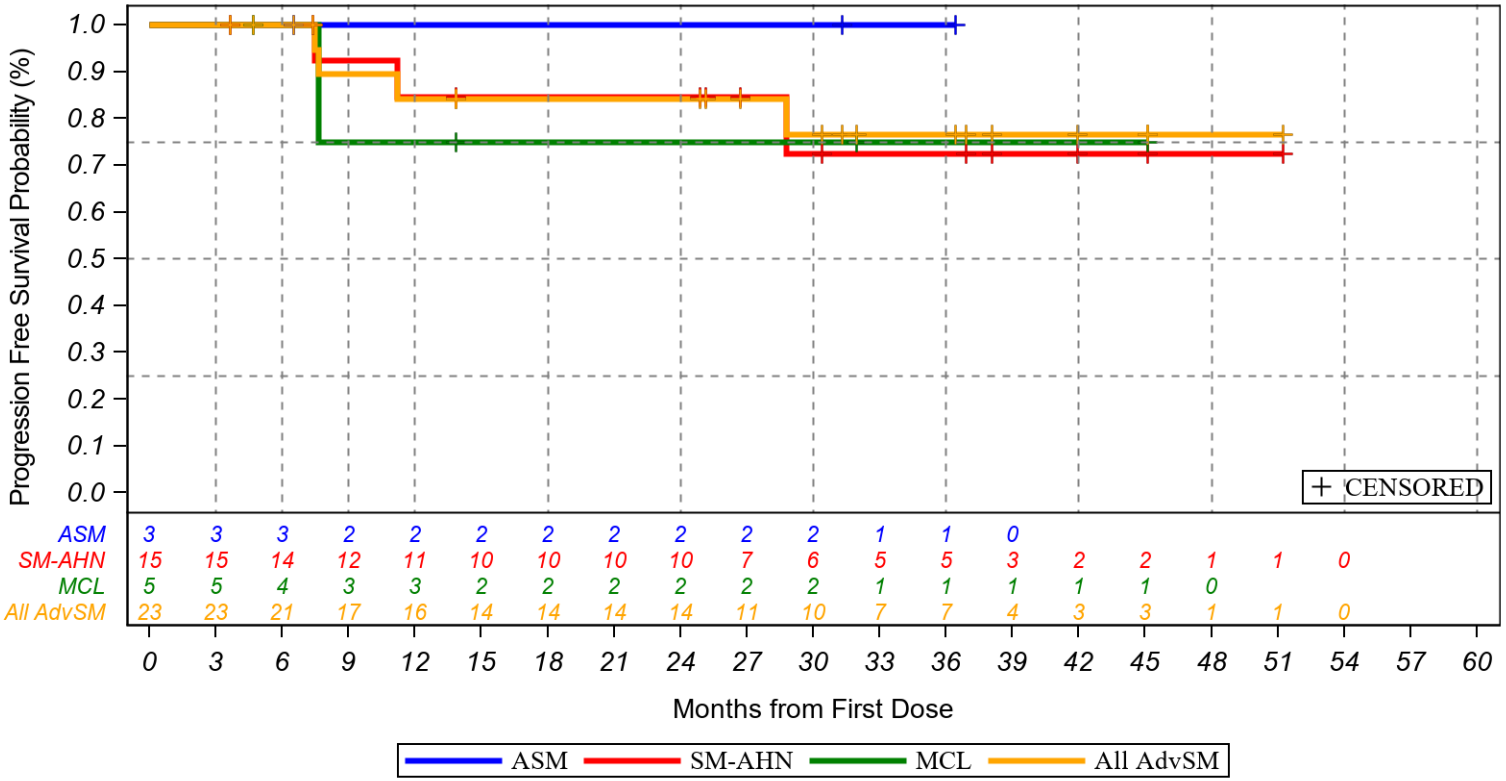
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_EUD120/Final/Programs/prod/figures/f-adj-m-dur-rac-tpy.sas Date: 18:07/22JUL2021

Figure 15.2.2.1b
Kaplan-Meier Curves of Adjudicated Duration of Response by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population - Responders (CR+CRh+PR+CI)
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg
Prior Antineoplastic Therapy = No
Responders (CR+CRh+PR)



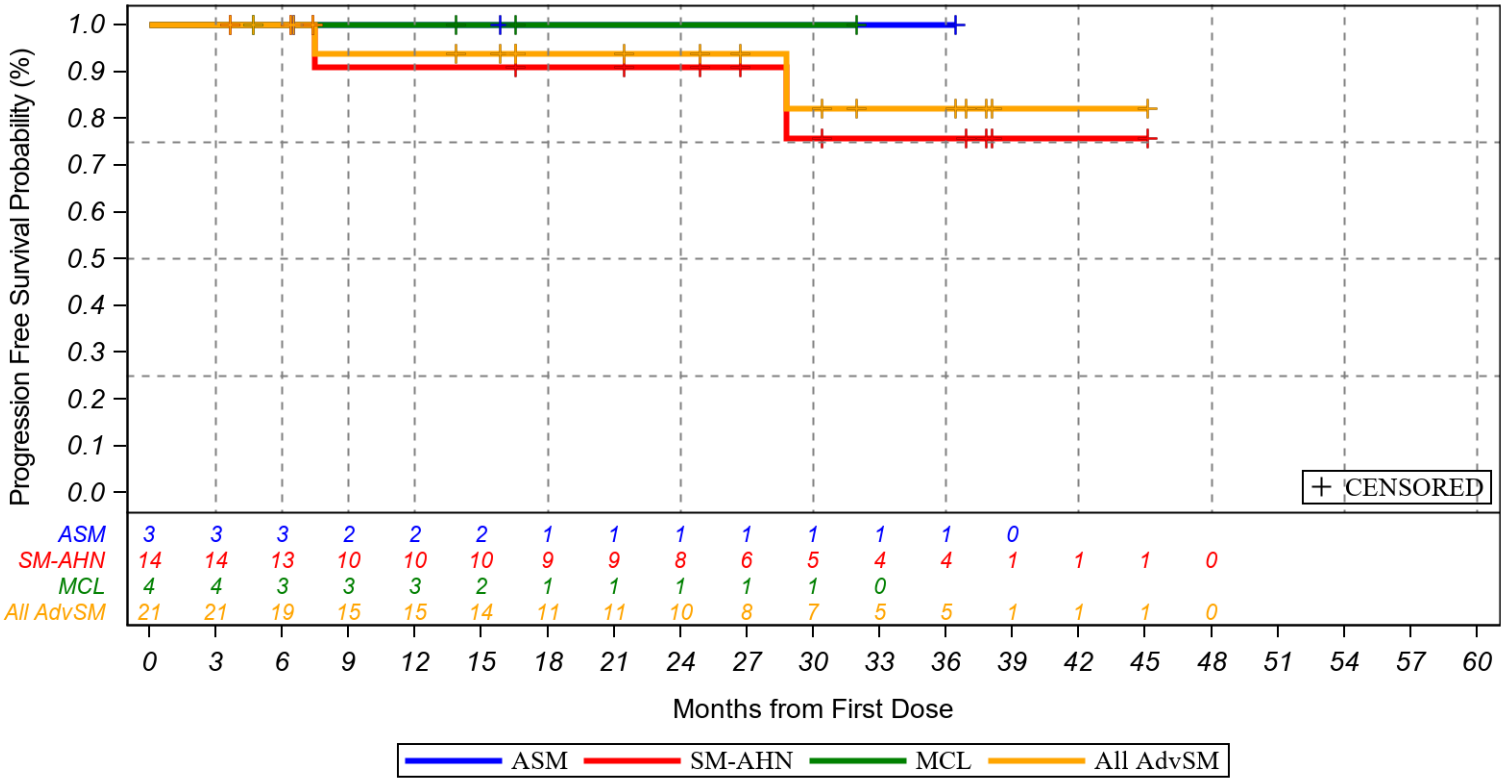
Program: R:/Clinical/Biostatistics/BLU-285/ISE_2101_EUD120/Final/Programs/prod/figures/f-adj-m-dur-rac-tpy.sas Date: 18:07/22JUL2021

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: Overall, Duration of Response



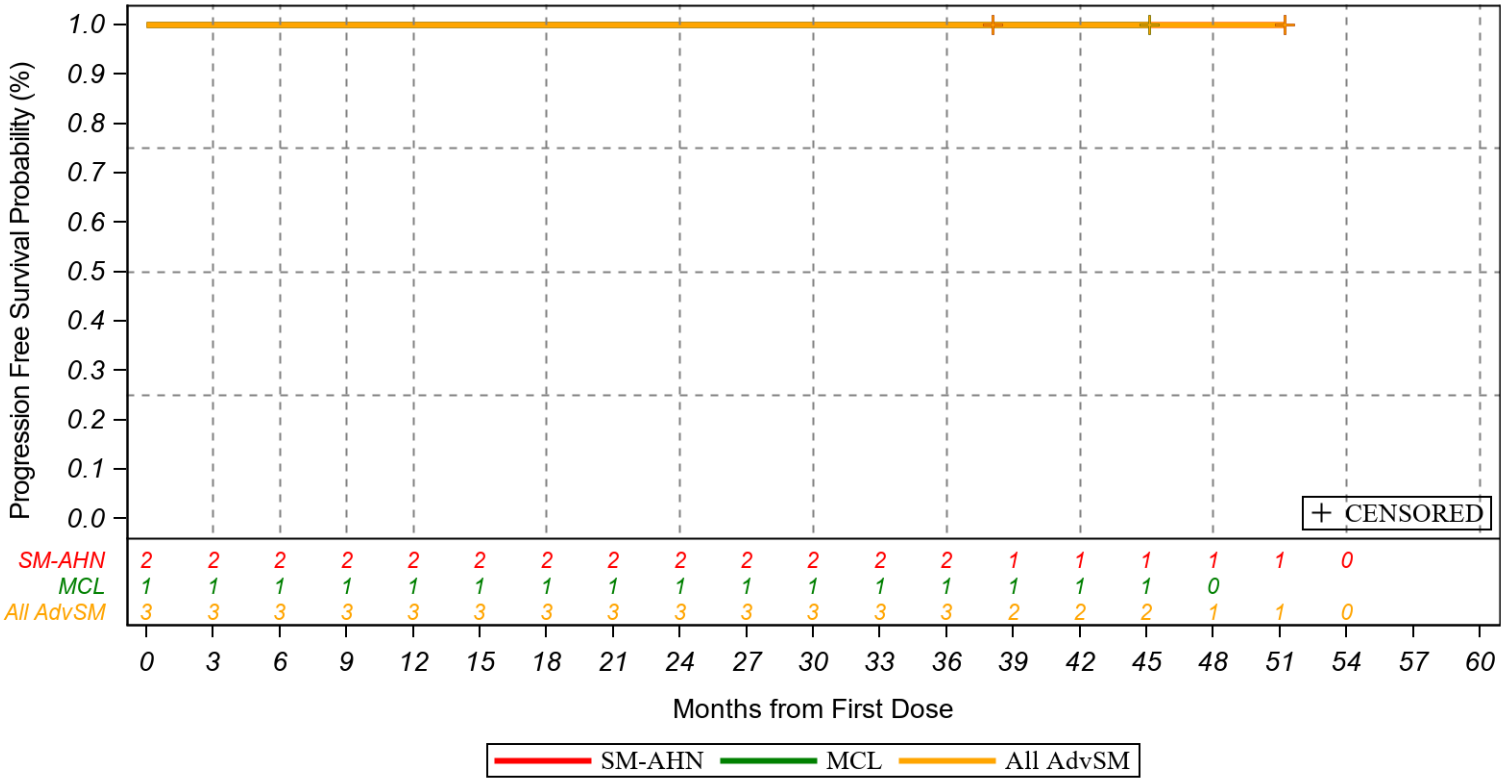
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_EUD120/Final/Programs/prod/adhoc/GermanyHTA/f-inv-dur-advsm.sas
Date: 10:26/18JAN2022

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: Overall, Duration of CR+CRh+PR



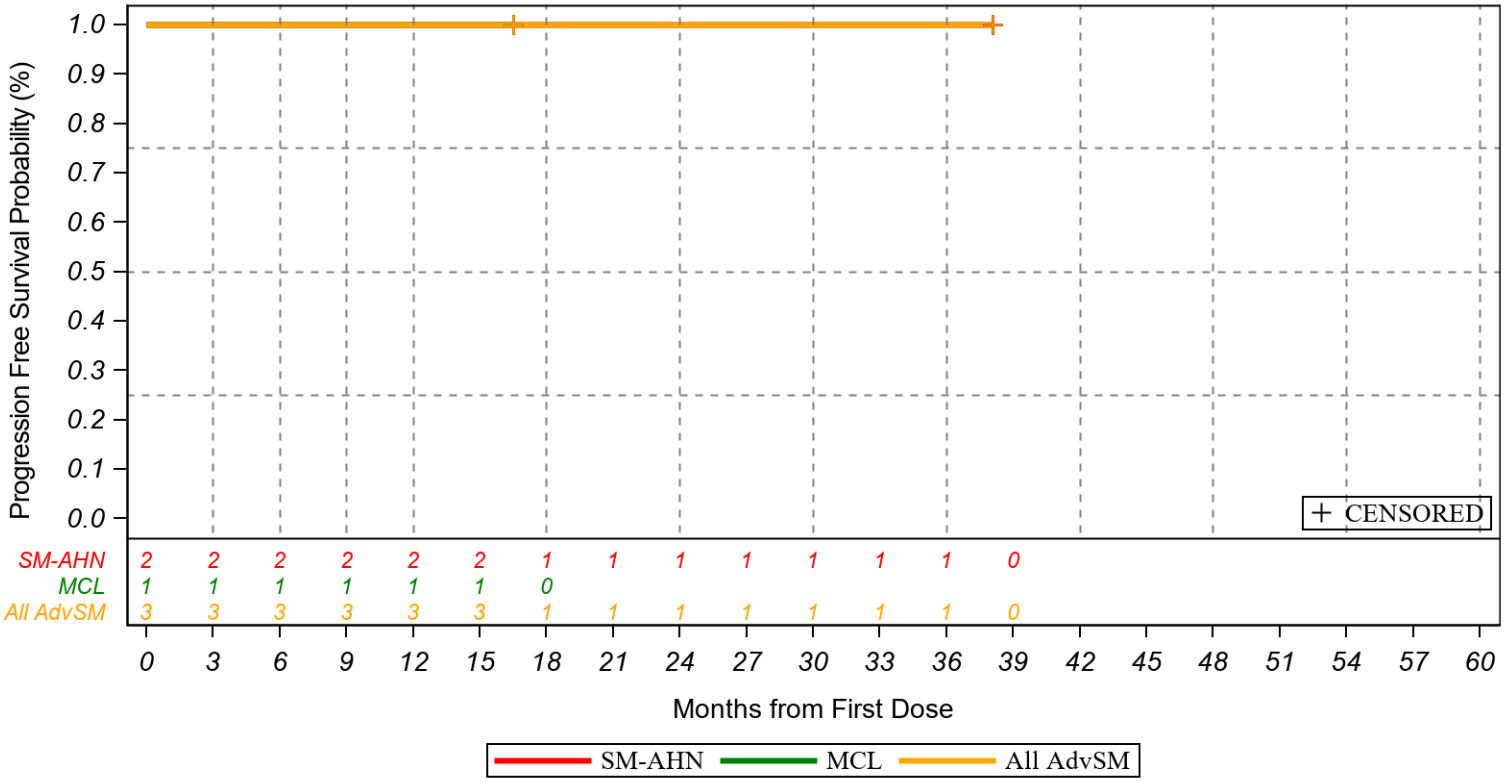
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_EUD120/Final/Programs/prod/adhoc/GermanyHTA/f-inv-dur-advsm.sas
Date: 10:26/18JAN2022

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: < 200 mg, Duration of Response



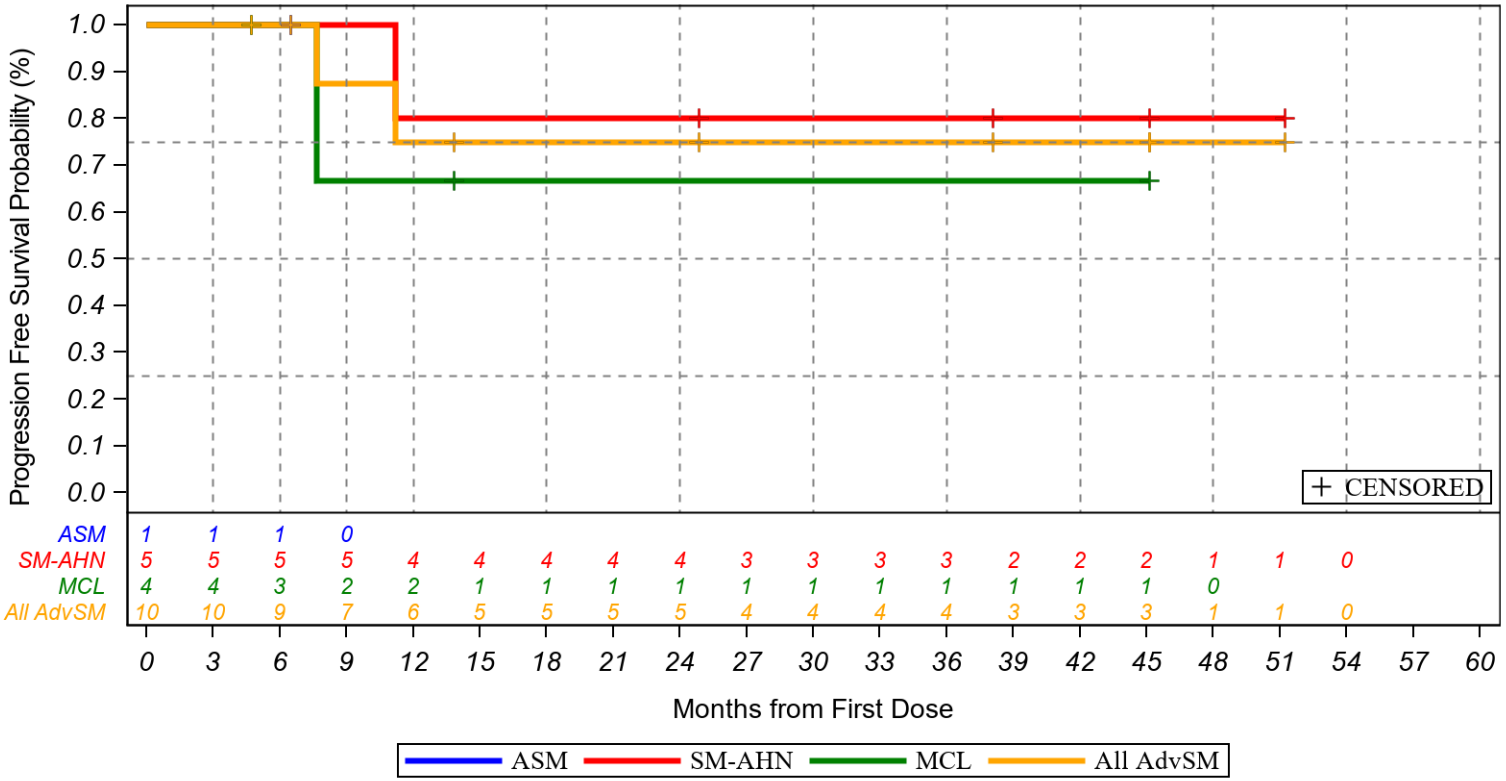
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_EUD120/Final/Programs/prod/adhoc/GermanyHTA/f-inv-dur-advsm.sas
Date: 10:26/18JAN2022

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: < 200 mg, Duration of CR+CRh+PR



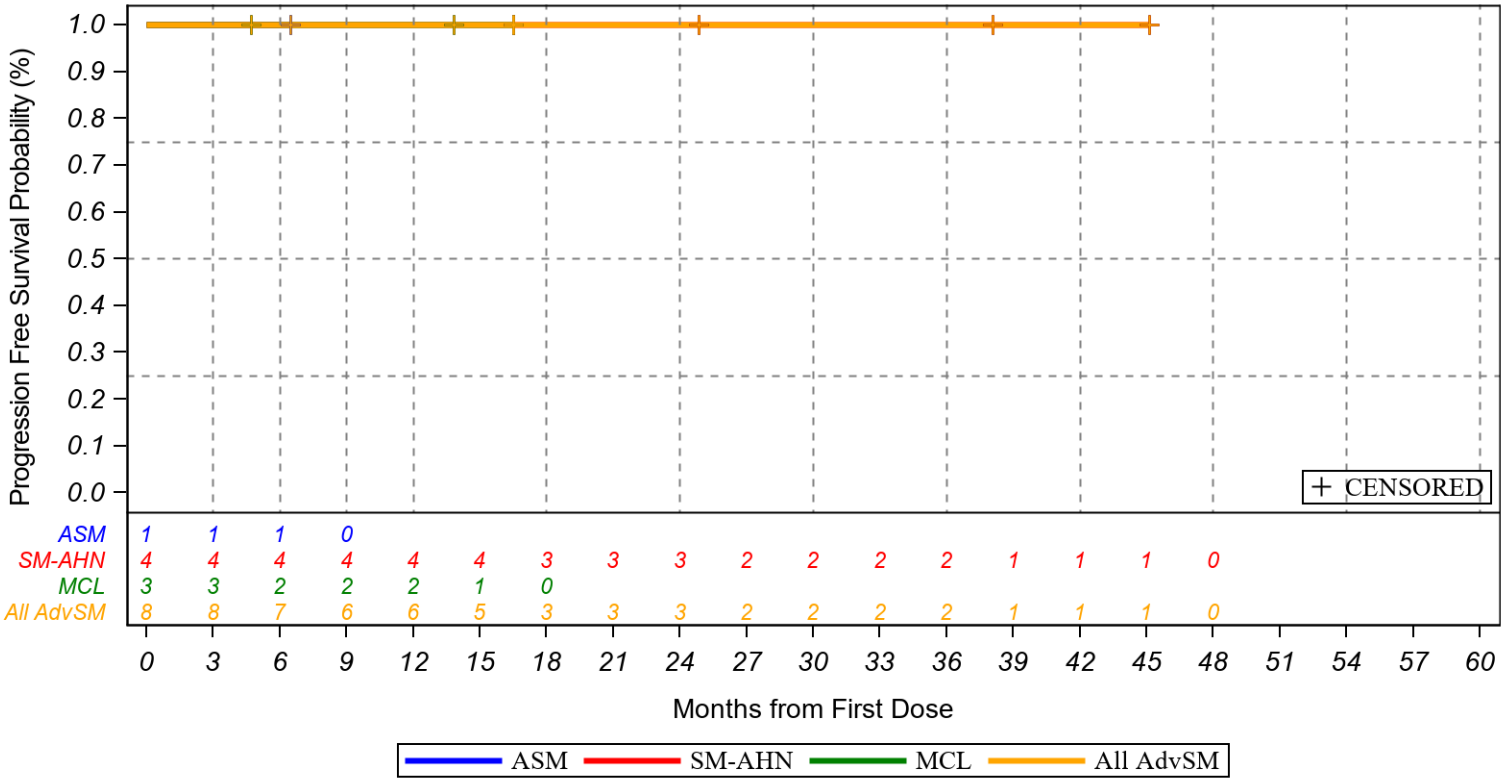
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_EUD120/Final/Programs/prod/adhoc/GermanyHTA/f-inv-dur-advsm.sas
Date: 10:26/18JAN2022

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: < 300 mg, Duration of Response



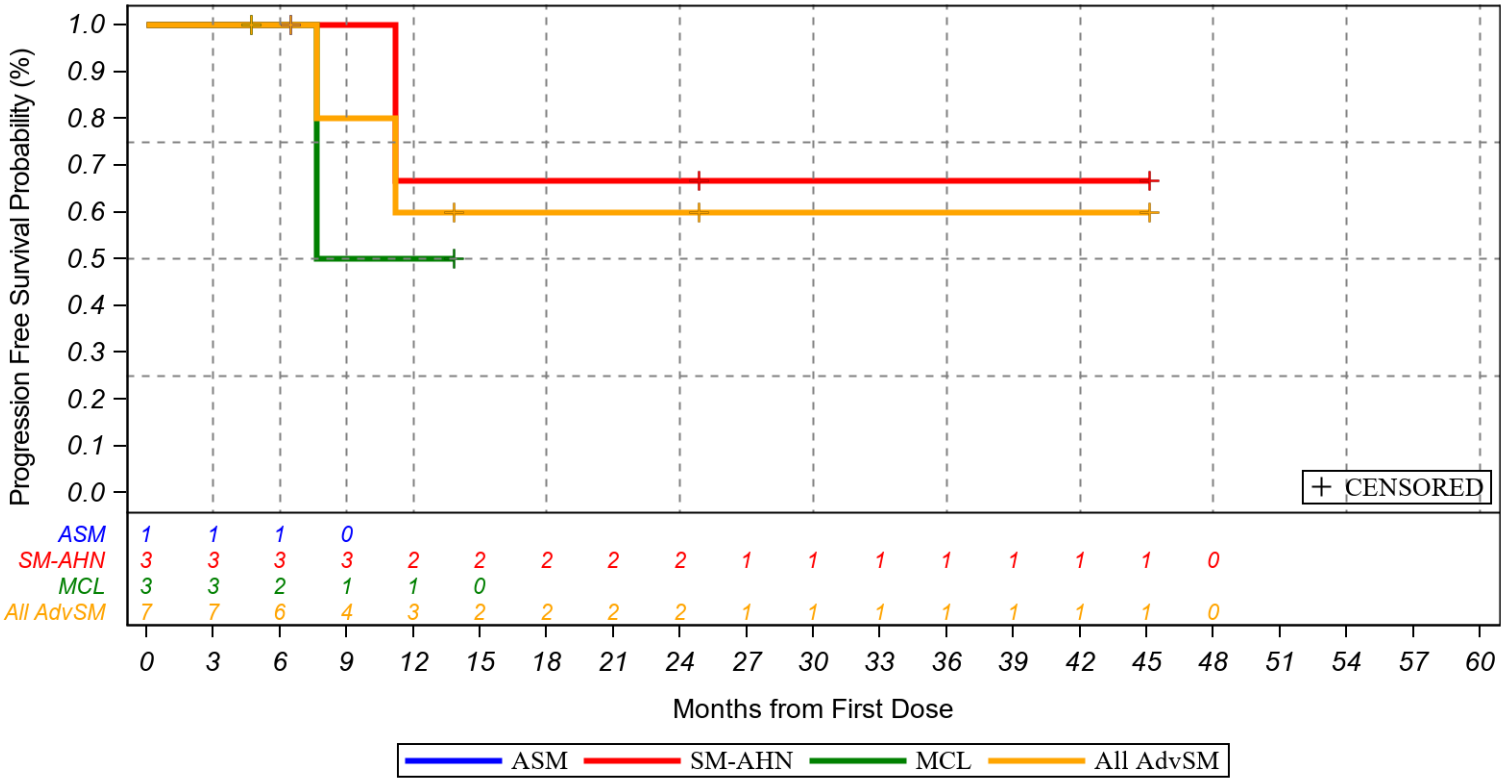
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_EUD120/Final/Programs/prod/adhoc/GermanyHTA/f-inv-dur-advsm.sas
Date: 10:26/18JAN2022

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: < 300 mg, Duration of CR+CRh+PR



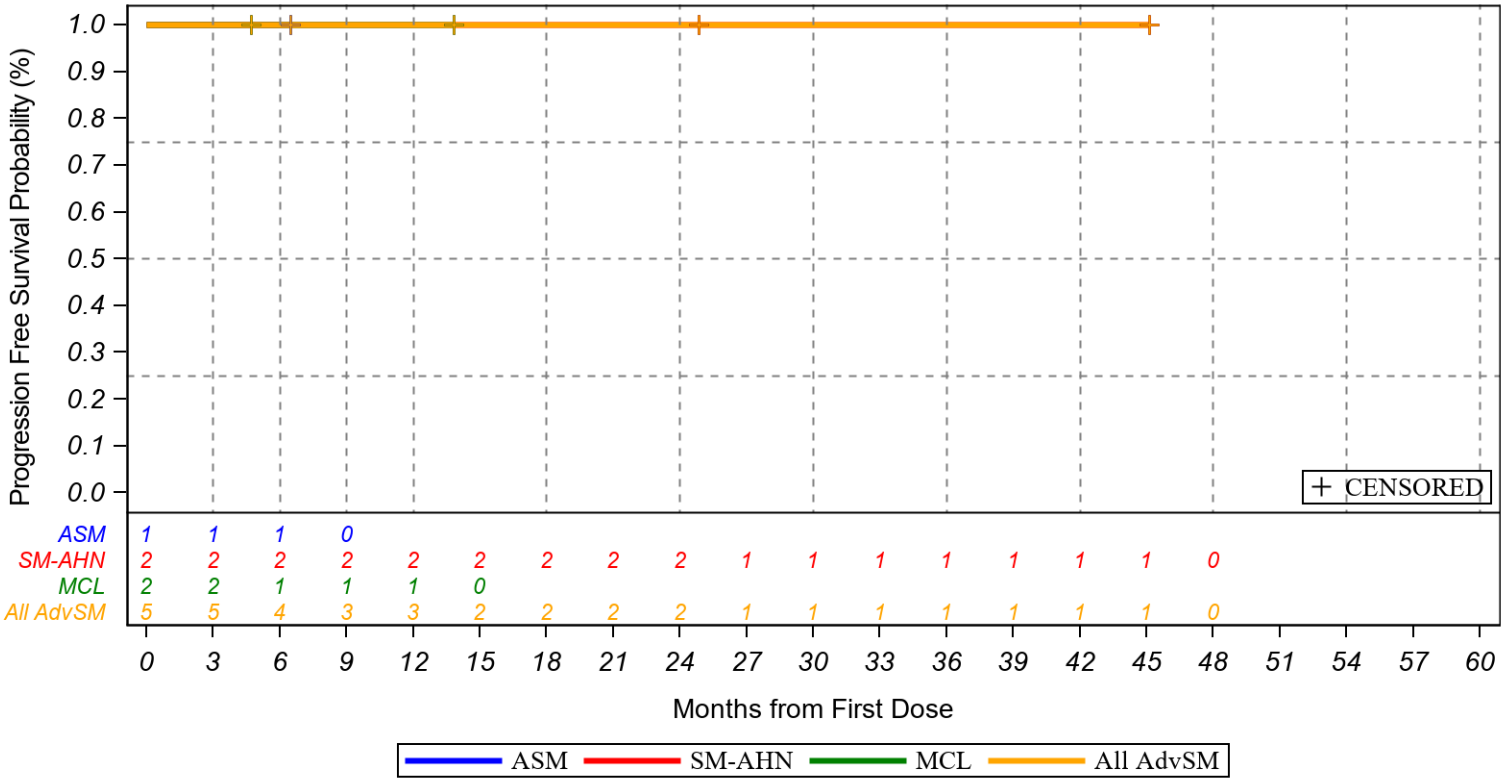
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_EUD120/Final/Programs/prod/adhoc/GermanyHTA/f-inv-dur-advsm.sas
Date: 10:26/18JAN2022

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: 200 mg, Duration of Response



Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_EUD120/Final/Programs/prod/adhoc/GermanyHTA/f-inv-dur-advsm.sas
Date: 10:26/18JAN2022

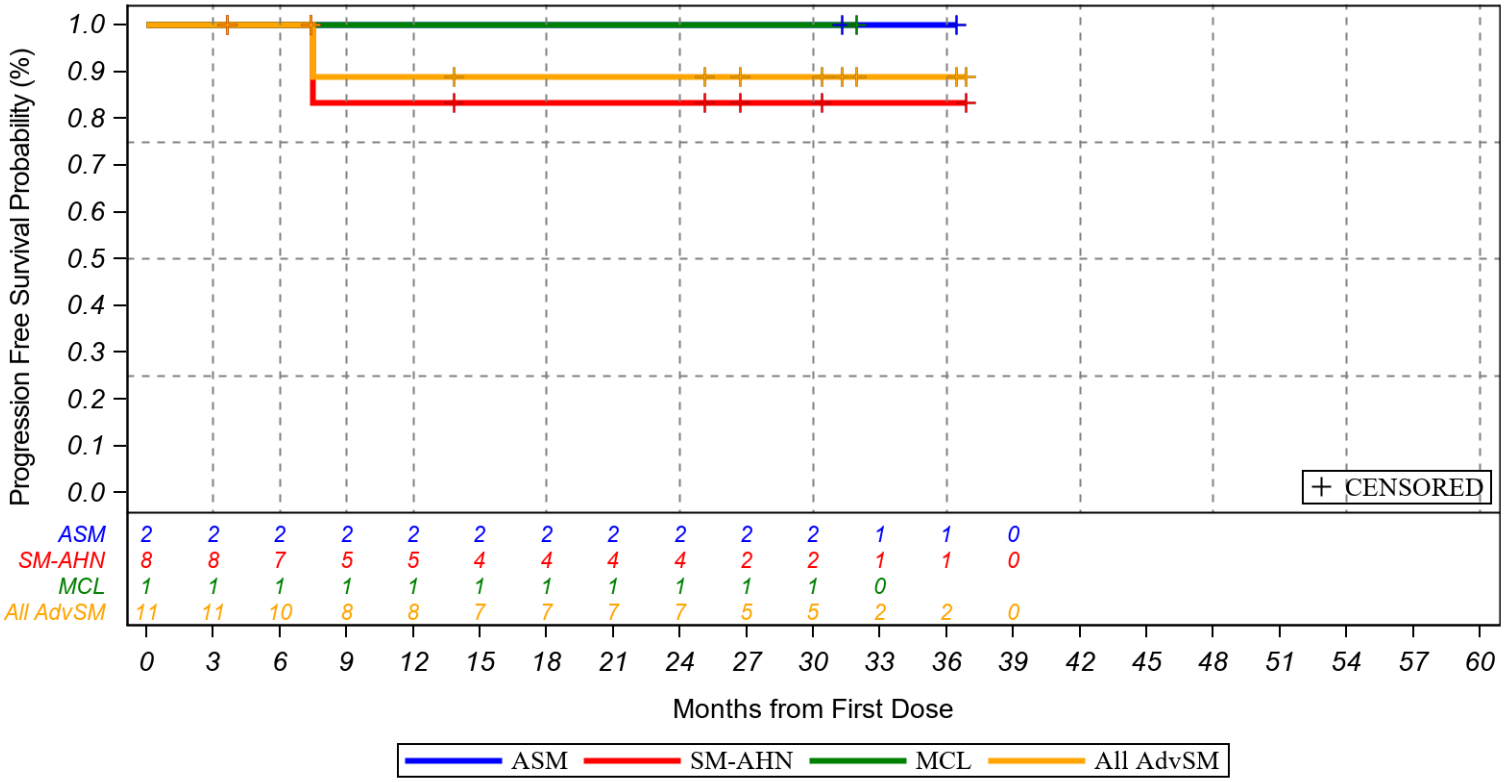
Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: 200 mg, Duration of CR+CRh+PR



Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.

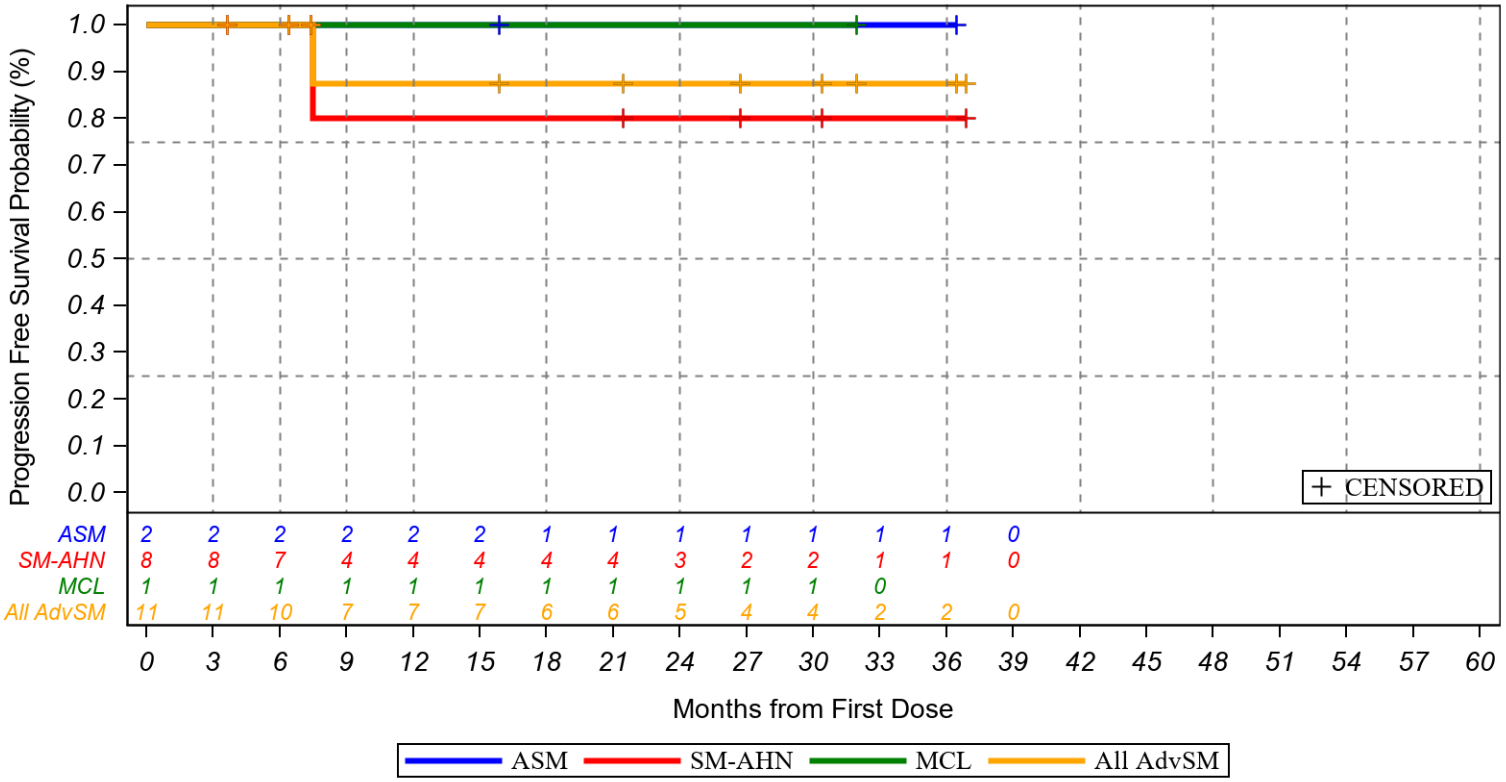
Program: ../BLU-285/ISE_2101_EUD120/Final/Programs/prod/adhoc/GermanyHTA/f-inv-dur-advsm.sas
Date: 10:26/18JAN2022

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: 300 mg, Duration of Response



Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_EUD120/Final/Programs/prod/adhoc/GermanyHTA/f-inv-dur-advsm.sas
Date: 10:26/18JAN2022

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: 300 mg, Duration of CR+CRh+PR



Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_EUD120/Final/Programs/prod/adhoc/GermanyHTA/f-inv-dur-advsm.sas
Date: 10:26/18JAN2022

Blueprint Medicines
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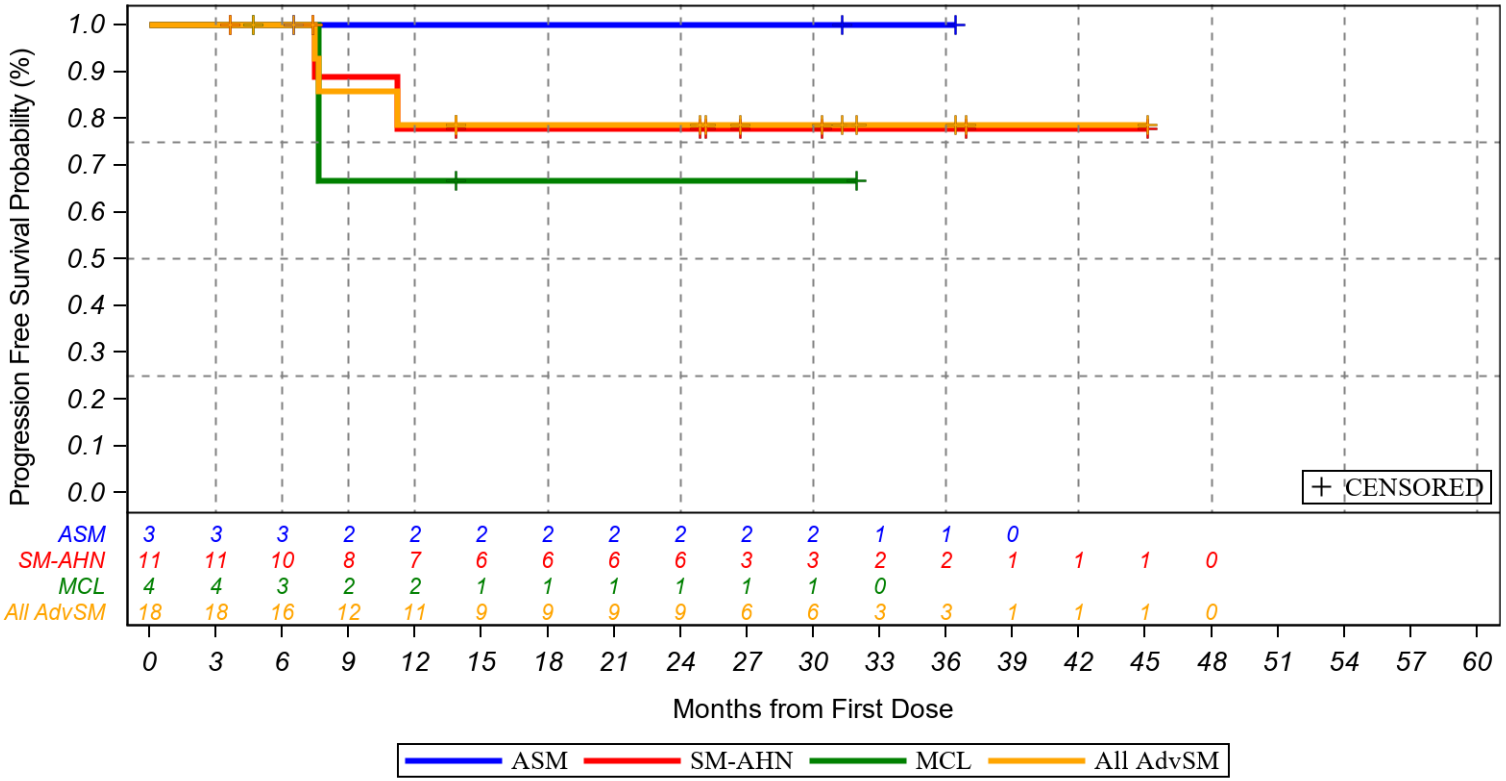
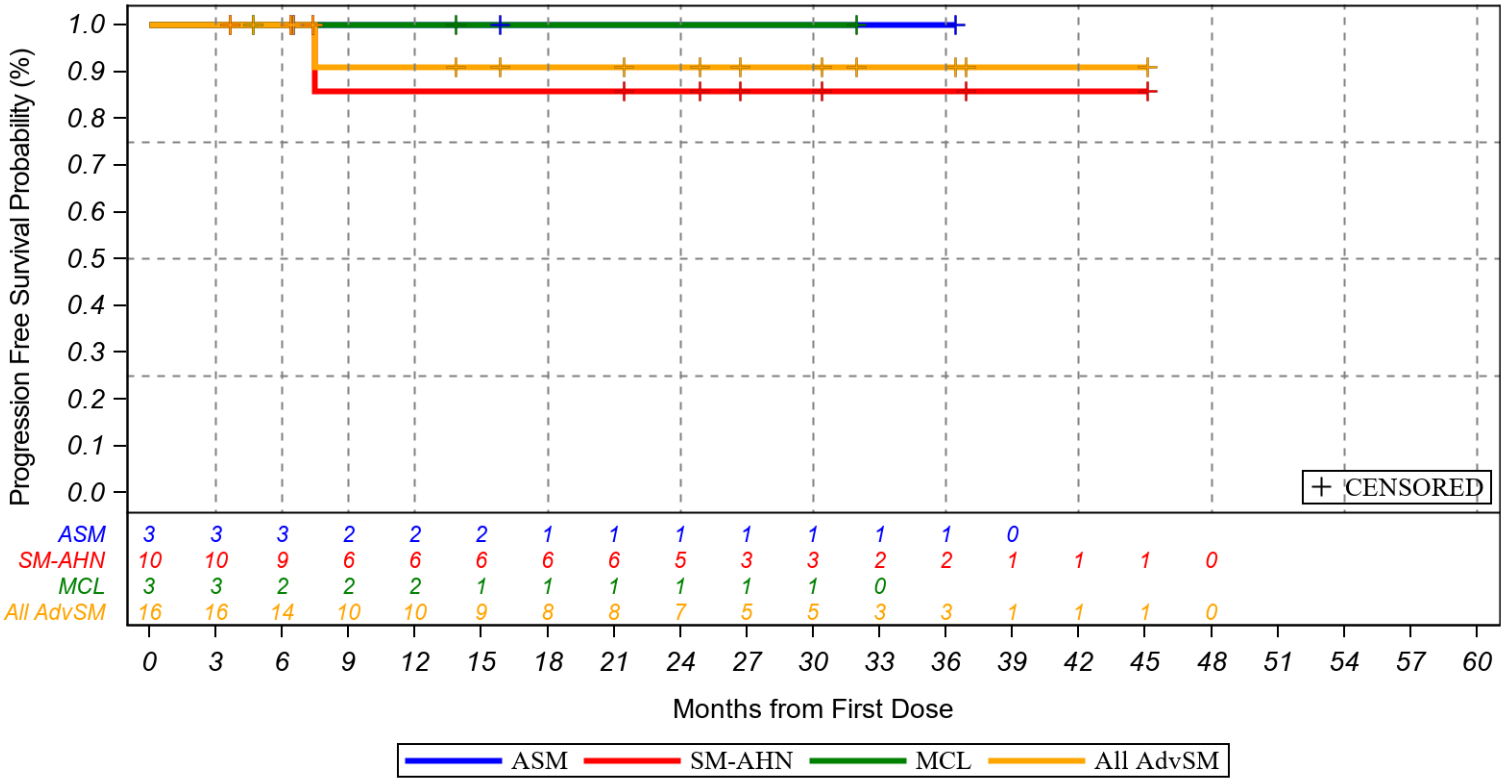
Avapritinib Systemic Mastocytosis Integrated Summary of Efficacy
BLU-285 SM Germany HTA Analysis
Cutoff date: 20apr2021

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: 200 mg and 300 mg, Duration of Response



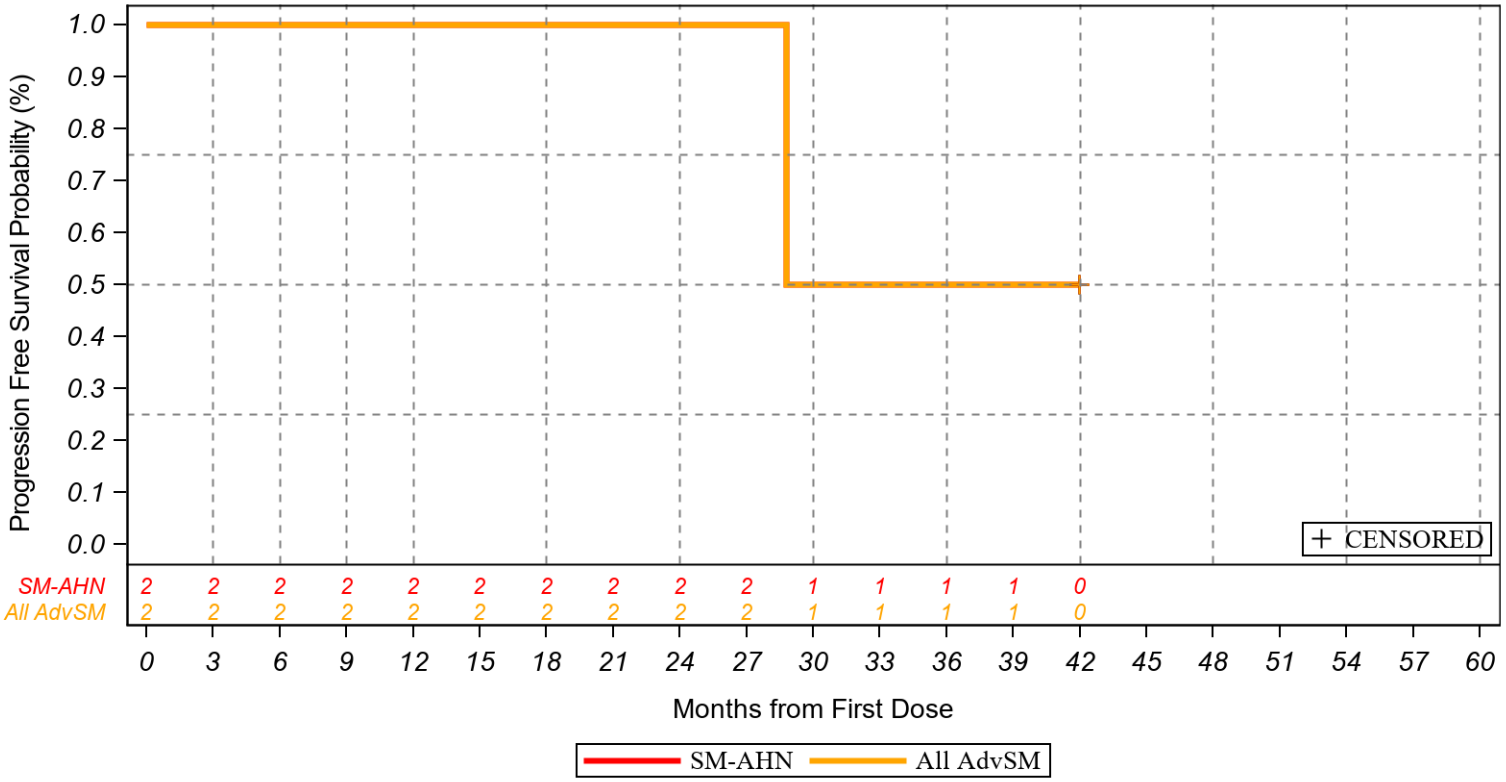
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_EUD120/Final/Programs/prod/adhoc/GermanyHTA/f-inv-dur-advsm.sas
Date: 10:26/18JAN2022

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: 200 mg and 300 mg, Duration of CR+CRh+PR



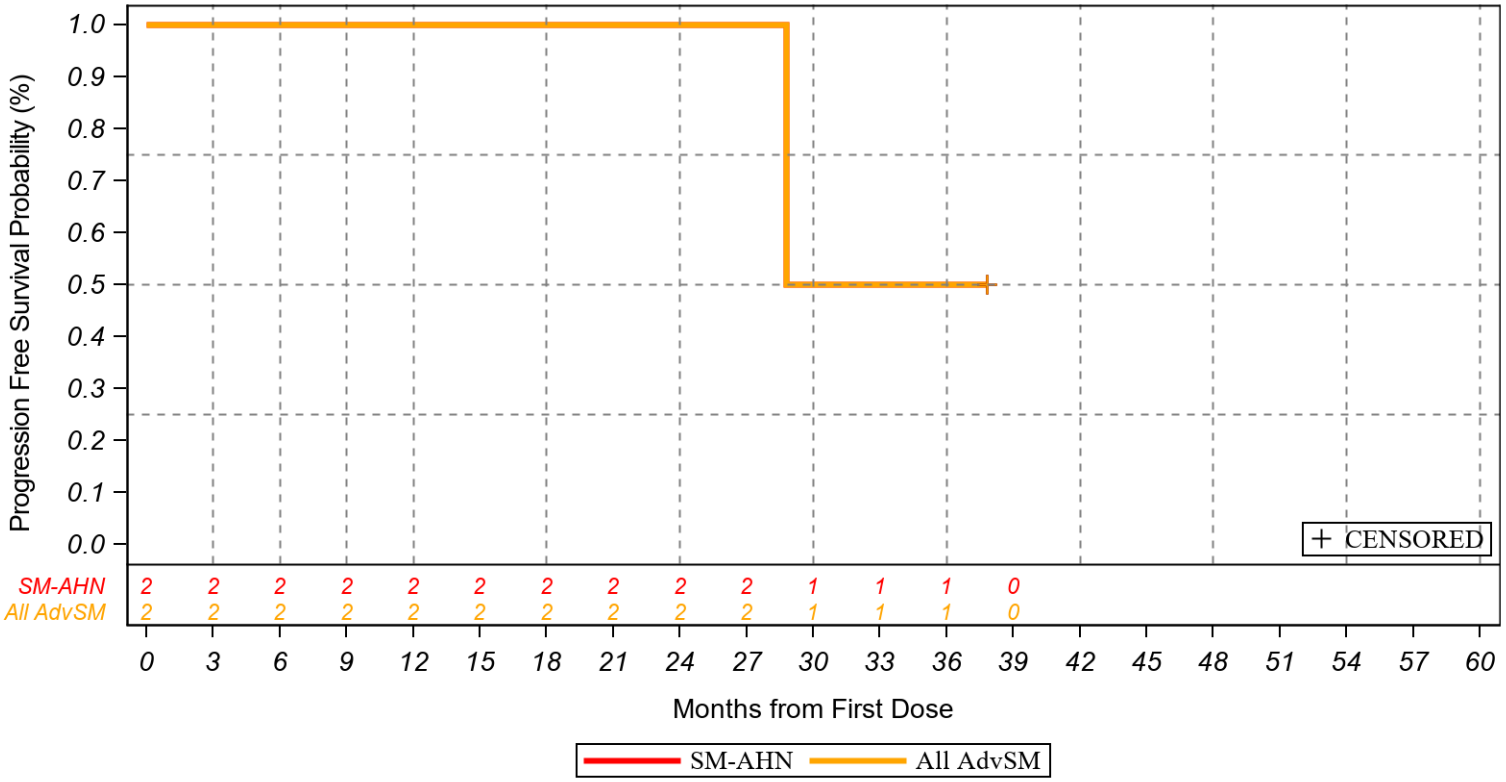
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_EUD120/Final/Programs/prod/adhoc/GermanyHTA/f-inv-dur-advsm.sas
Date: 10:26/18JAN2022

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: 400 mg, Duration of Response



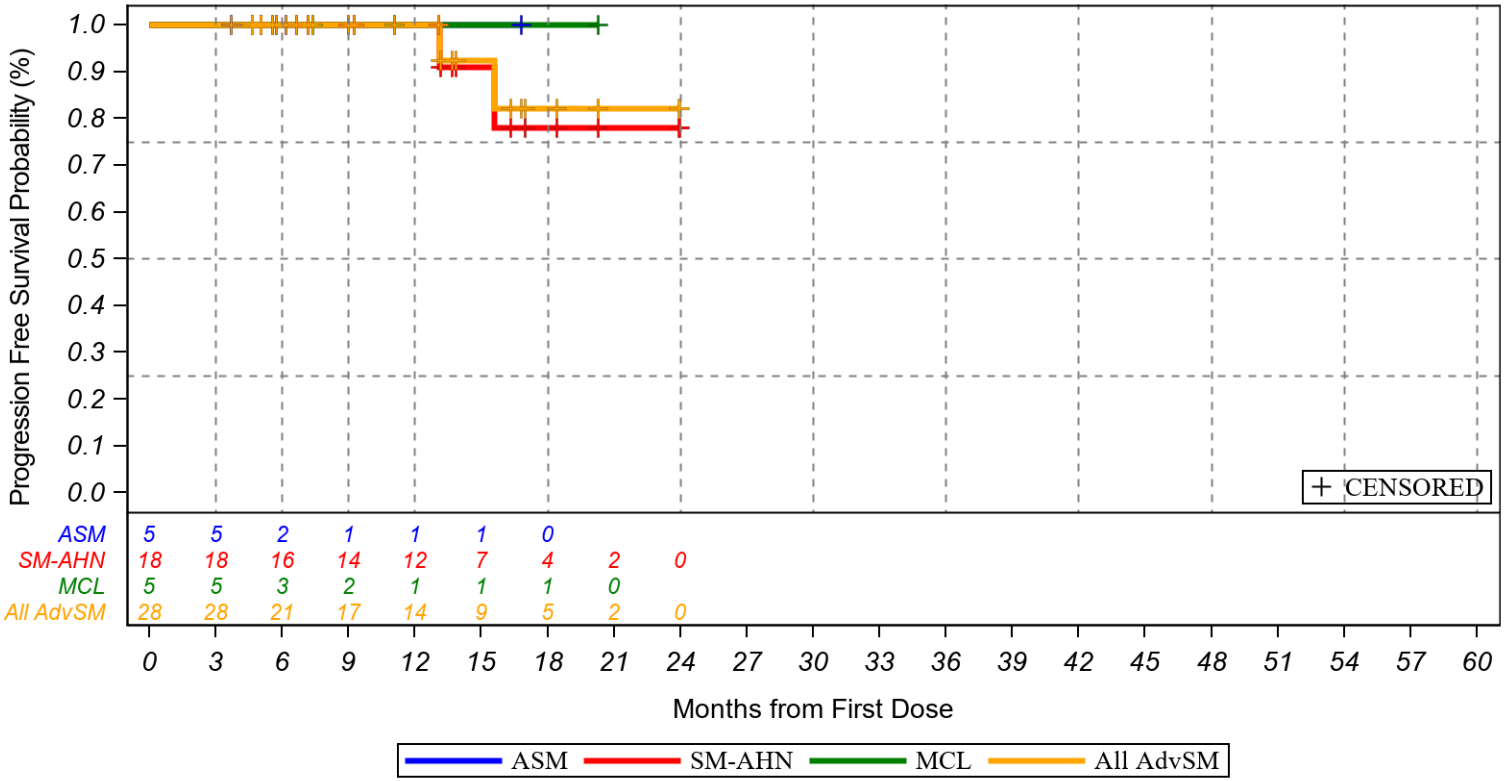
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_EUD120/Final/Programs/prod/adhoc/GermanyHTA/f-inv-dur-advsm.sas
Date: 10:26/18JAN2022

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: 400 mg, Duration of CR+CRh+PR



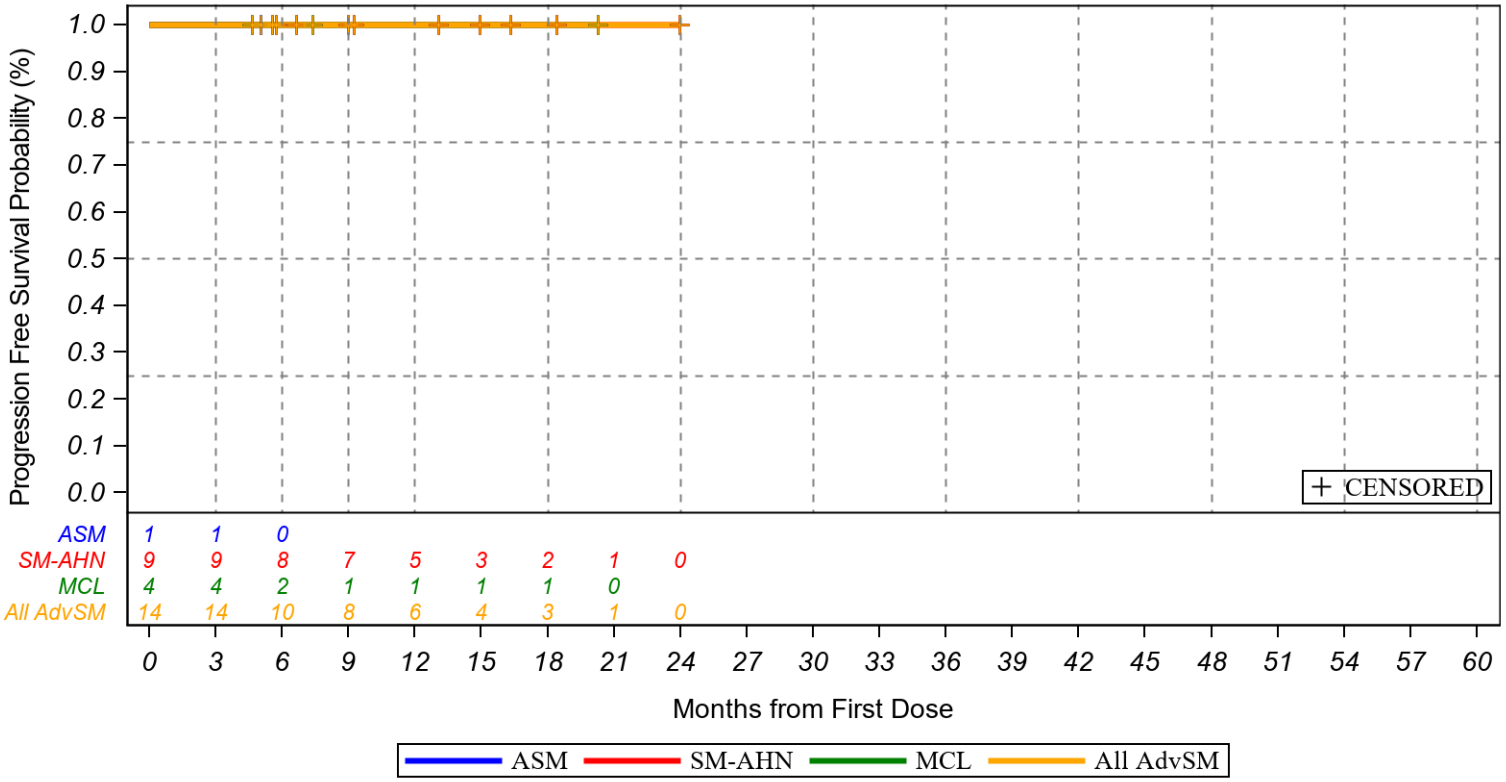
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_EUD120/Final/Programs/prod/adhoc/GermanyHTA/f-inv-dur-advsm.sas
Date: 10:26/18JAN2022

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study BLU-285-2202
Starting Dose: Overall, Duration of Response



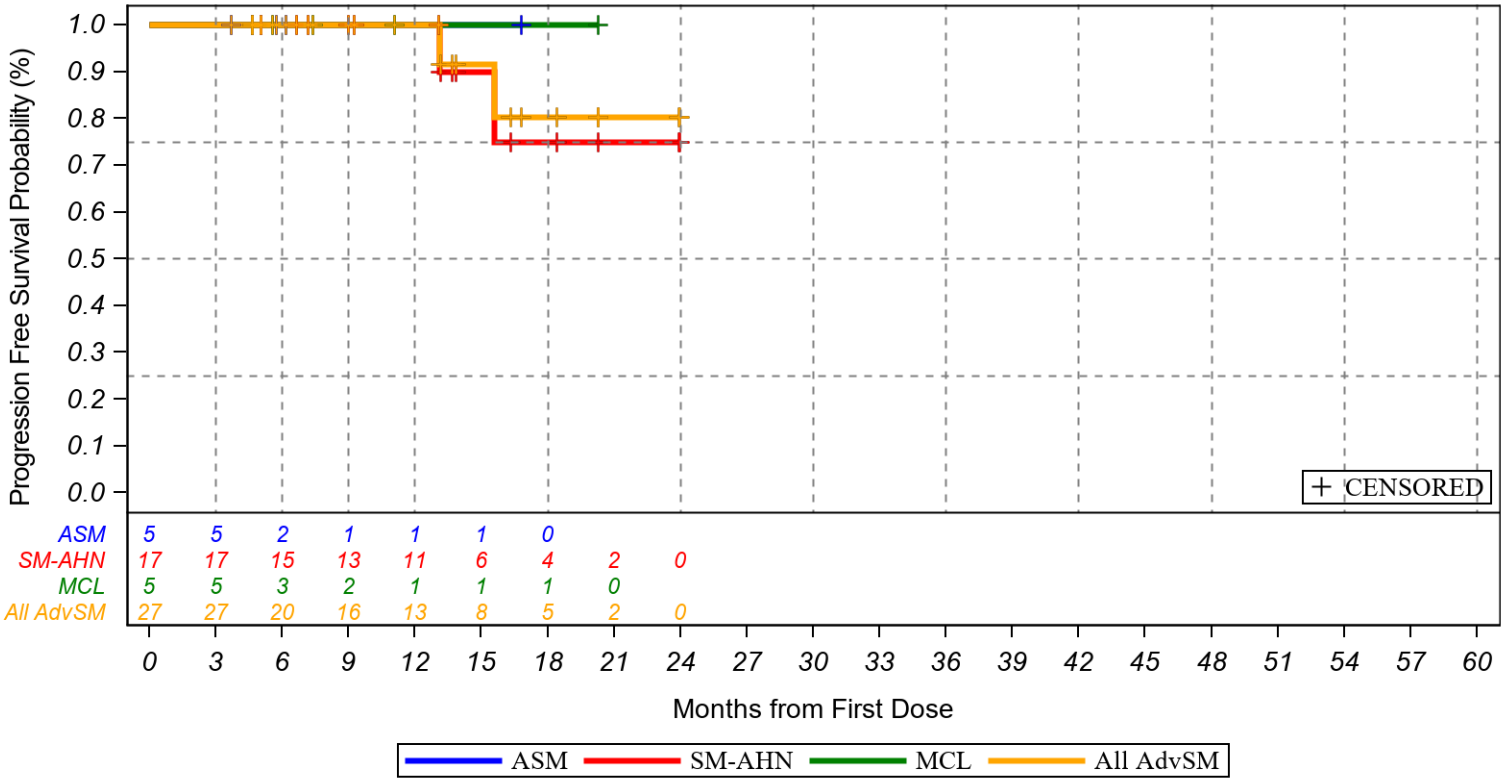
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_EUD120/Final/Programs/prod/adhoc/GermanyHTA/f-inv-dur-advsm.sas
Date: 10:26/18JAN2022

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study BLU-285-2202
Starting Dose: Overall, Duration of CR+CRh+PR



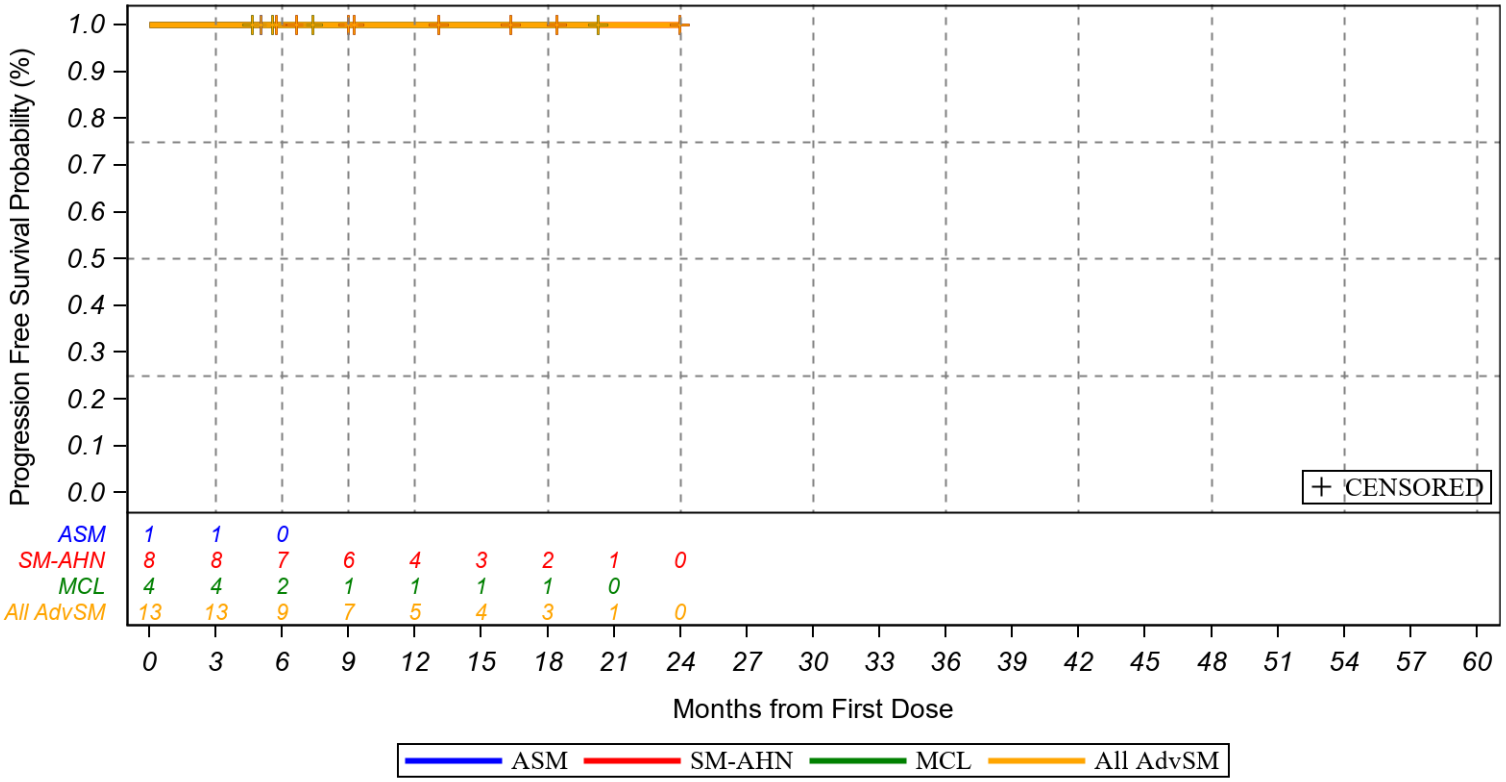
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_EUD120/Final/Programs/prod/adhoc/GermanyHTA/f-inv-dur-advsm.sas
Date: 10:26/18JAN2022

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study BLU-285-2202
Starting Dose: 200 mg, Duration of Response



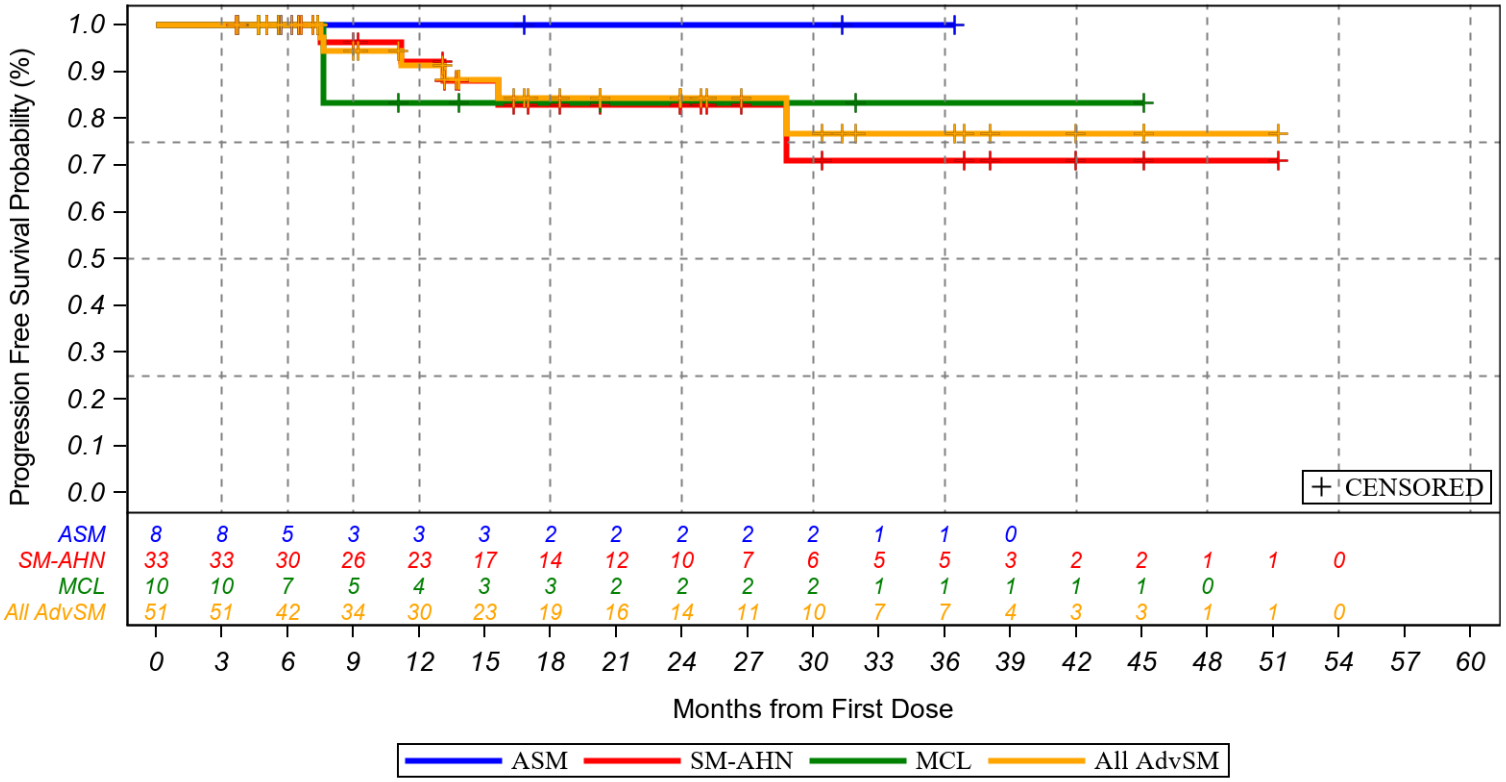
Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_EUD120/Final/Programs/prod/adhoc/GermanyHTA/f-inv-dur-advsm.sas
Date: 10:26/18JAN2022

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Study BLU-285-2202
Starting Dose: 200 mg, Duration of CR+CRh+PR



Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_EUD120/Final/Programs/prod/adhoc/GermanyHTA/f-inv-dur-advsm.sas
Date: 10:26/18JAN2022

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall, Duration of Response



Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
Program: ../BLU-285/ISE_2101_EUD120/Final/Programs/prod/adhoc/GermanyHTA/f-inv-dur-advsm.sas
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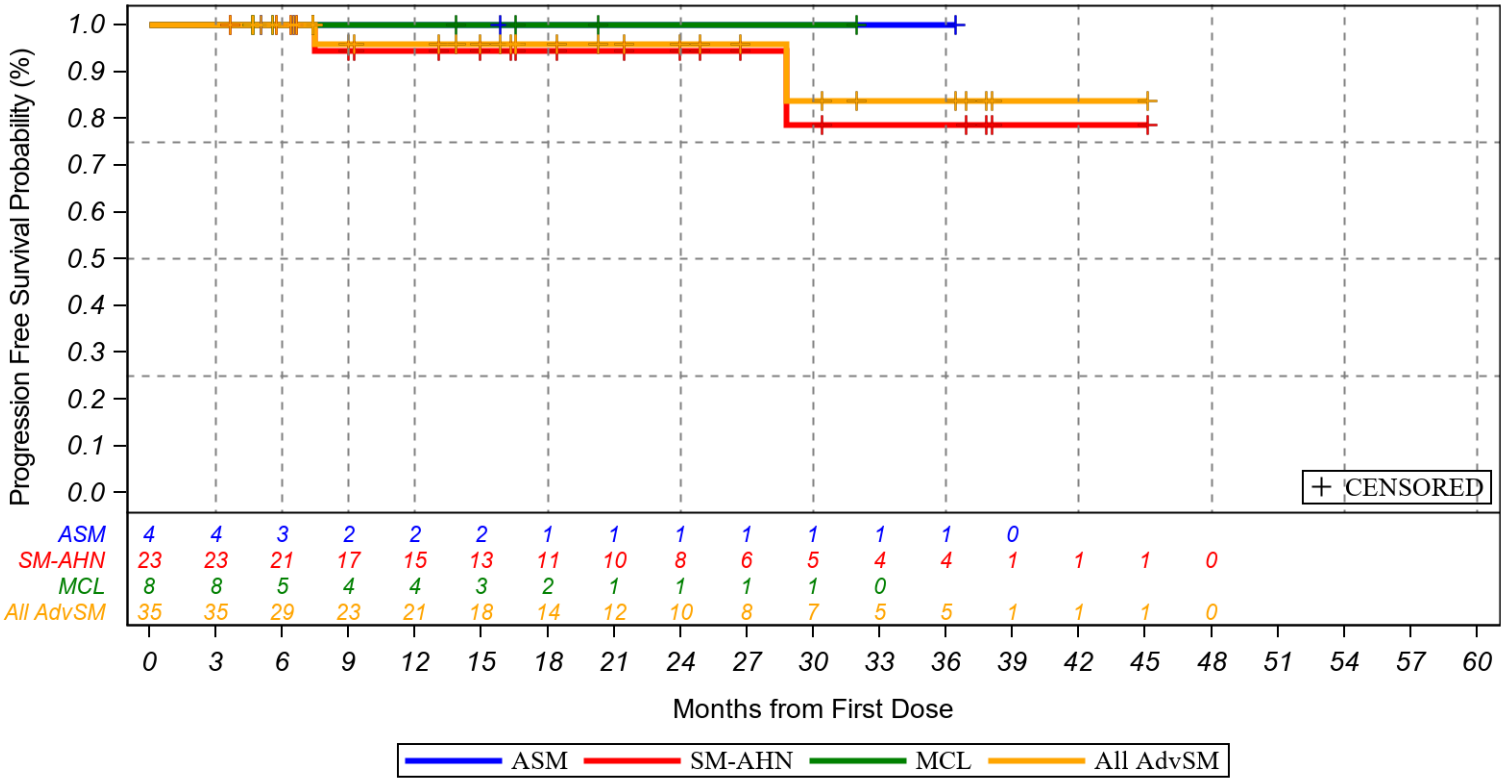
Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall, Duration of CR+CRh+PR



Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
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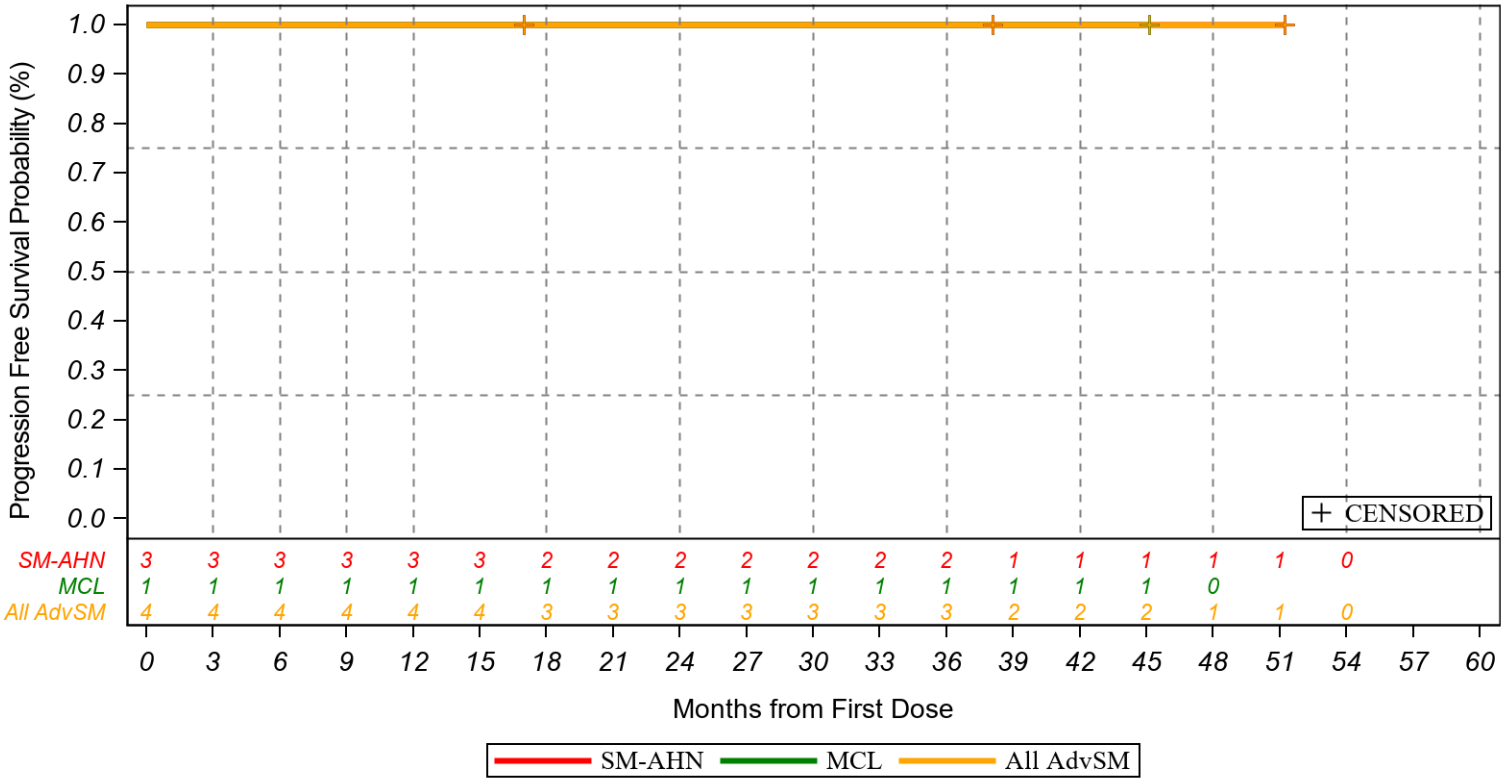
Date: 10:26/18JAN2022

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg, Duration of Response



Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
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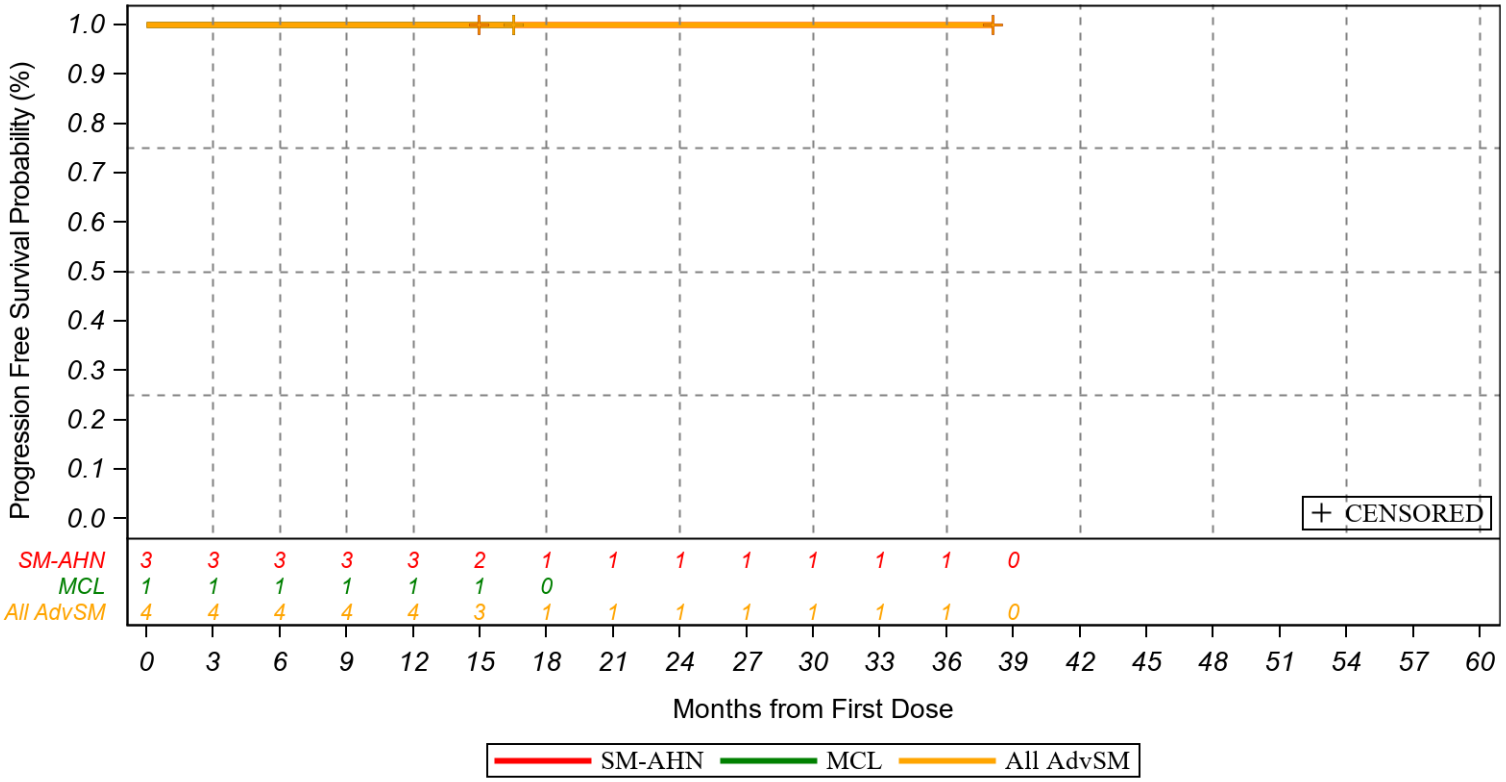
Date: 10:26/18JAN2022

Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg, Duration of CR+CRh+PR



Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
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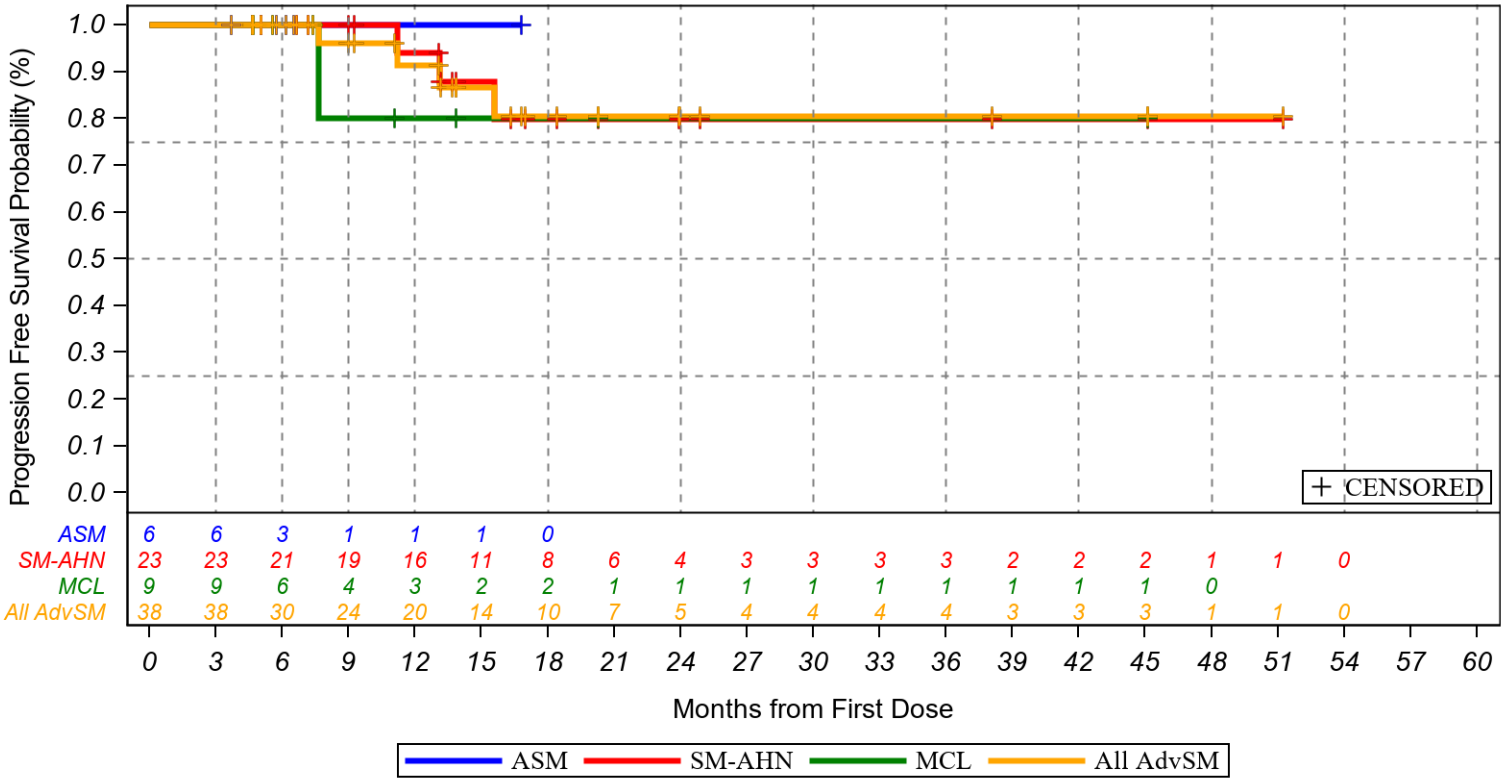
Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg, Duration of Response



Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
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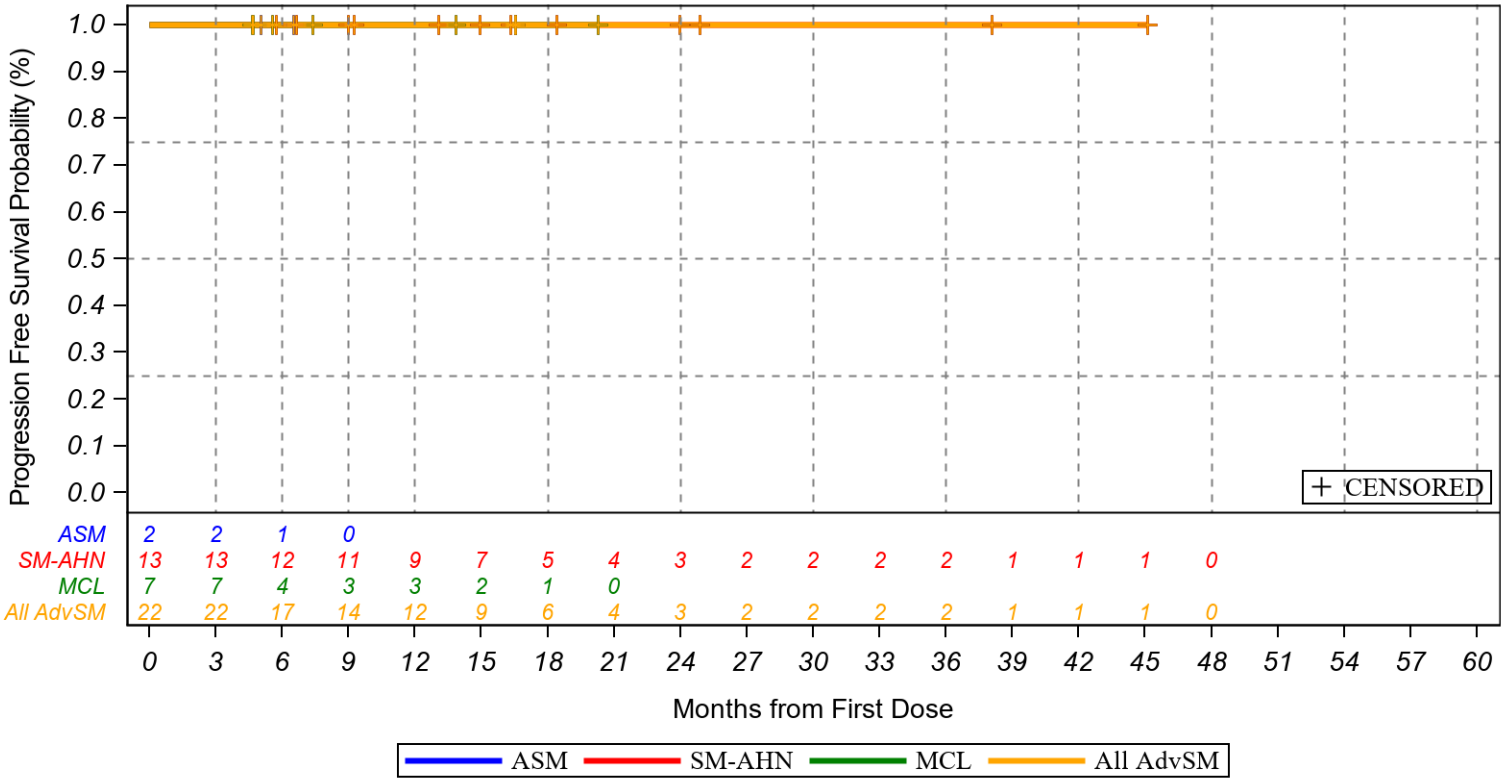
Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg, Duration of CR+CRh+PR



Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
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Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg, Duration of Response

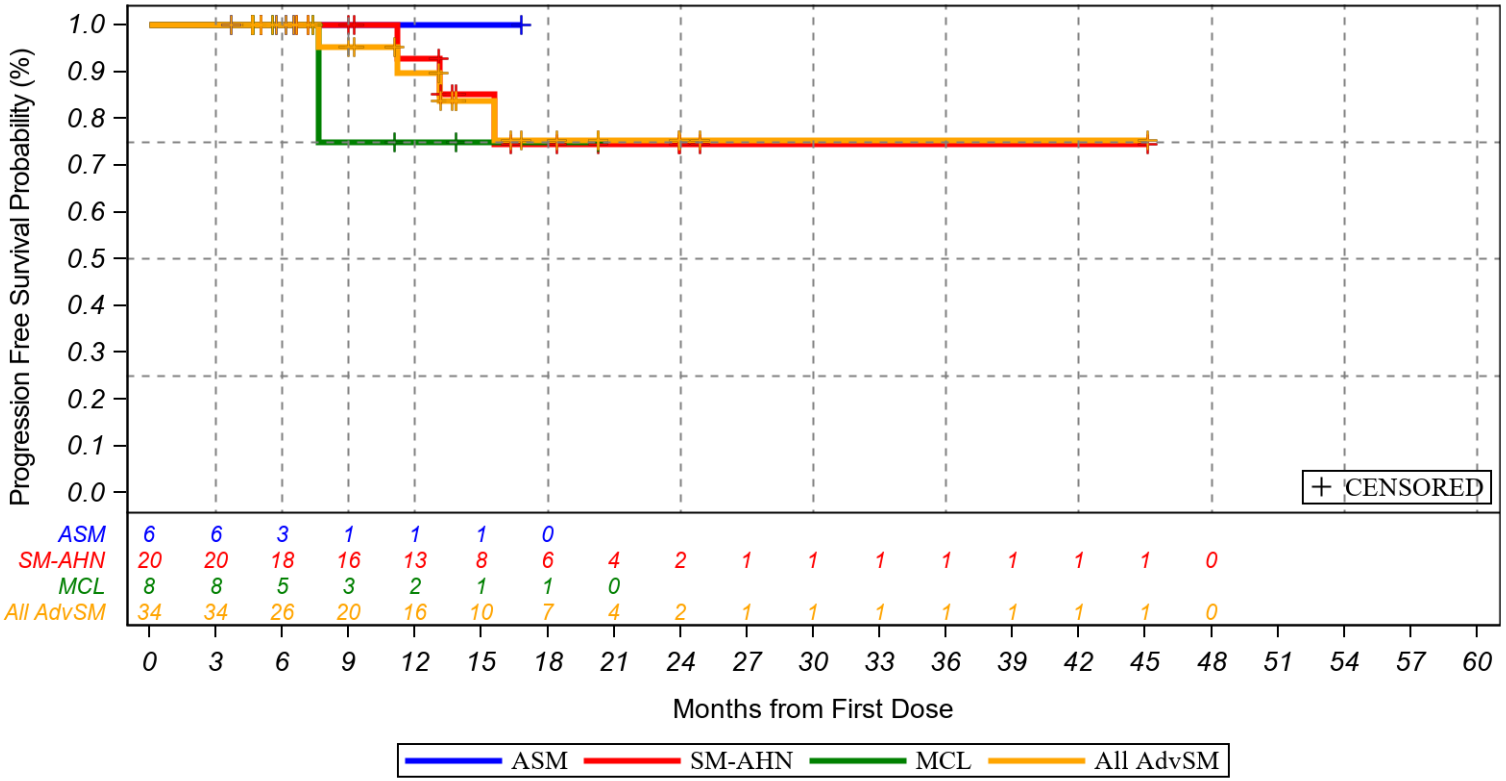

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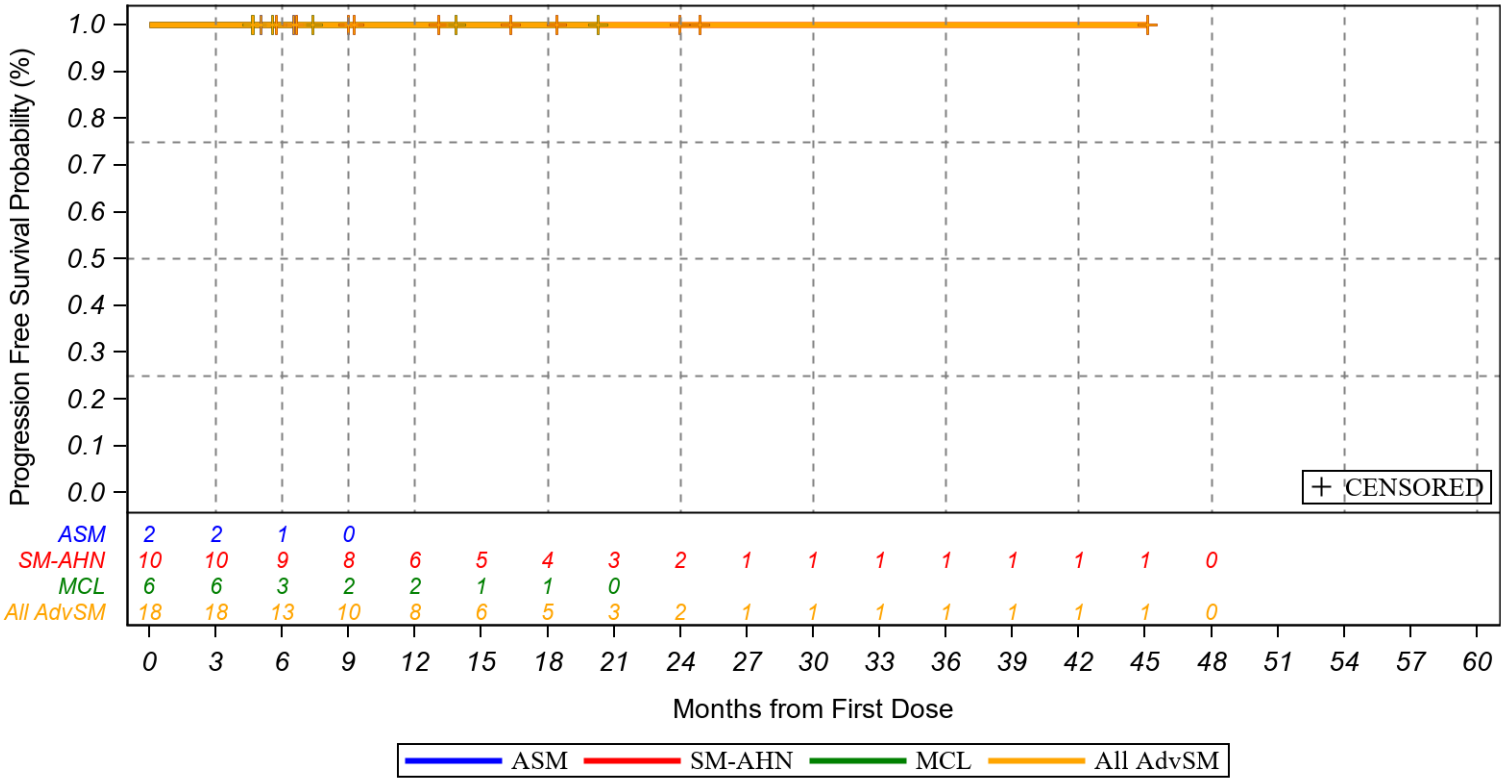
Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg, Duration of CR+CRh+PR



Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
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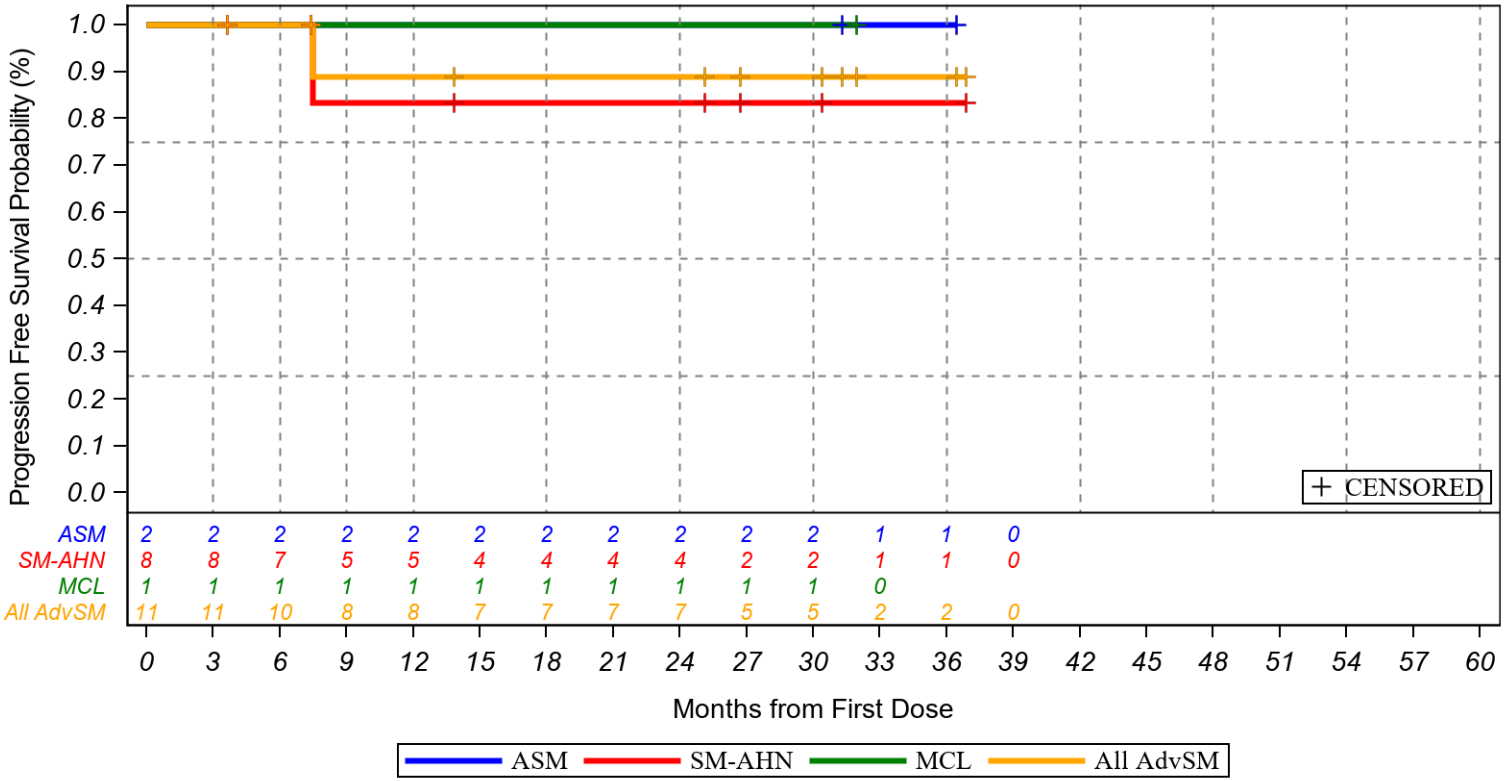
Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg, Duration of Response



Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
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Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg, Duration of CR+CRh+PR

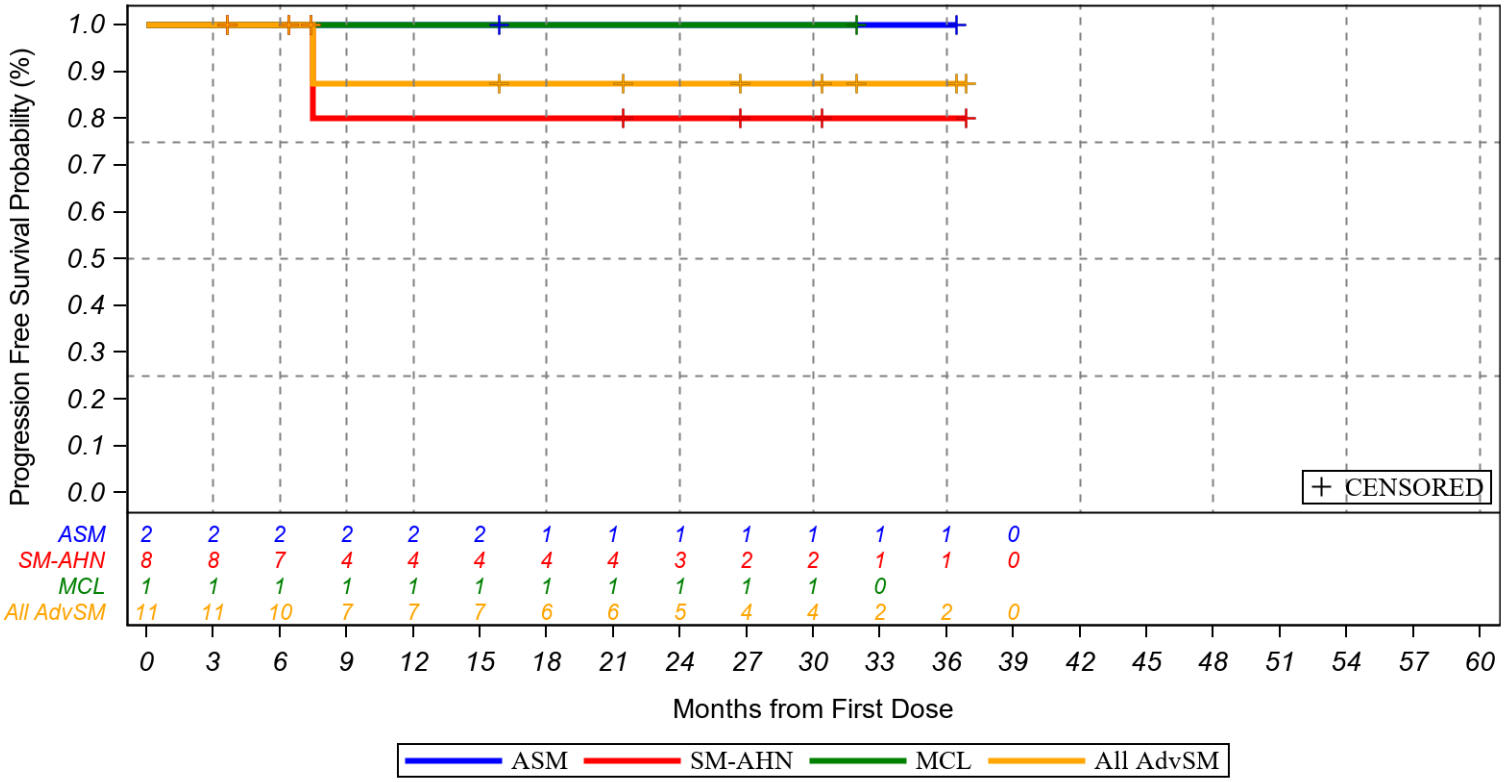

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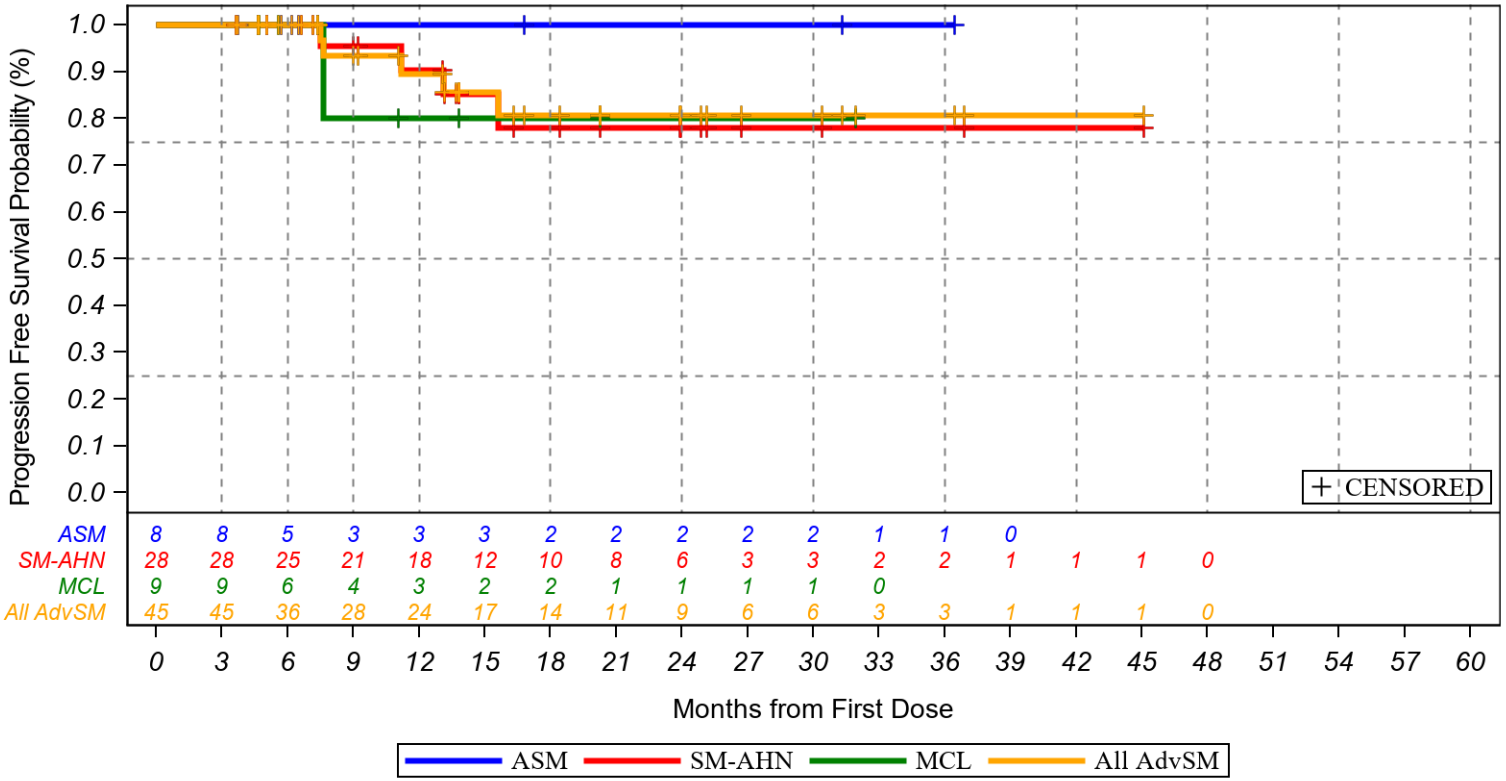
Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg, Duration of Response



Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
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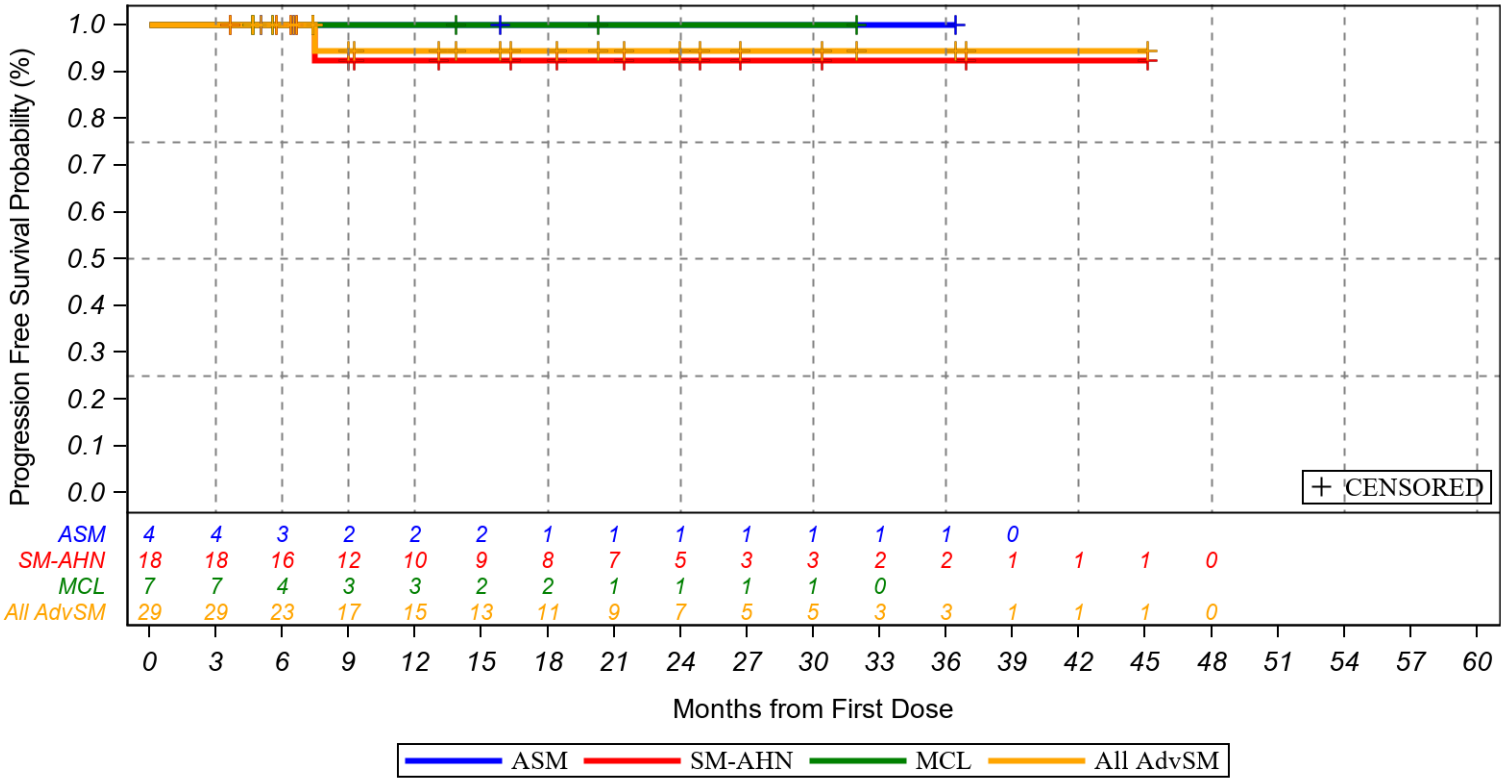
Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg, Duration of CR+CRh+PR



Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
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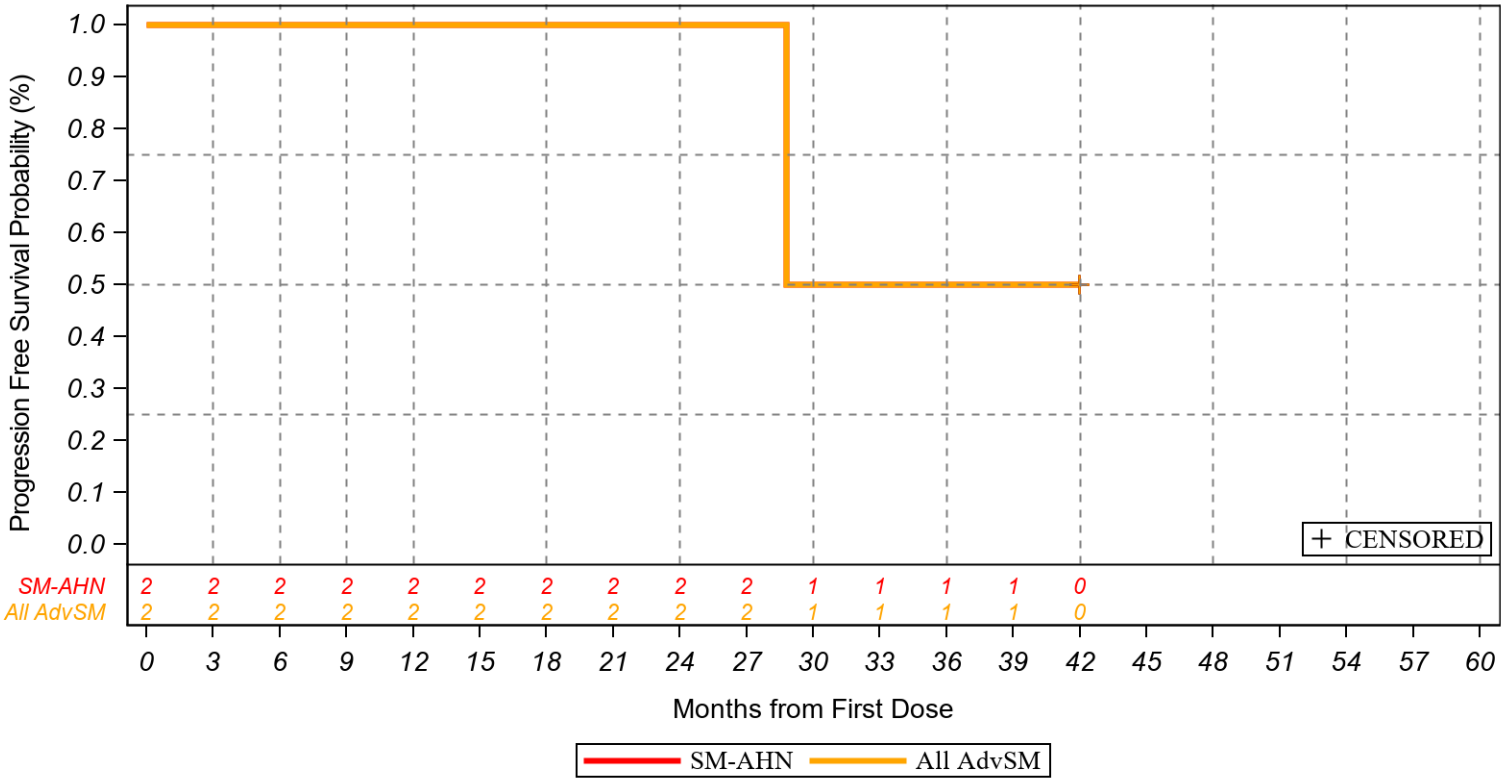
Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg, Duration of Response



Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
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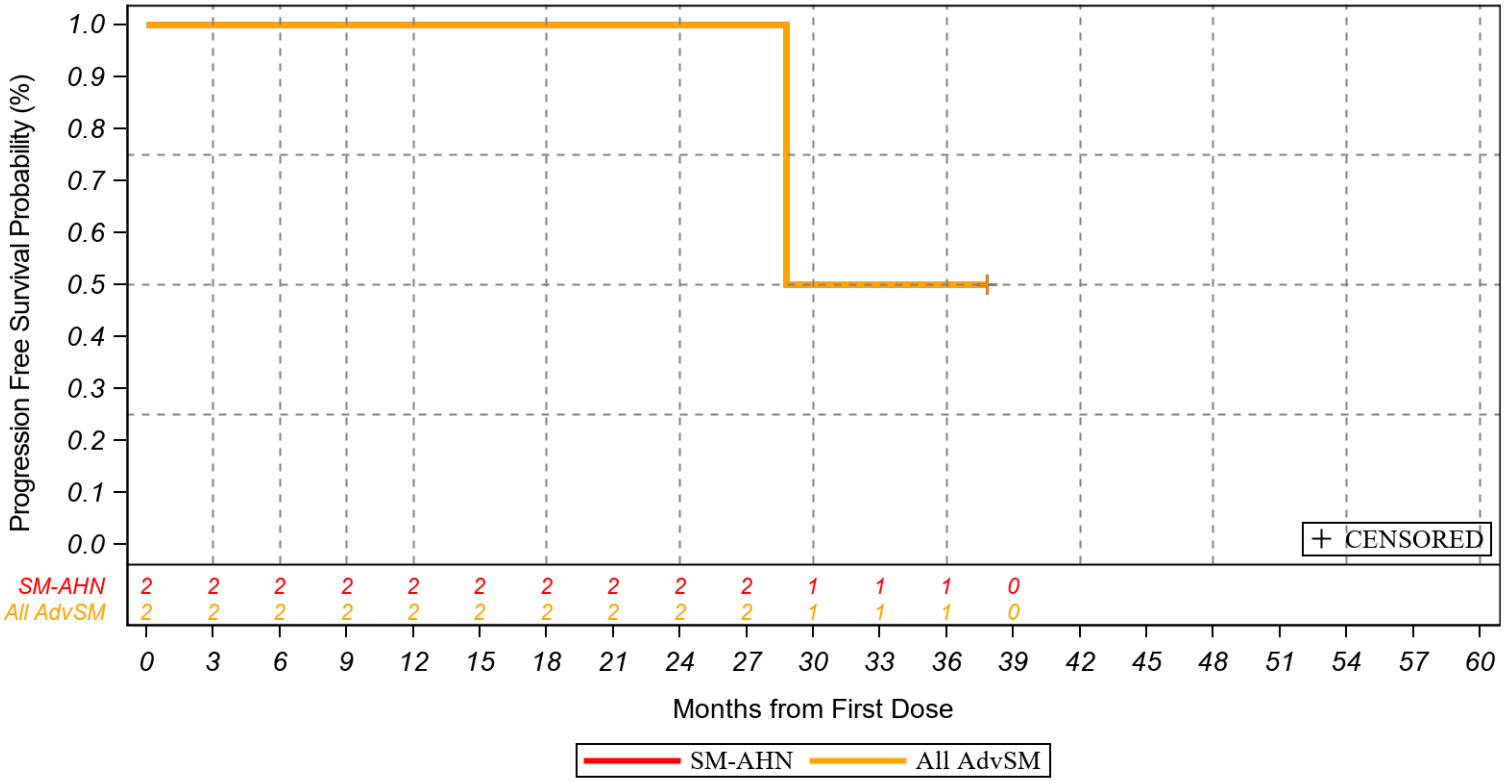
Figure 35.2.2.2
Kaplan-Meier Curves of Investigator Assessed Duration of Response
RAC-RE Population with at least one prior antineoplastic therapy - Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg, Duration of CR+CRh+PR



Notes: Duration of response is defined as the time in months from first documented response to the date of first documented PD/LoR or death due to any cause, whichever occurs first. Patients without confirmed response are excluded from this analysis. Patients who are still in response at time of data cutoff are censored at their last valid assessment.
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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: Overall
Prior Antineoplastic Therapy = Yes
Responders (CR+PR+CI)

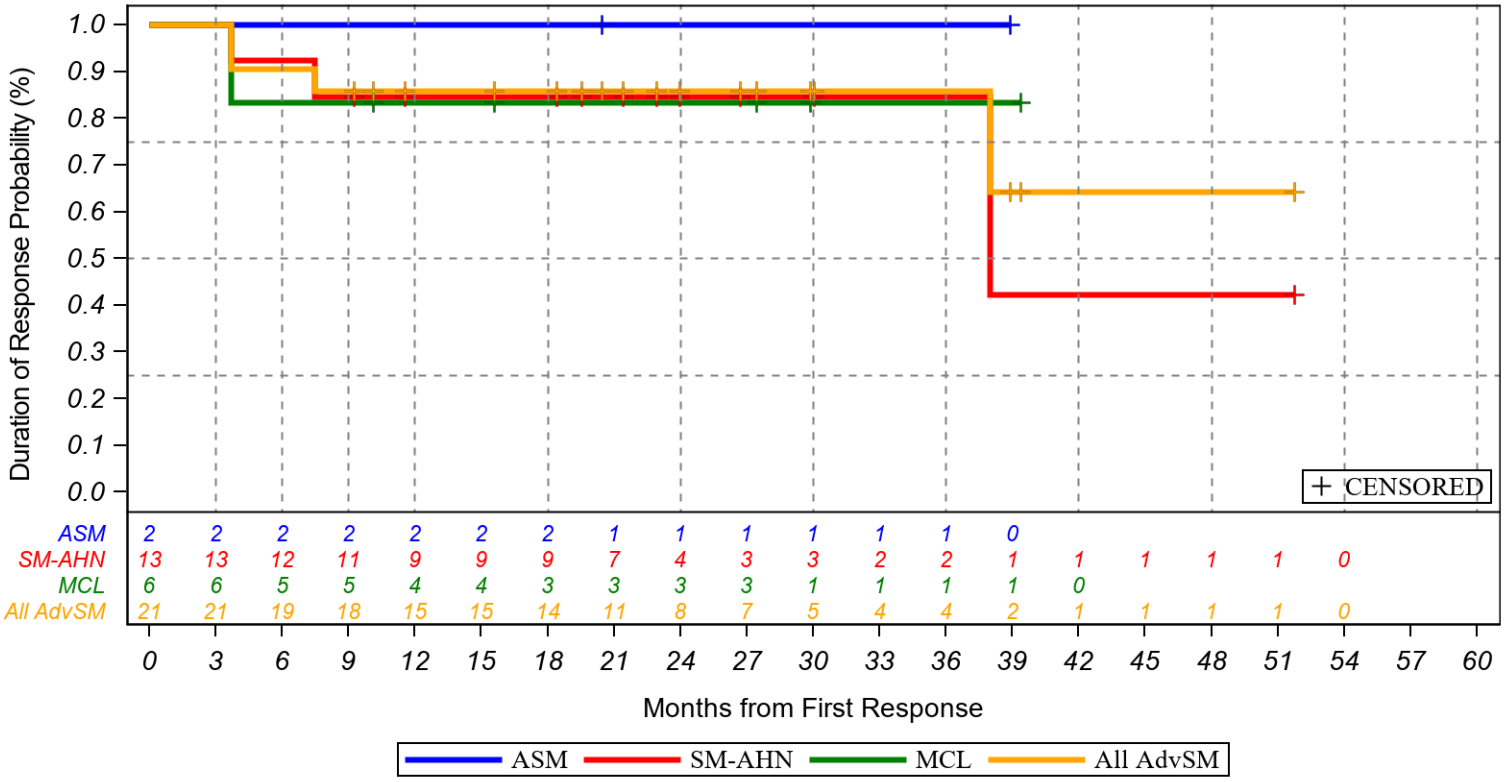

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: Overall
Prior Antineoplastic Therapy = Yes
Responders (CR+PR)

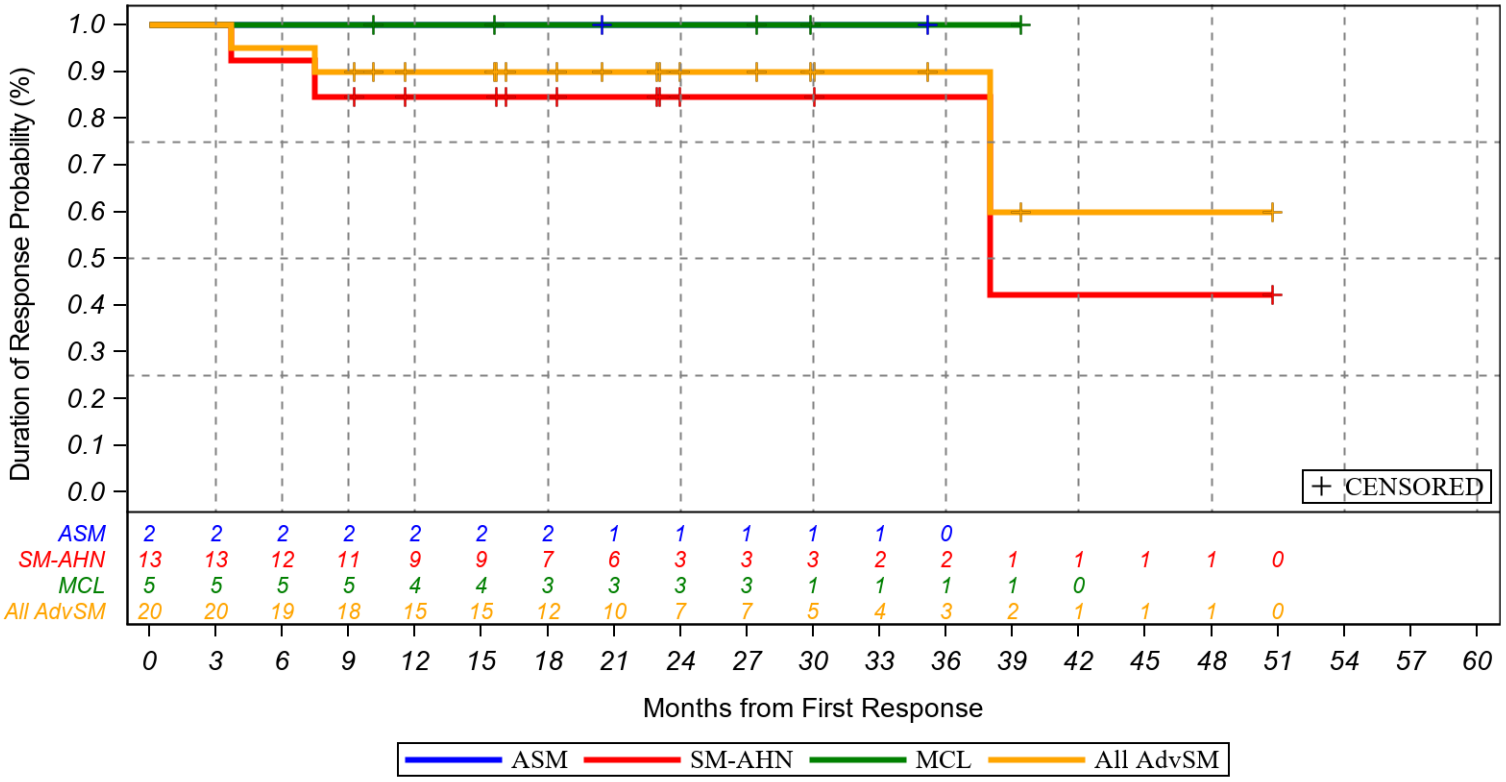

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: Overall
Prior Antineoplastic Therapy = No
Responders (CR+PR+CI)

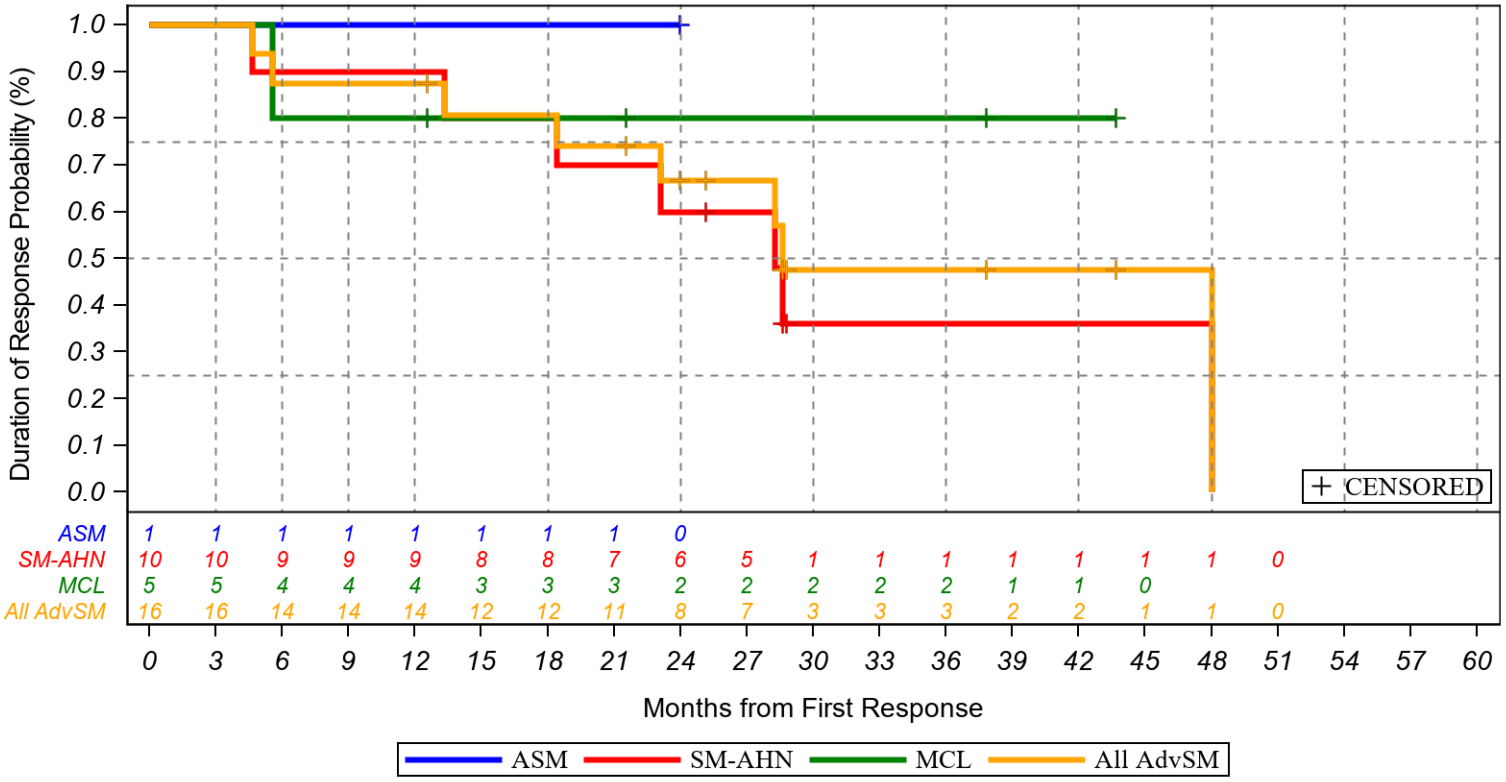

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: Overall
Prior Antineoplastic Therapy = No
Responders (CR+PR)

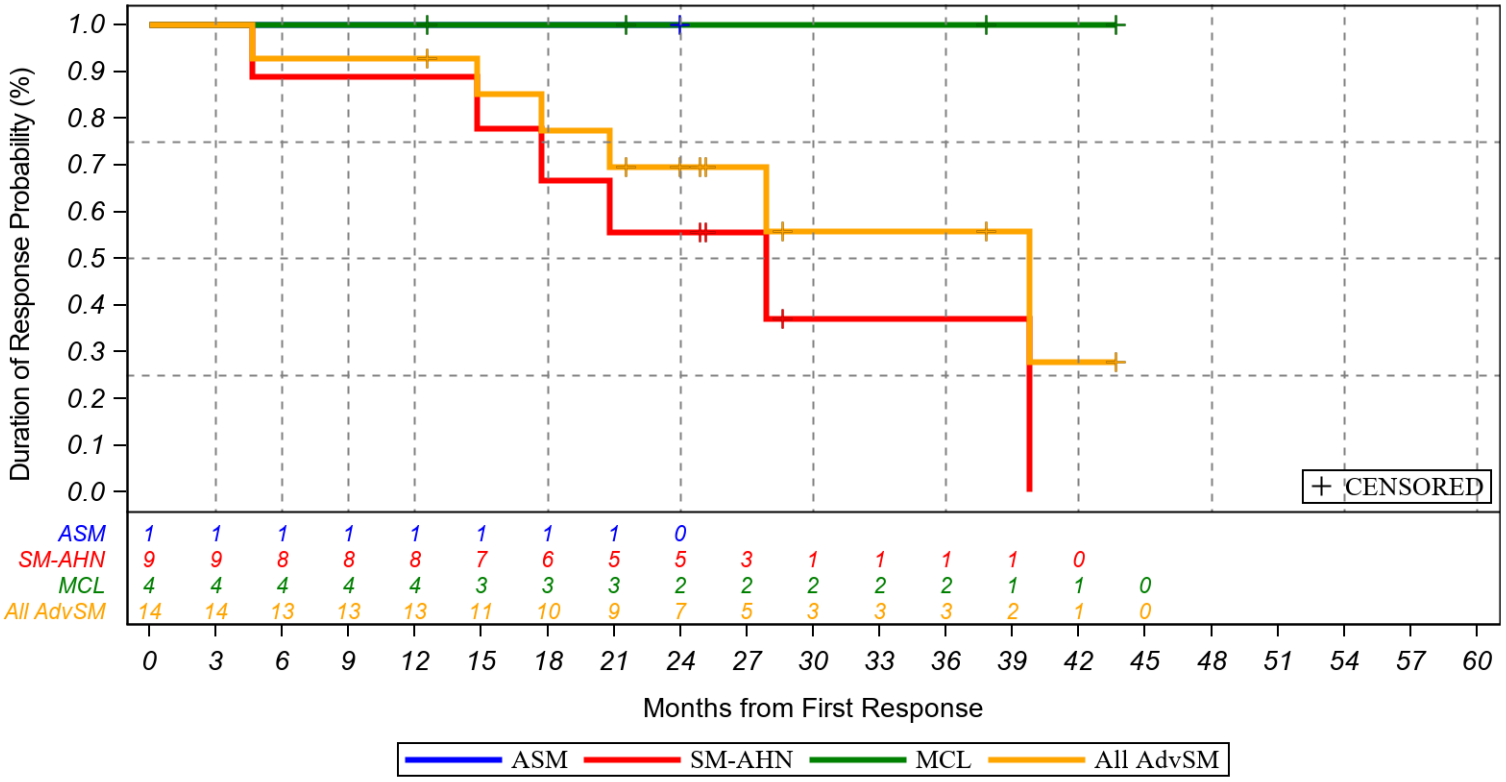

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: < 200 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR+CI)

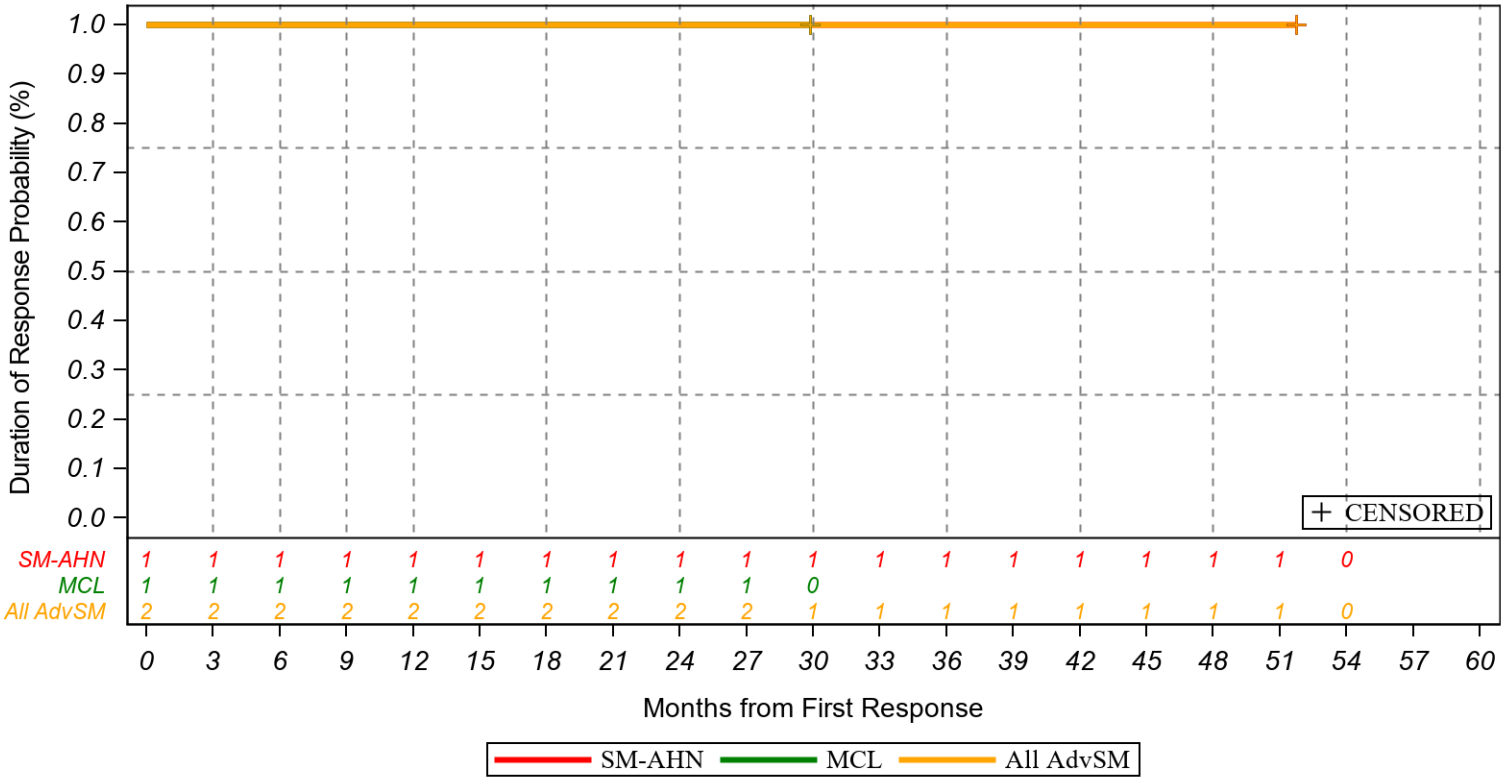

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: < 200 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR)

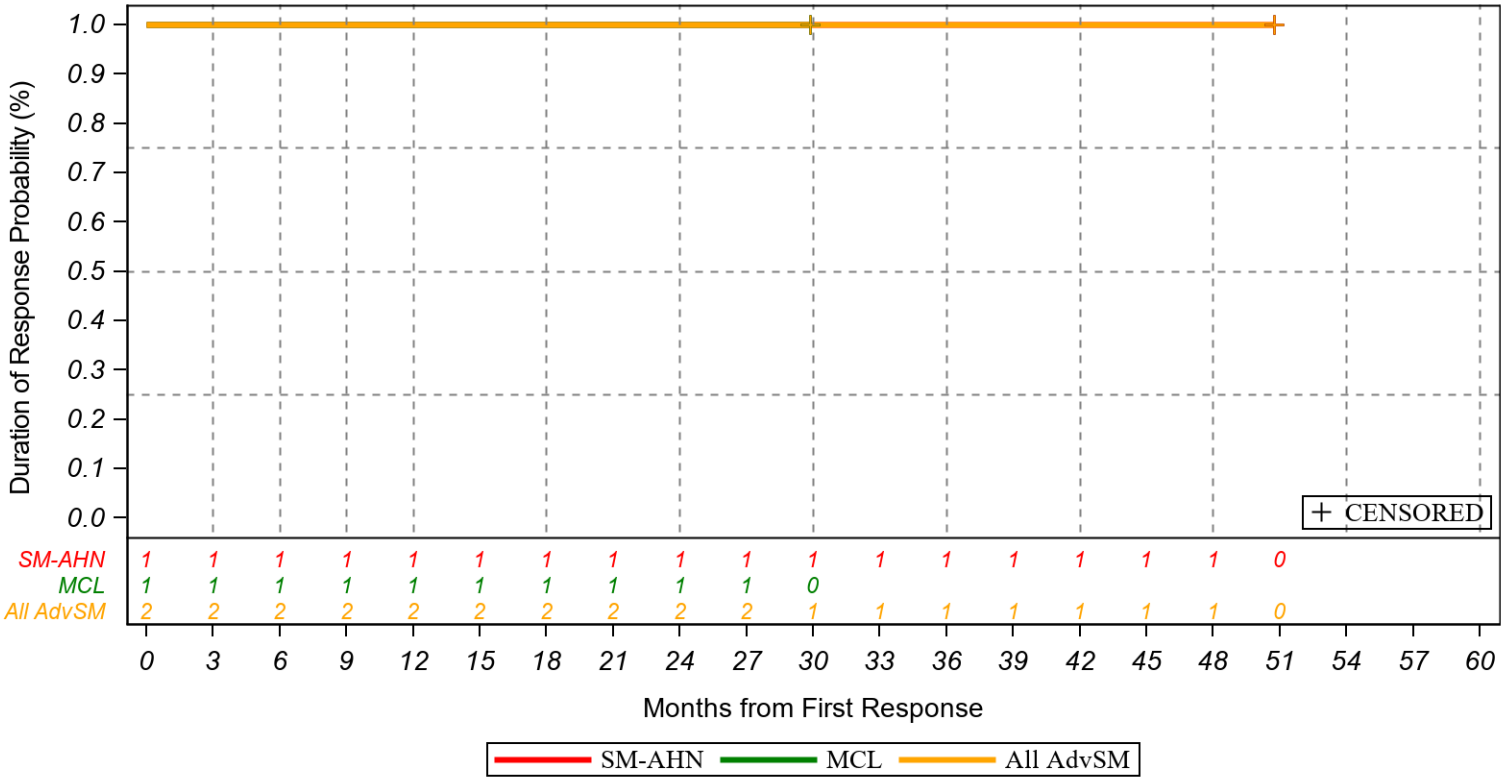

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: < 200 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR+CI)

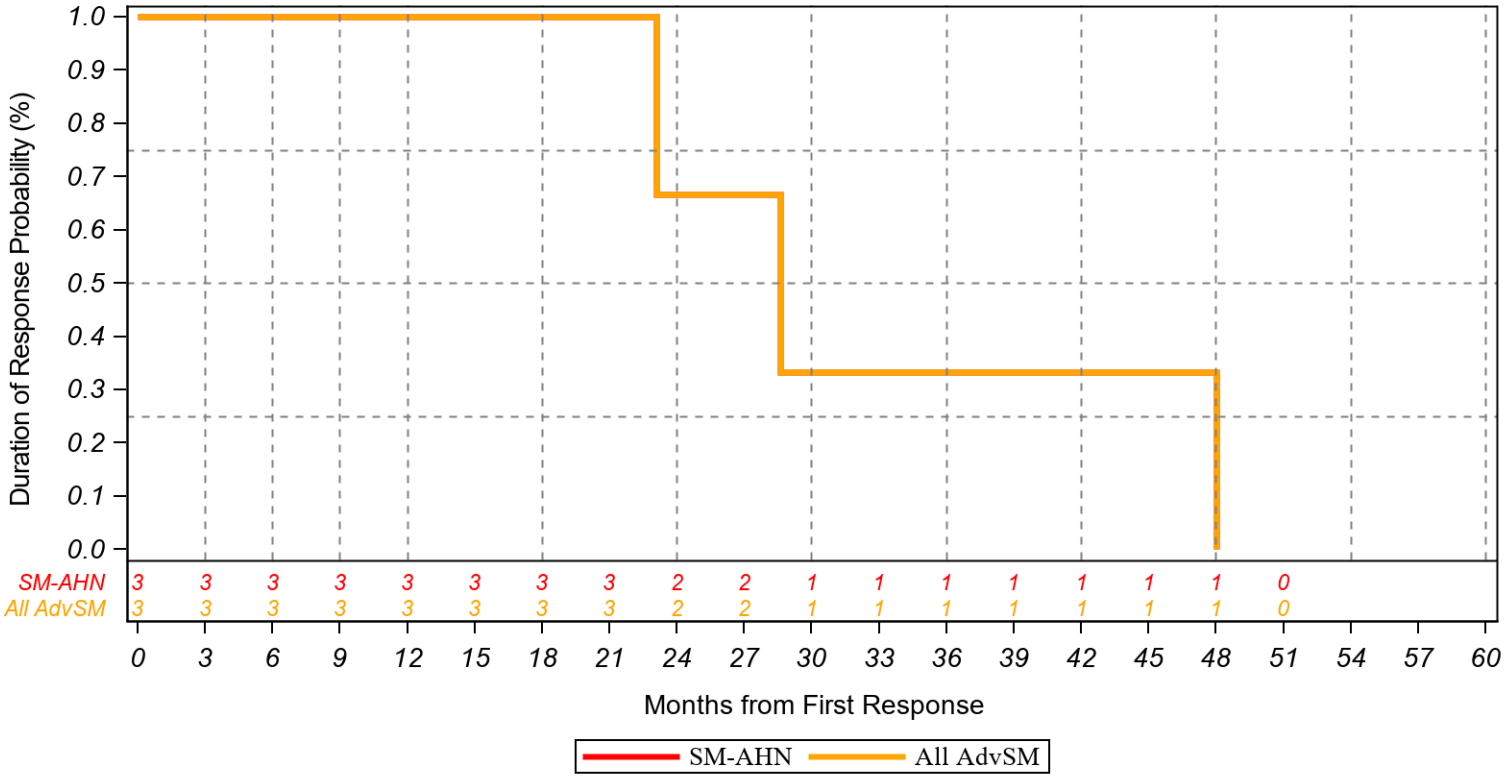

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: < 200 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR)

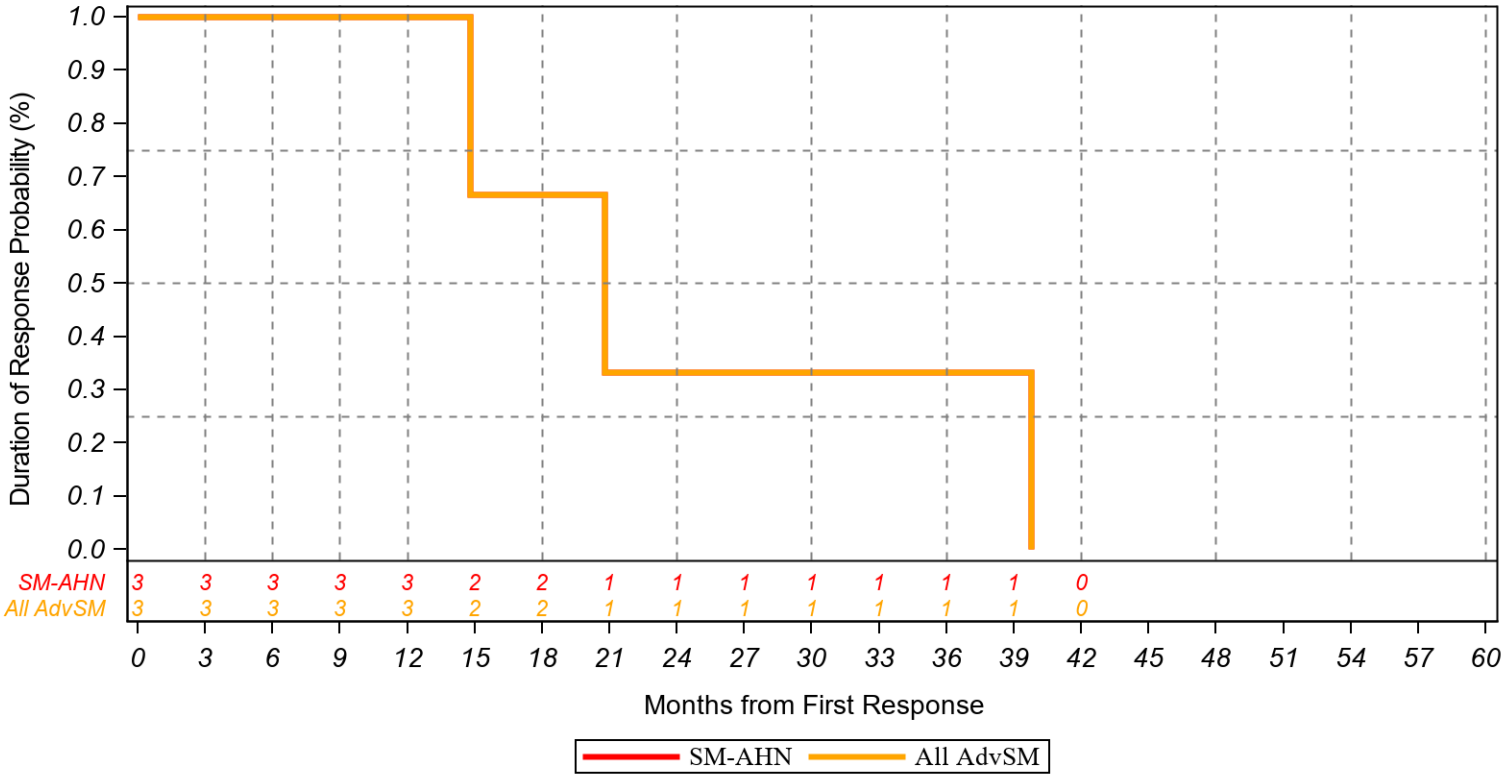

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: < 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR+CI)

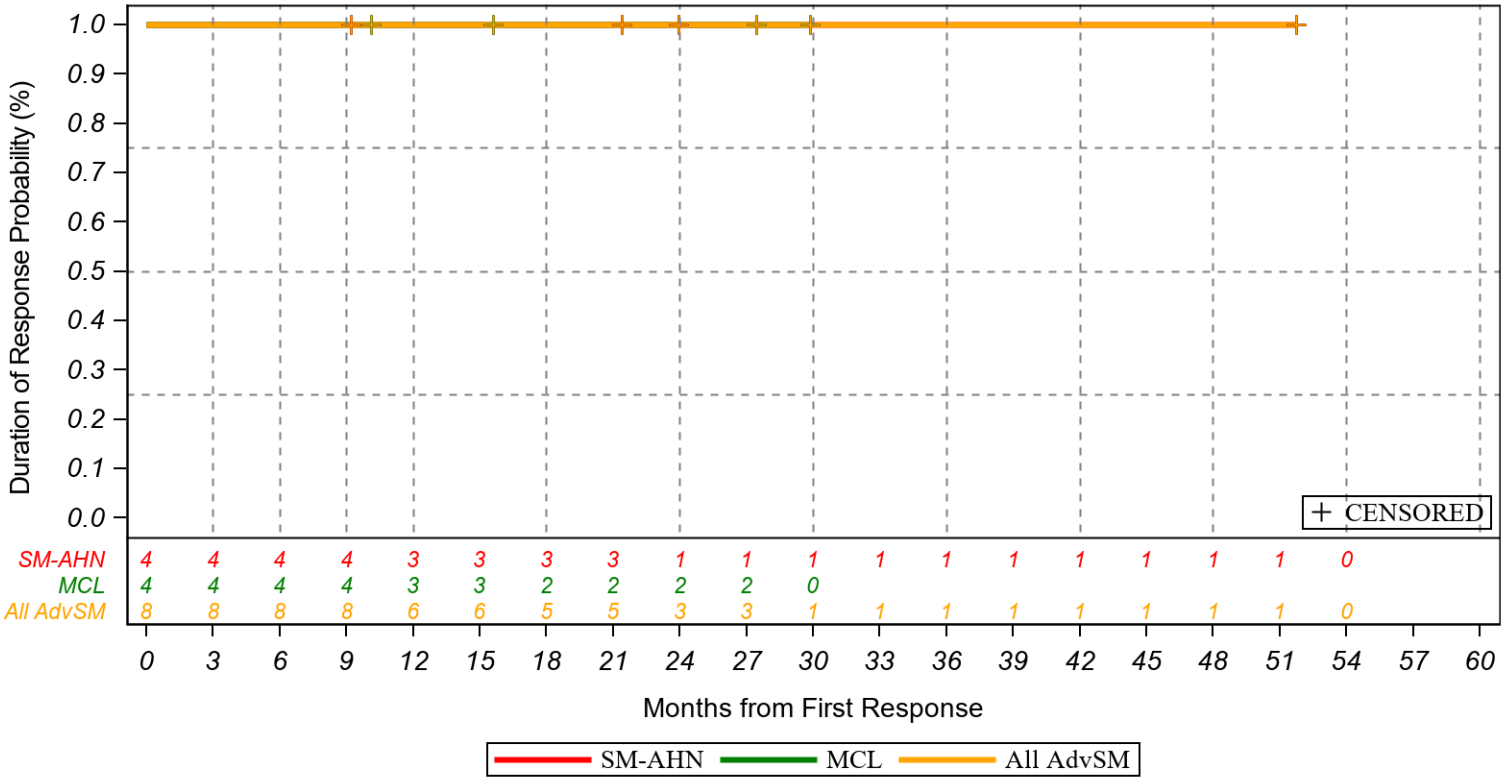

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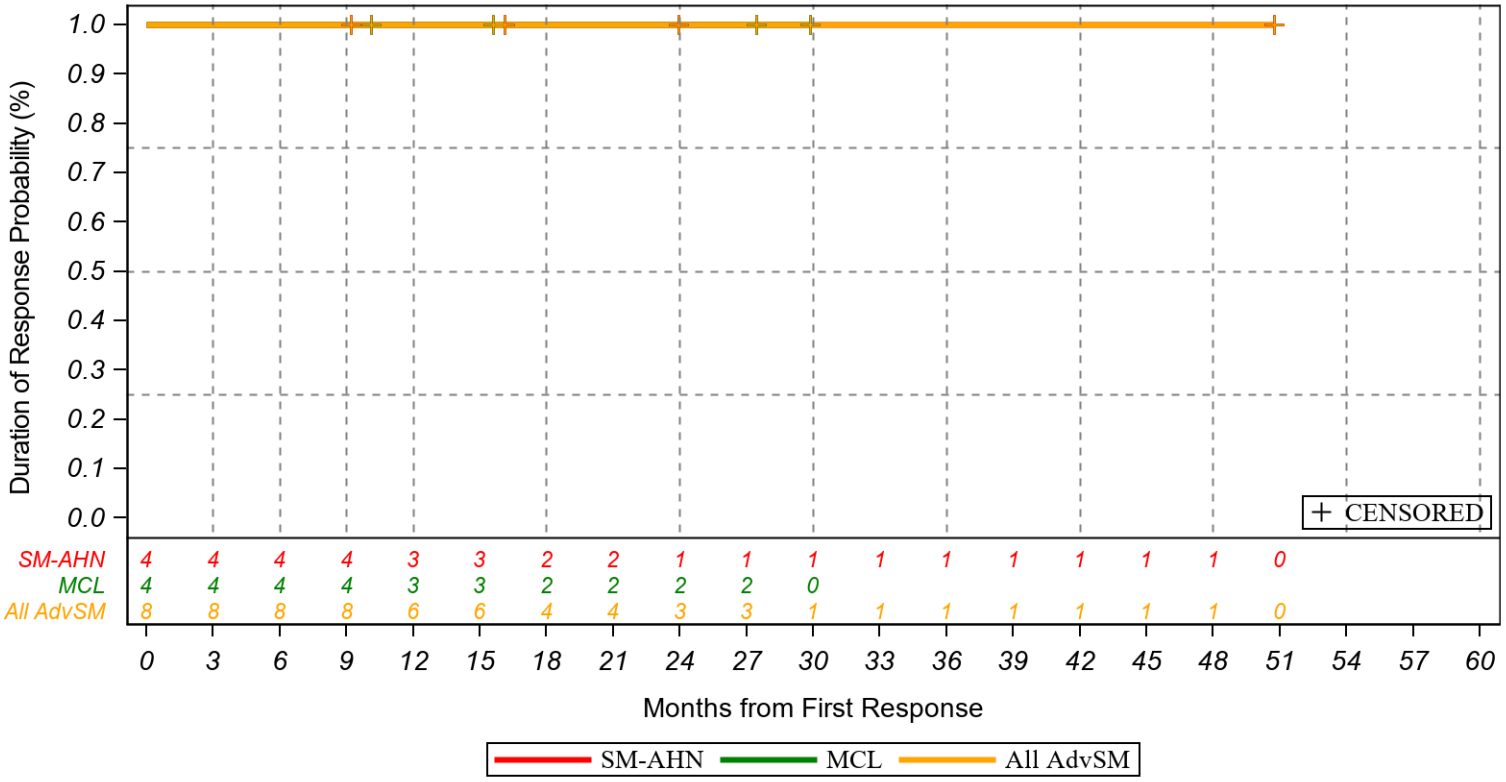
Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: < 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR)



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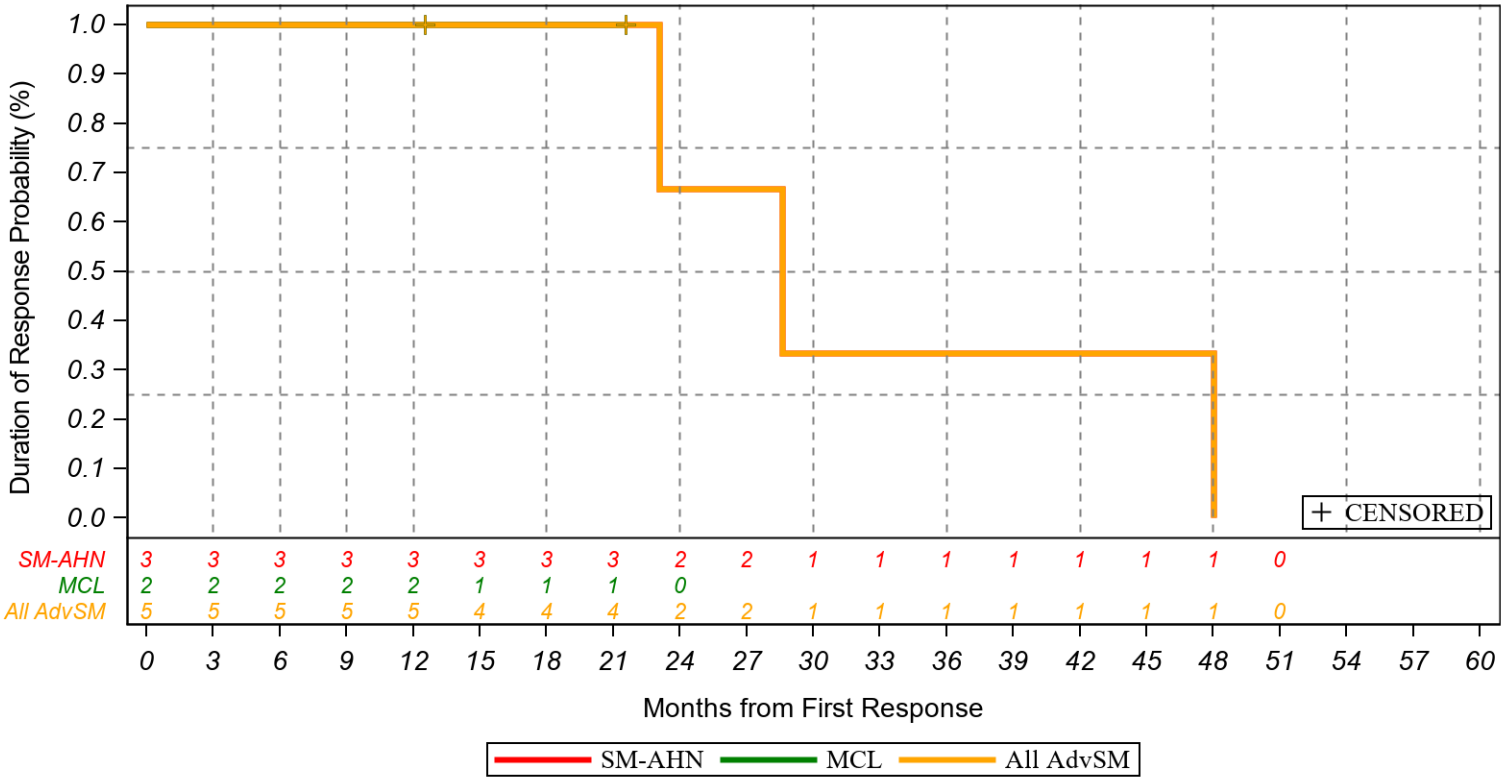
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: < 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR+CI)



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Prior Antineoplastic Therapy = No
Responders (CR+PR)

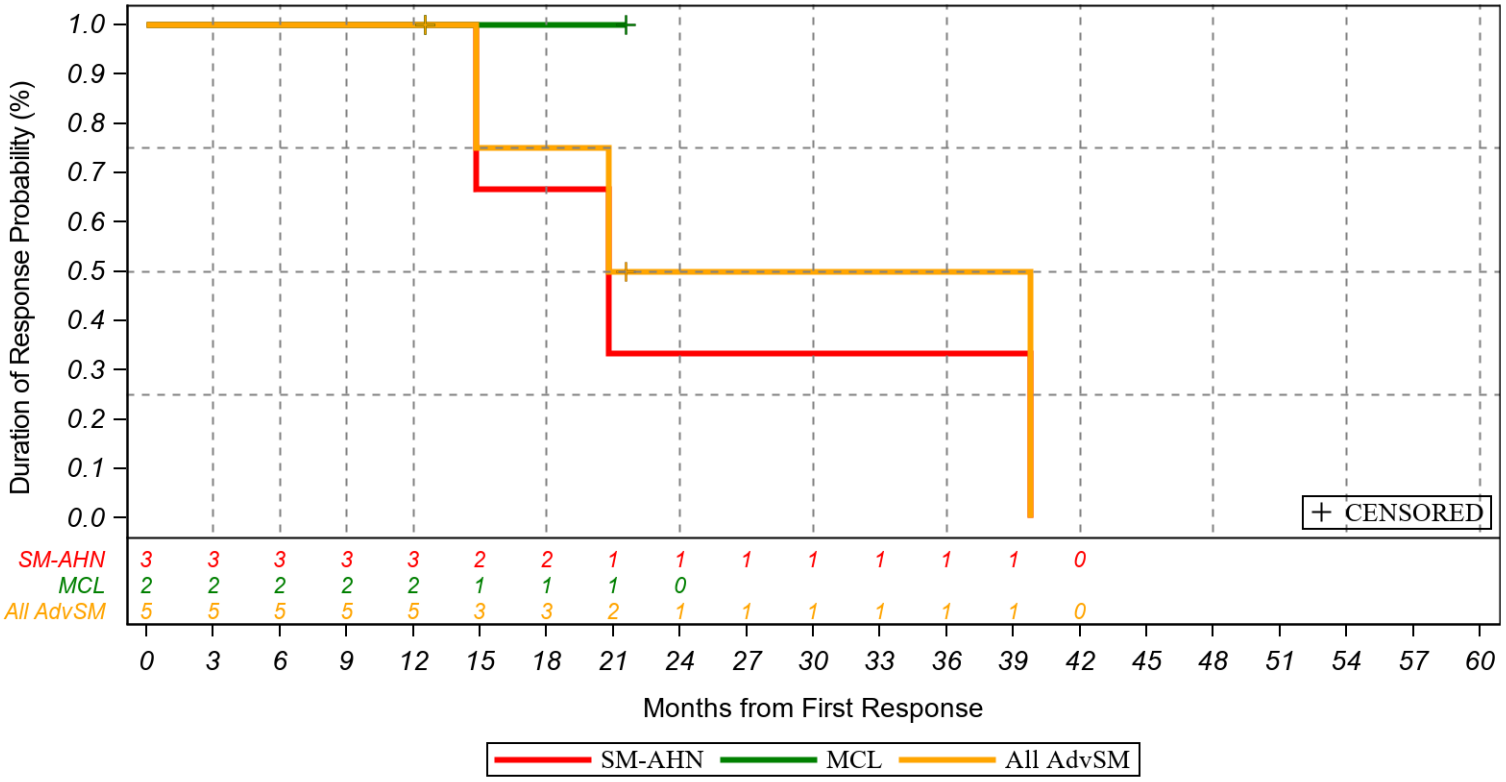

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: 200 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR+CI)

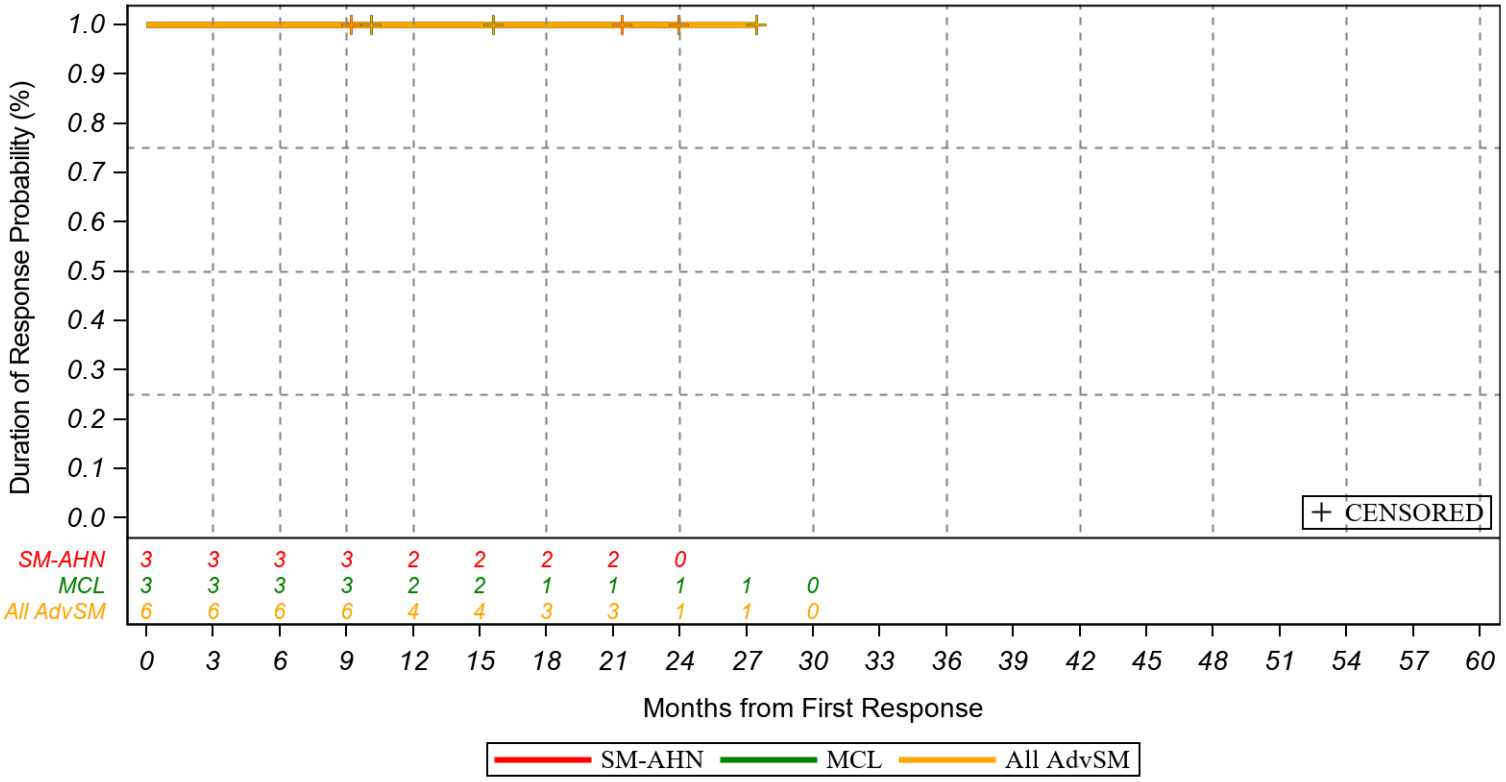

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: 200 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR)

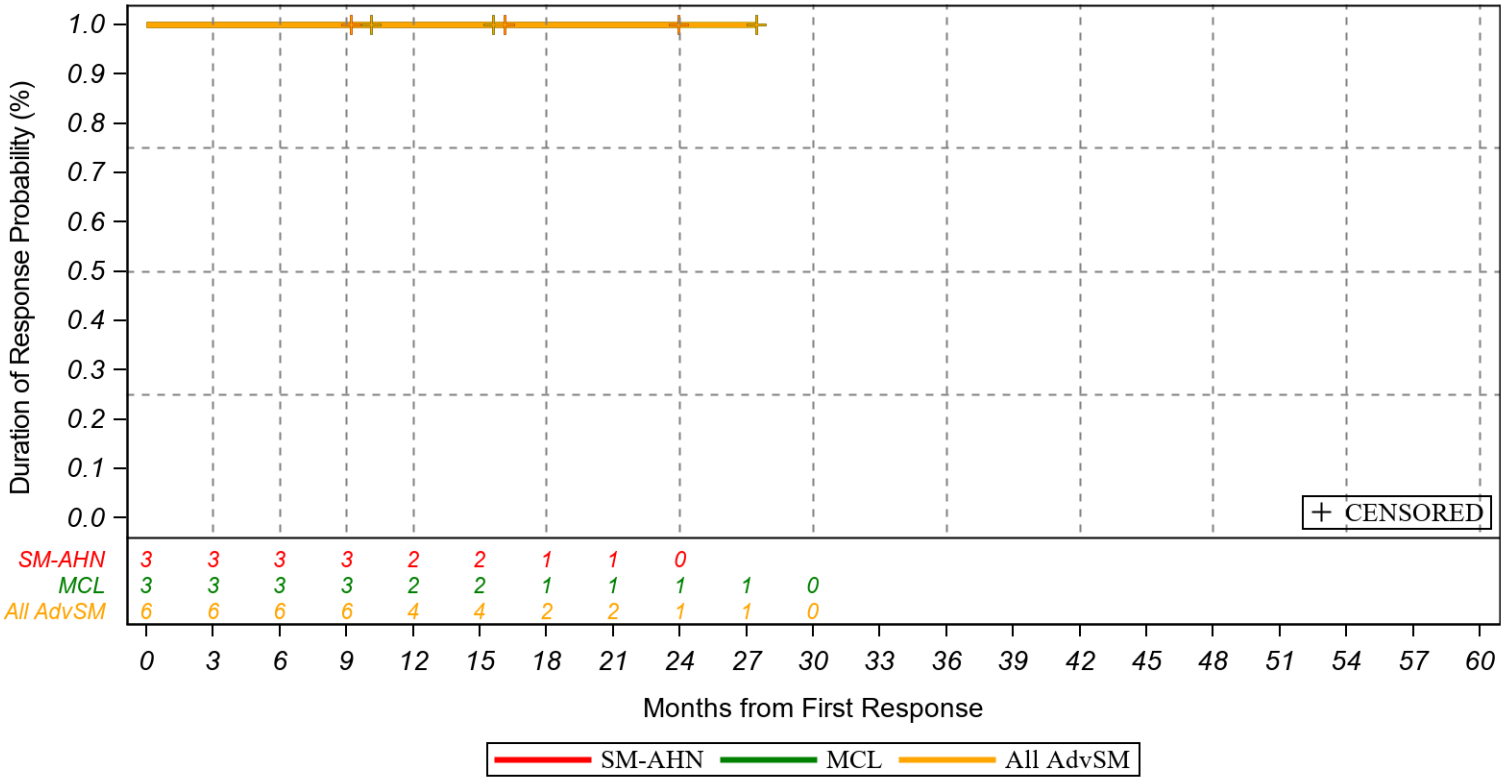

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: 200 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR+CI)

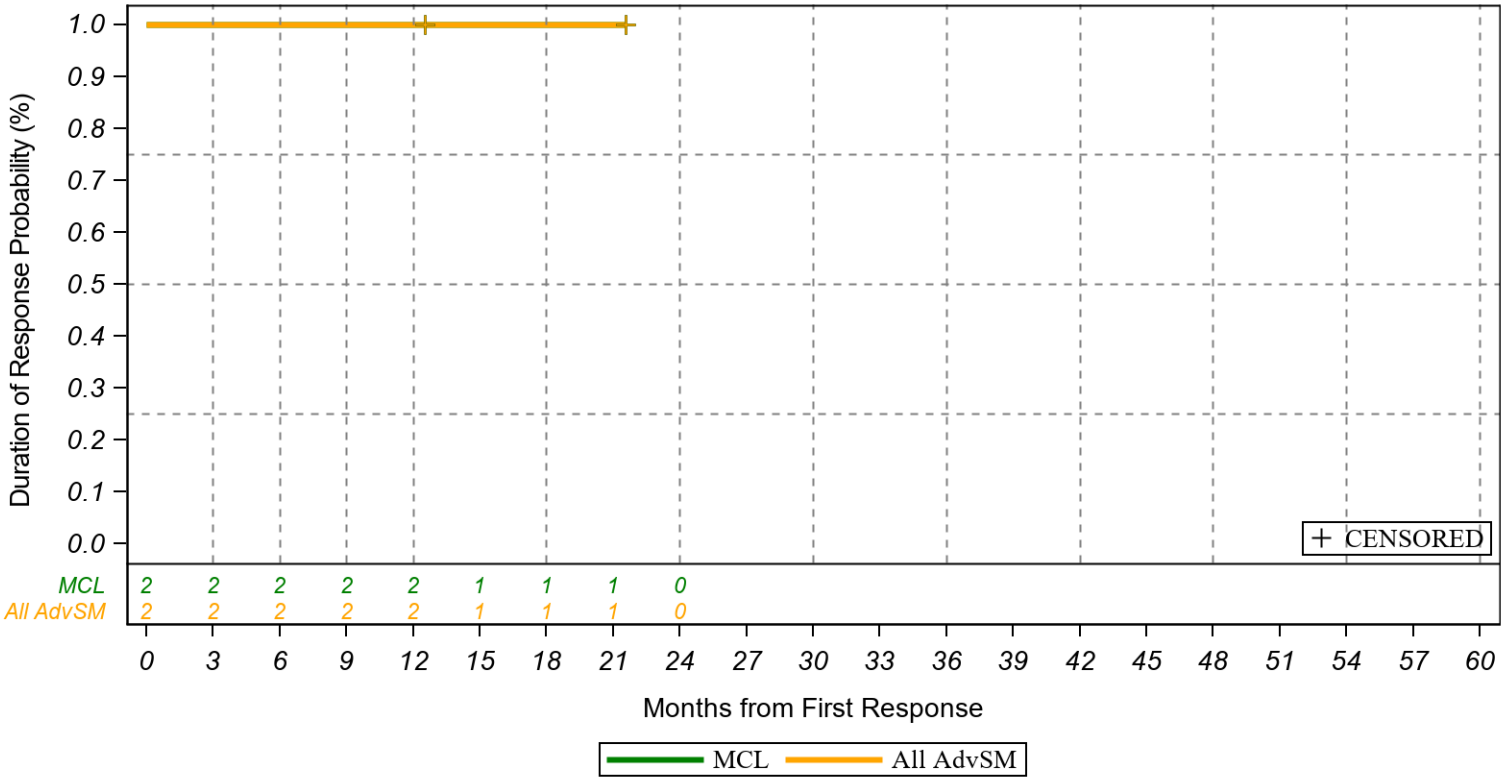

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: 200 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR)

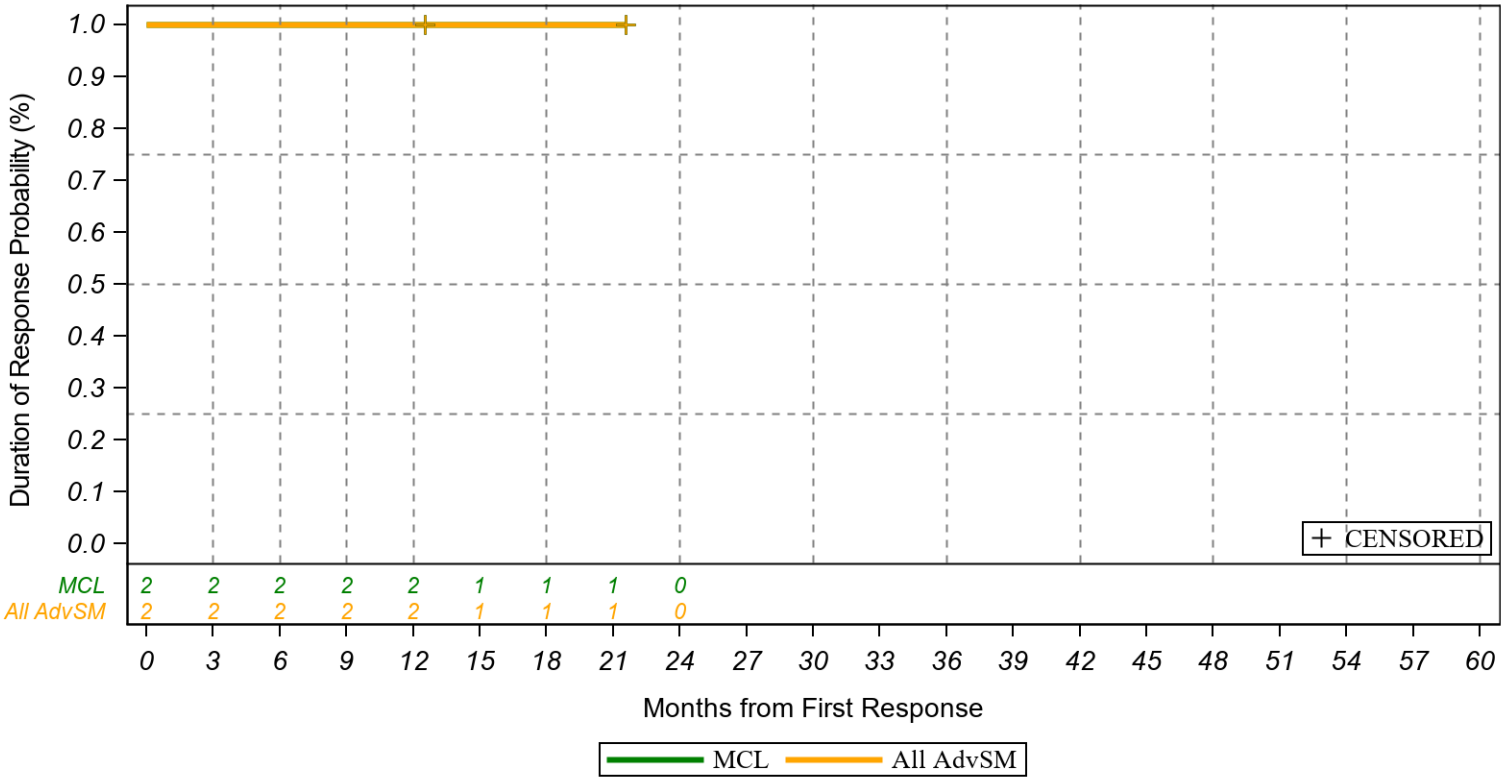

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR+CI)

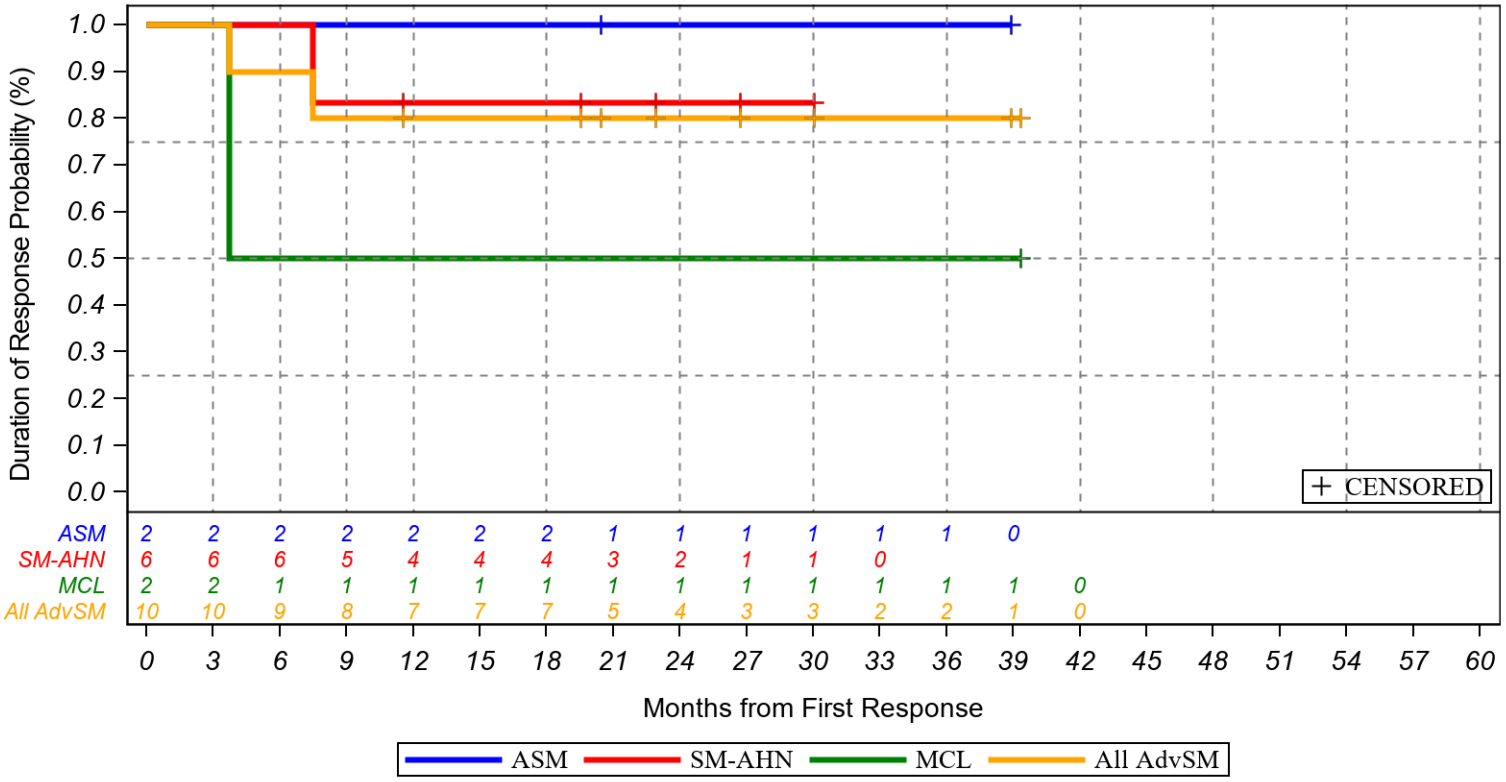

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR)

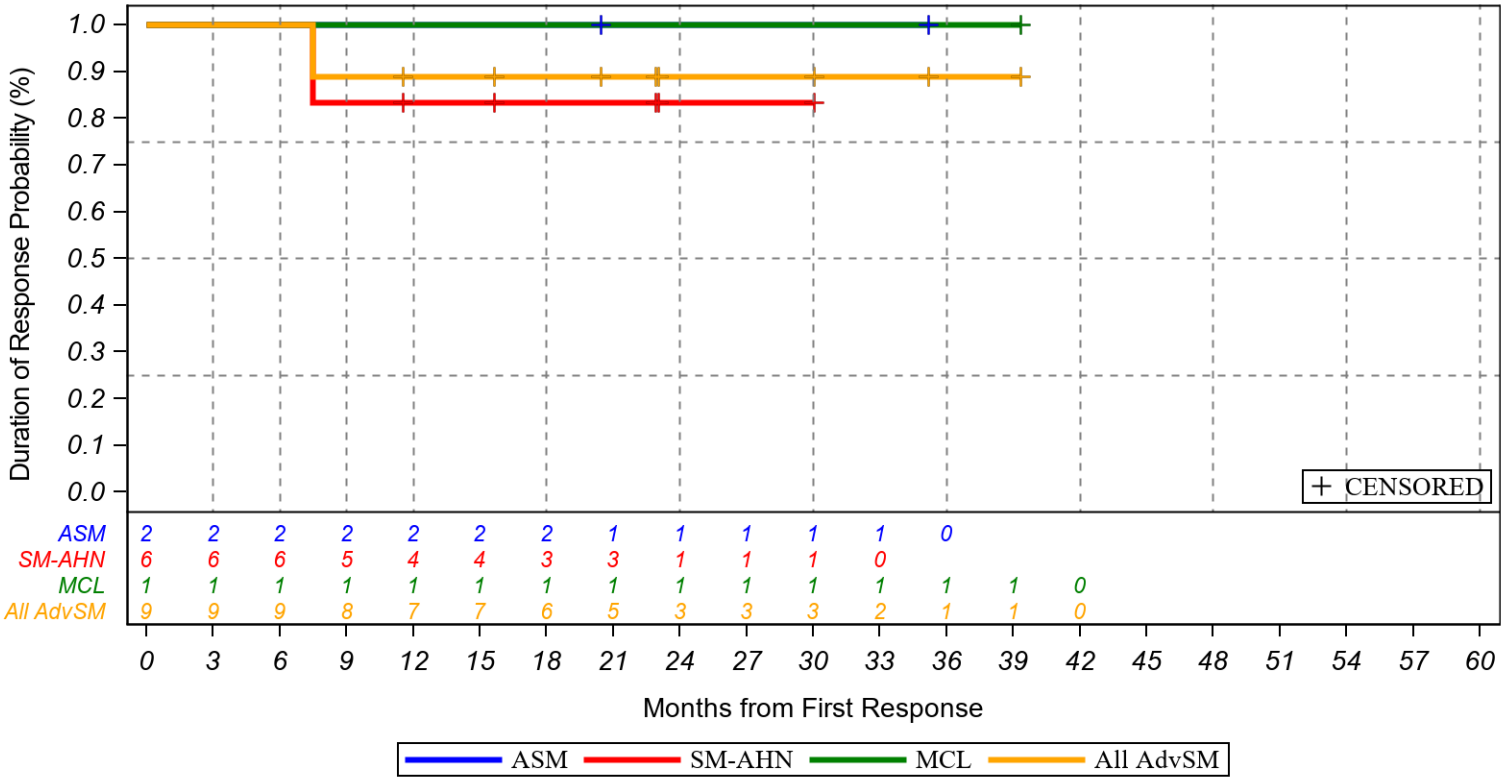

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR+CI)

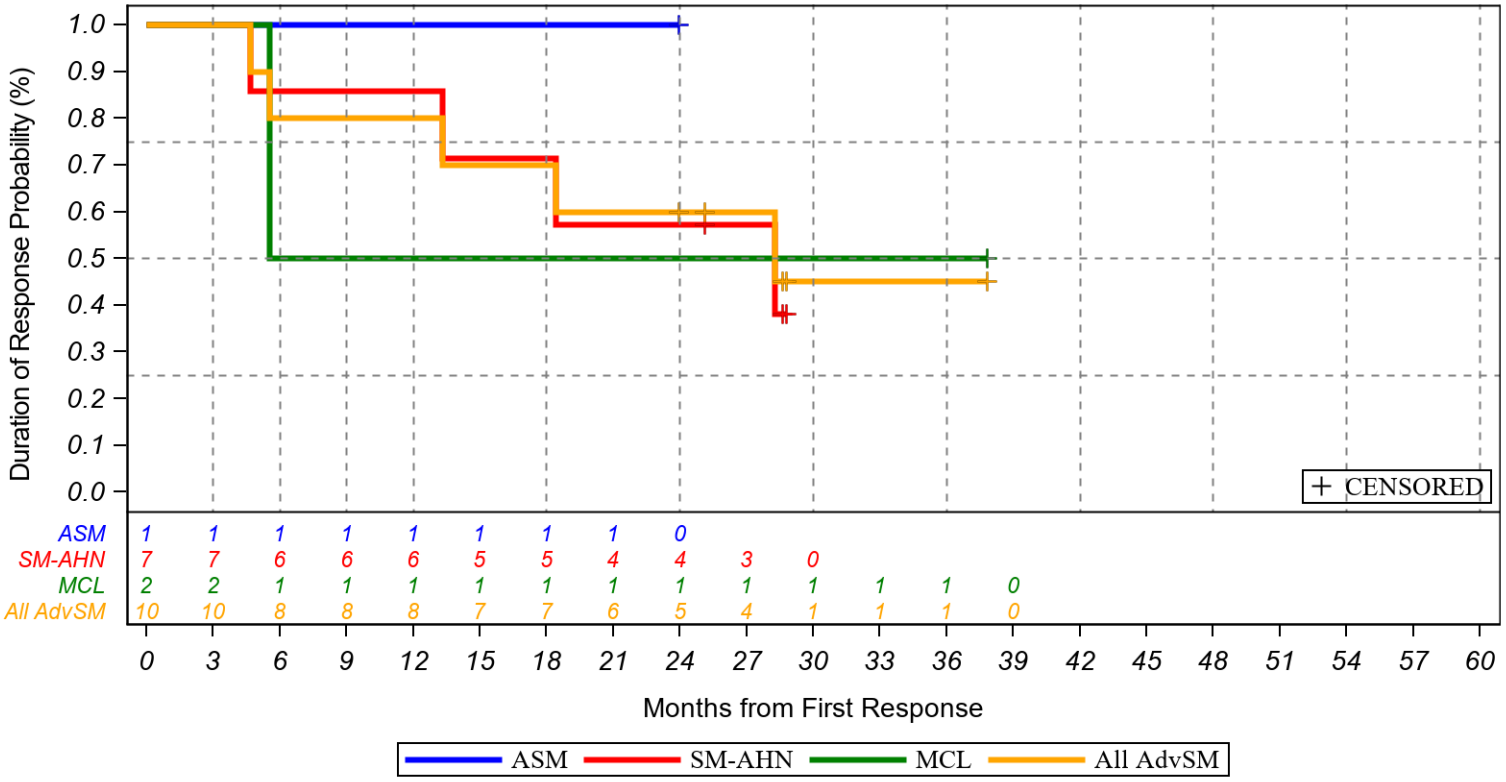

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR)

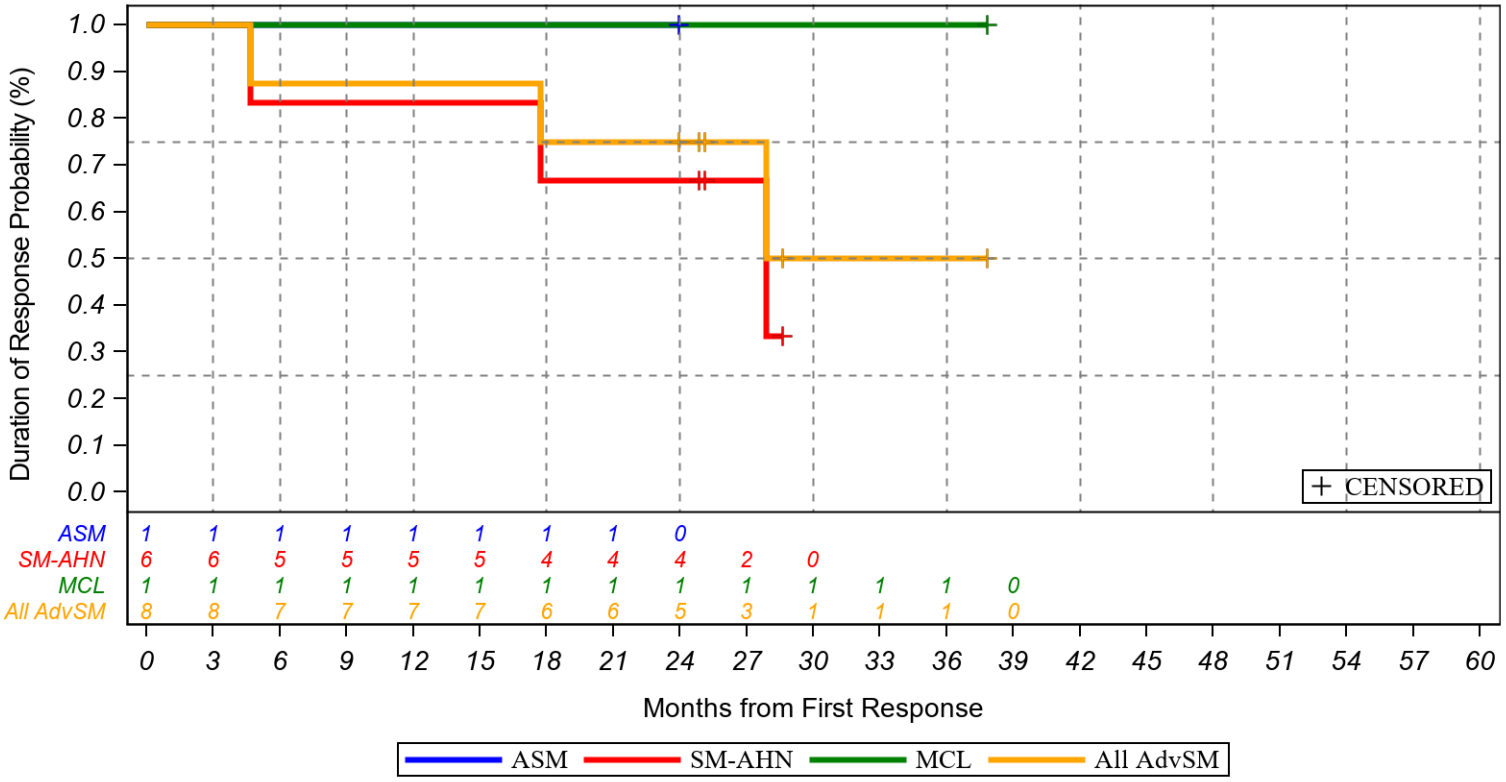

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: 200 mg and 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR+CI)

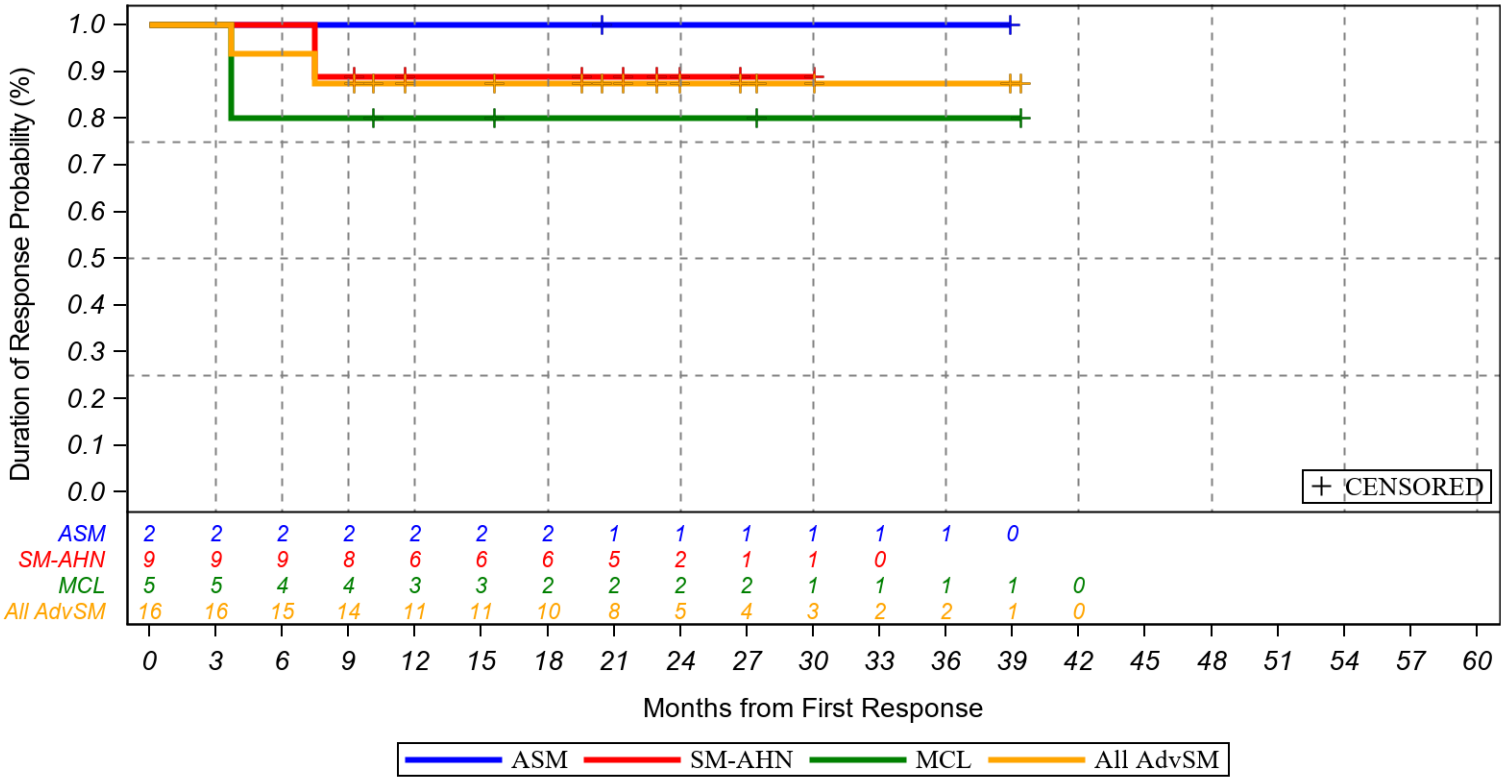

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: 200 mg and 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR)

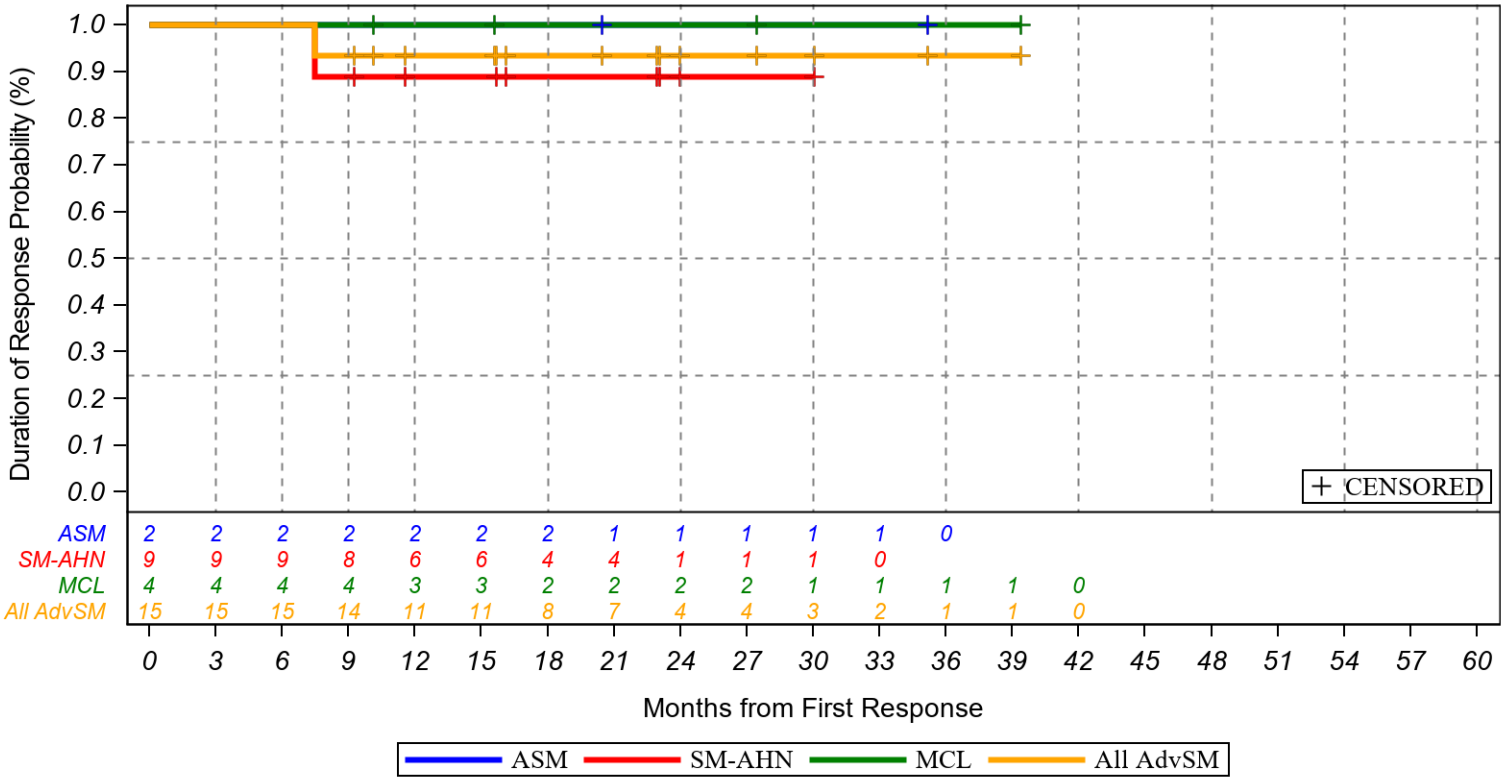

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: 200 mg and 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR+CI)

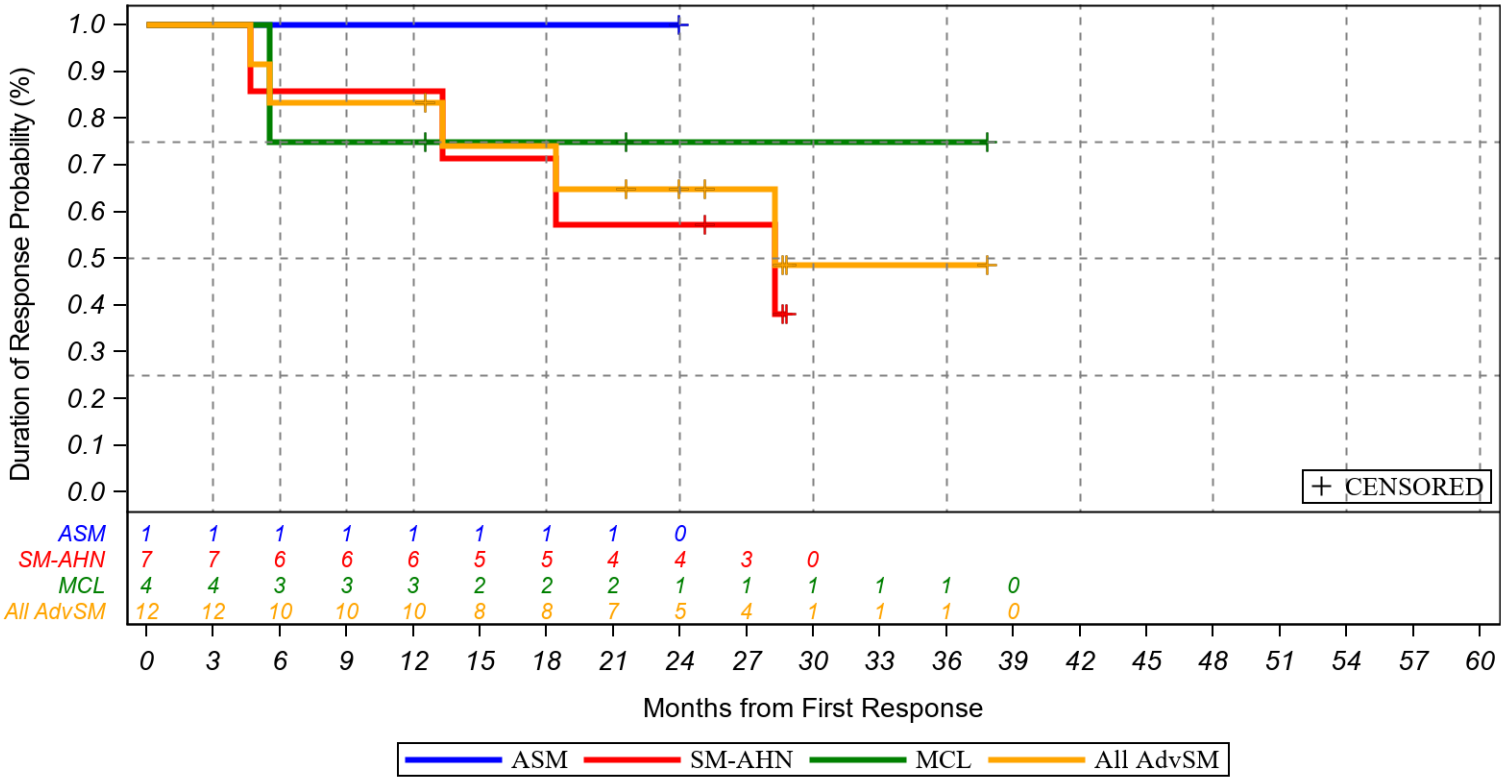

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: 200 mg and 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR)

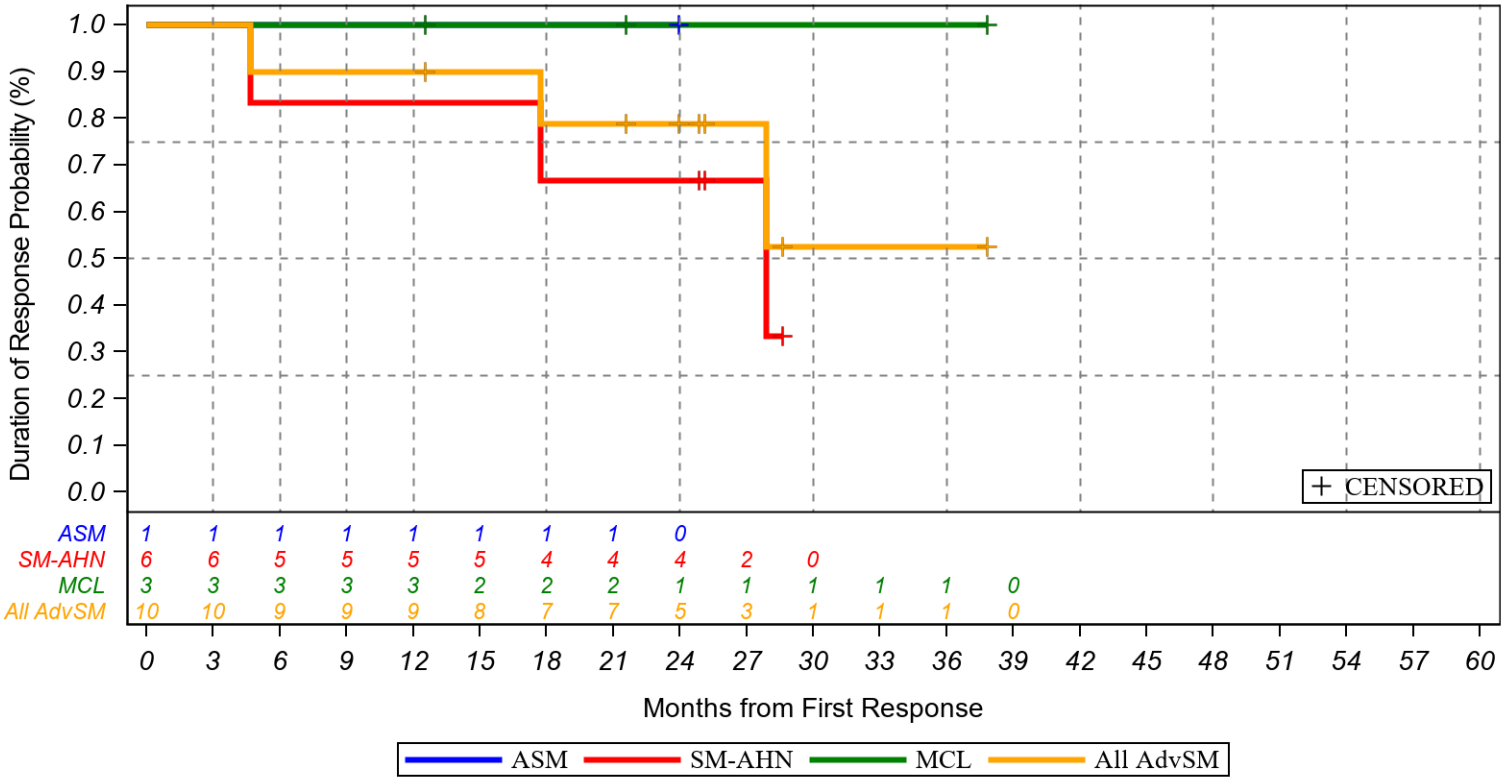

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: 400 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR+CI)

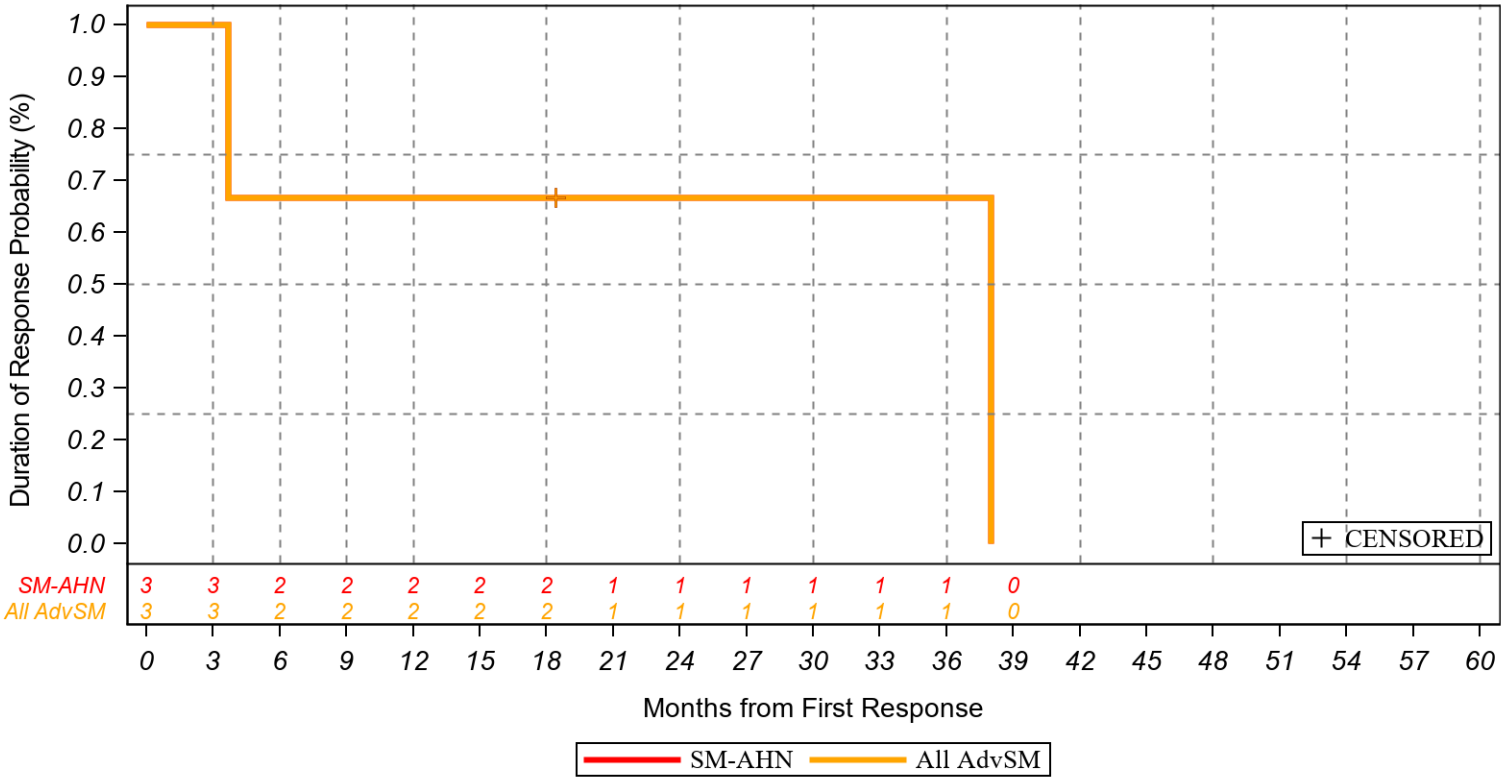

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: 400 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR)

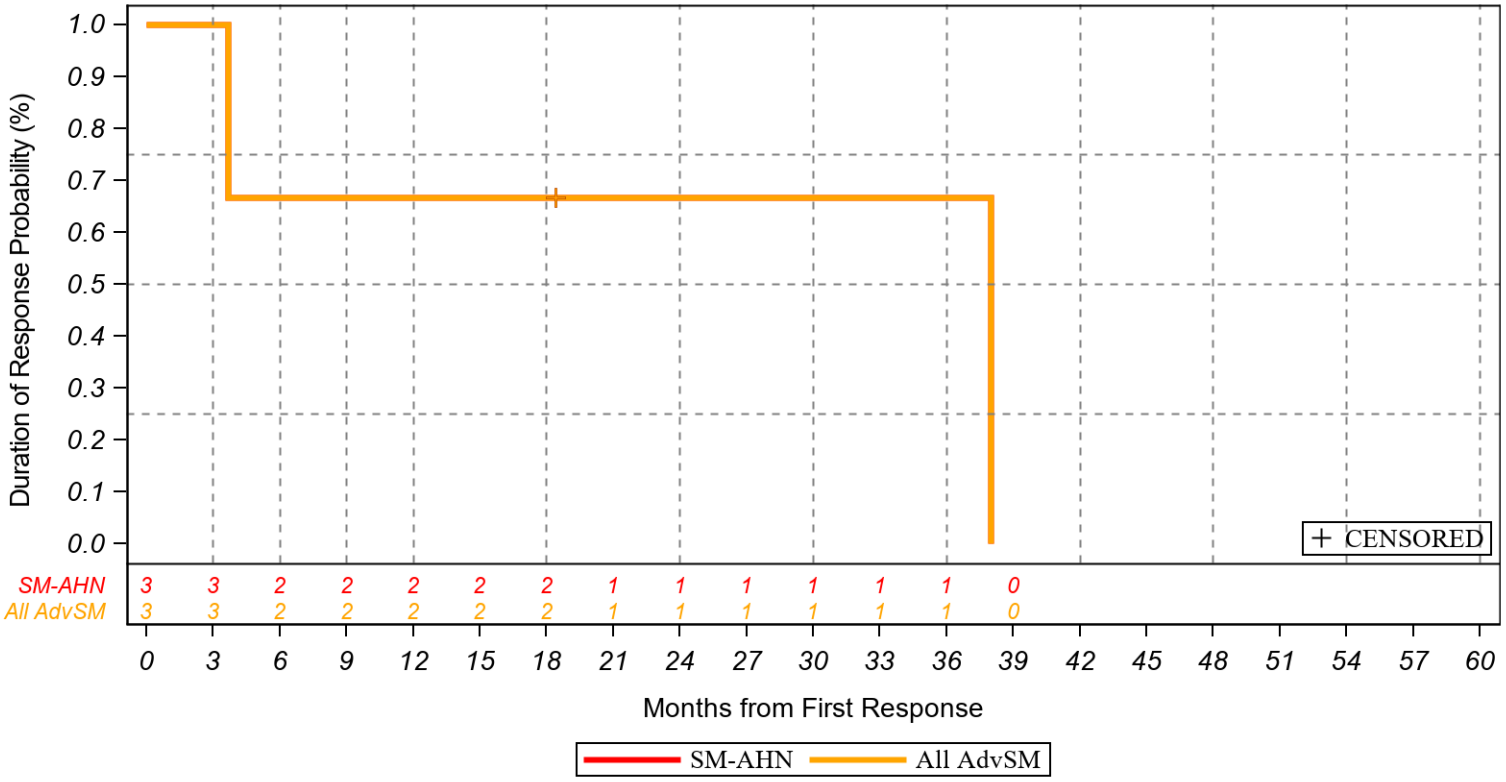

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: 400 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR+CI)

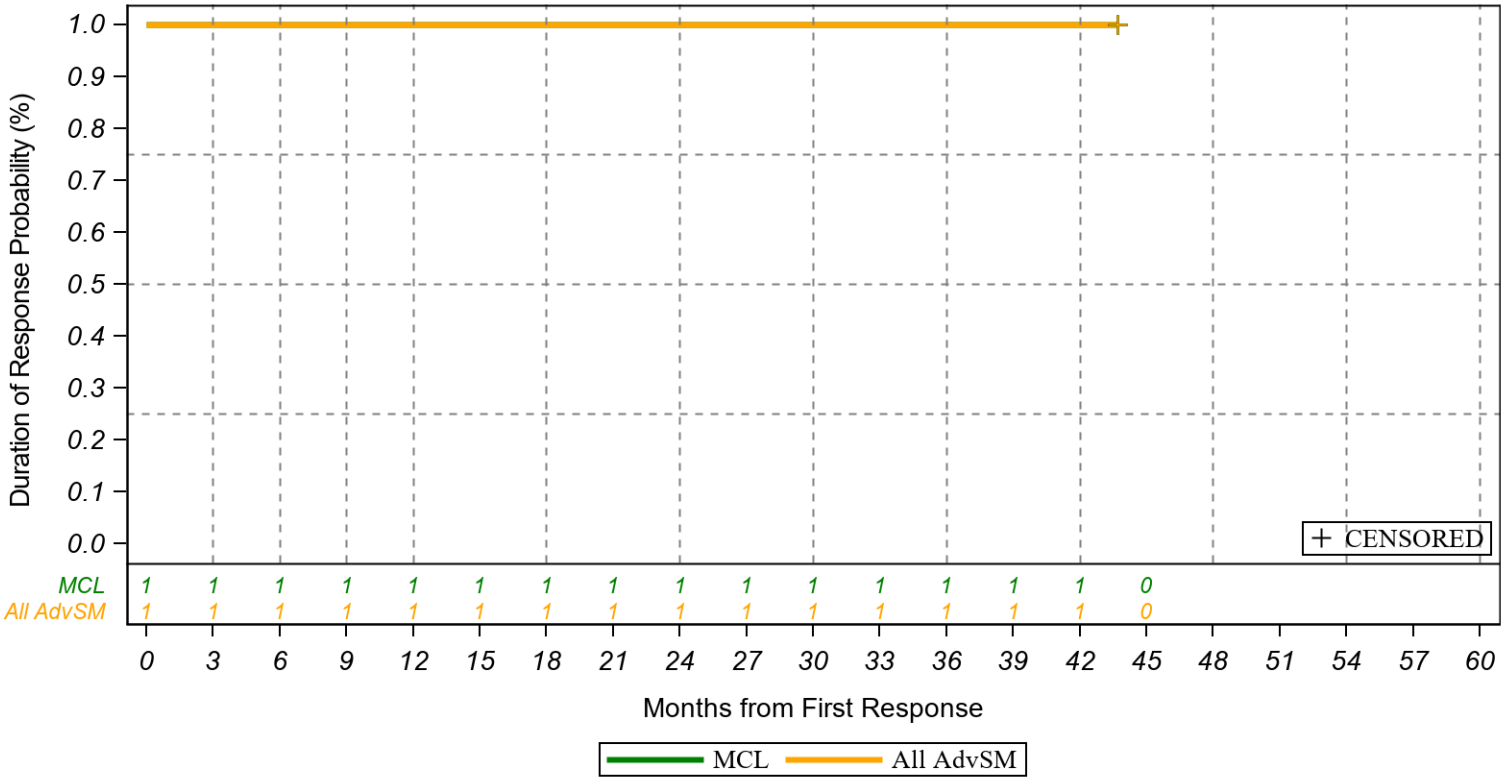

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: 400 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR)

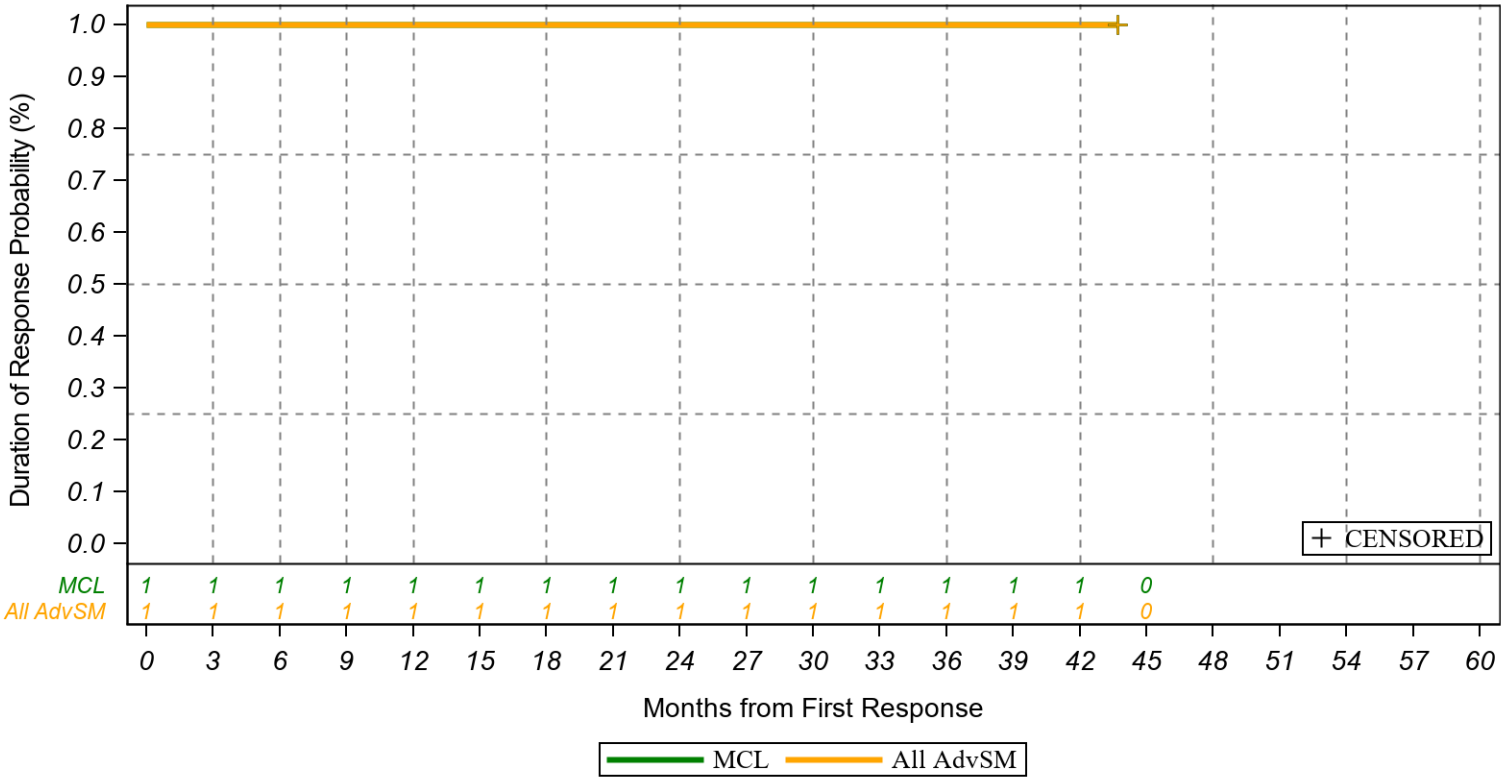

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Starting Dose: Overall
Prior Antineoplastic Therapy = Yes
Responders (CR+PR+CI)

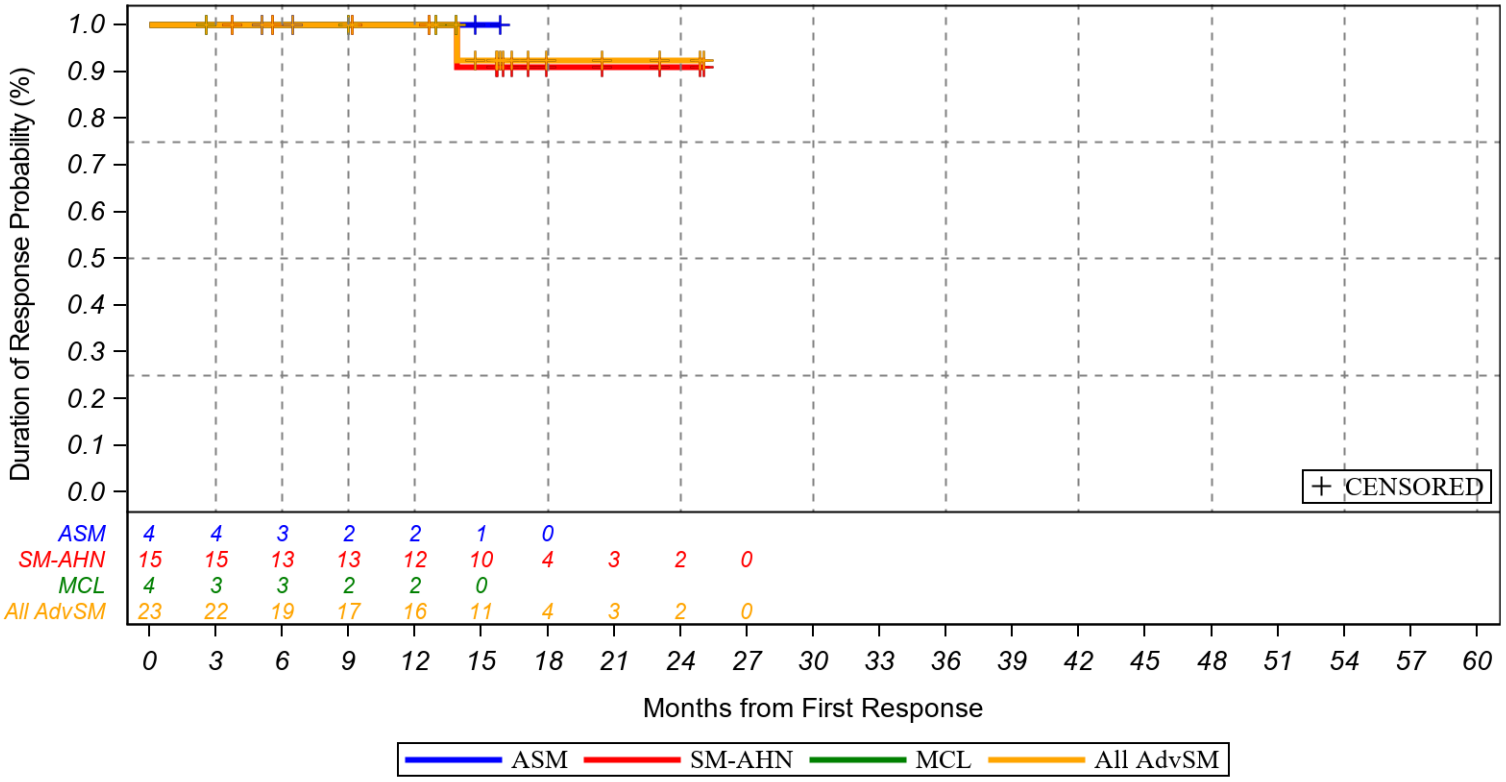

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Starting Dose: Overall
Prior Antineoplastic Therapy = Yes
Responders (CR+PR)

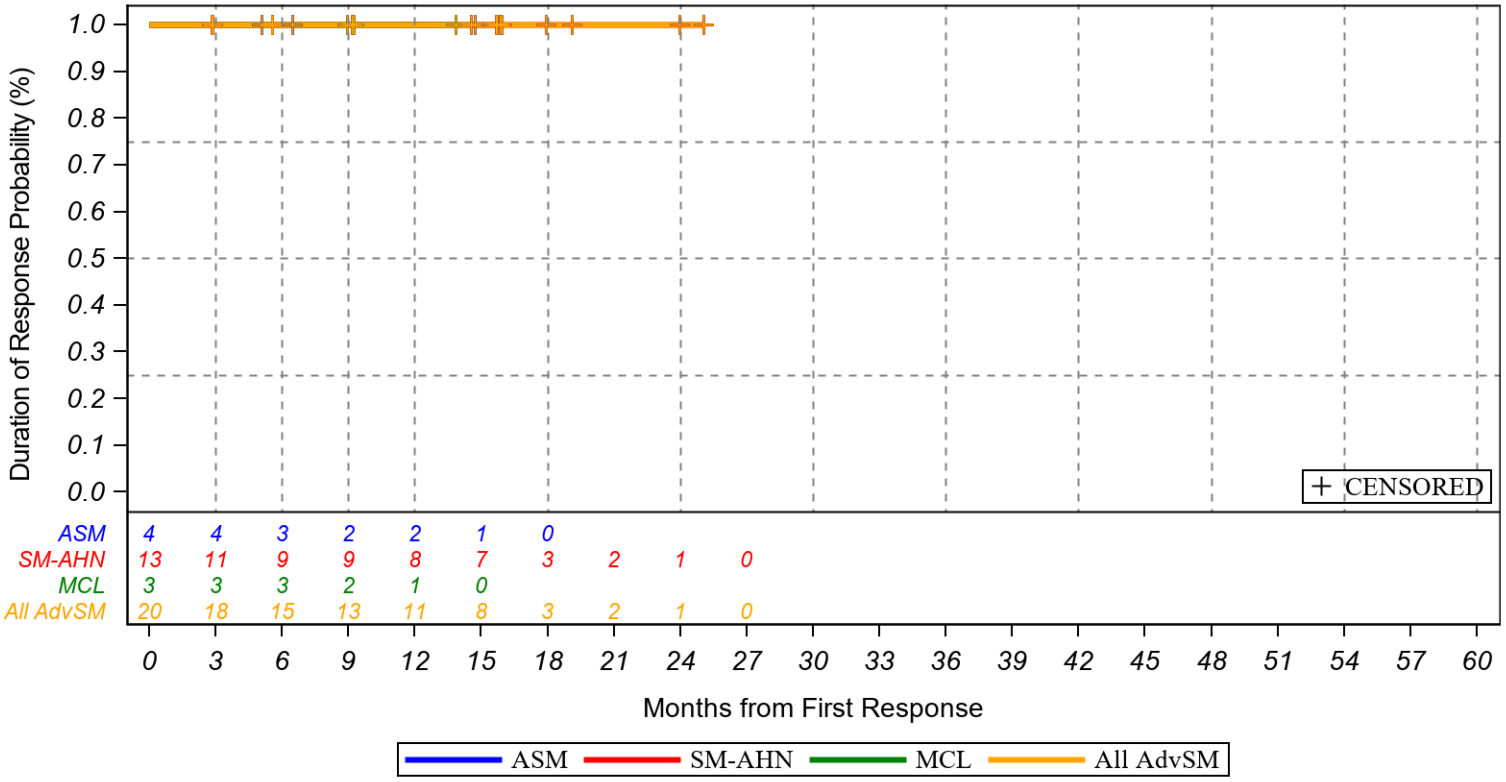

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Starting Dose: Overall
Prior Antineoplastic Therapy = No
Responders (CR+PR+CI)

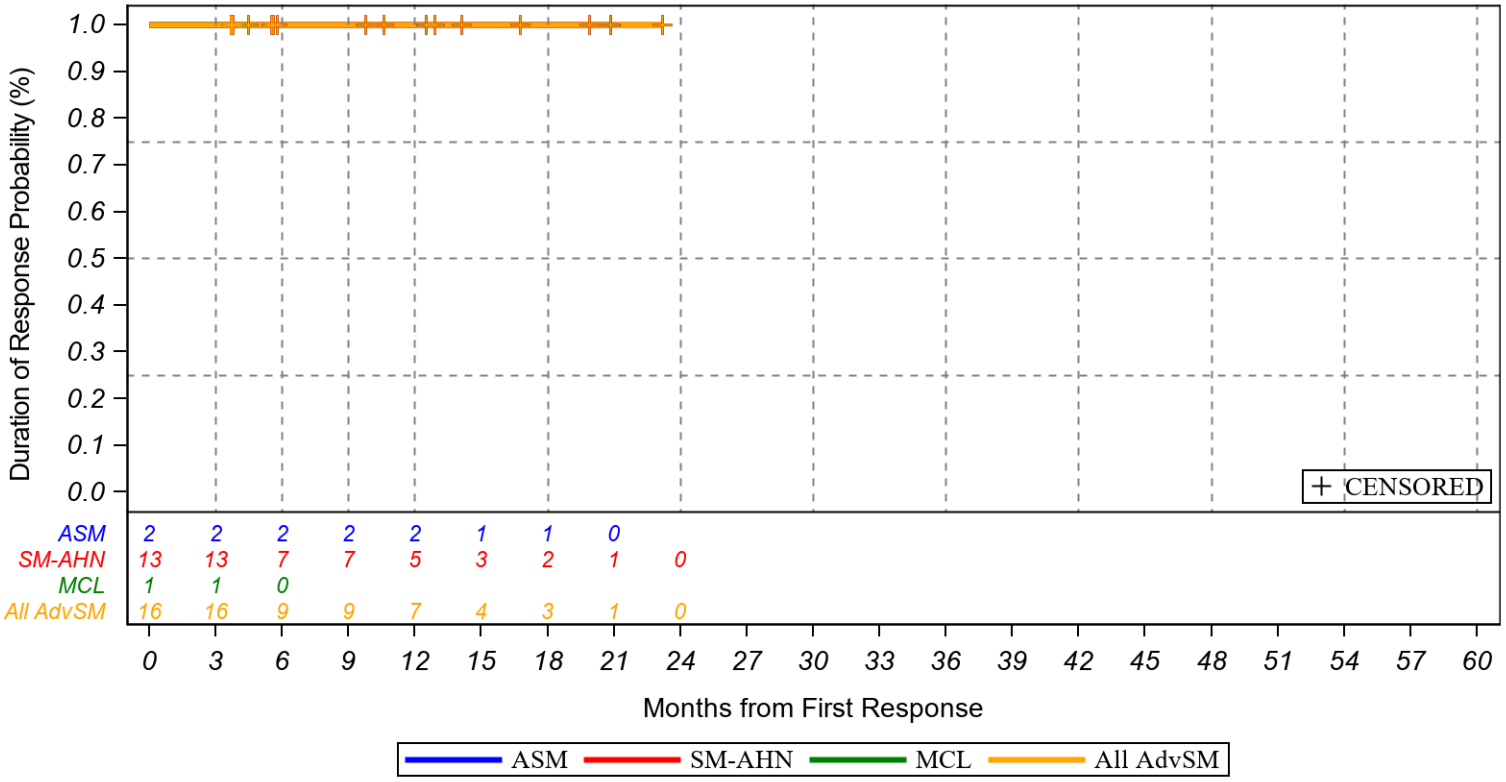

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Starting Dose: Overall
Prior Antineoplastic Therapy = No
Responders (CR+PR)

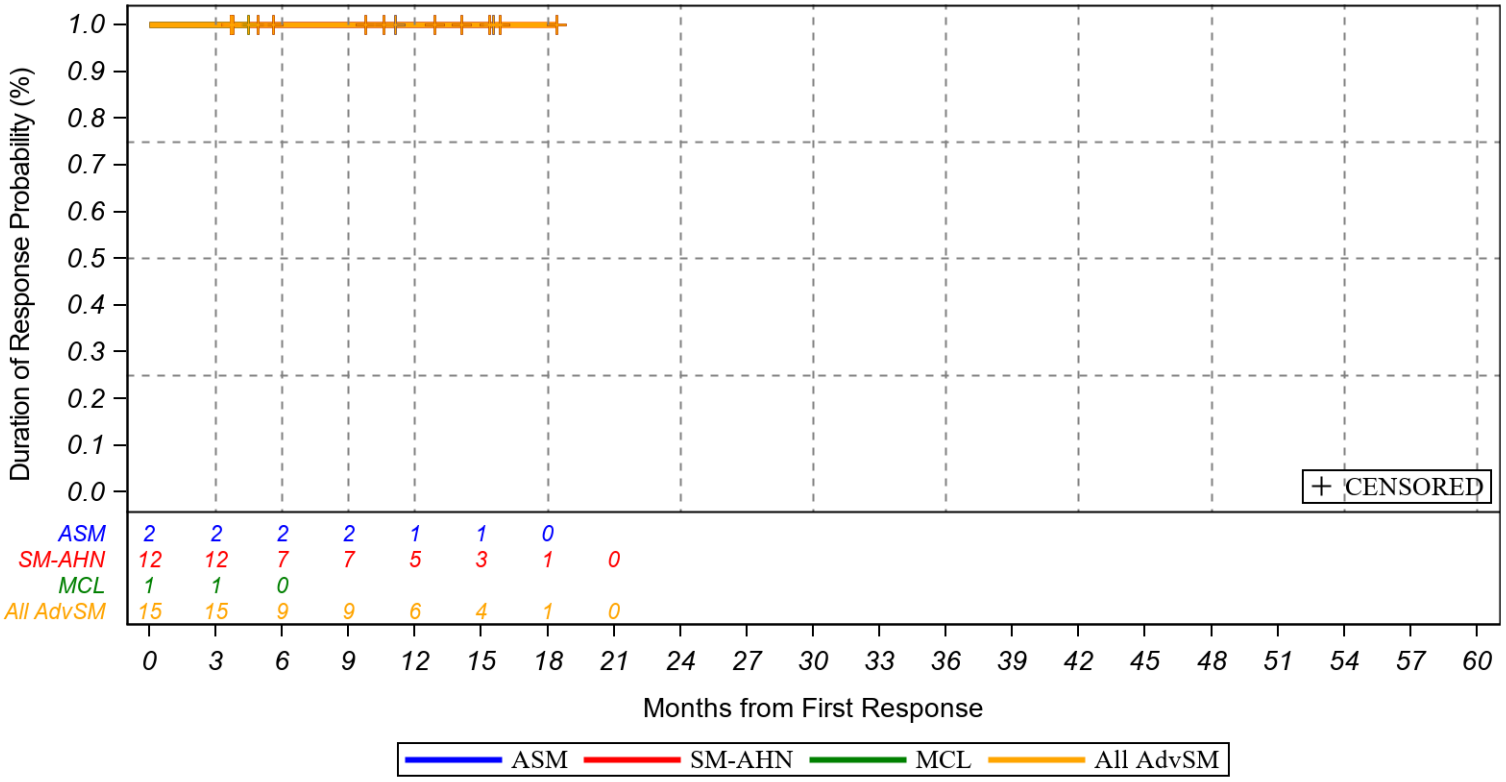

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Starting Dose: 200 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR+CI)

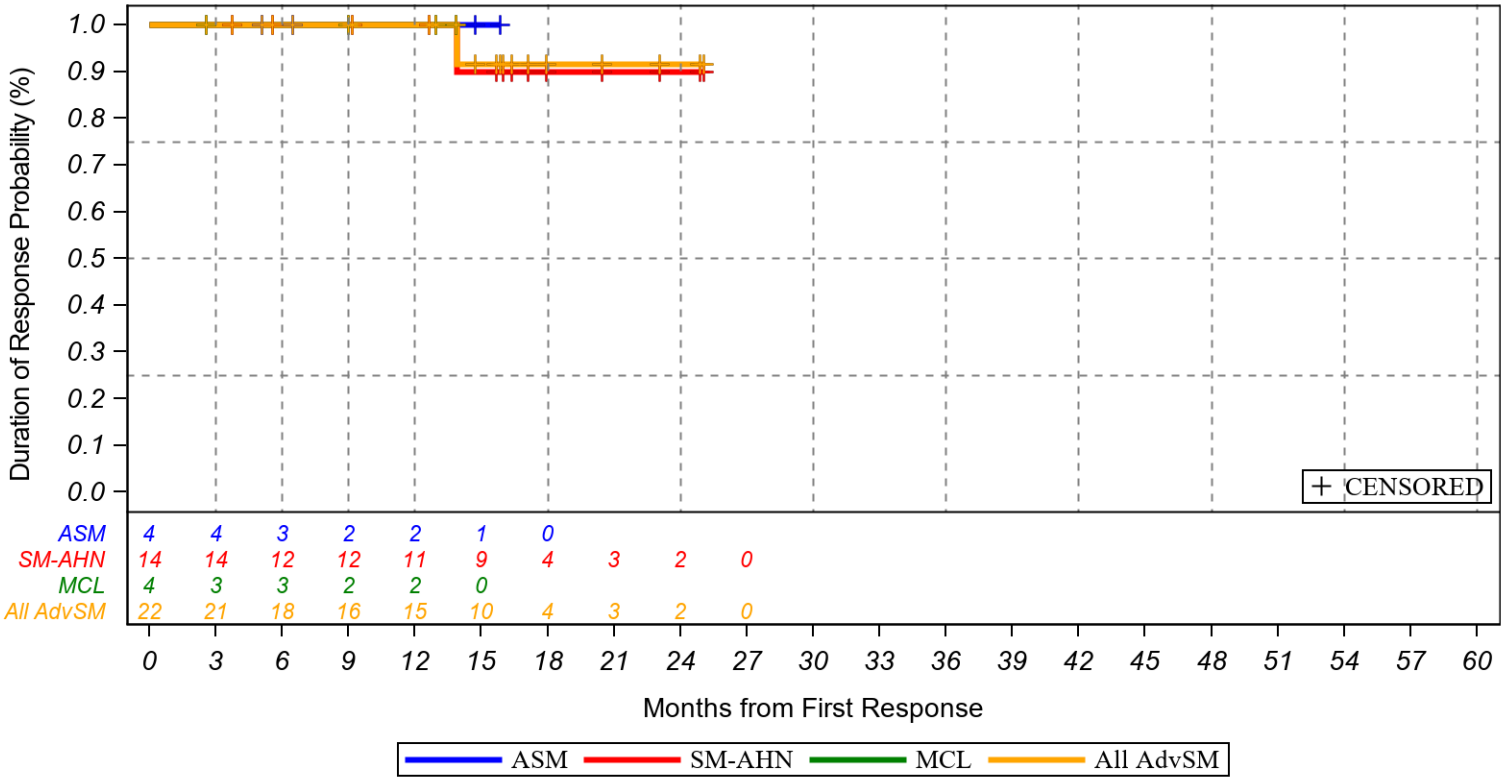

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Starting Dose: 200 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR)

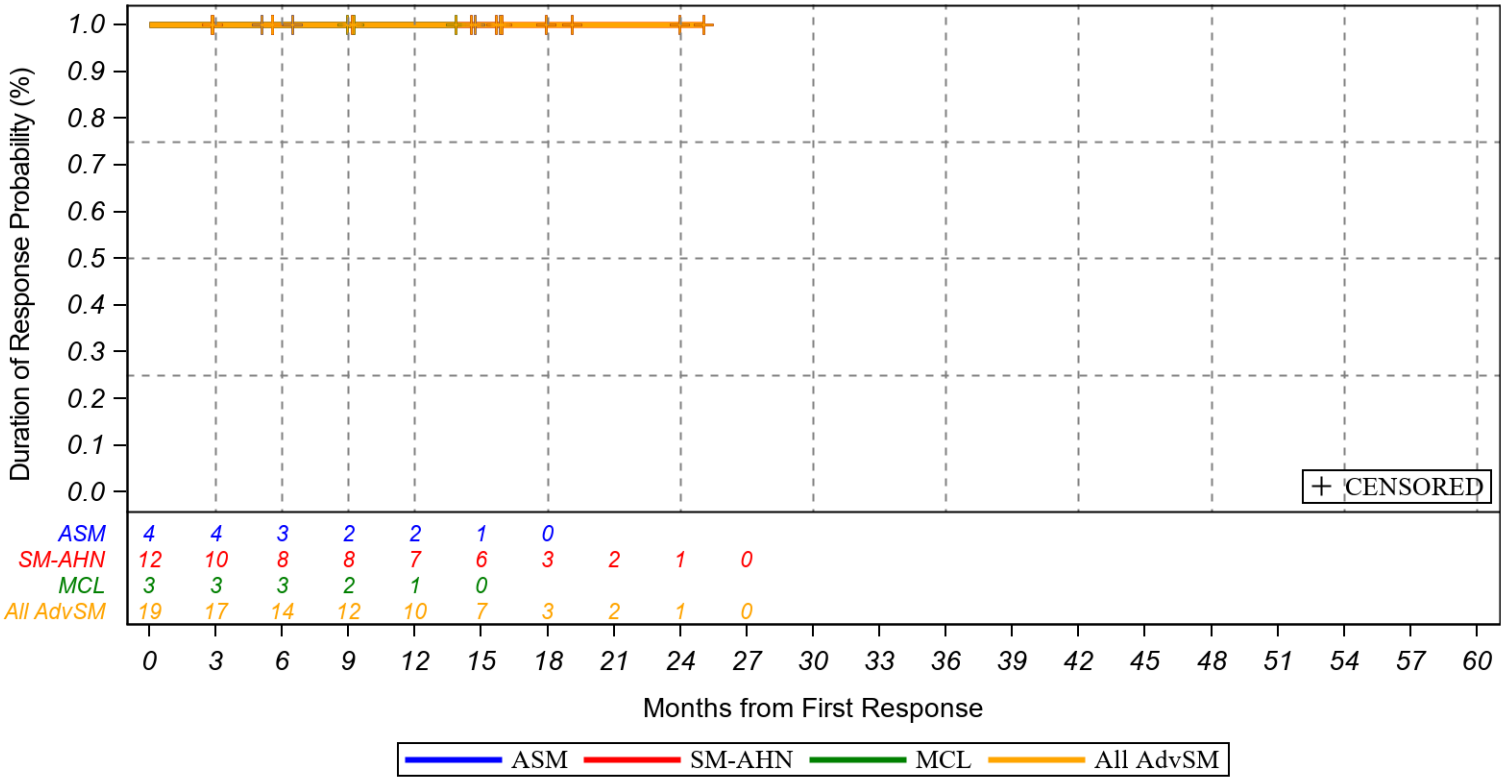

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Starting Dose: 200 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR+CI)

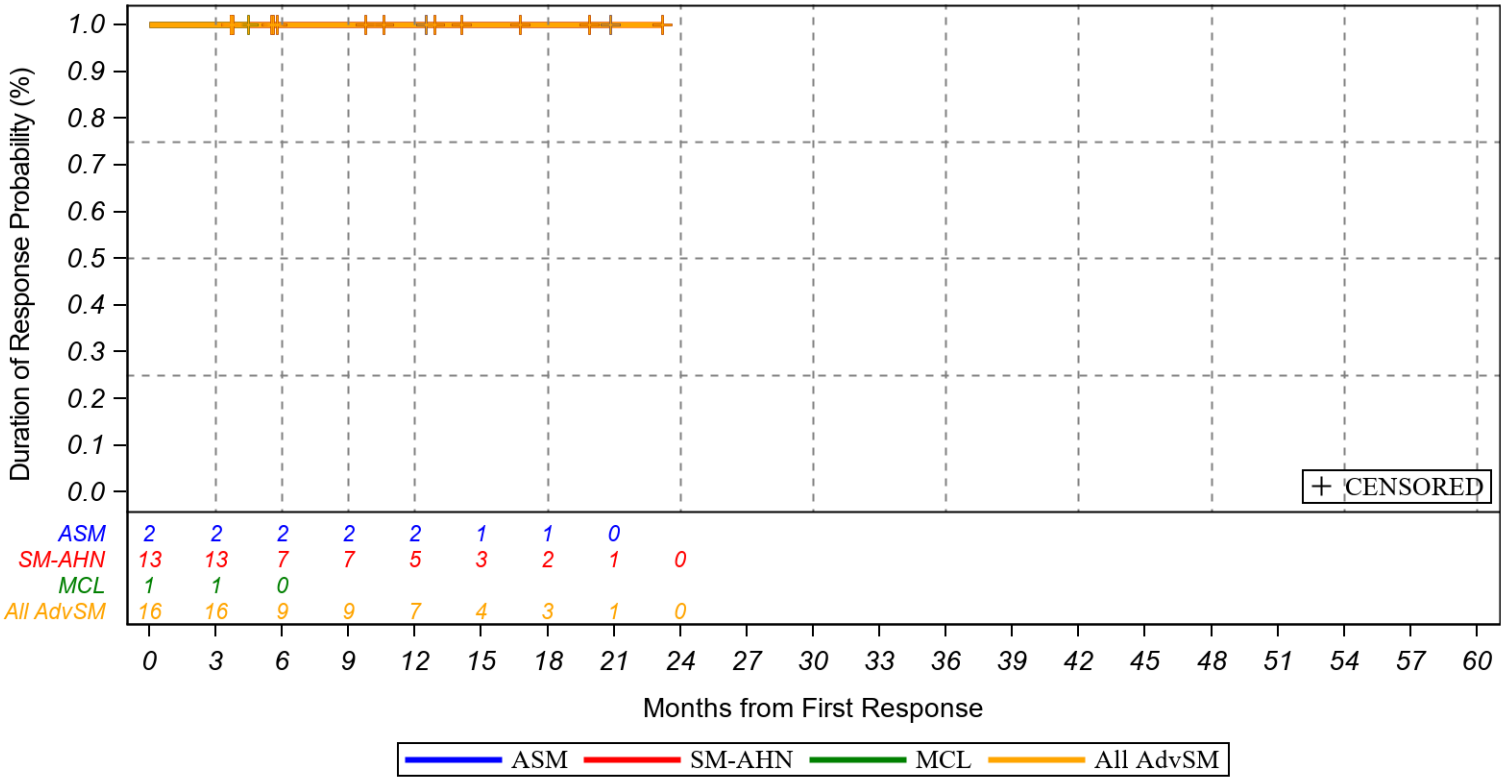

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Starting Dose: 200 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR)

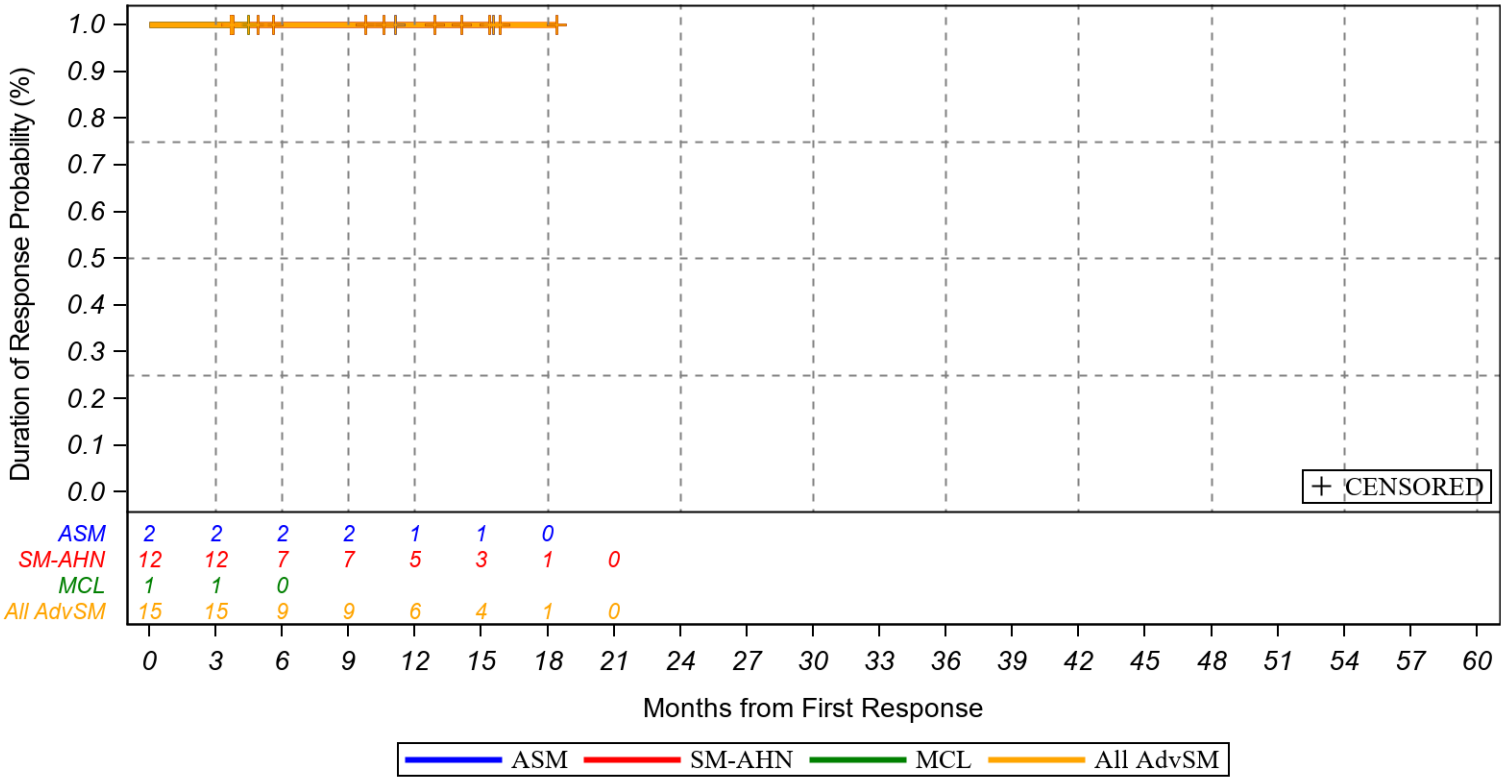

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall
Prior Antineoplastic Therapy = Yes
Responders (CR+PR+CI)

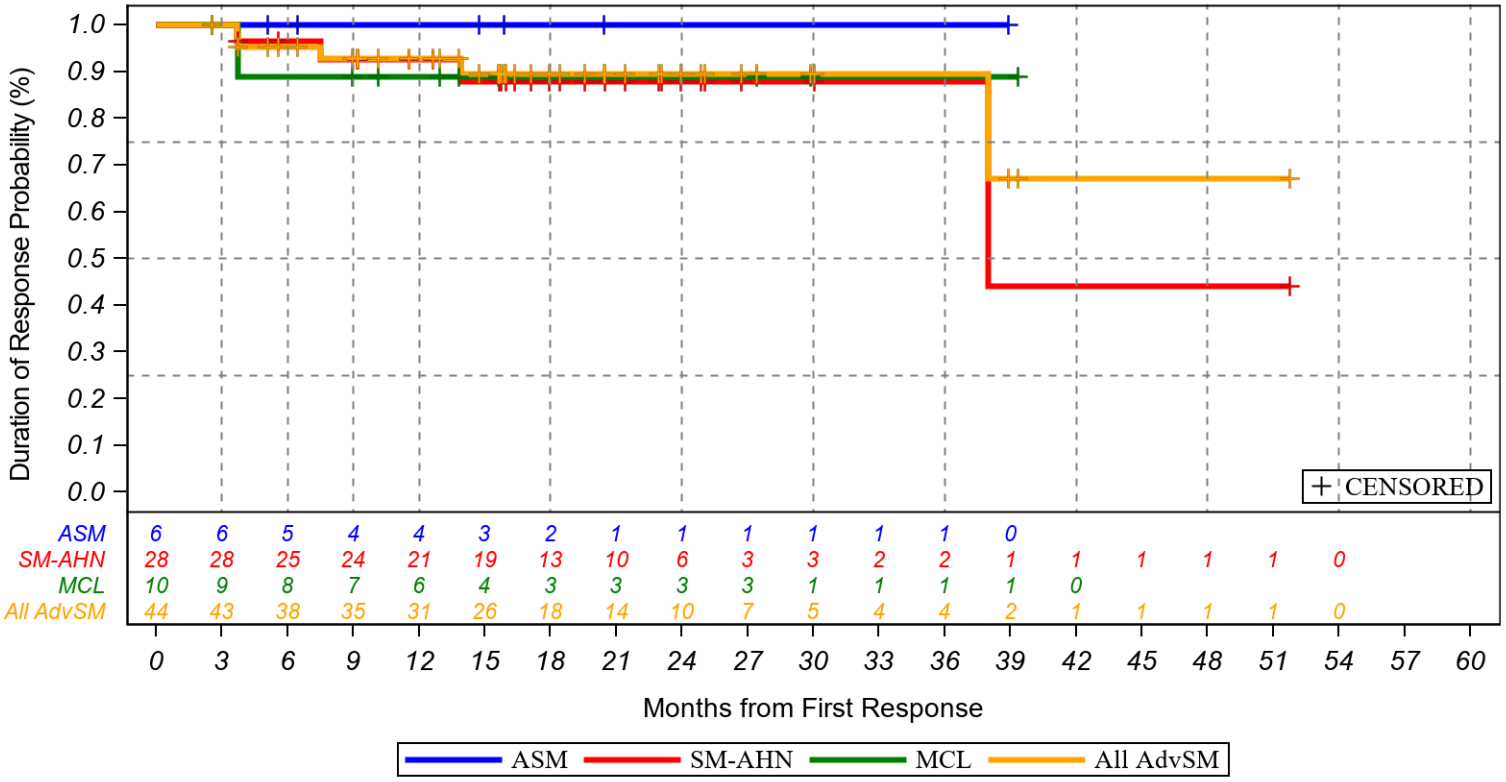

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall
Prior Antineoplastic Therapy = Yes
Responders (CR+PR)

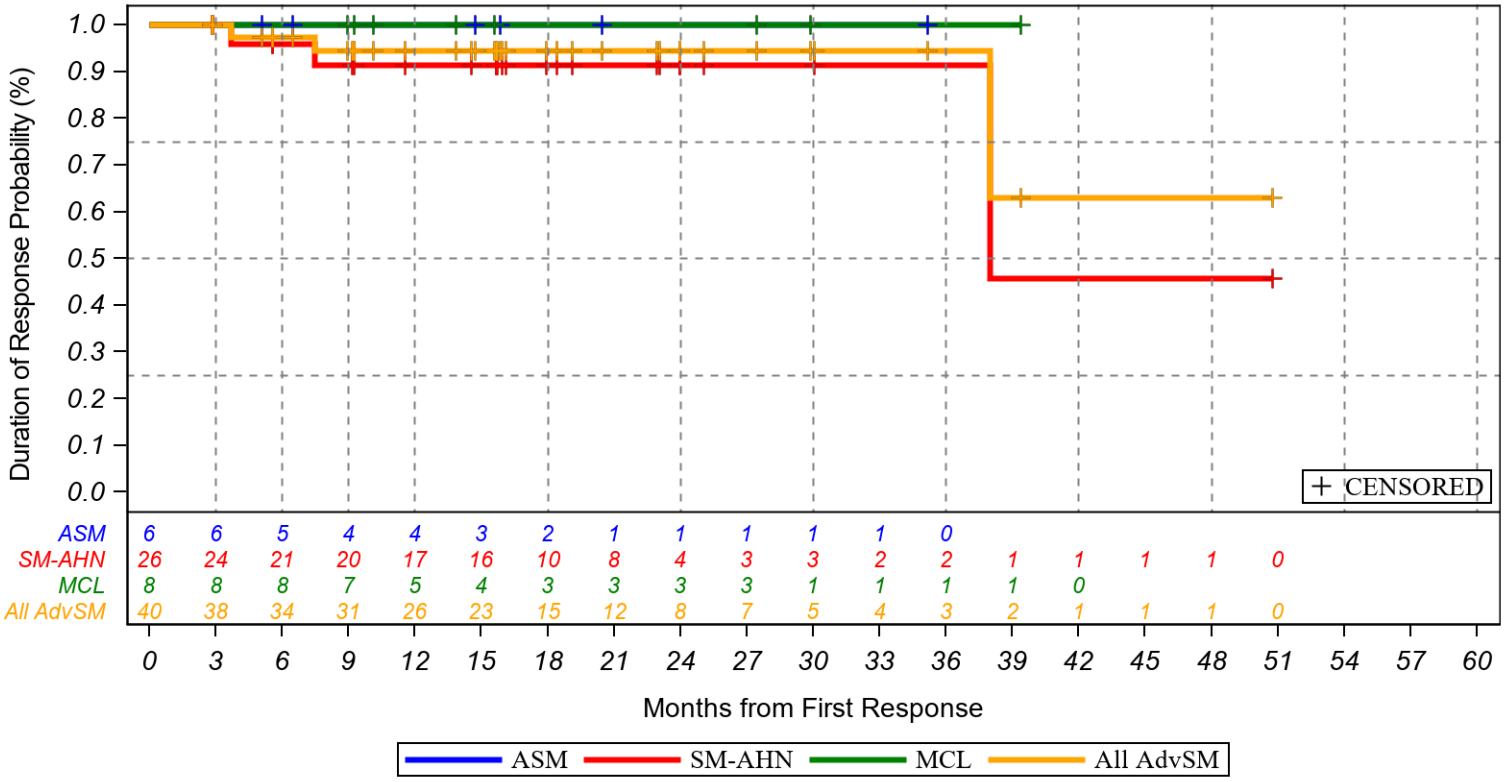

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall
Prior Antineoplastic Therapy = No
Responders (CR+PR+CI)

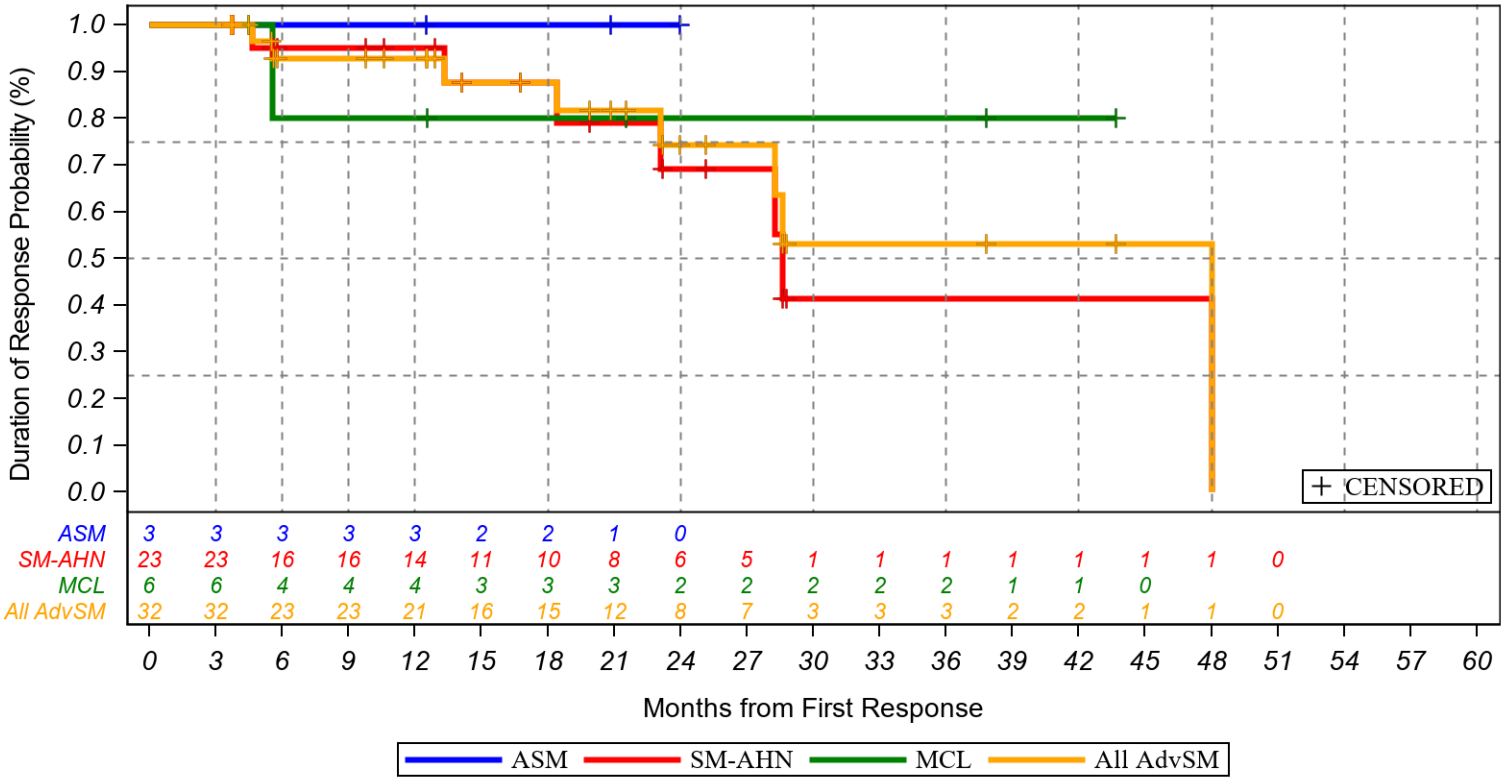

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall
Prior Antineoplastic Therapy = No
Responders (CR+PR)

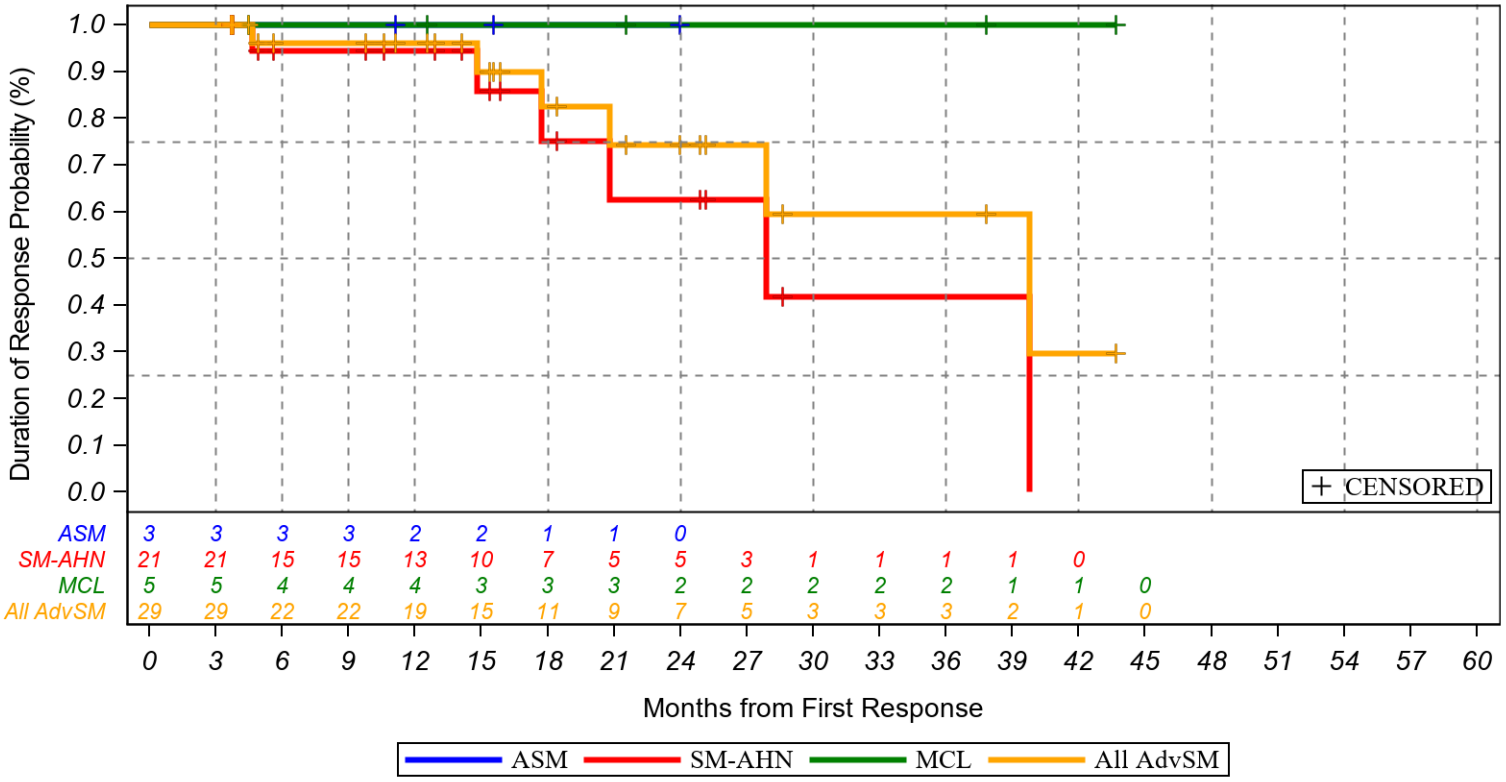

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR+CI)

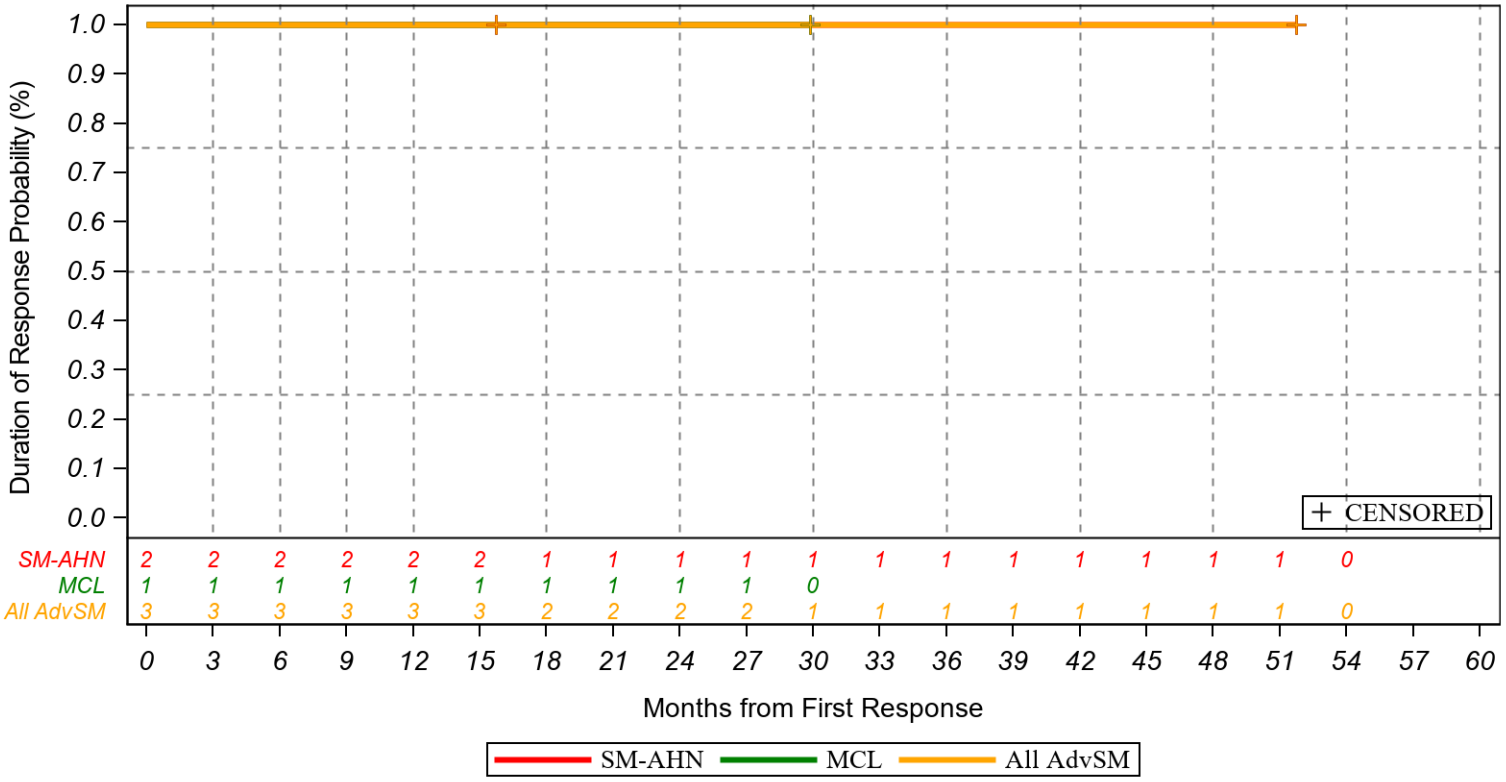

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR)

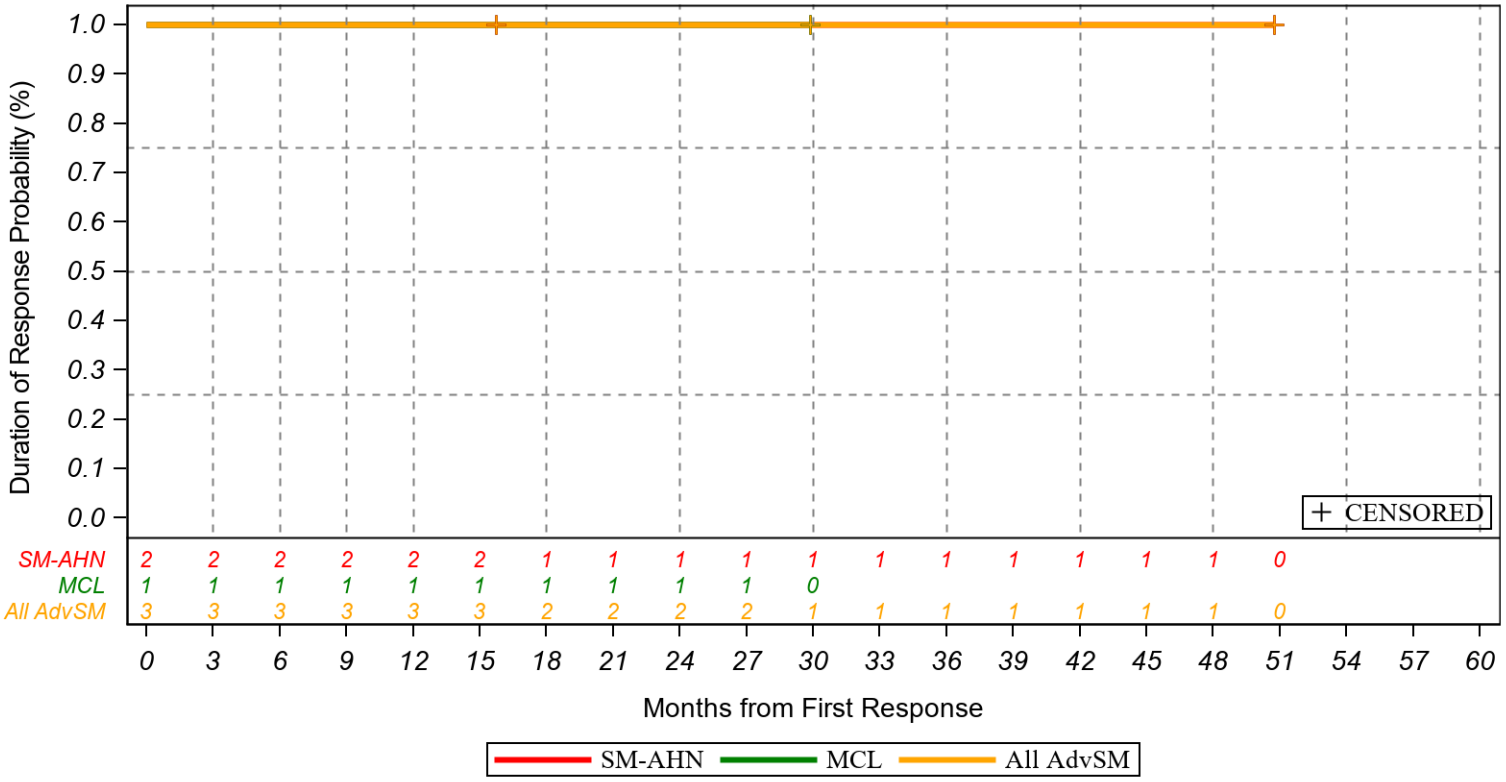

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR+CI)

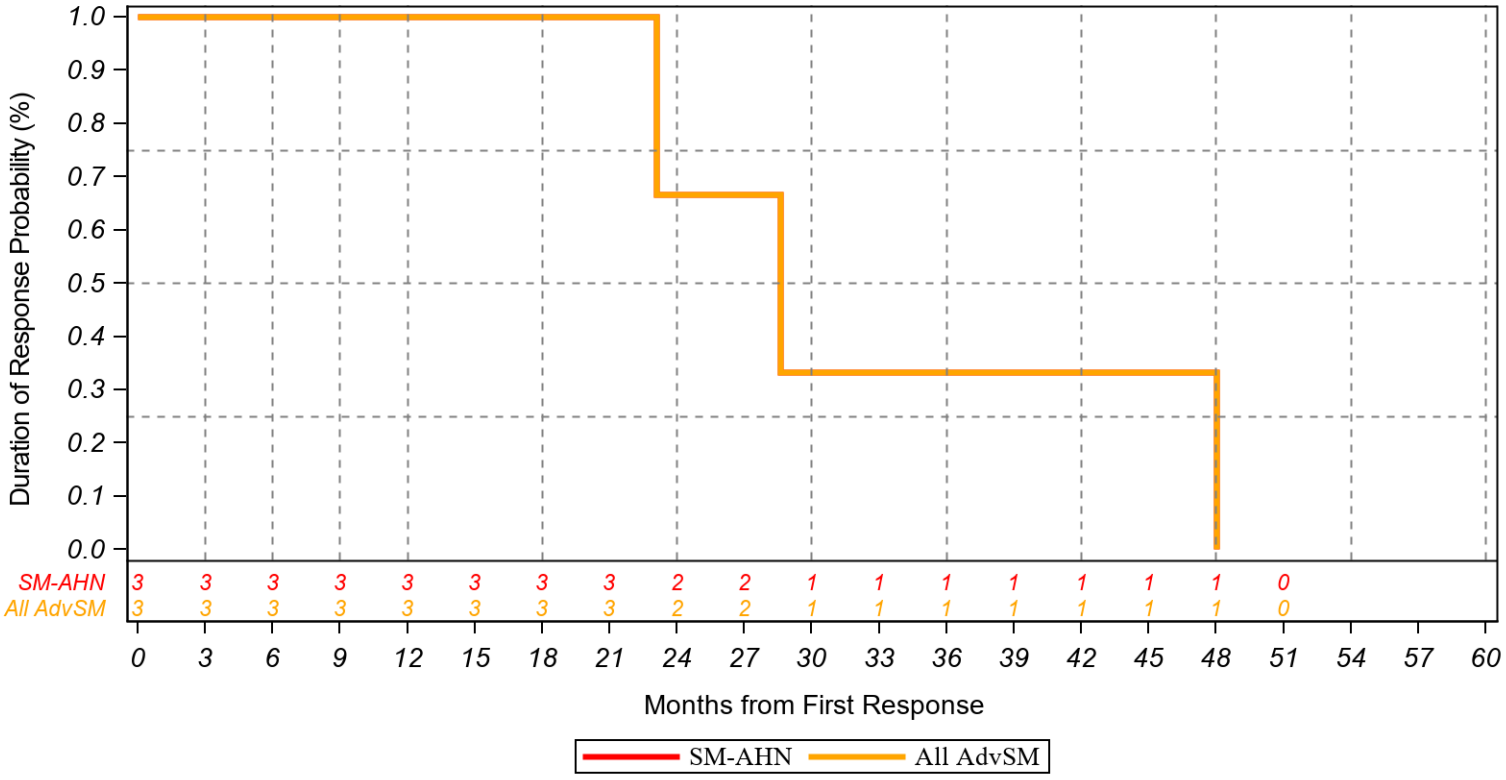

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR)

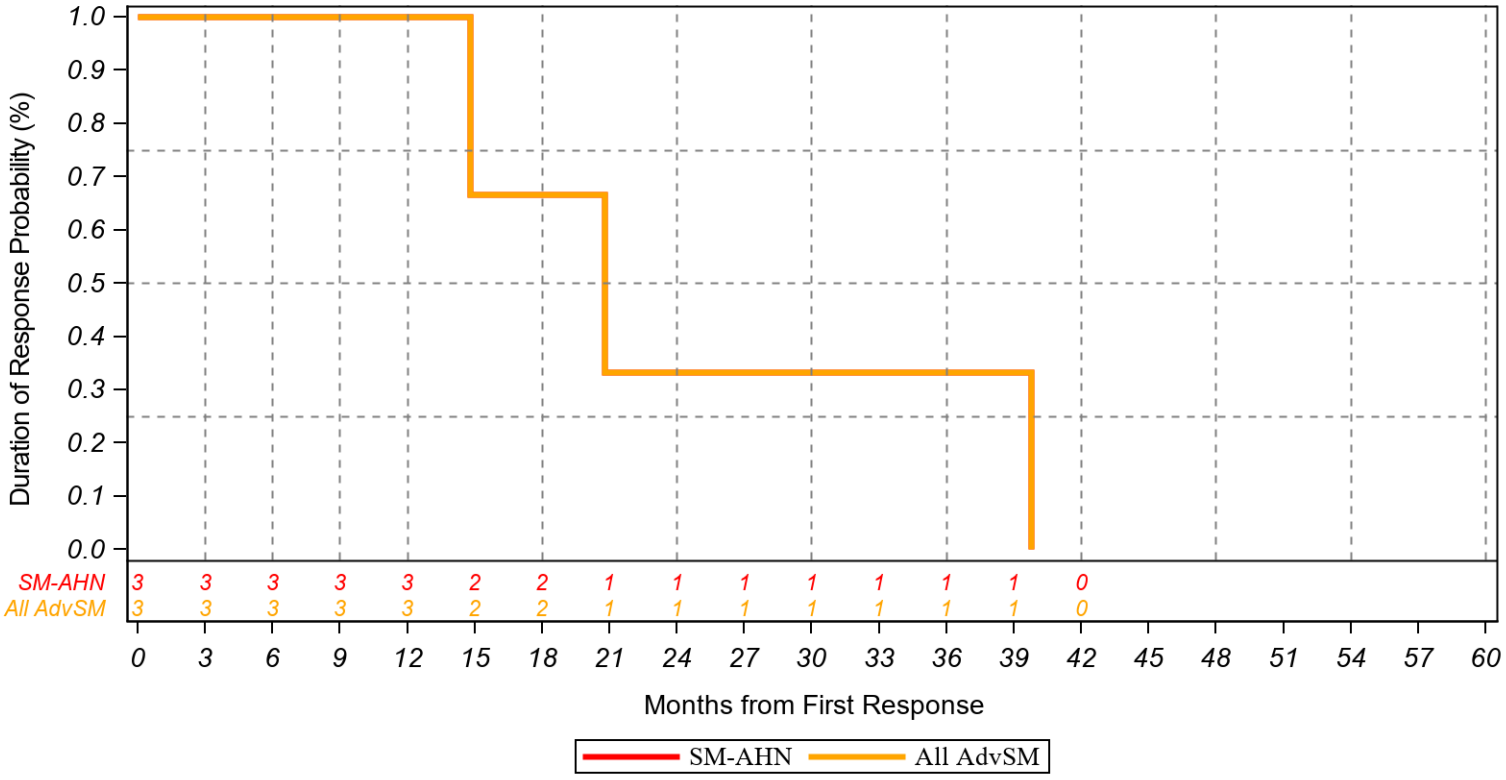

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR+CI)

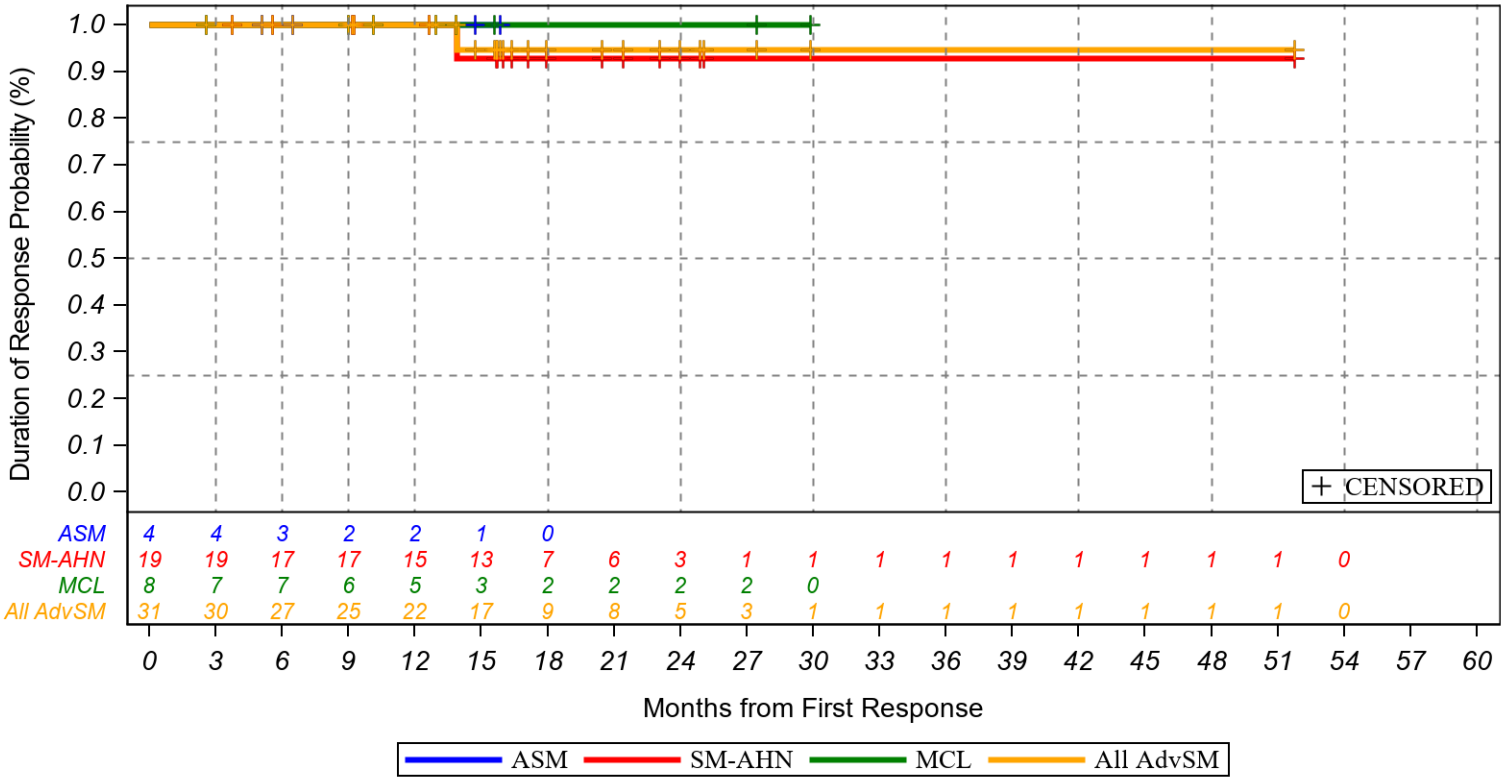

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR)

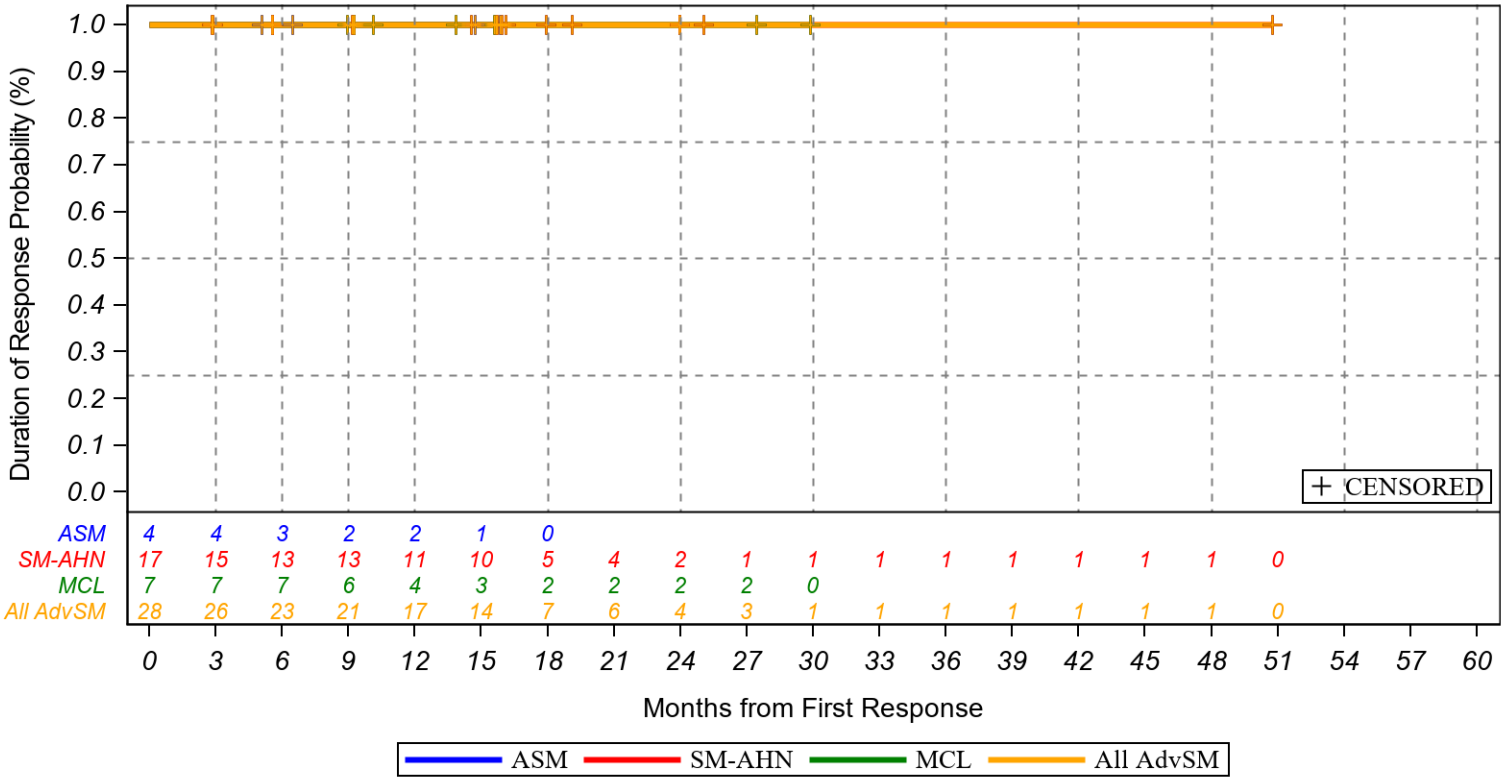

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR+CI)

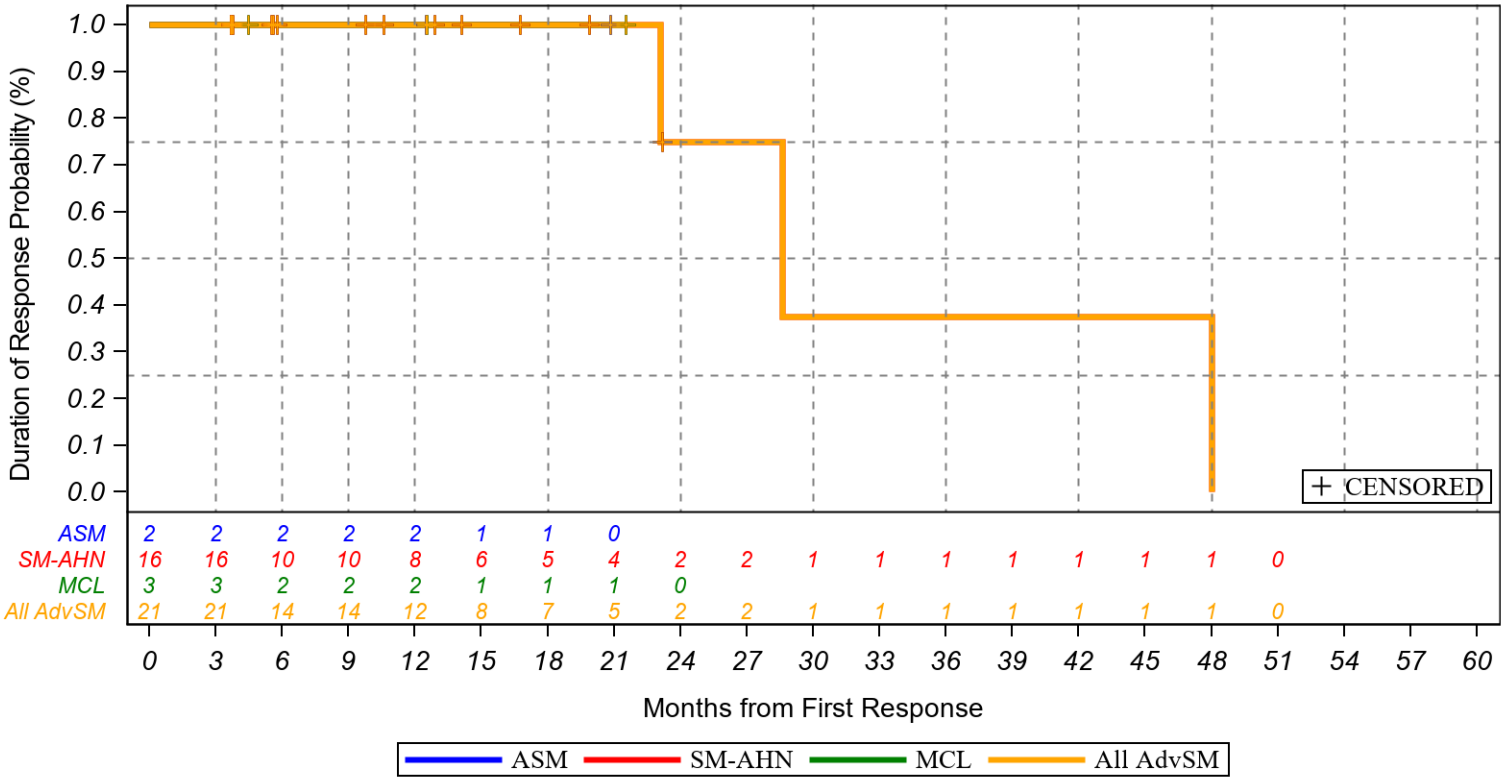

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR)

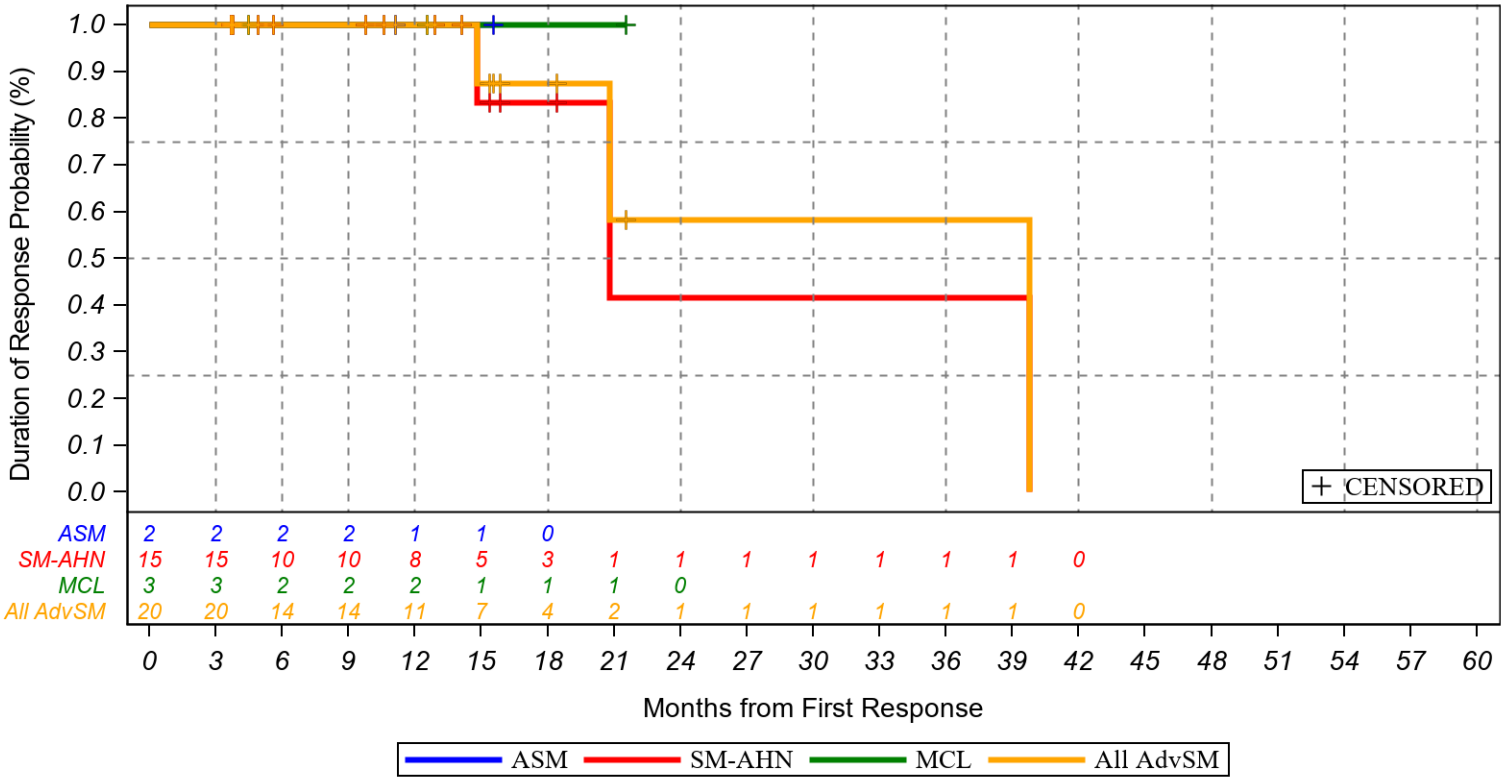

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR+CI)

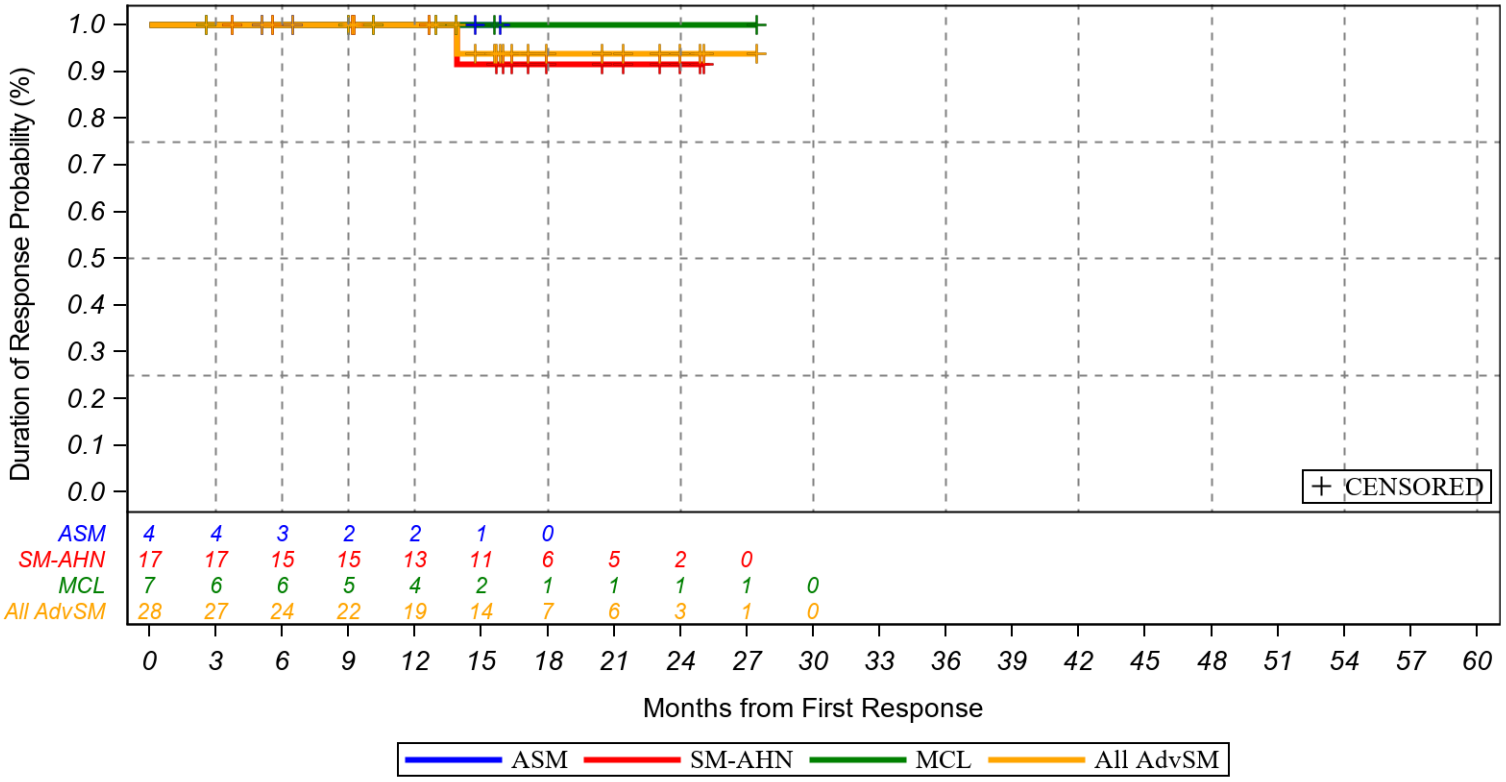

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR)

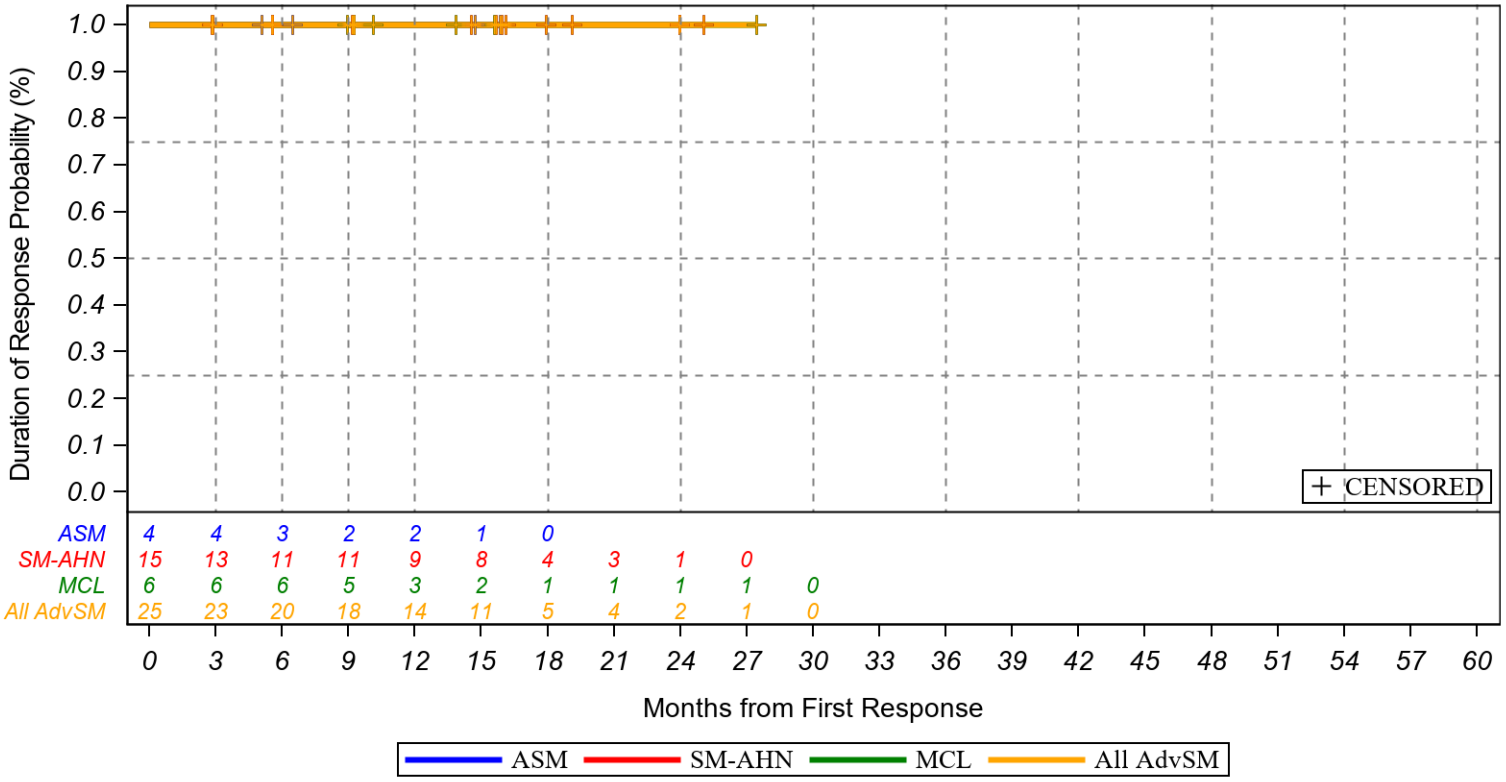

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR+CI)

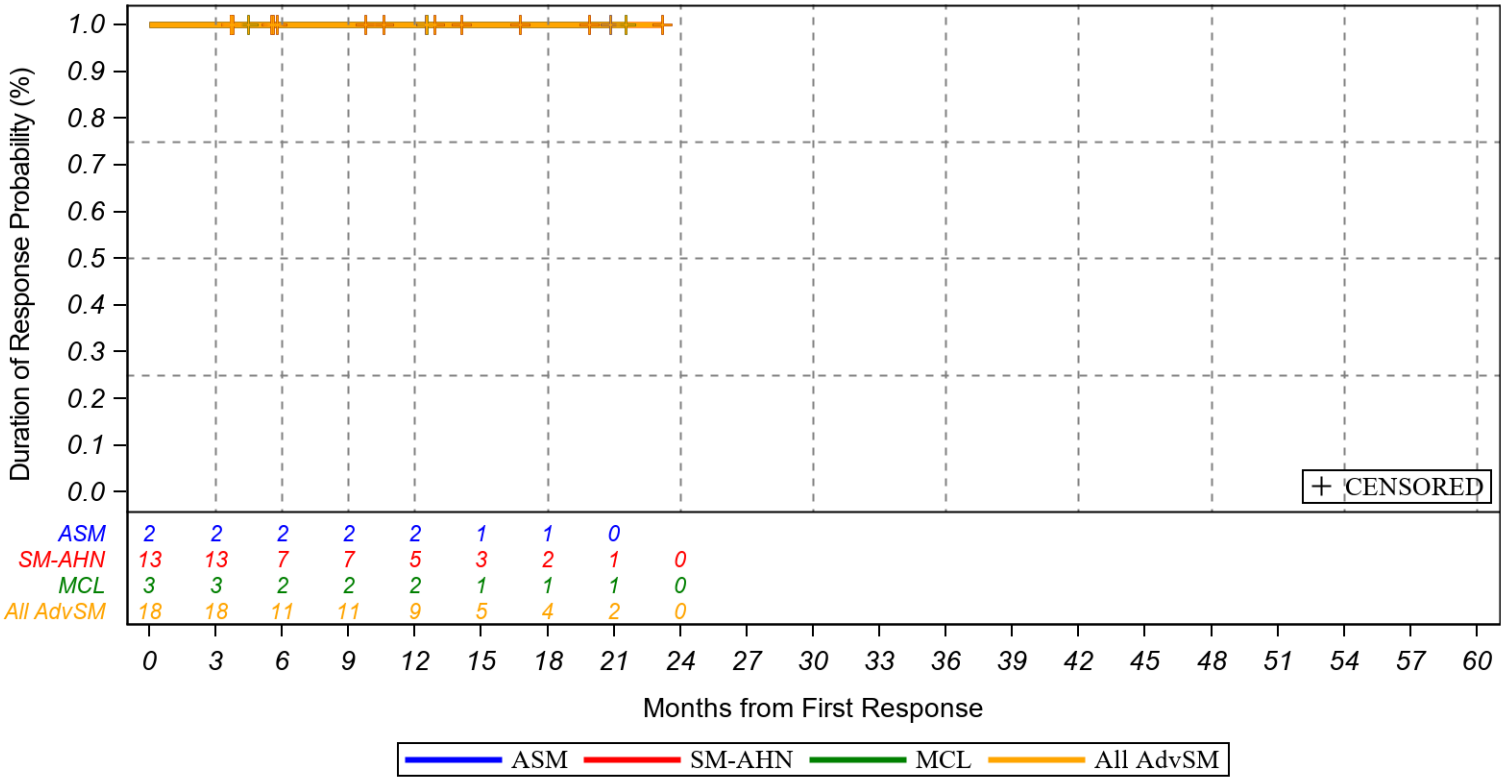

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR)

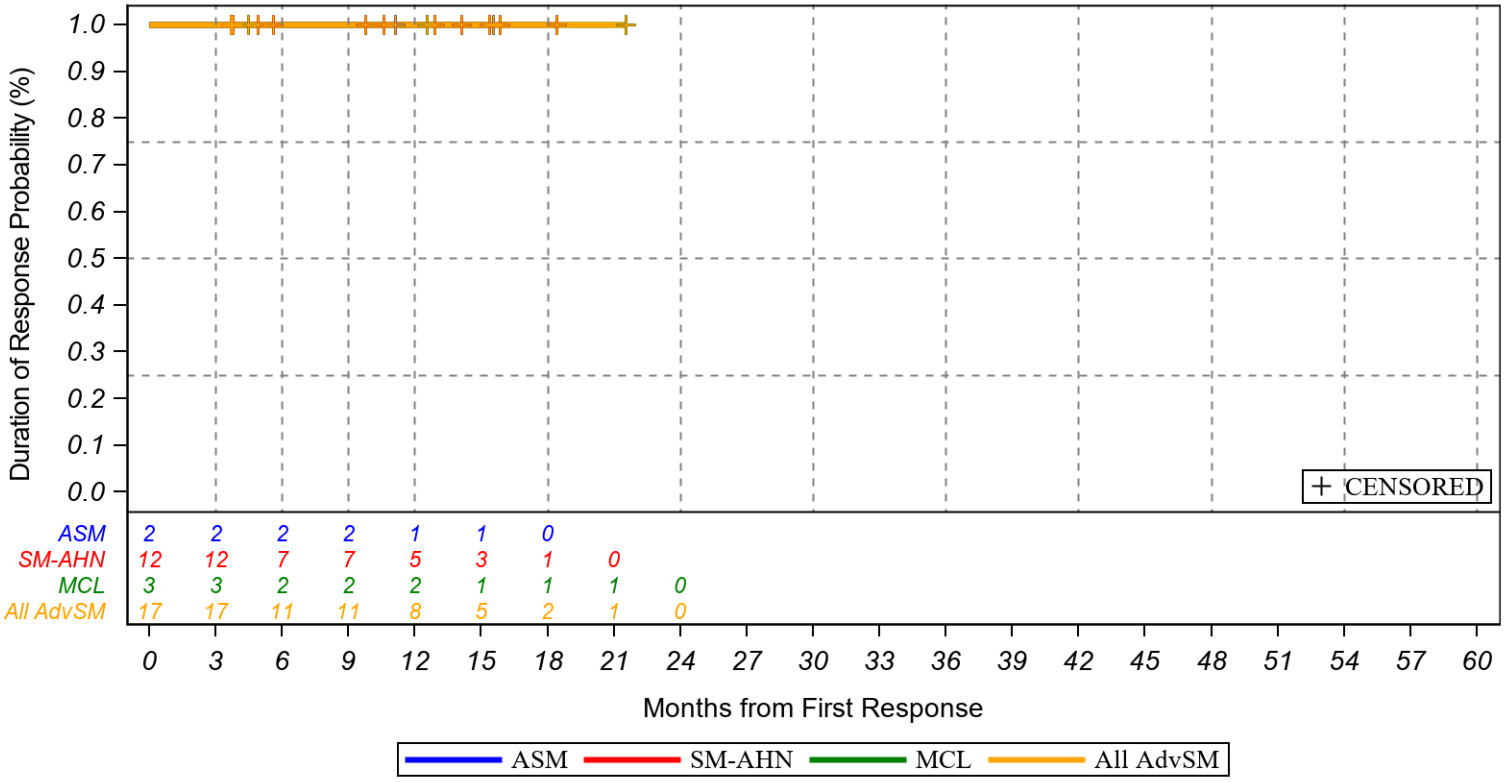

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR+CI)

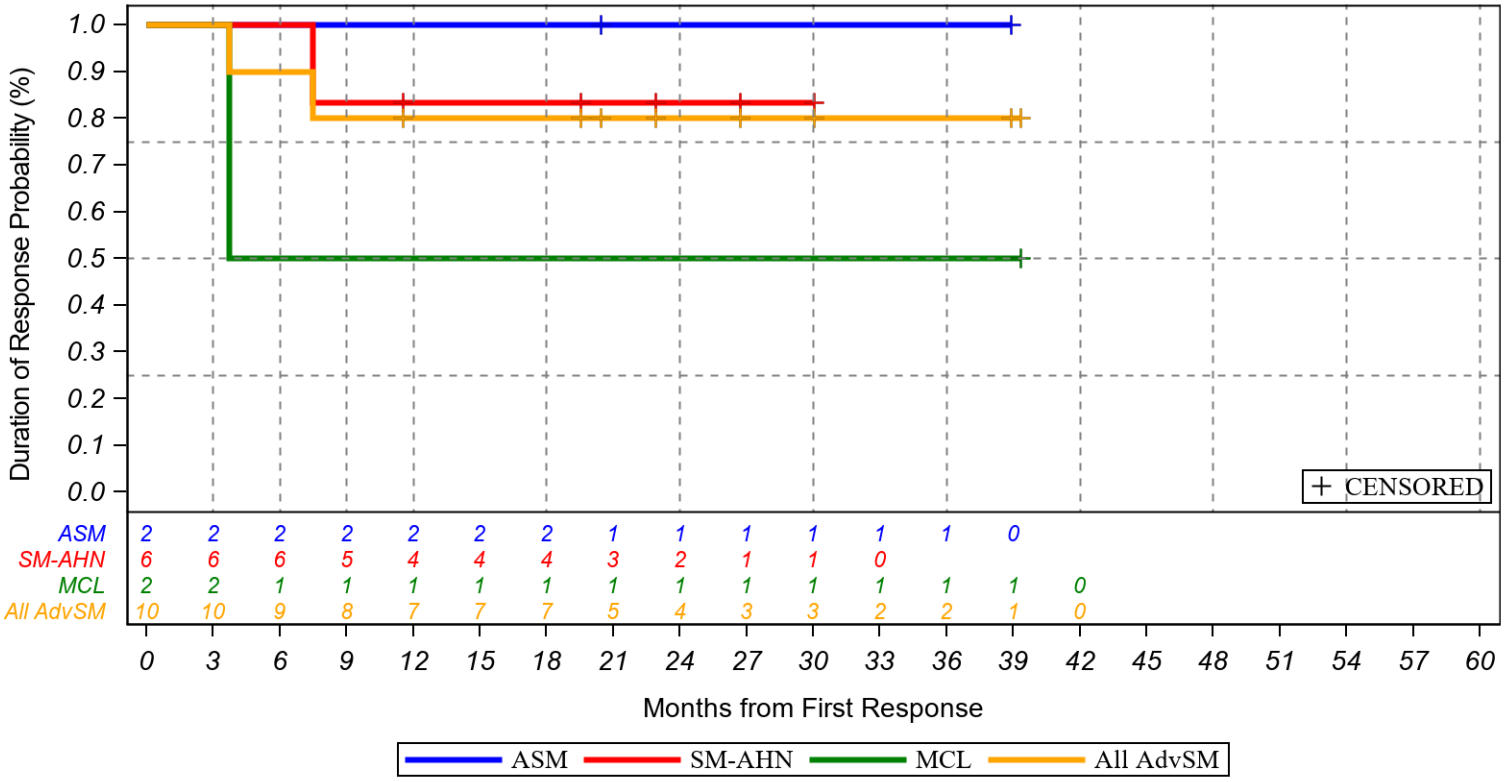

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR)

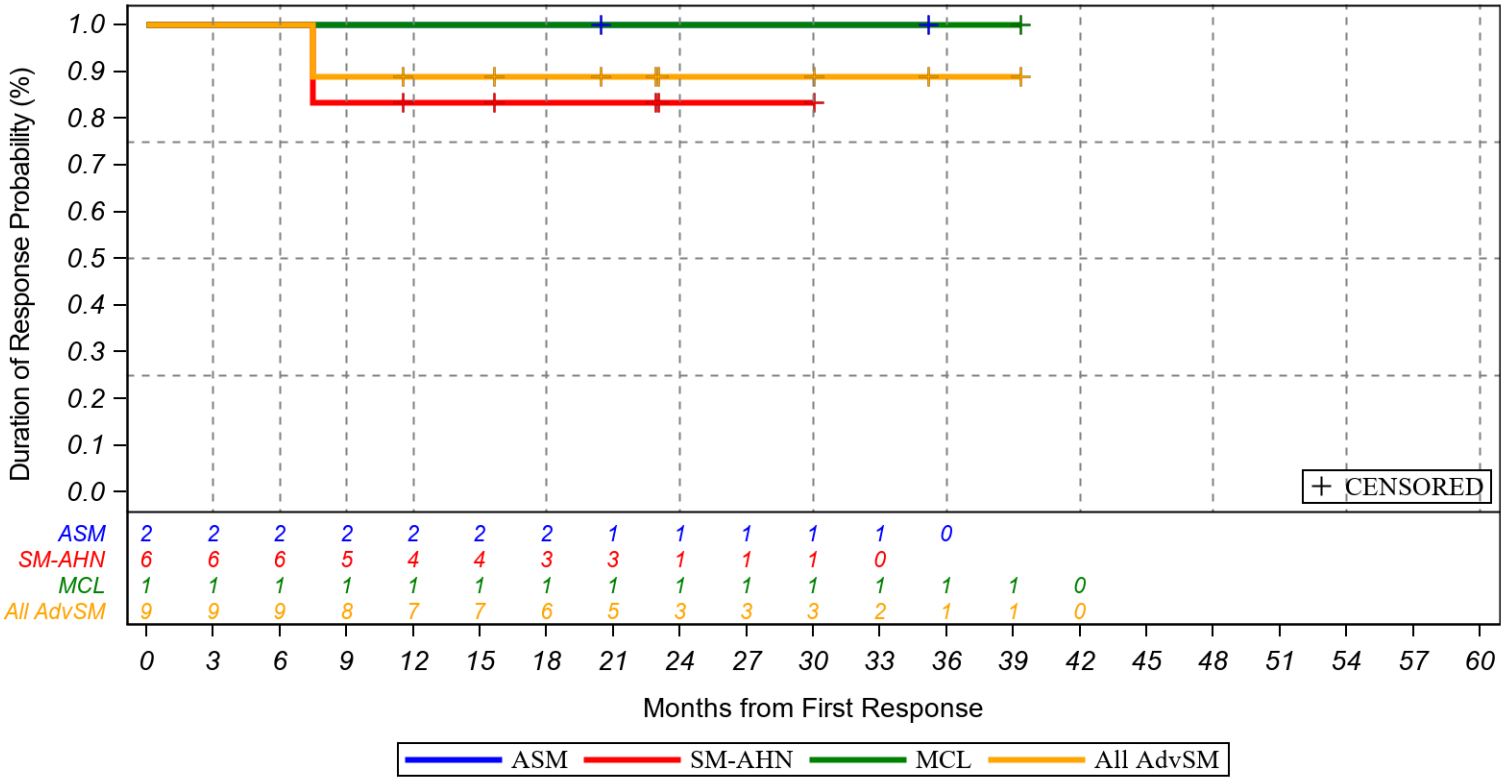

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR+CI)

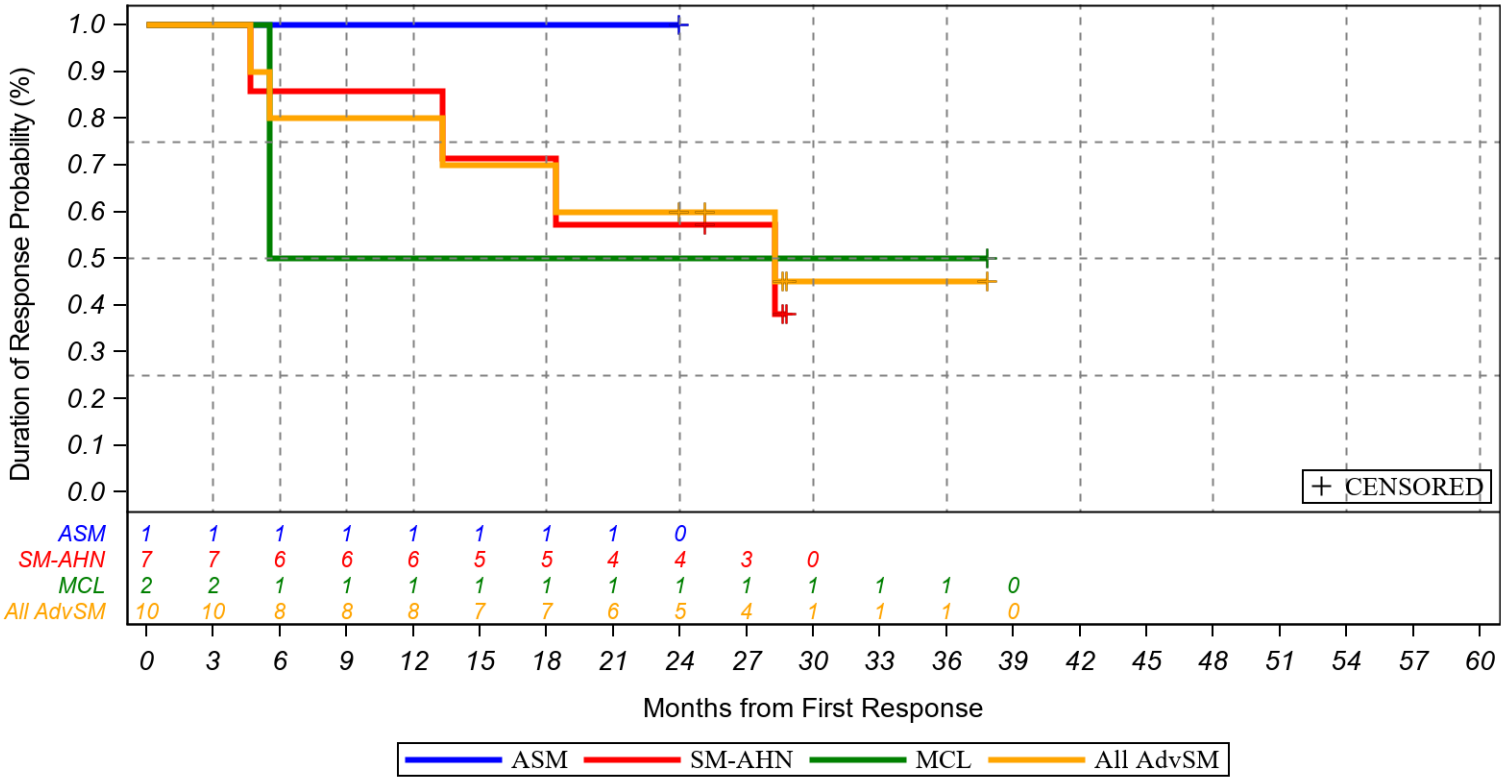

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR)

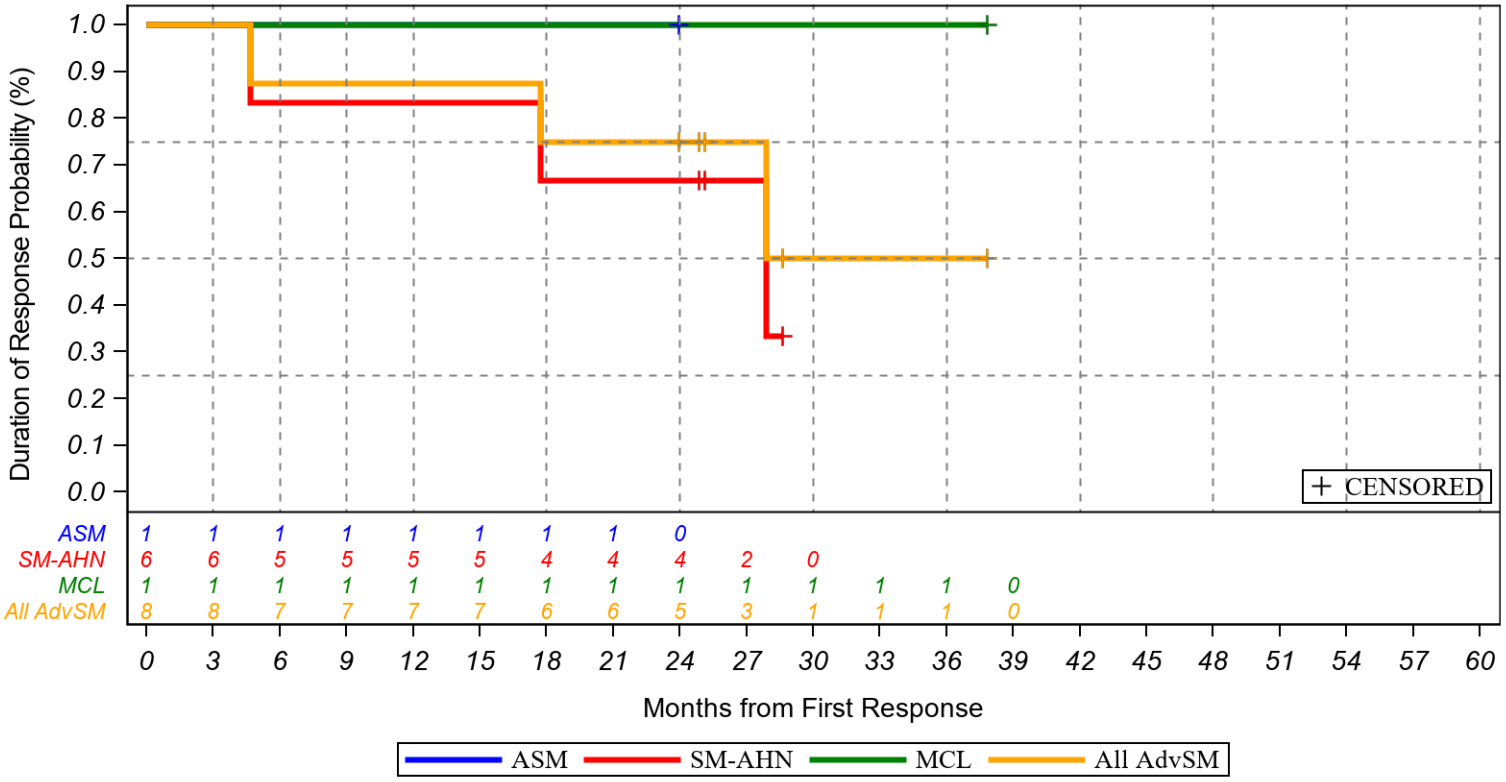

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR+CI)

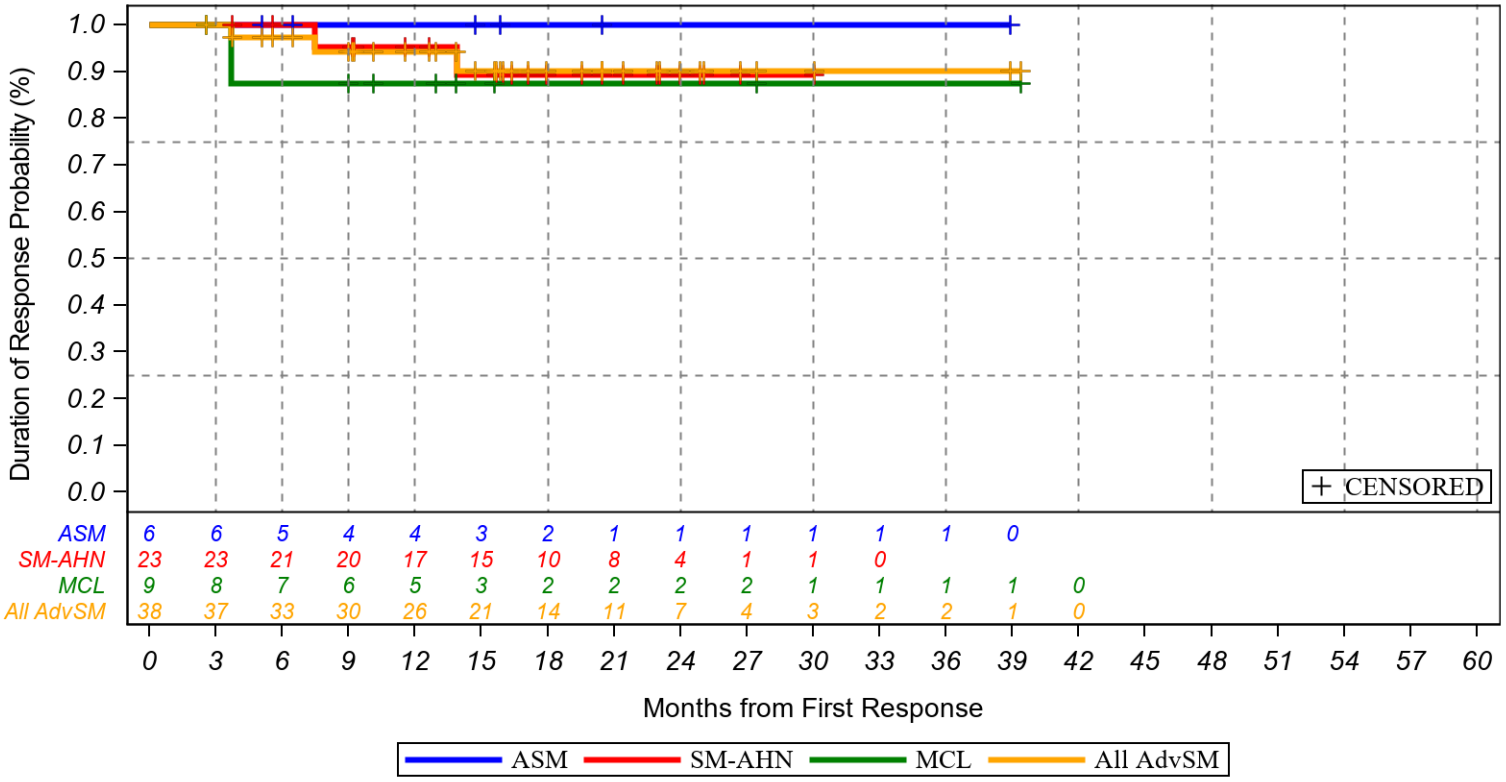

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR)

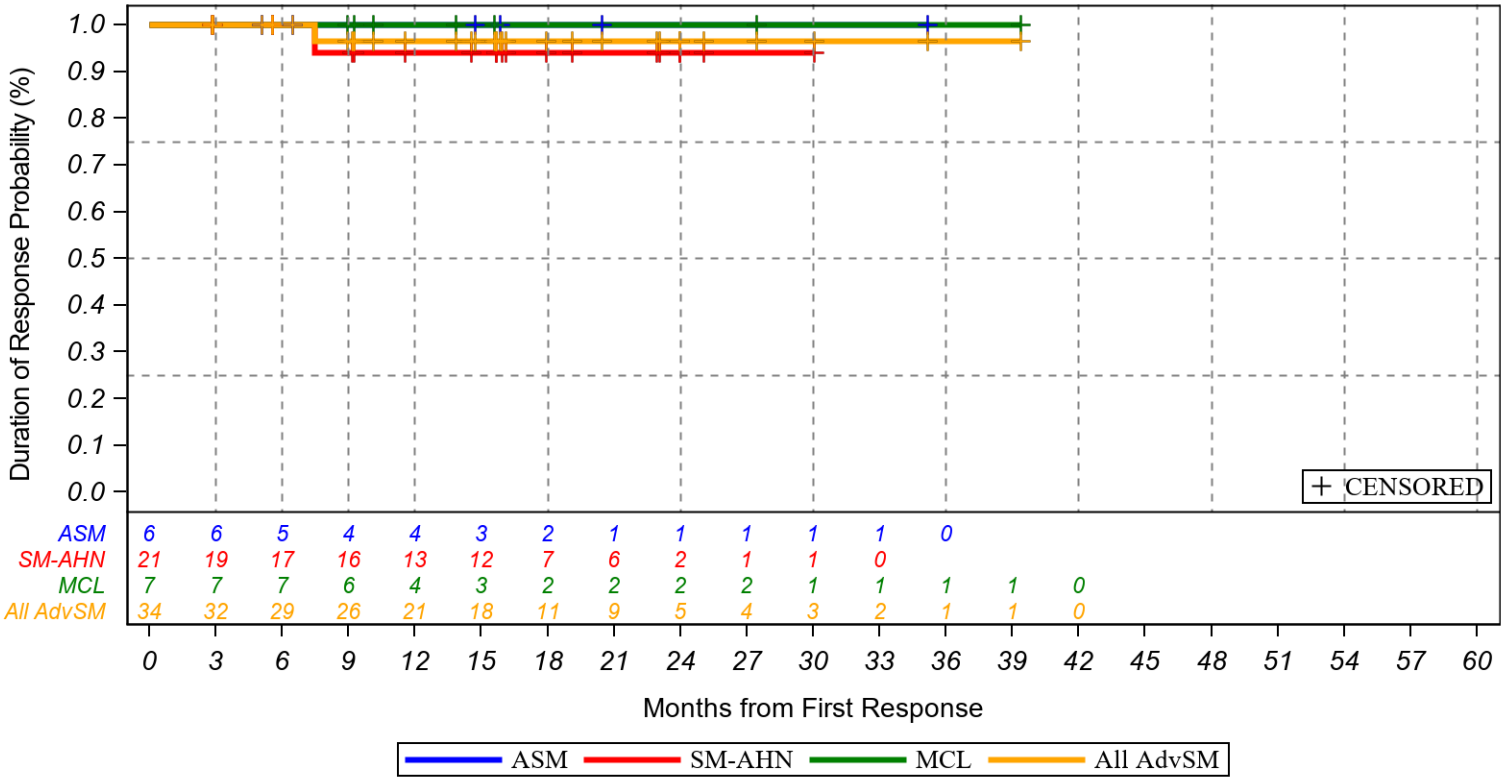

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR+CI)

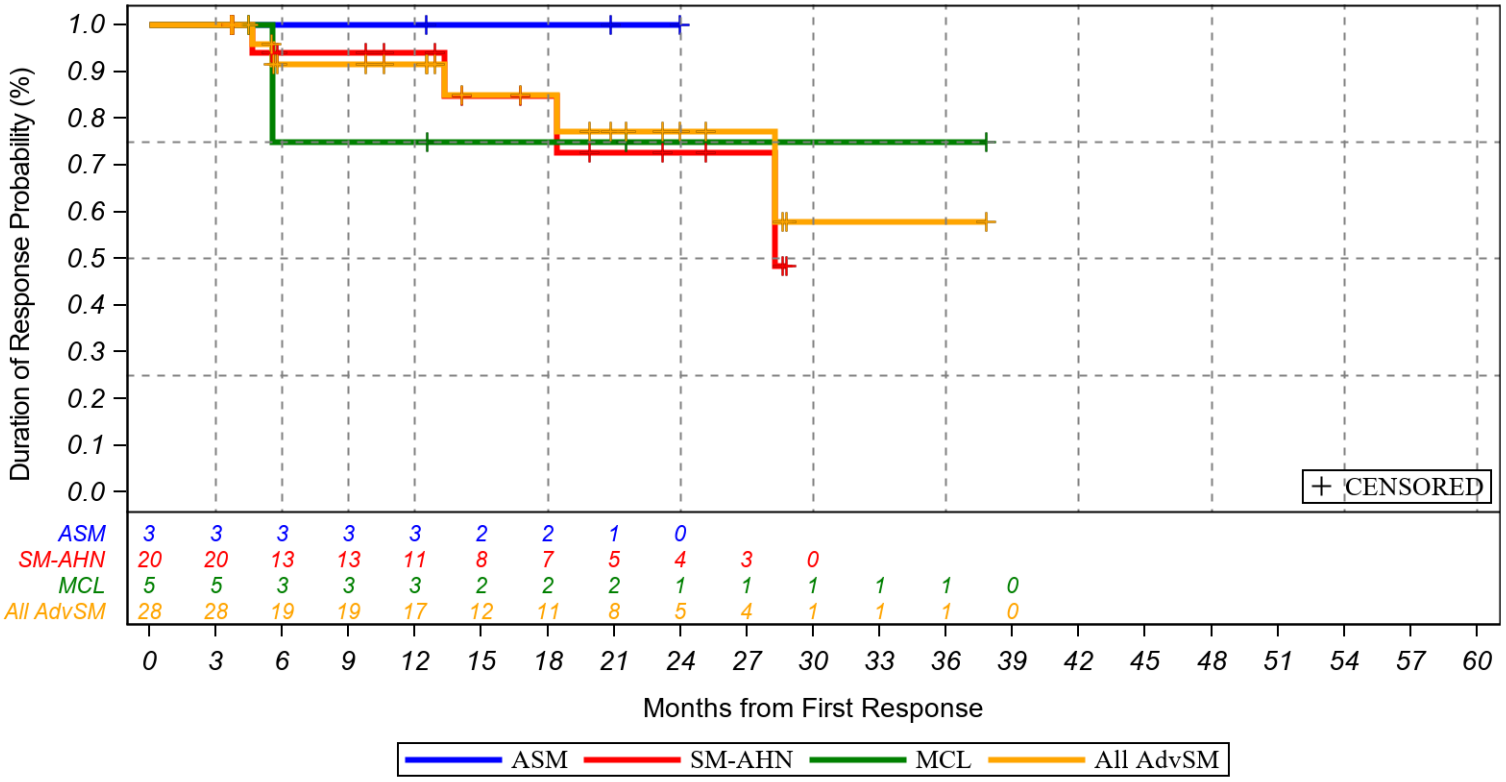

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR)

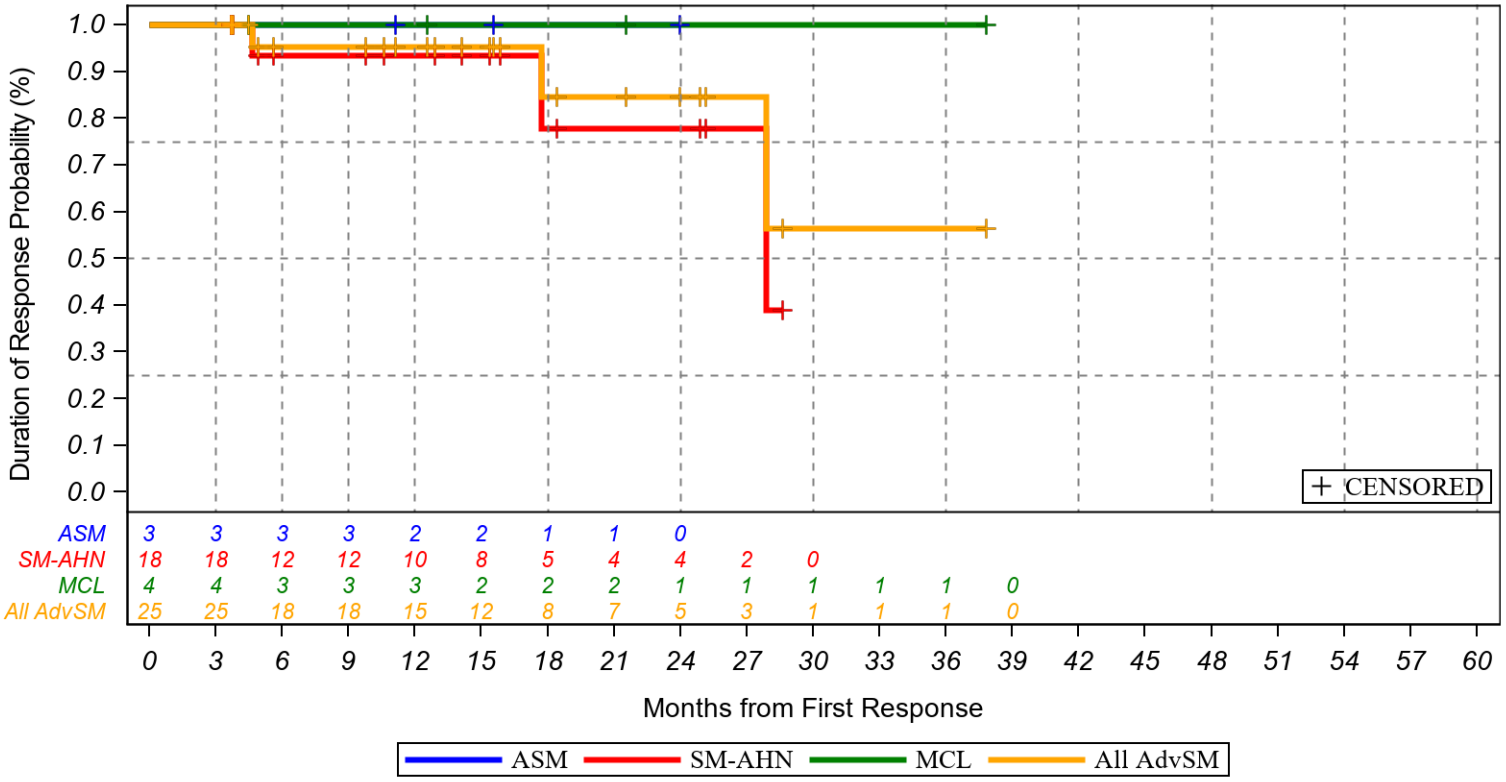

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR+CI)

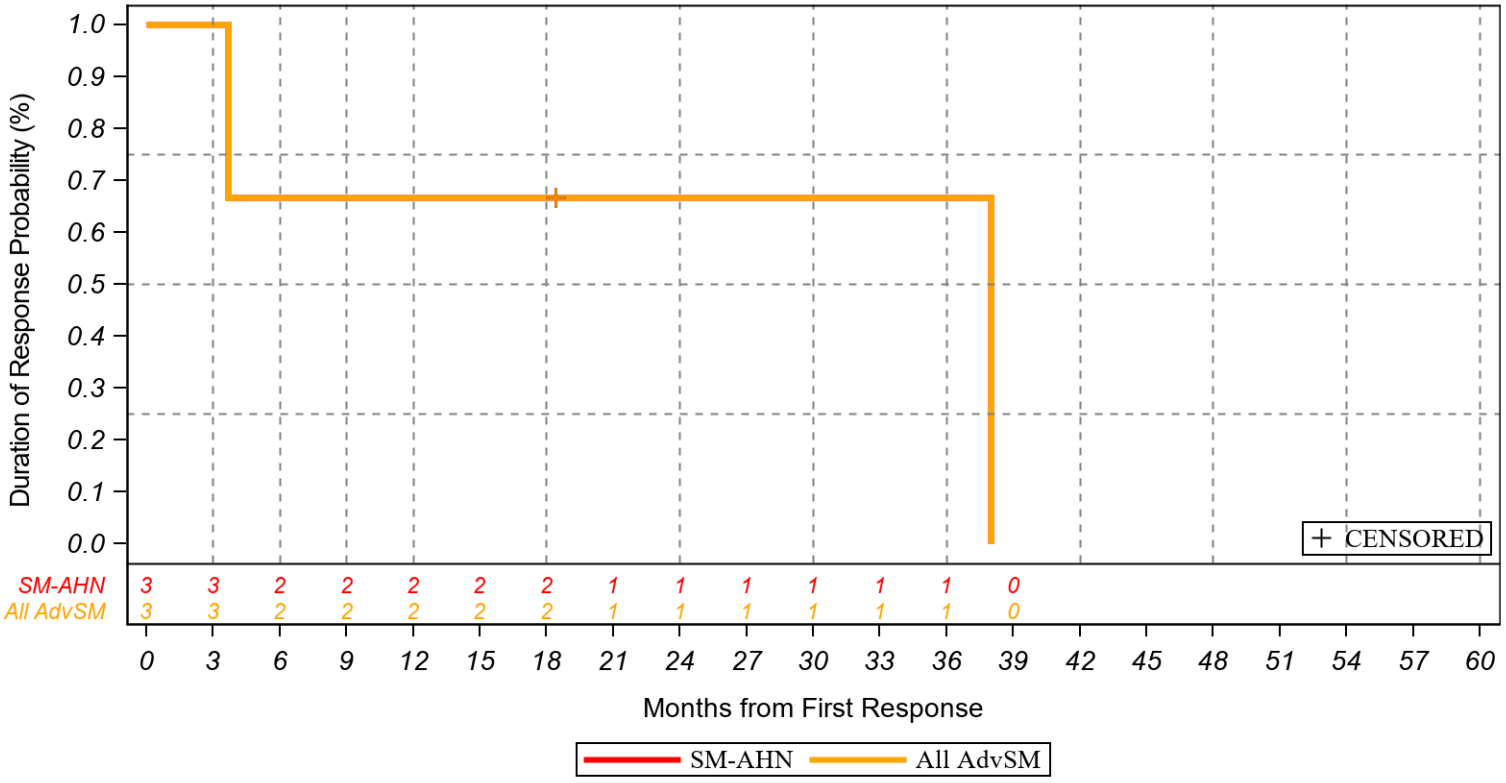

Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg
Prior Antineoplastic Therapy = Yes
Responders (CR+PR)

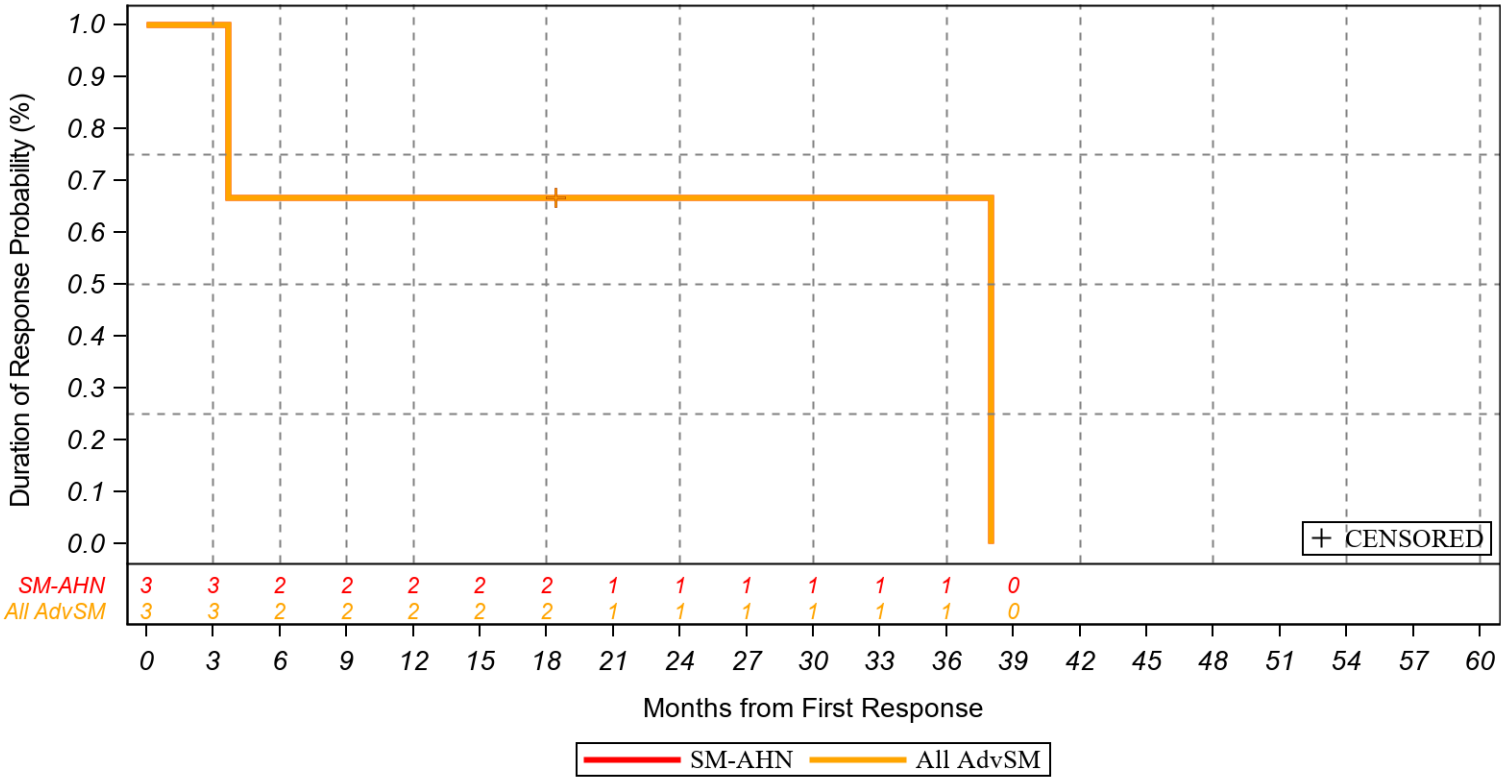

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Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR+CI)

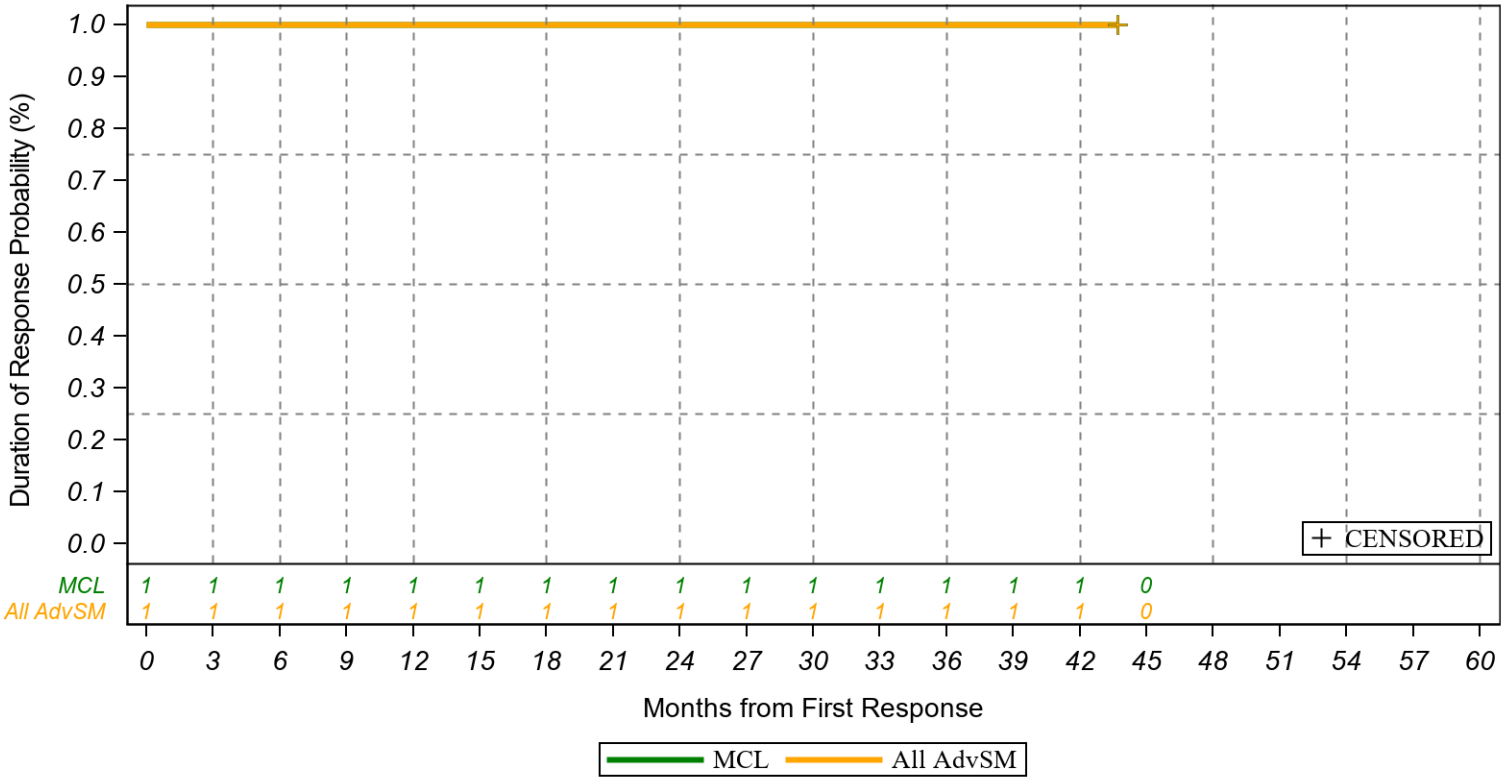

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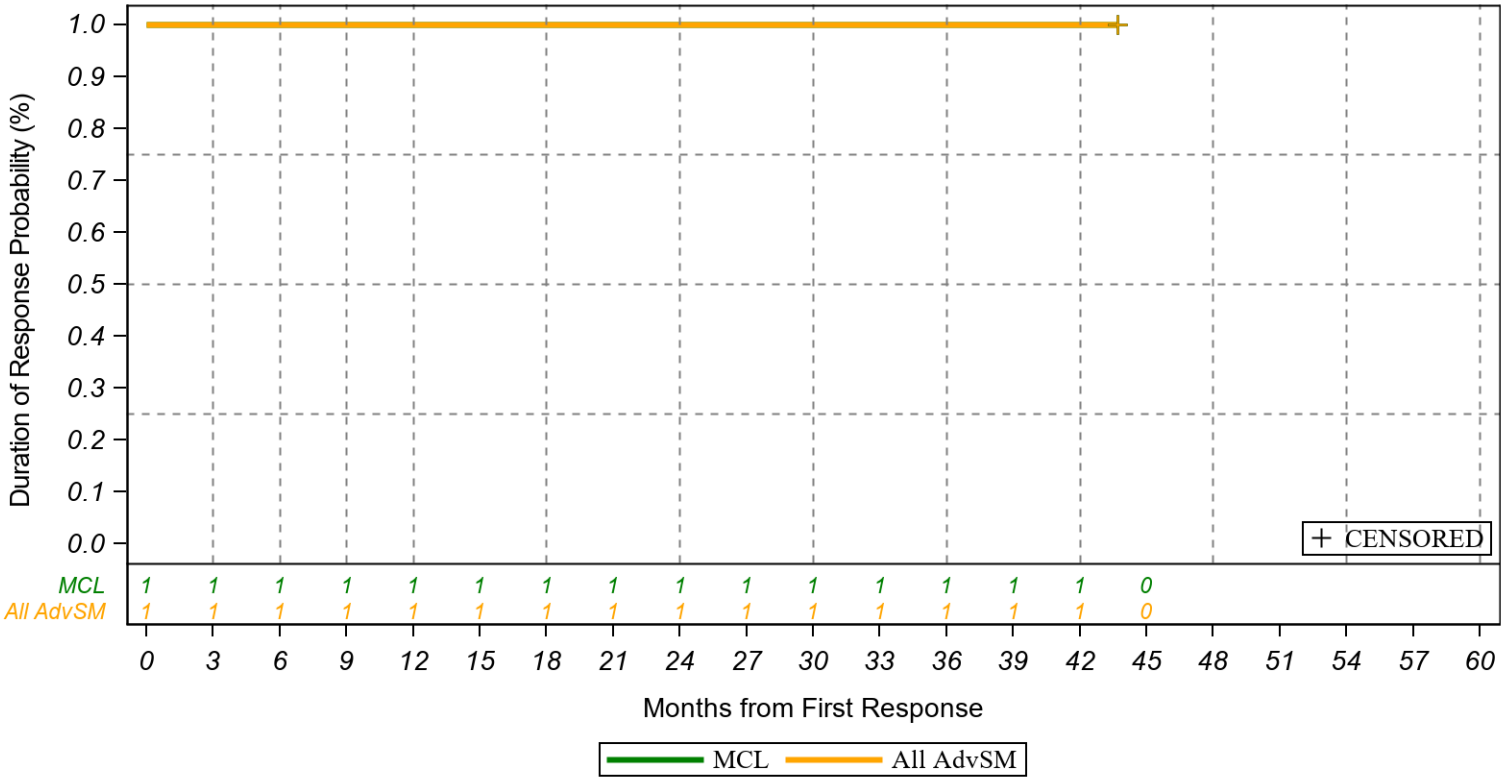
Figure 15.2.2.7b
Kaplan-Meier Curves of Algorithm Duration of Response by IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg
Prior Antineoplastic Therapy = No
Responders (CR+PR)



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Blueprint Medicines
Page 1 of 48
Avapritinib Systemic Mastocytosis Integrated Summary of Efficacy
BLU-285 SM Germany HTA Analysis
Cutoff date: 20apr2021

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Study BLU-285-2101
Starting Dose: Overall

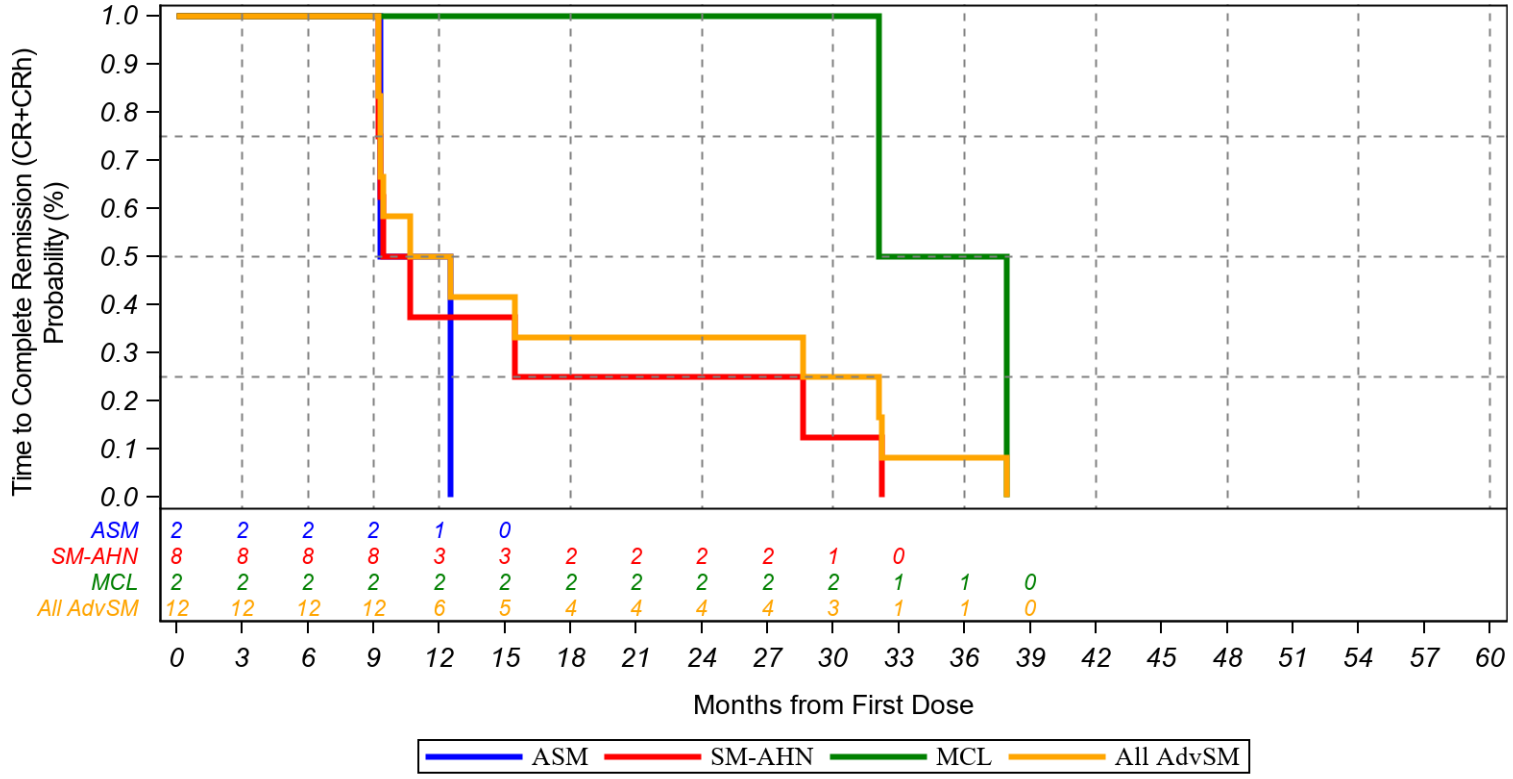

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Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Study BLU-285-2101
Starting Dose: Overall

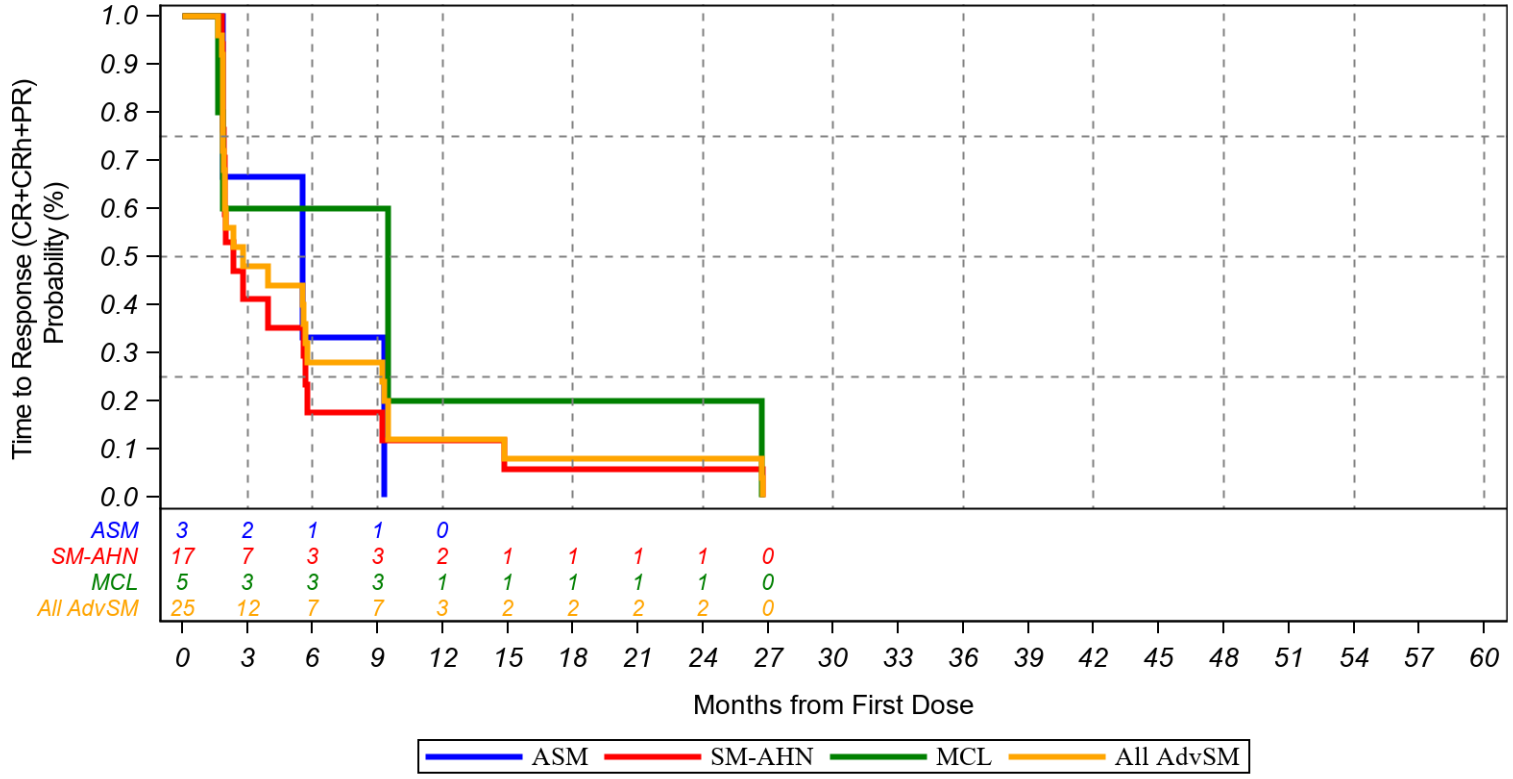

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: Overall

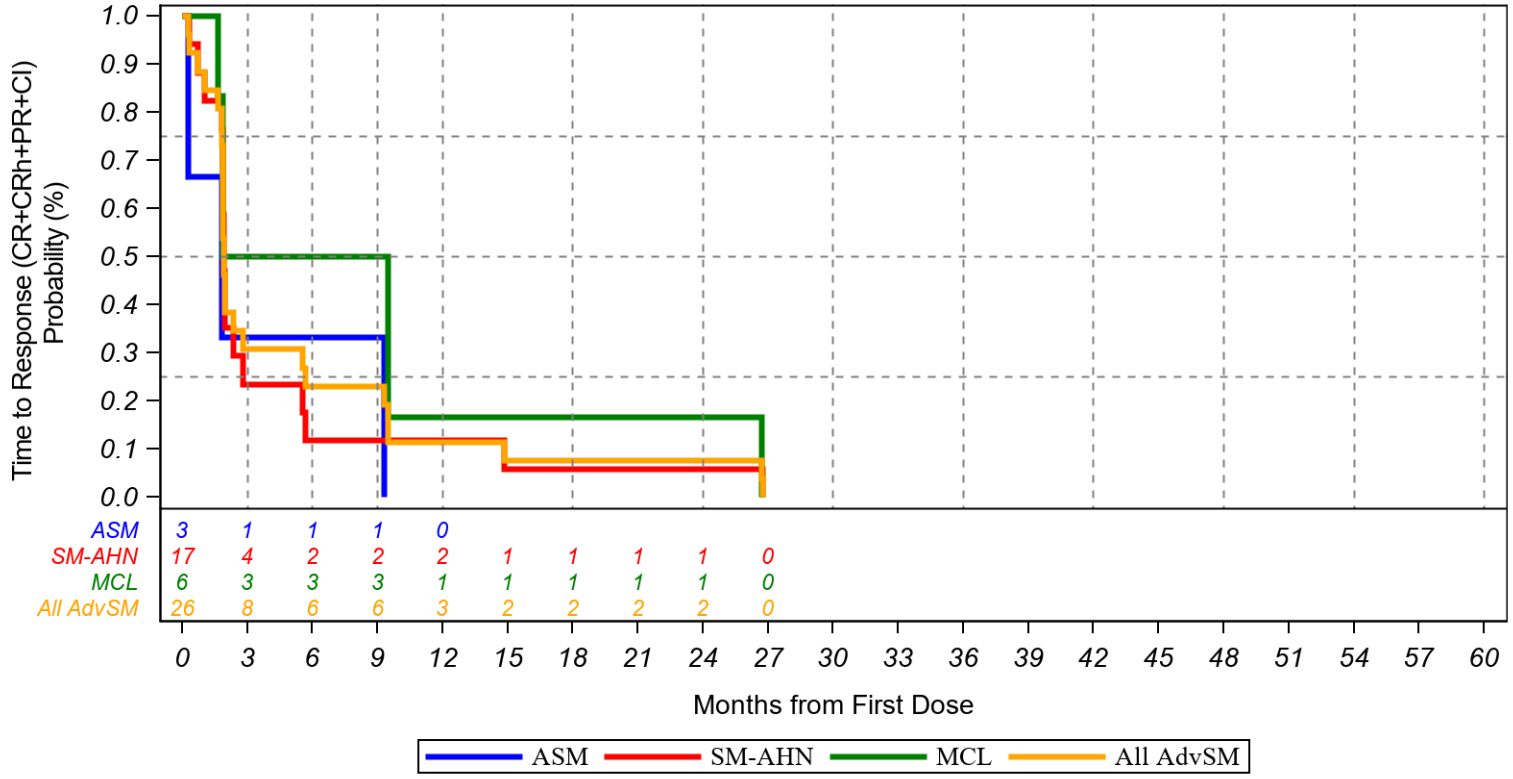

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Study BLU-285-2101
Starting Dose: < 200 mg

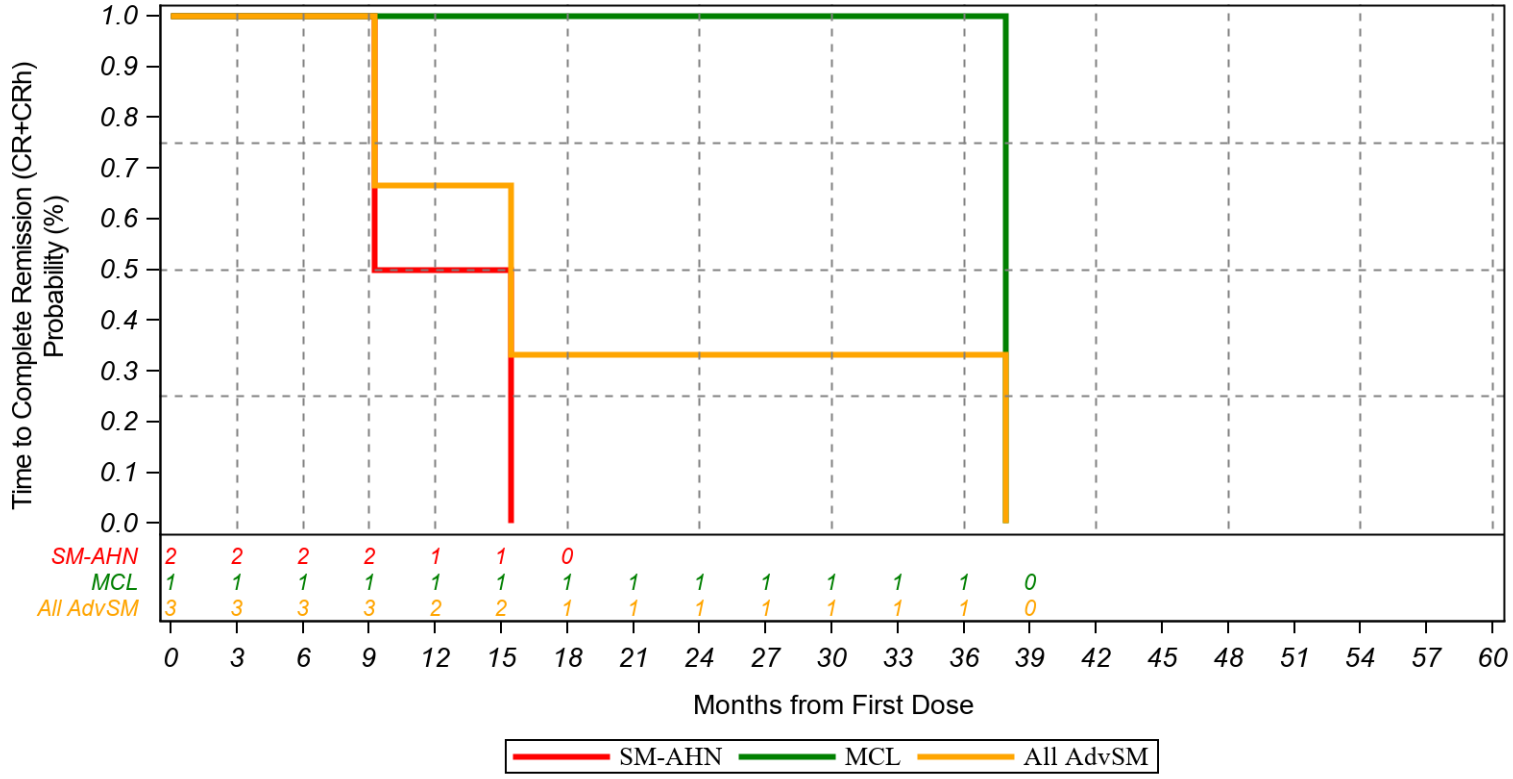

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Study BLU-285-2101
Starting Dose: < 200 mg

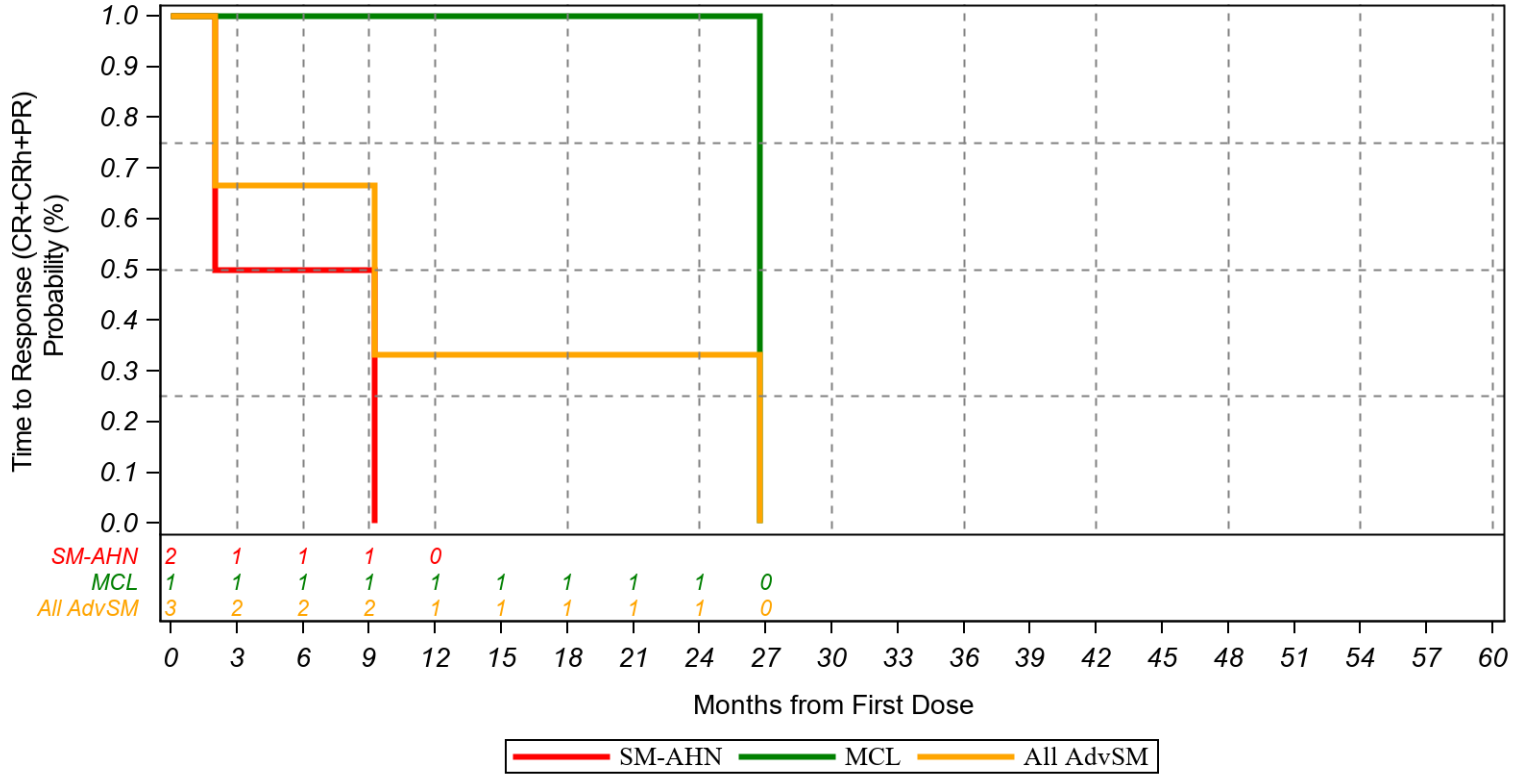

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: < 200 mg

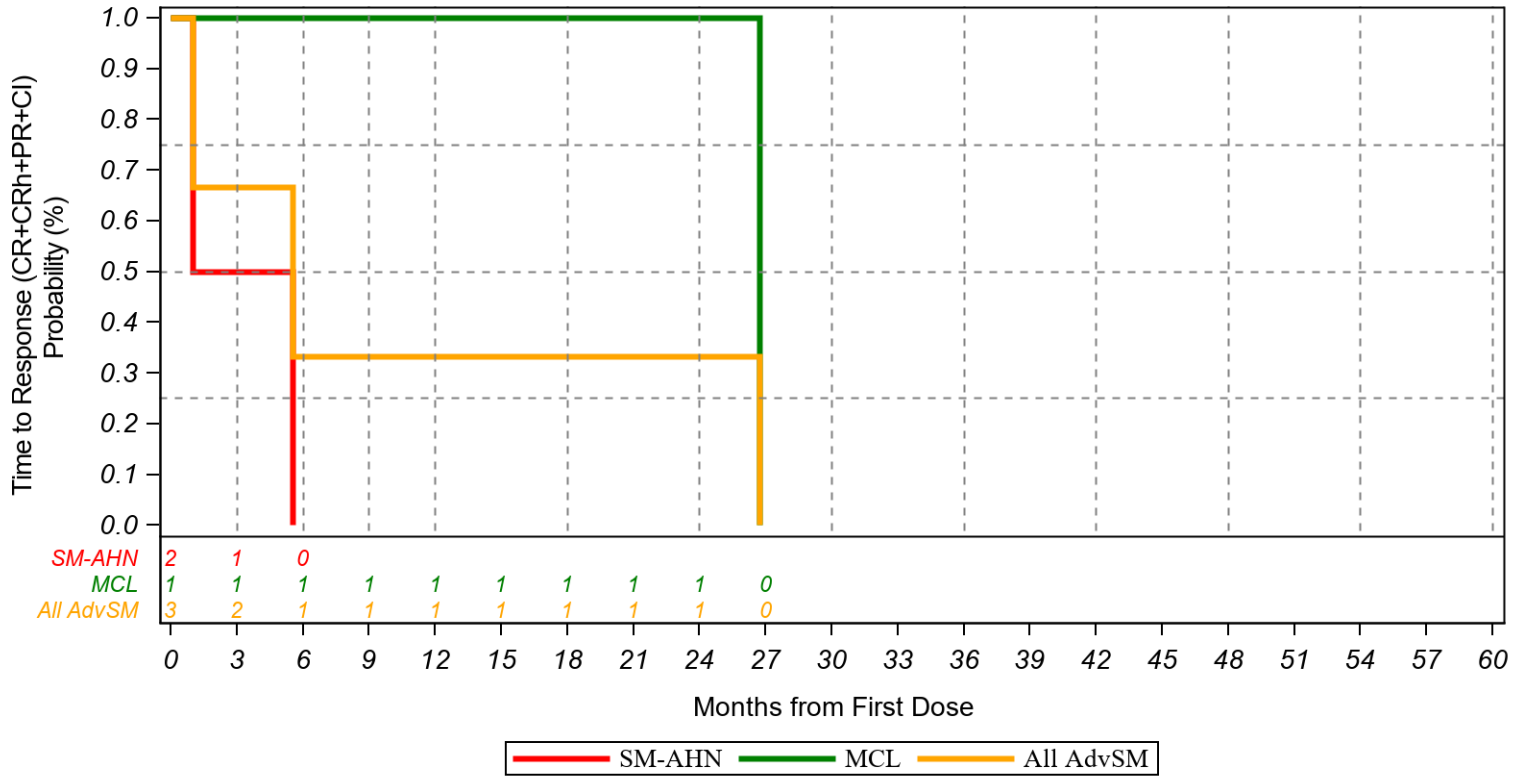

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Study BLU-285-2101
Starting Dose: < 300 mg

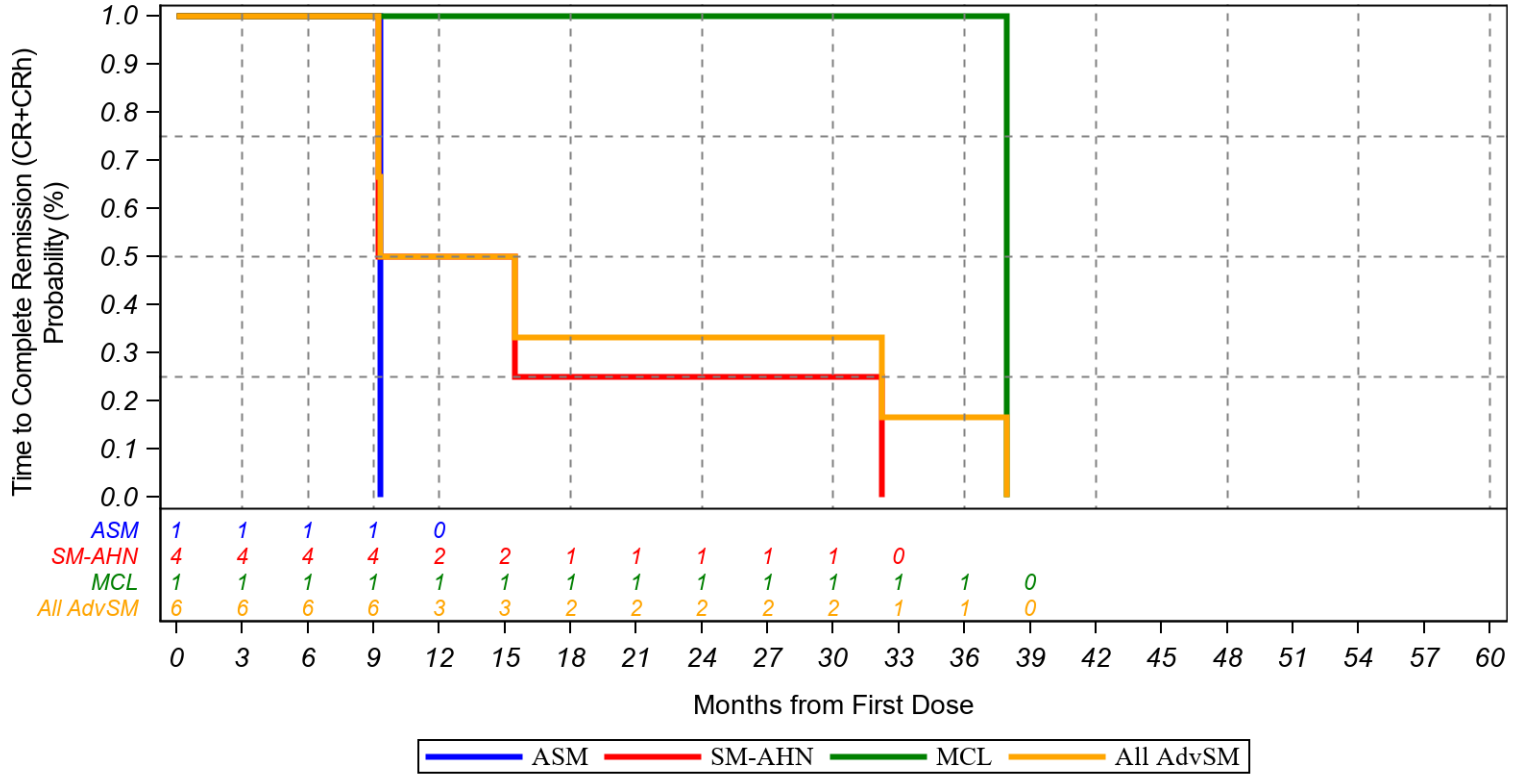

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Study BLU-285-2101
Starting Dose: < 300 mg

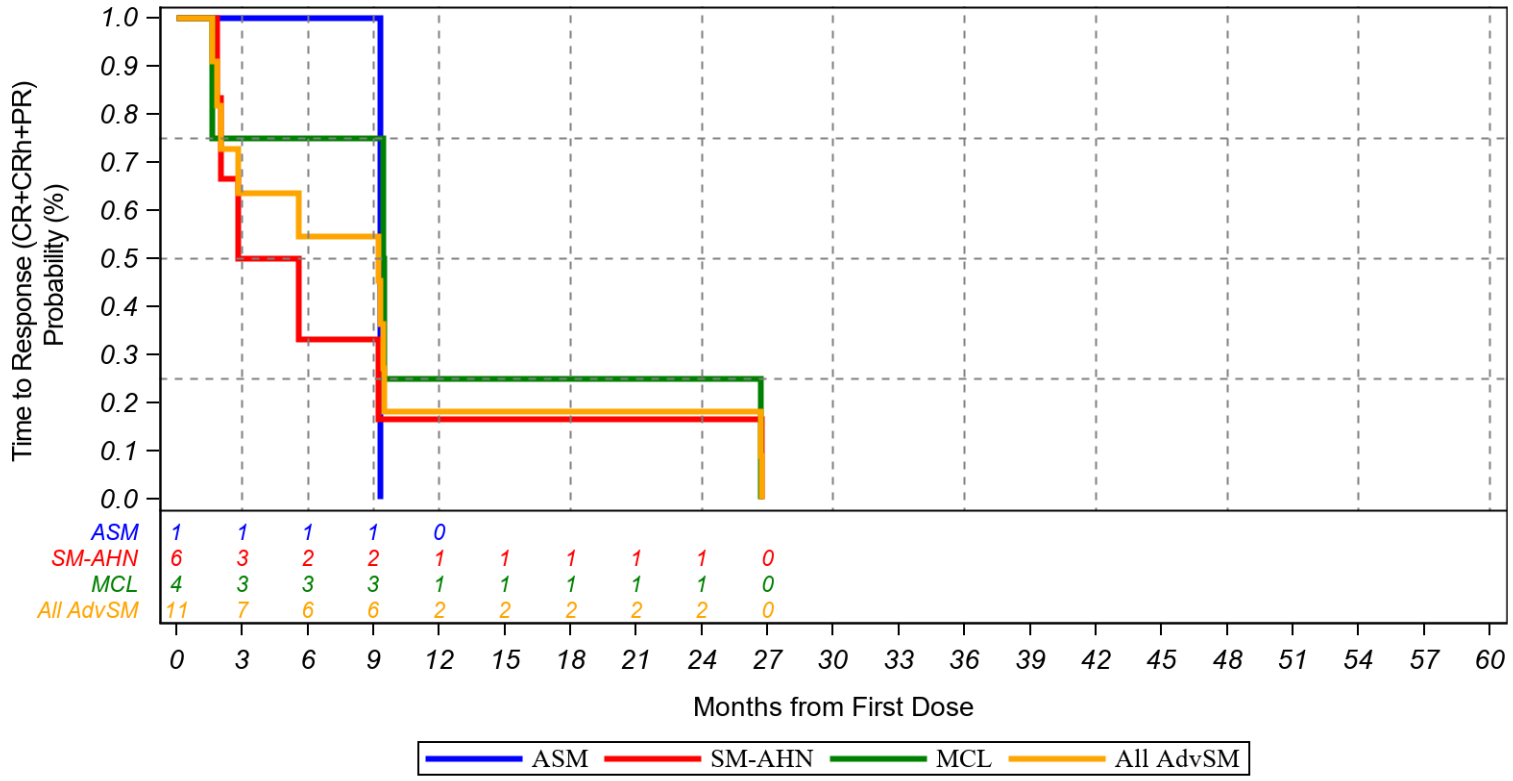

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: < 300 mg

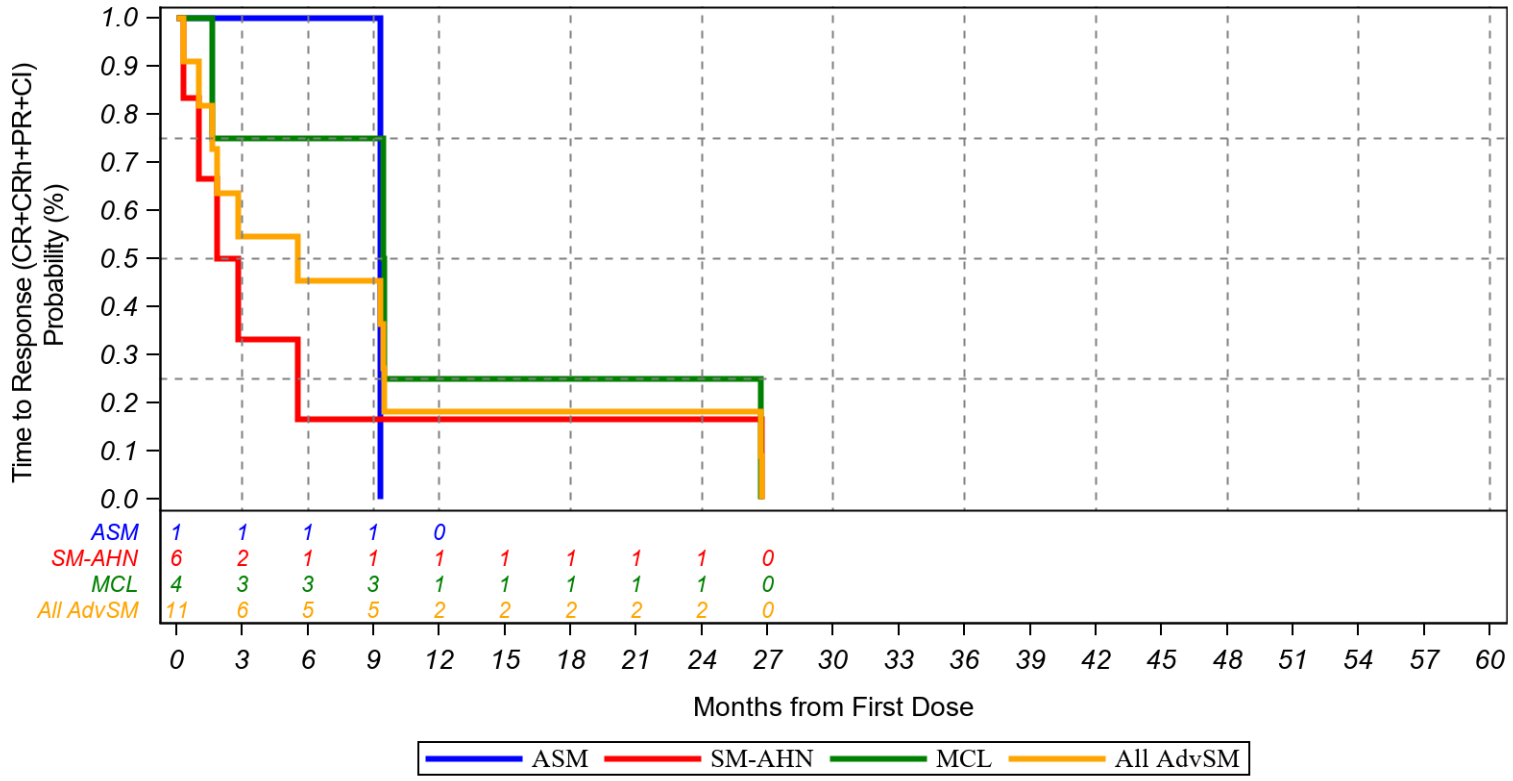

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Study BLU-285-2101
Starting Dose: 200 mg

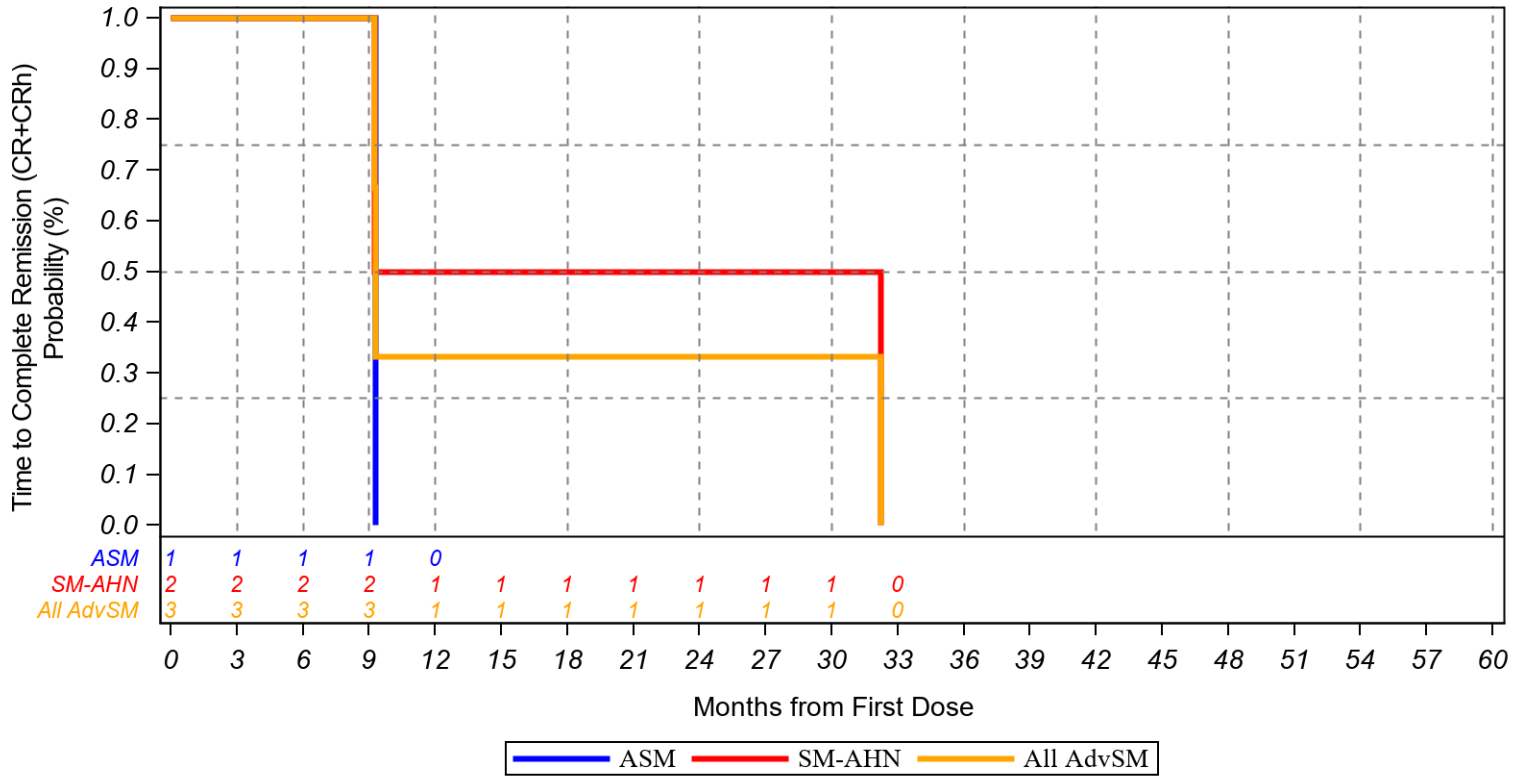

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Study BLU-285-2101
Starting Dose: 200 mg

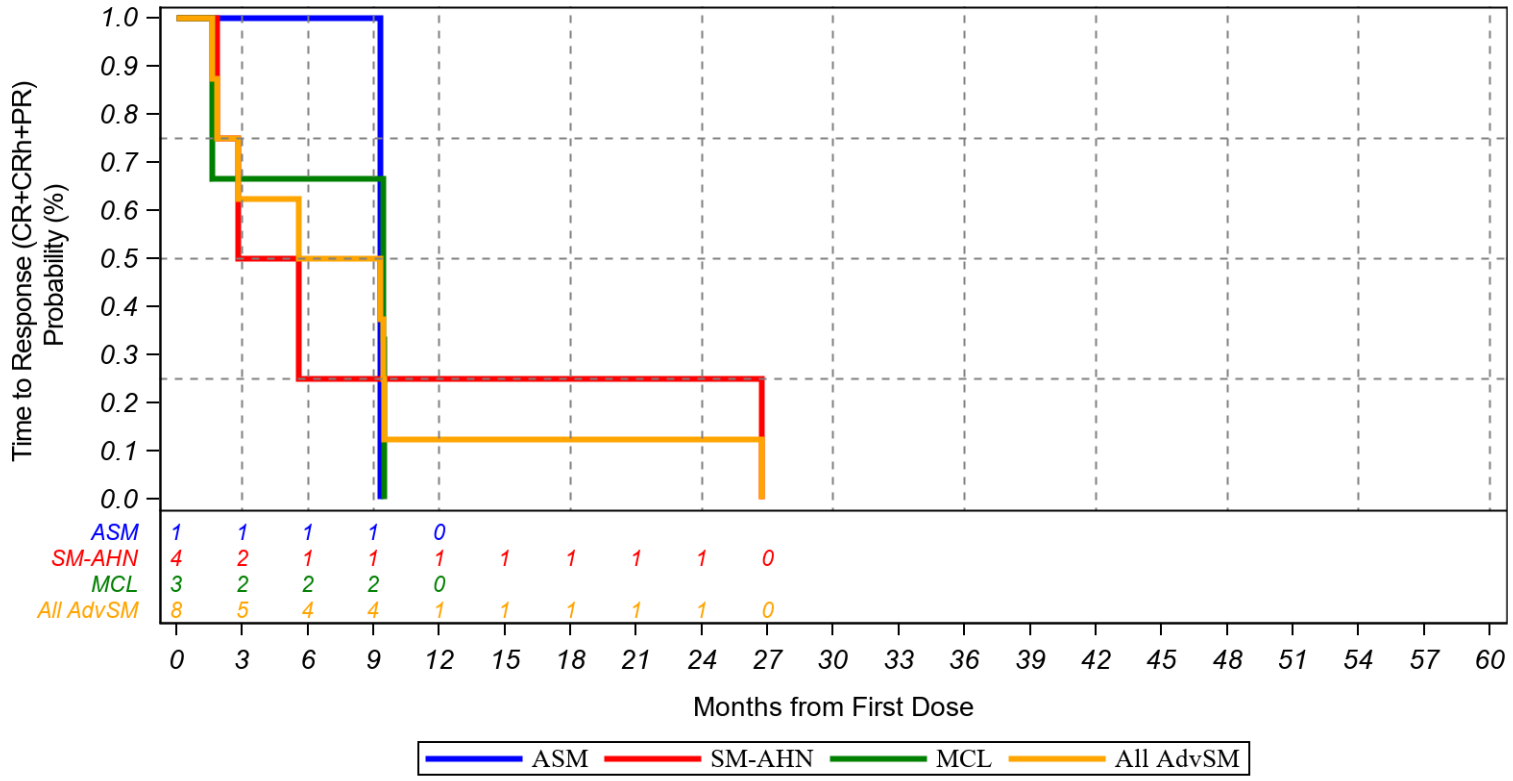

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: 200 mg

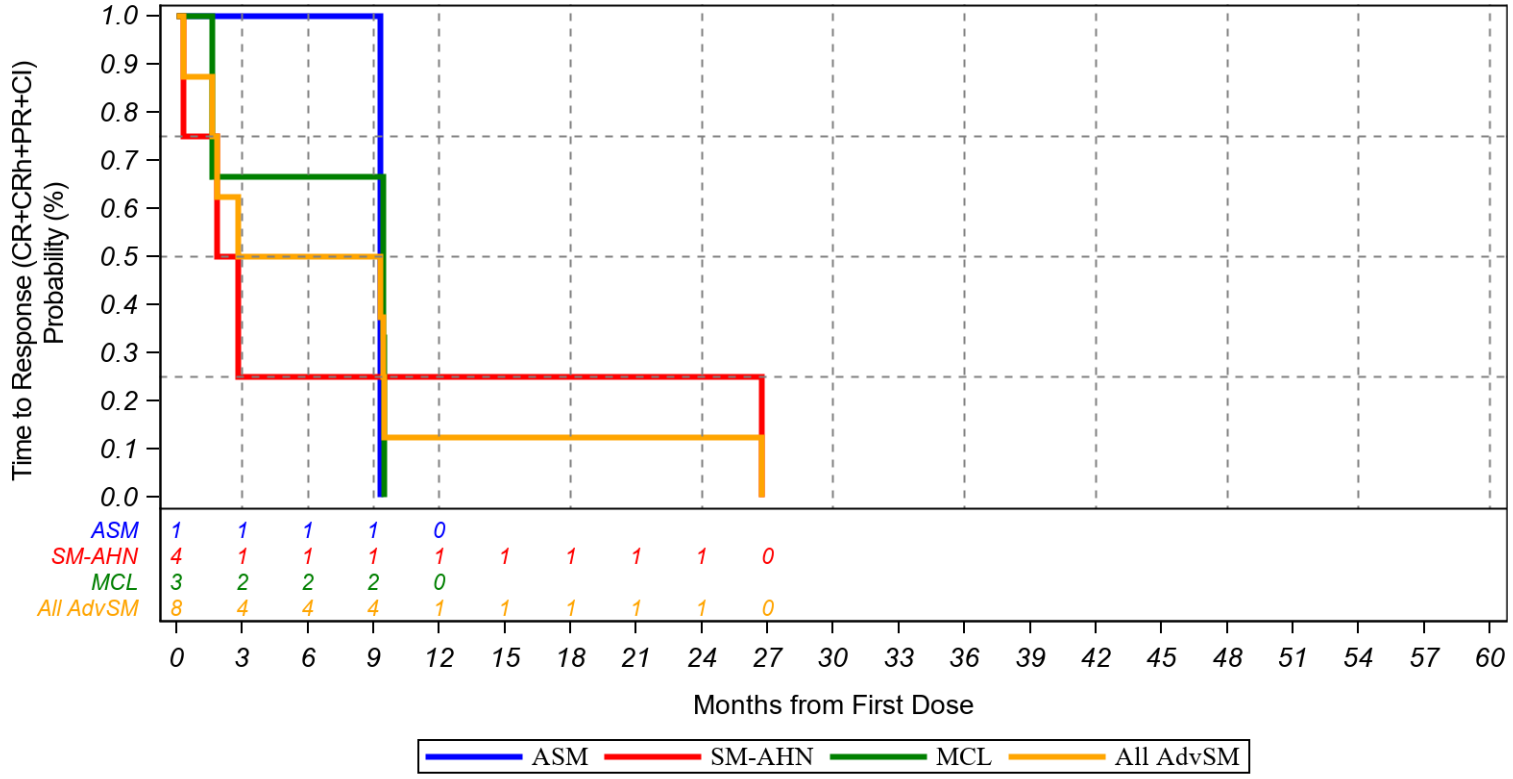

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Study BLU-285-2101
Starting Dose: 300 mg

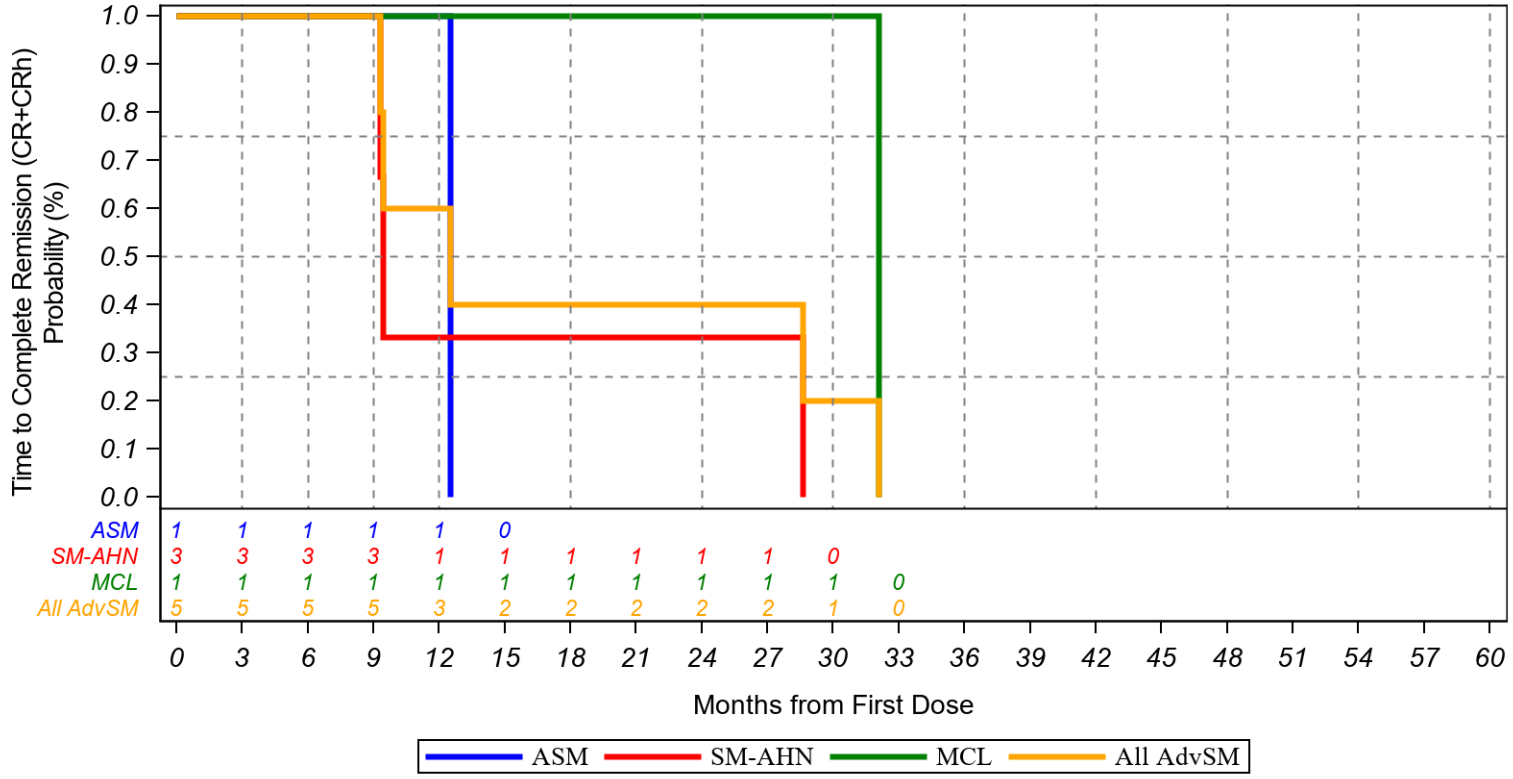

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Study BLU-285-2101
Starting Dose: 300 mg

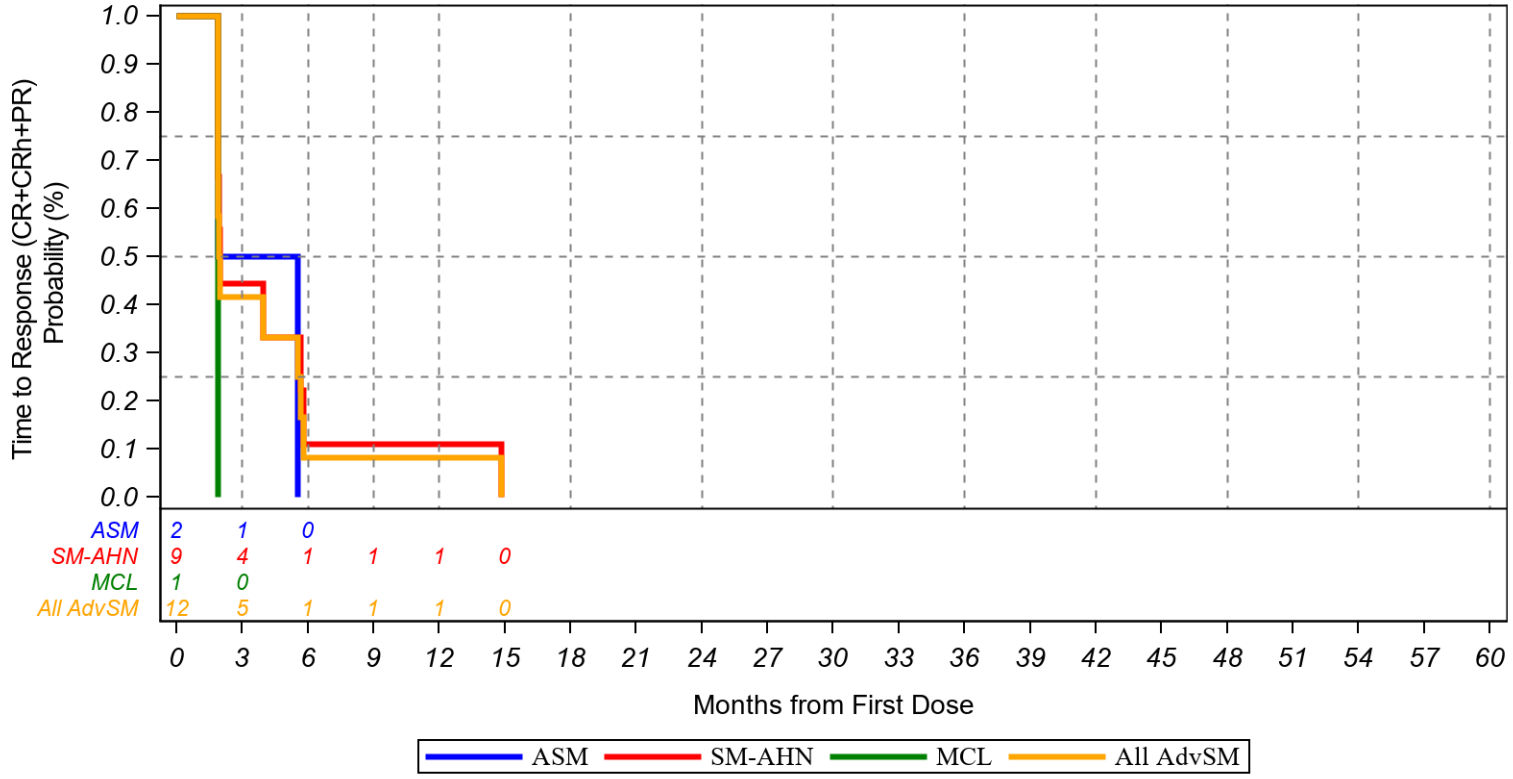

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: 300 mg

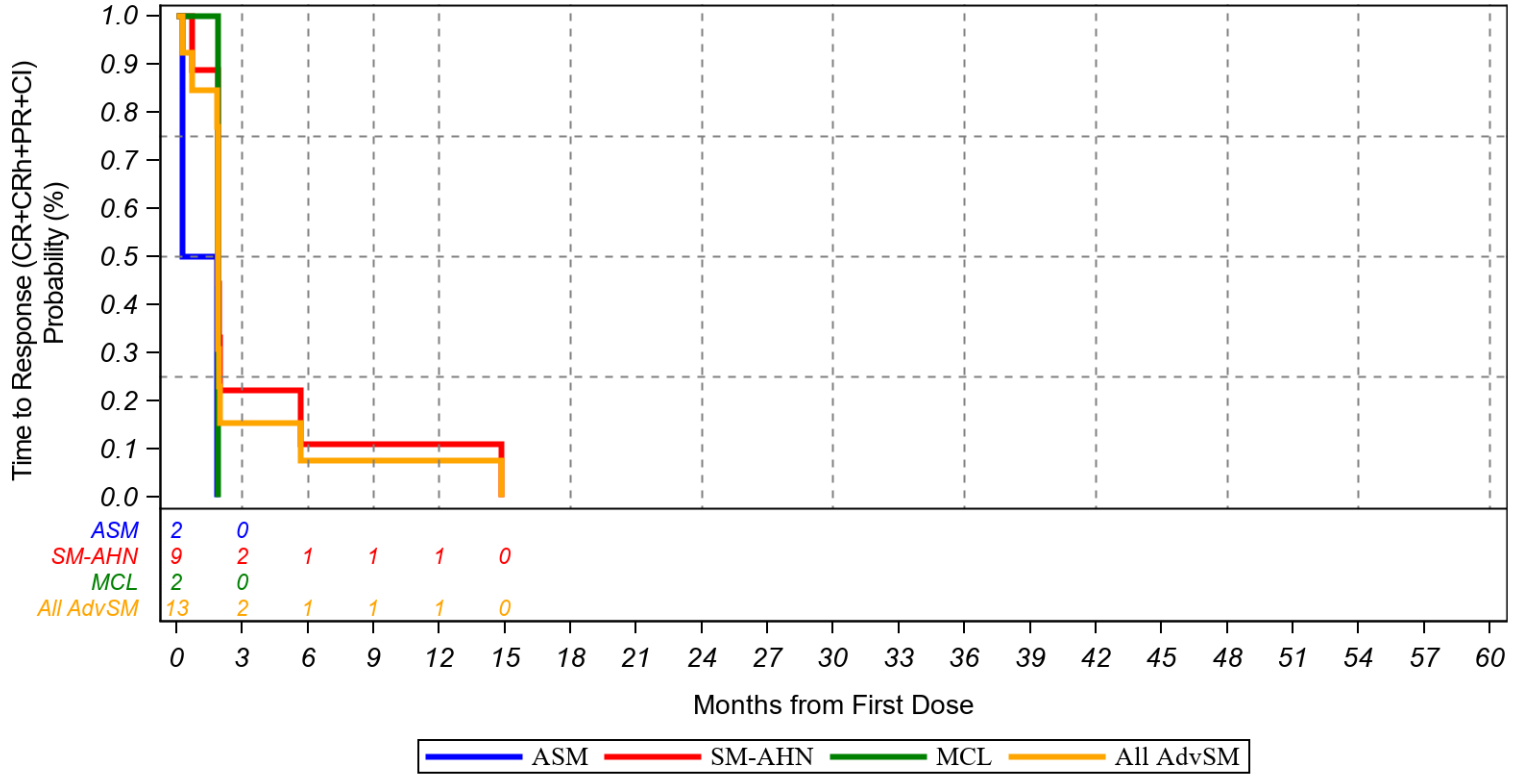

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Study BLU-285-2101
Starting Dose: 200 mg and 300 mg

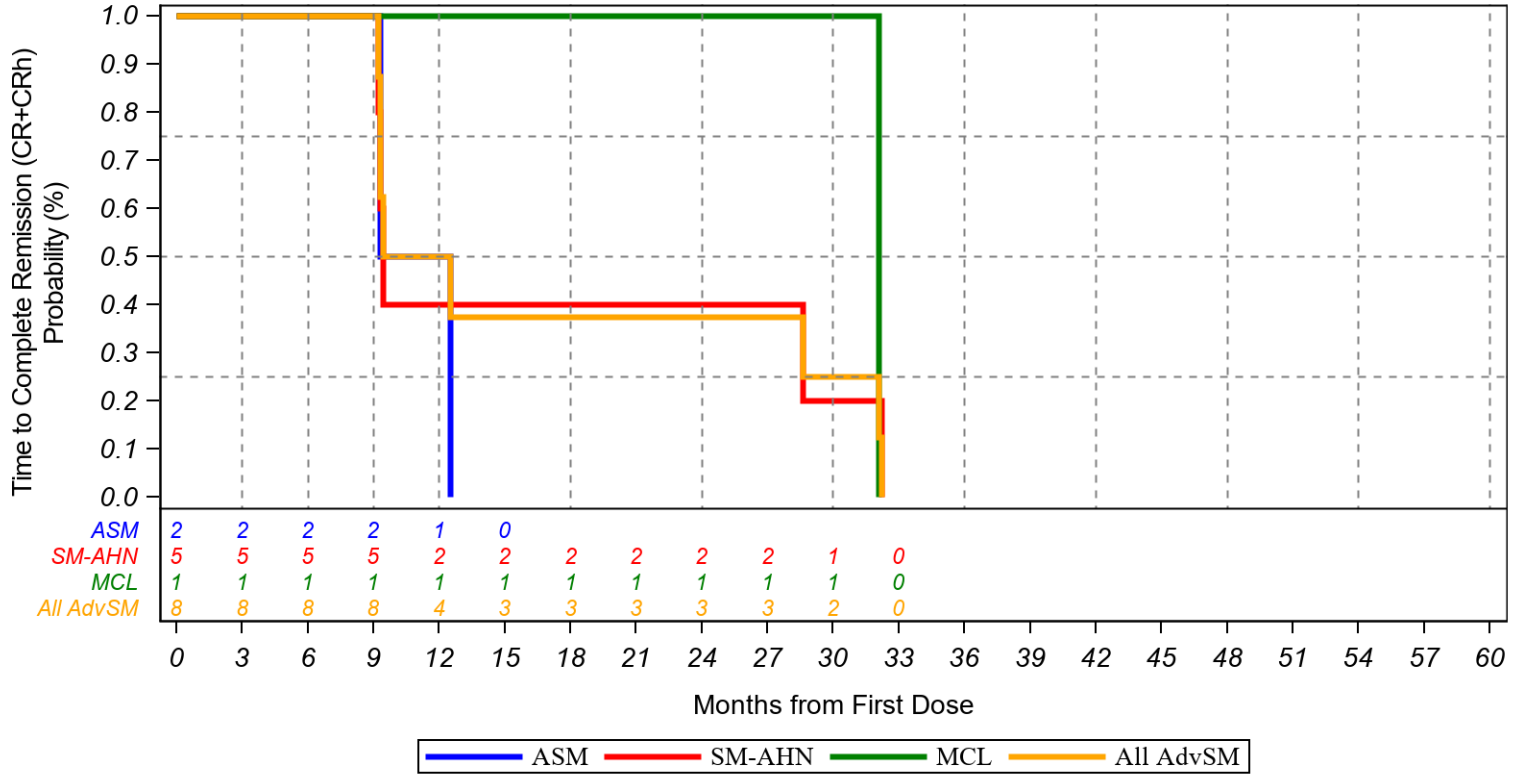

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Study BLU-285-2101
Starting Dose: 200 mg and 300 mg

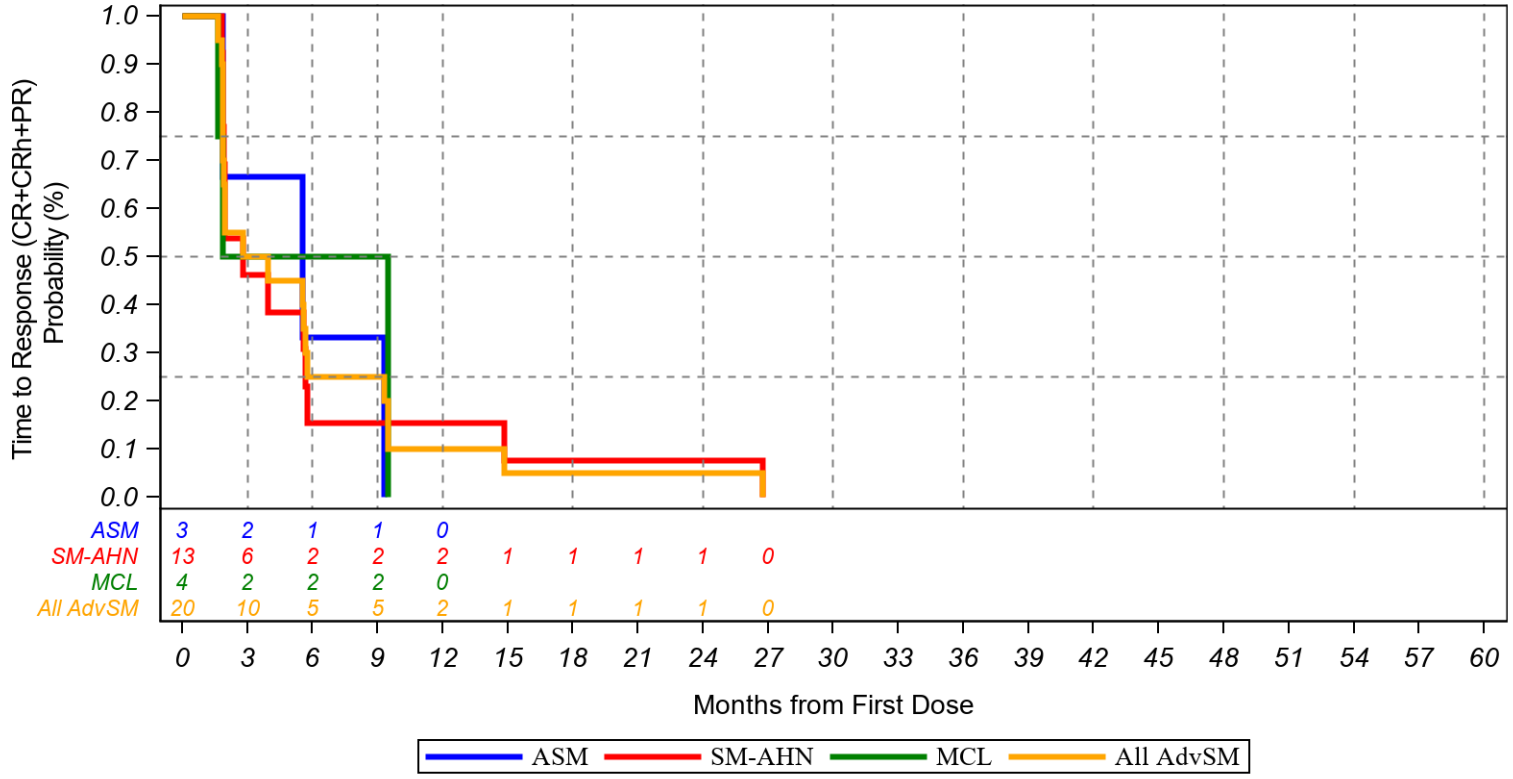

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: 200 mg and 300 mg

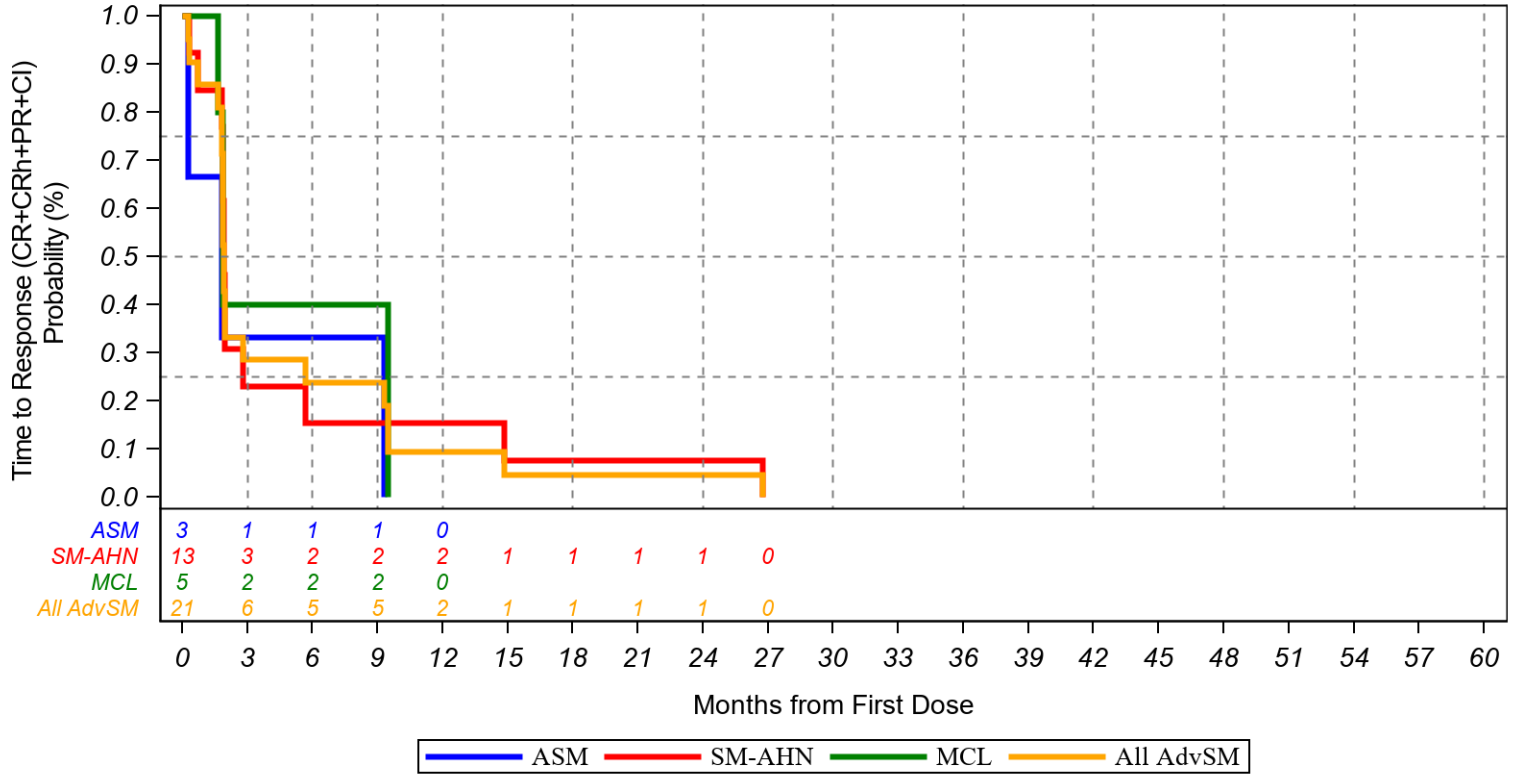

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Study BLU-285-2101
Starting Dose: 400 mg

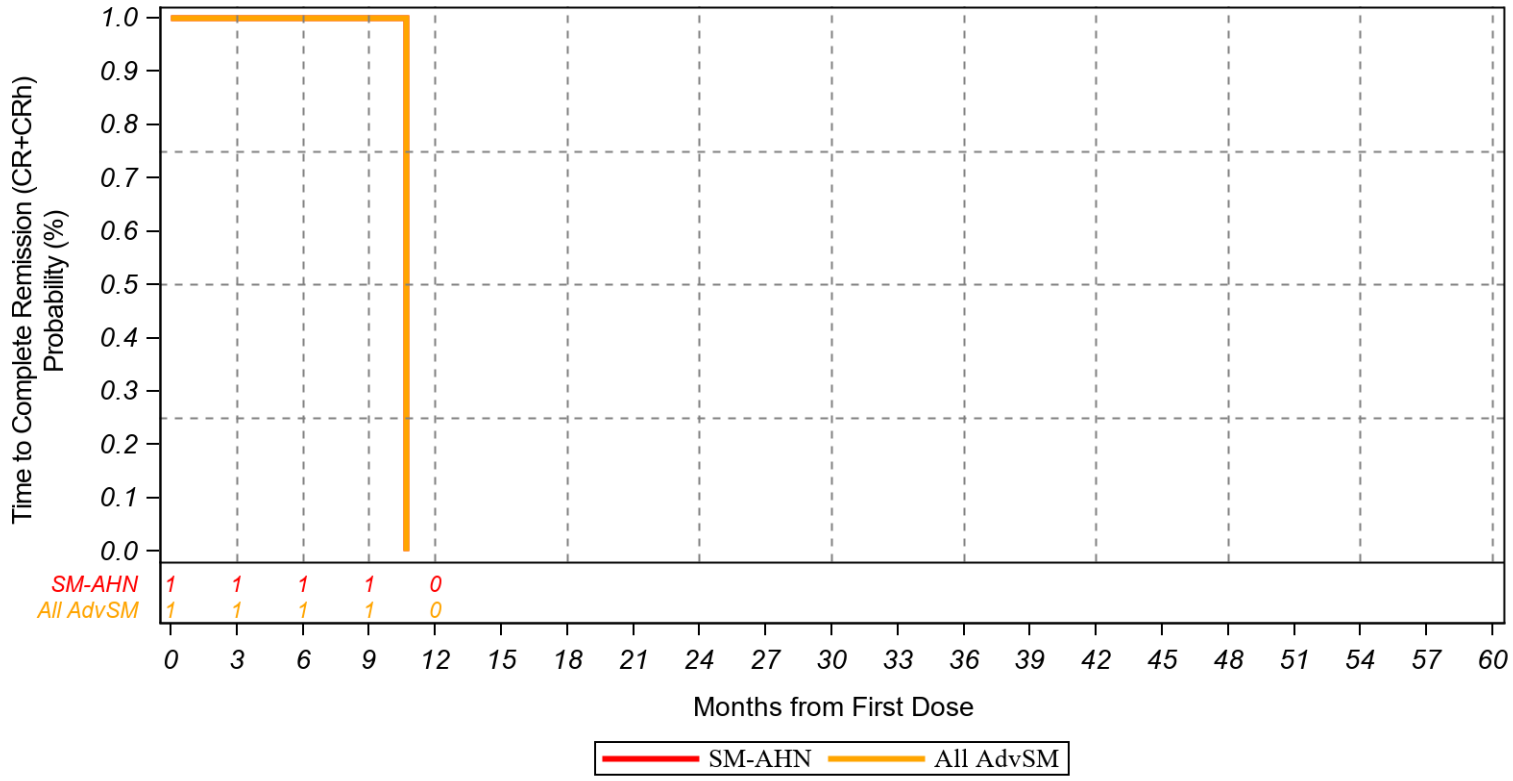

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Study BLU-285-2101
Starting Dose: 400 mg

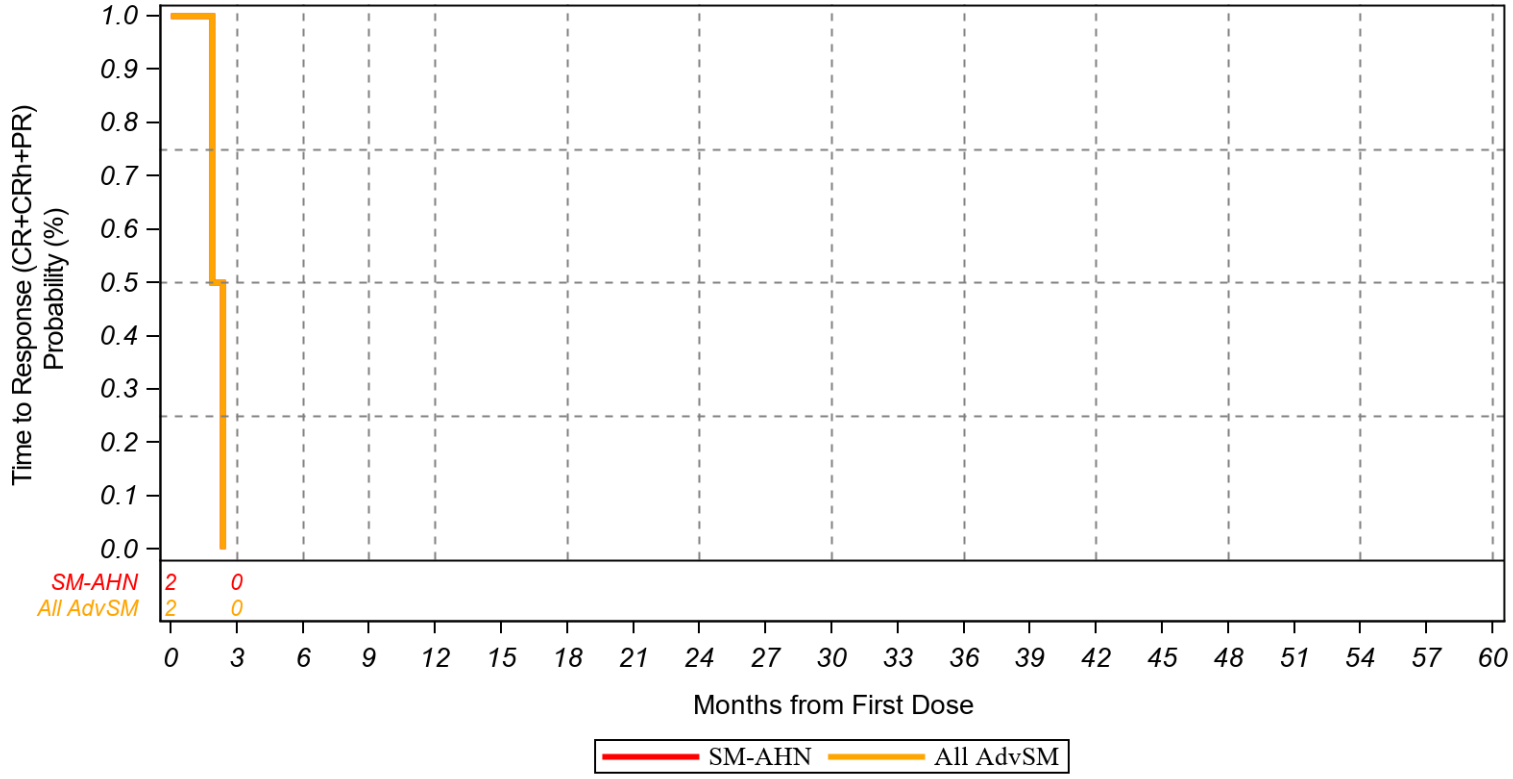

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: 400 mg

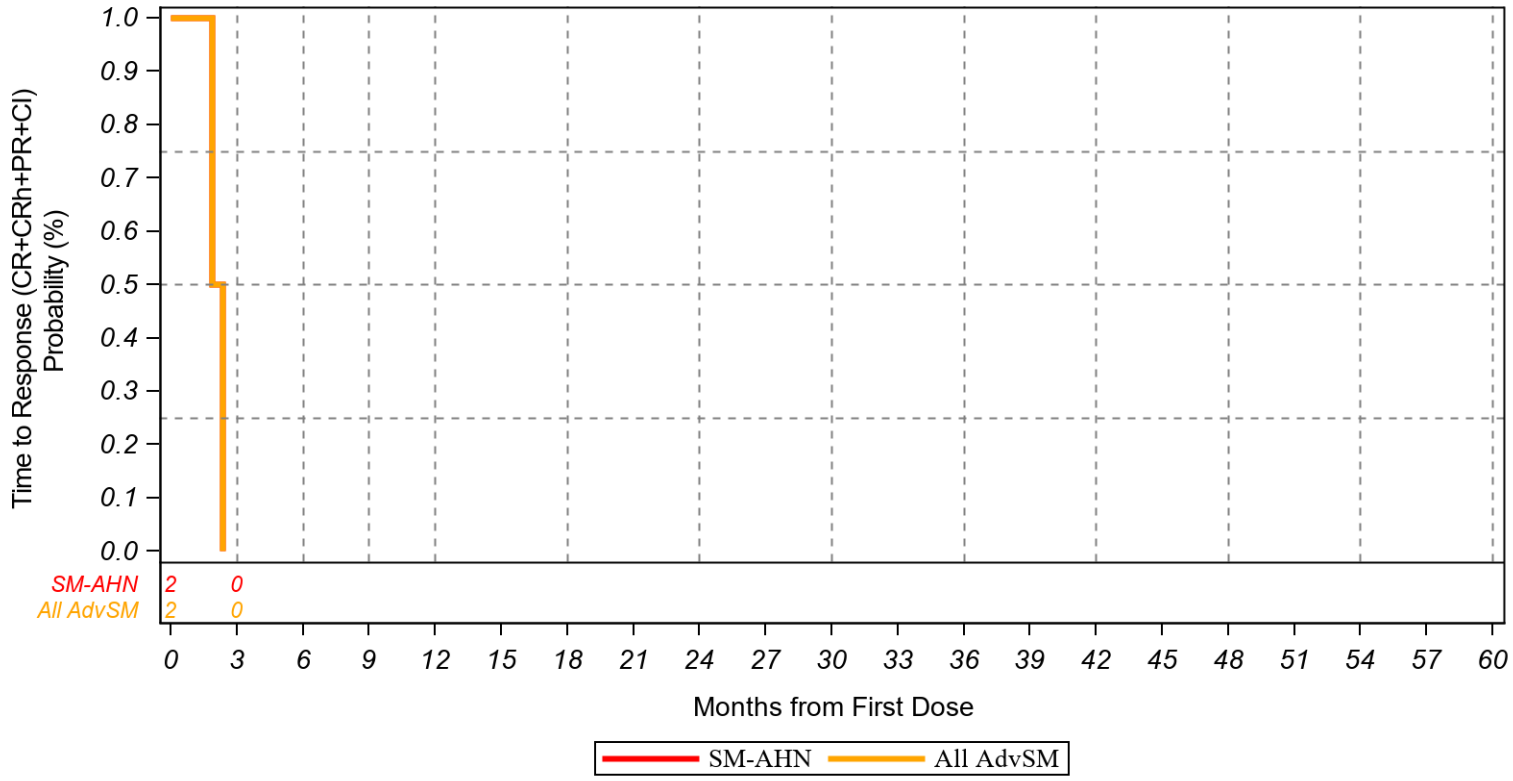

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Study BLU-285-2202
Starting Dose: Overall

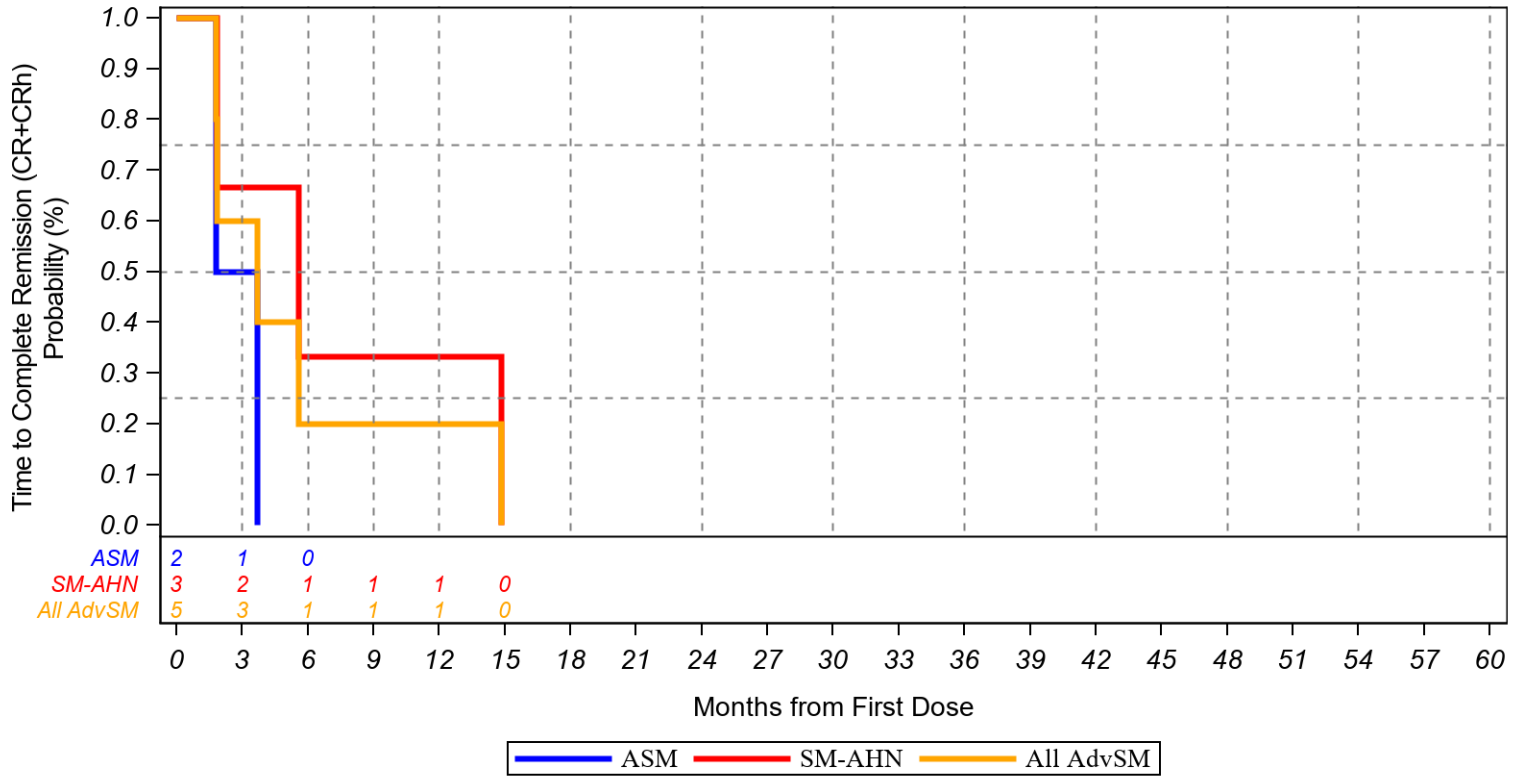

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Study BLU-285-2202
Starting Dose: Overall

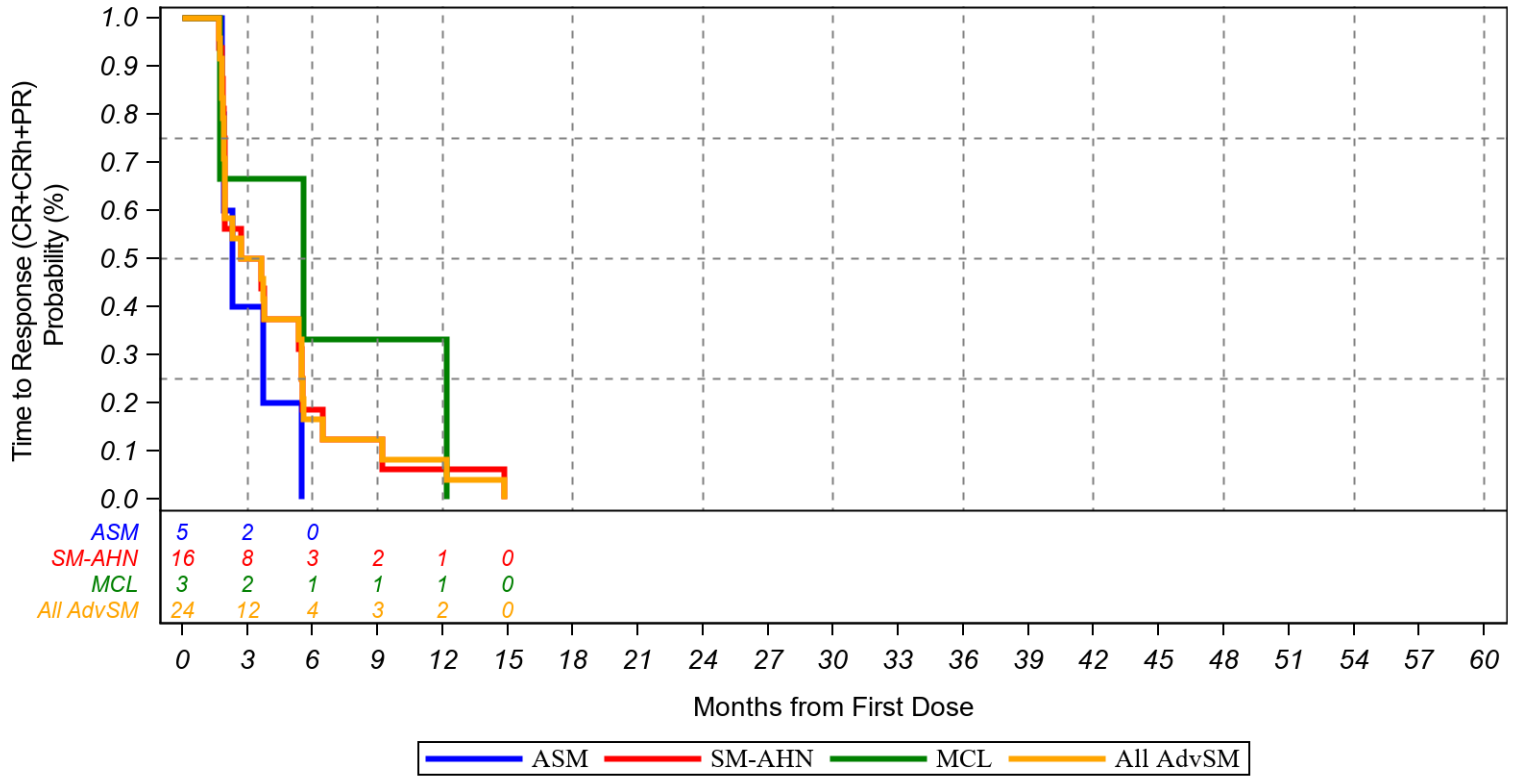

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Study BLU-285-2202
Starting Dose: Overall

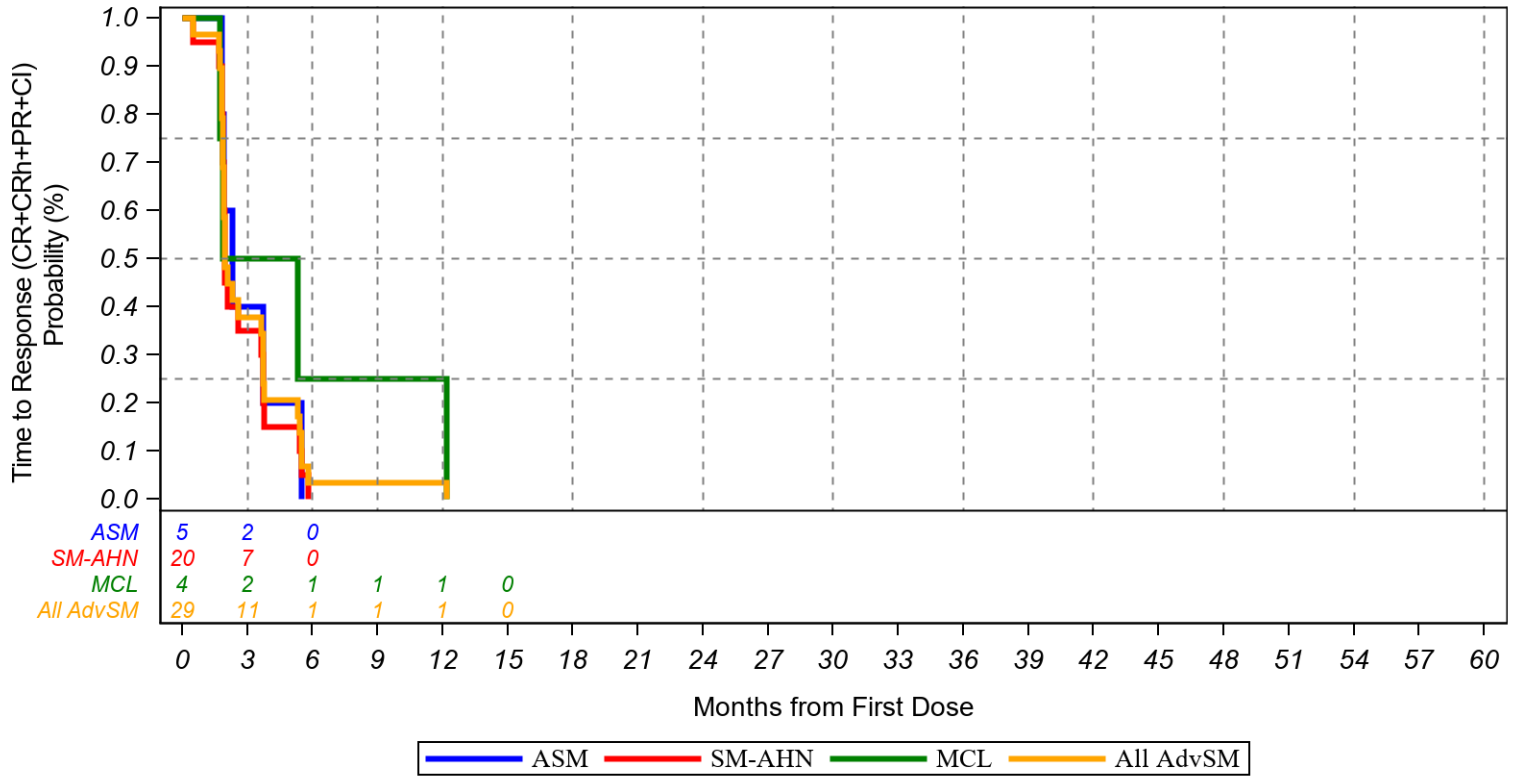

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Study BLU-285-2202
Starting Dose: 200 mg

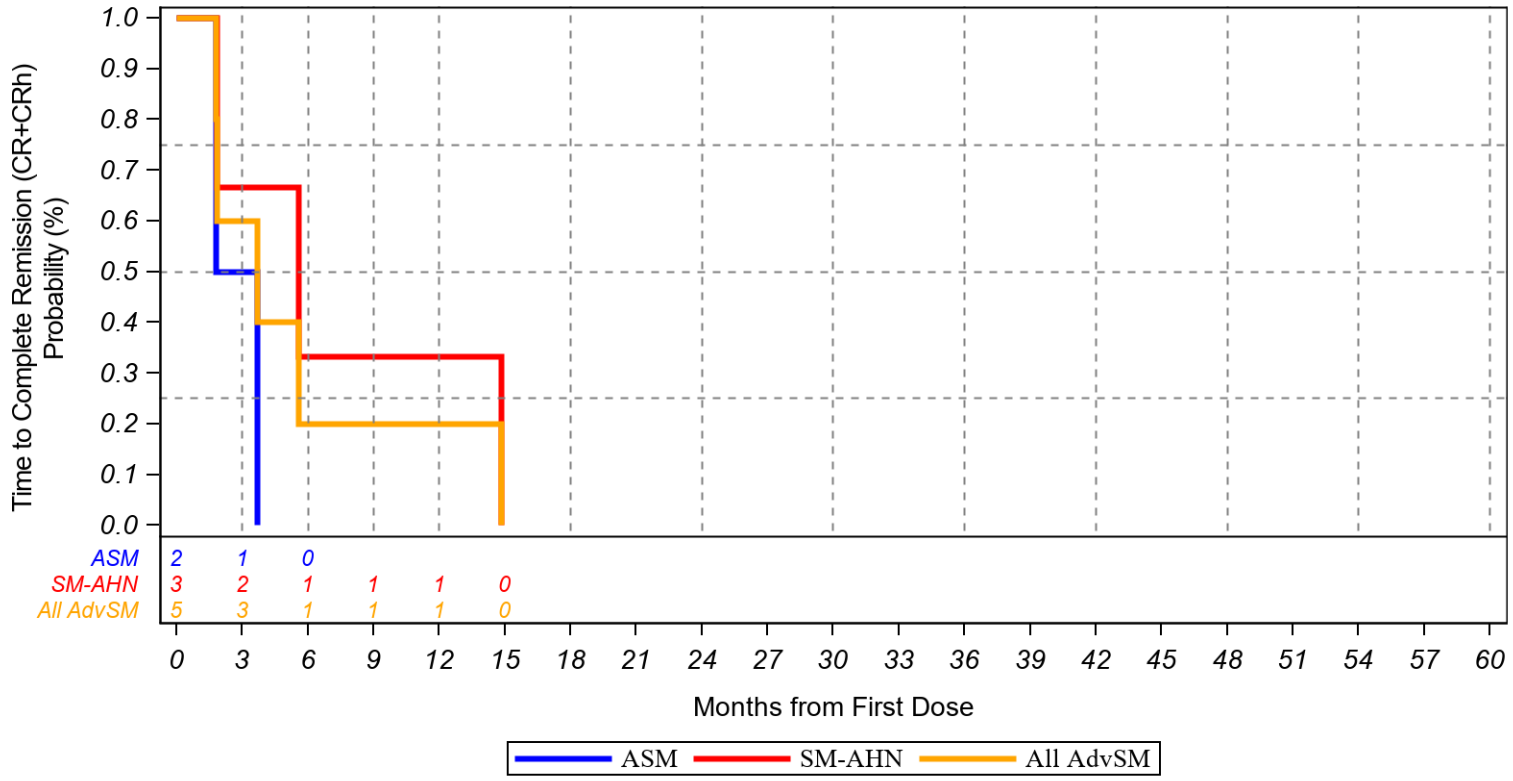

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Study BLU-285-2202
Starting Dose: 200 mg

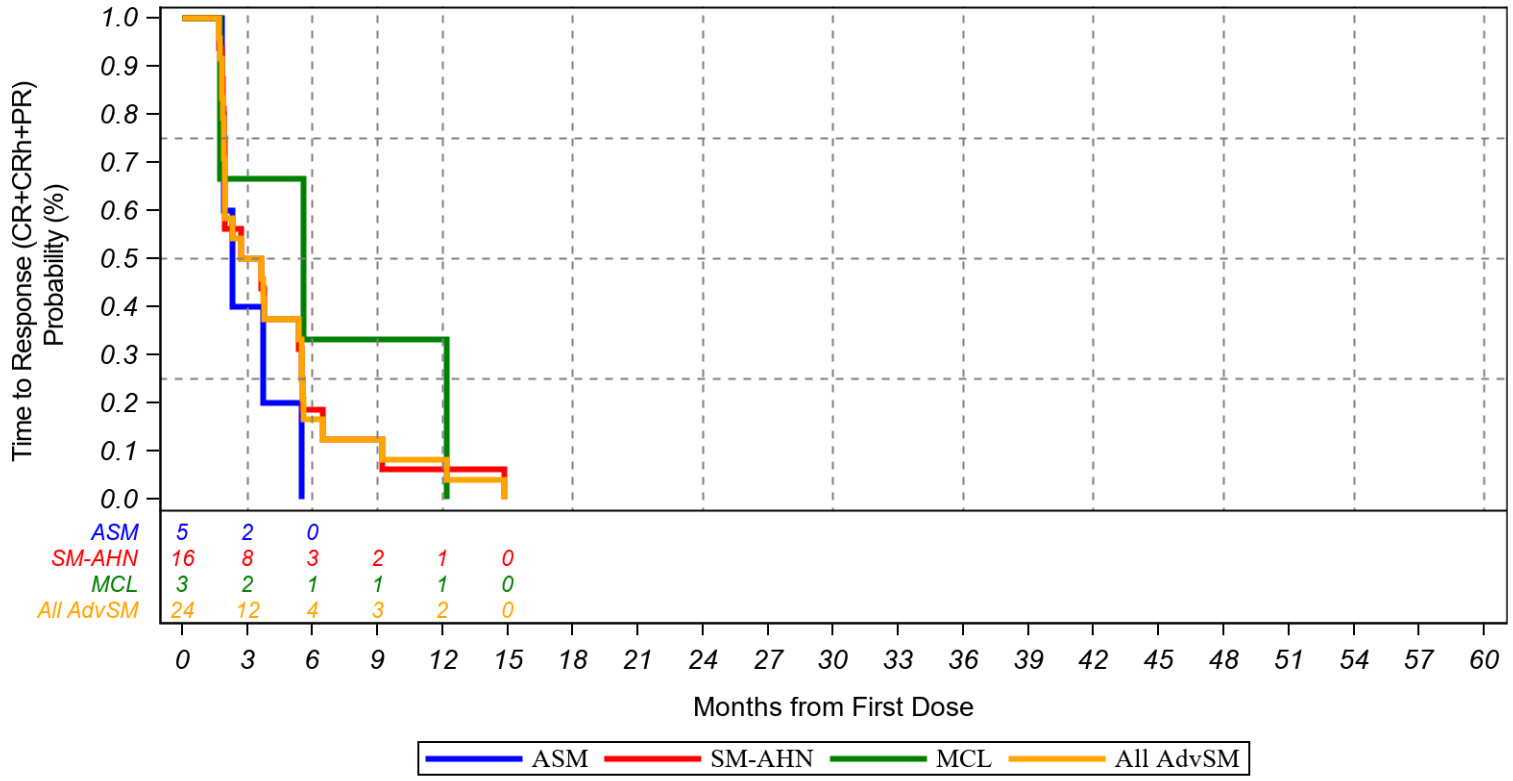

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Study BLU-285-2202
Starting Dose: 200 mg

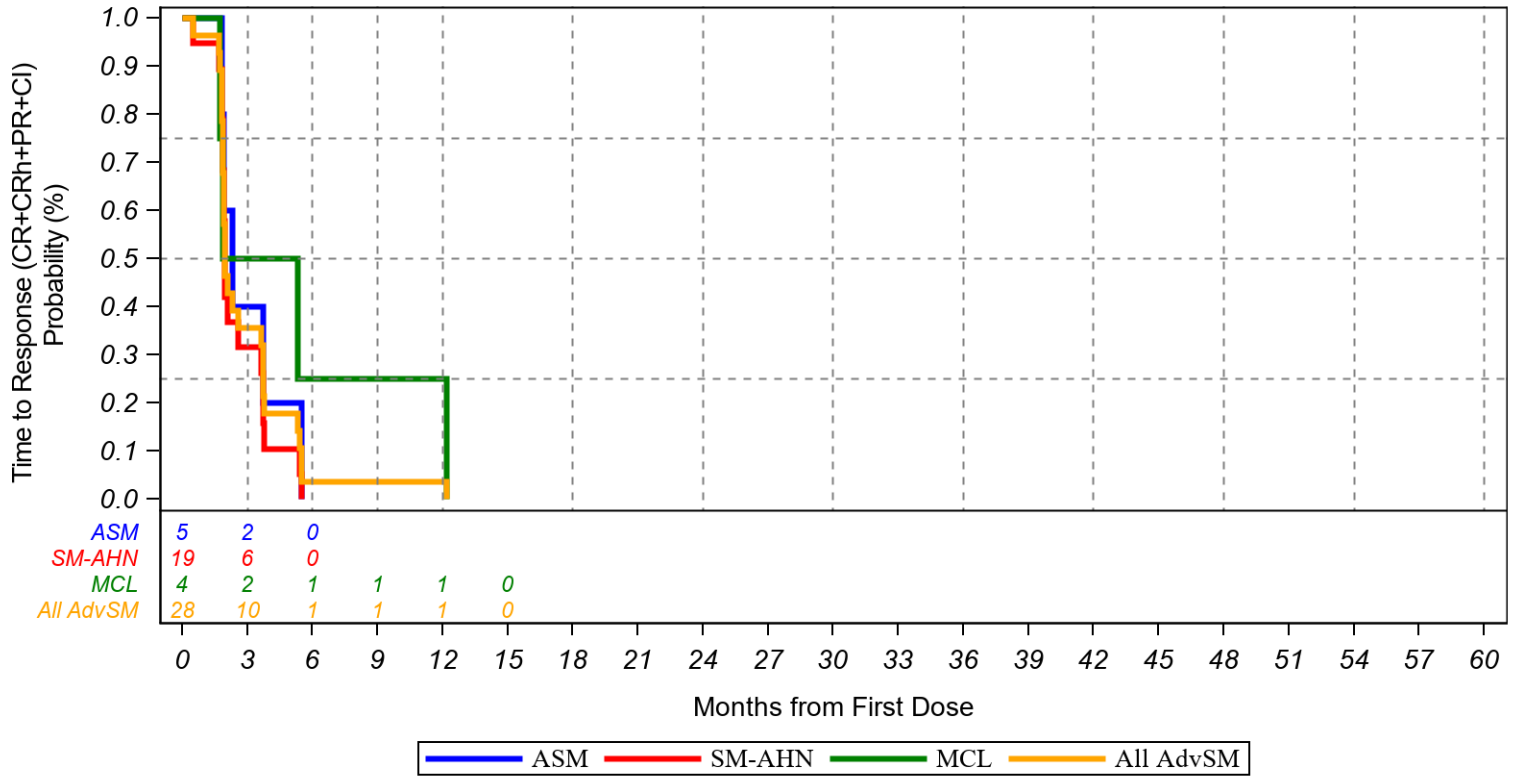

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall

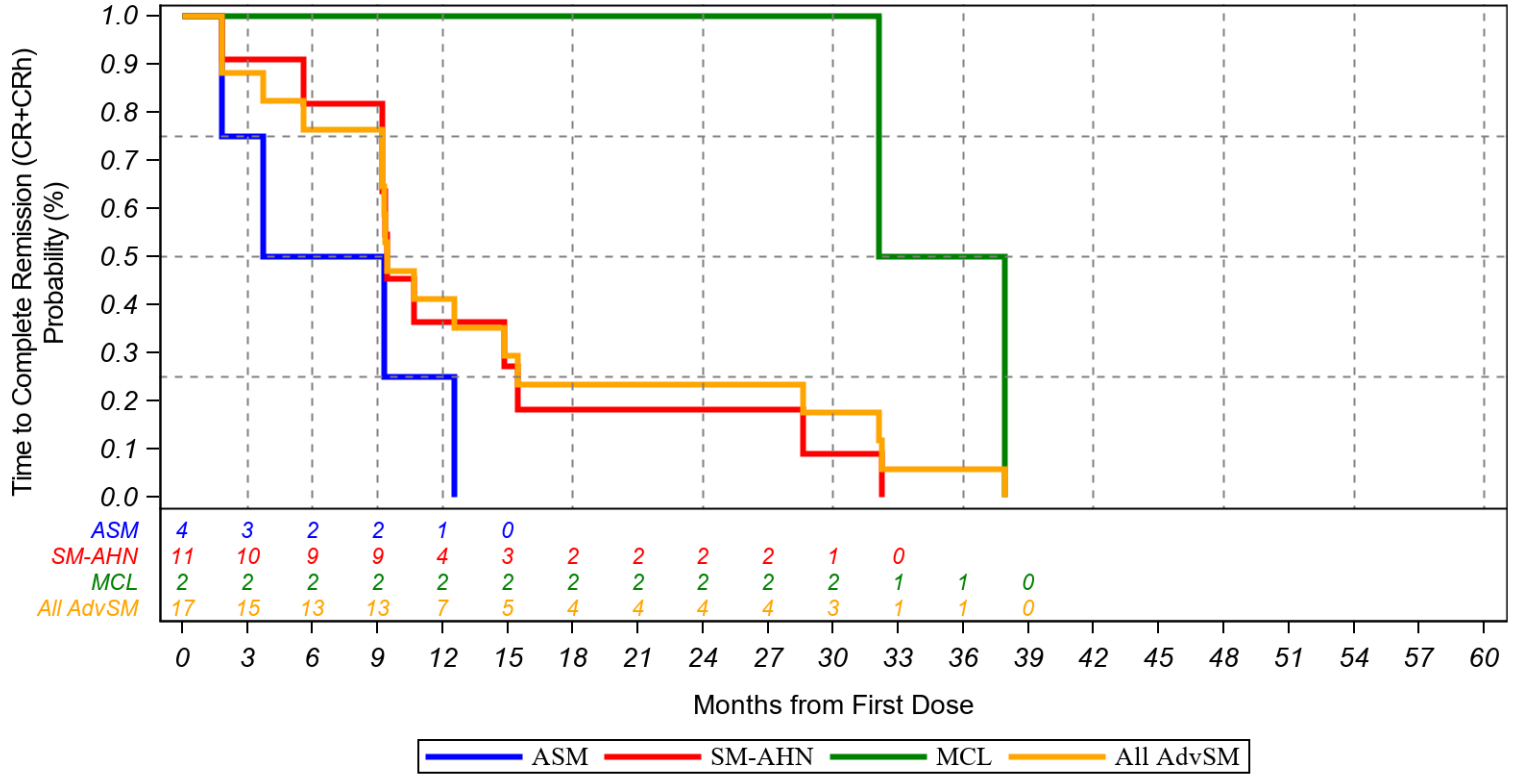

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall

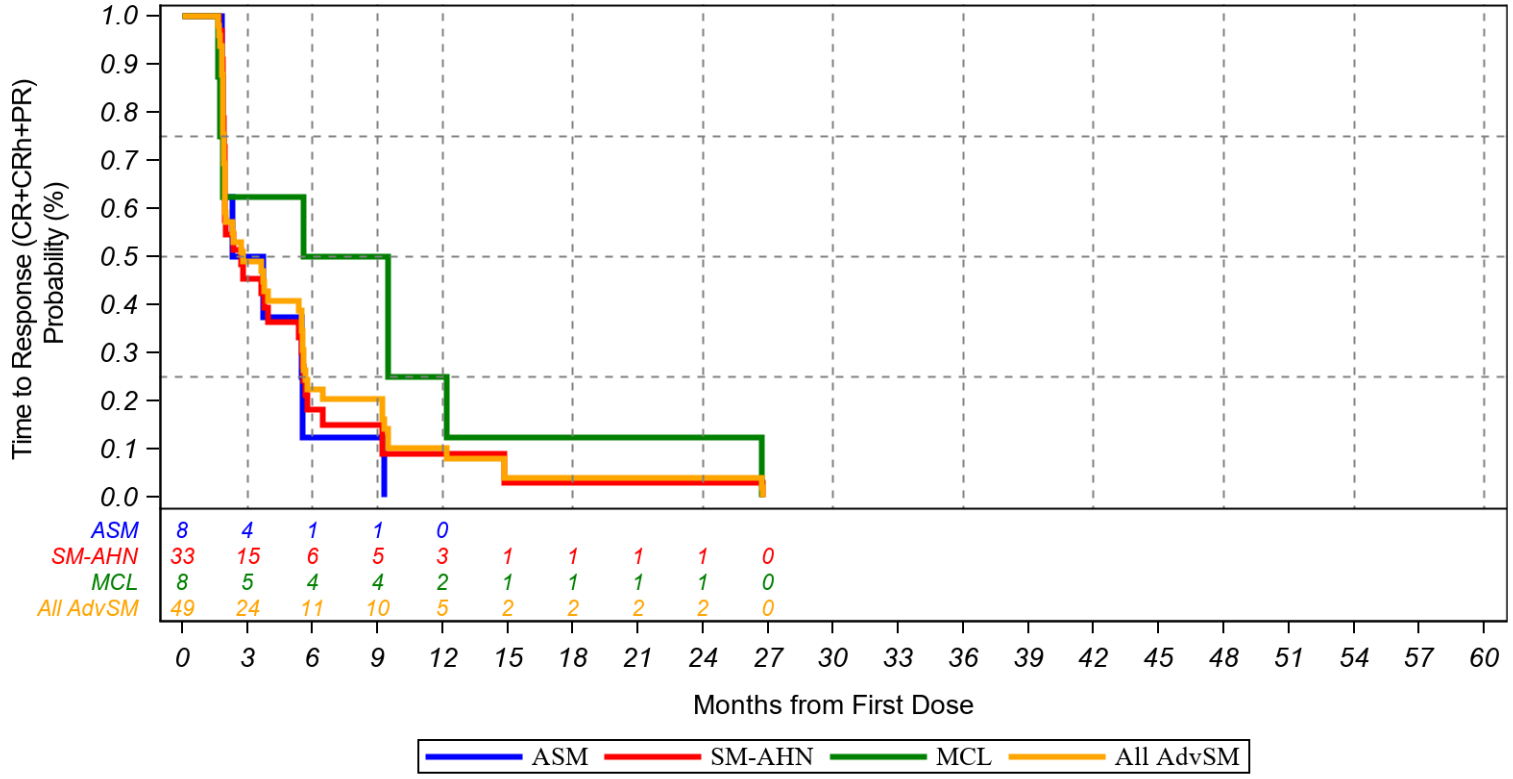

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall

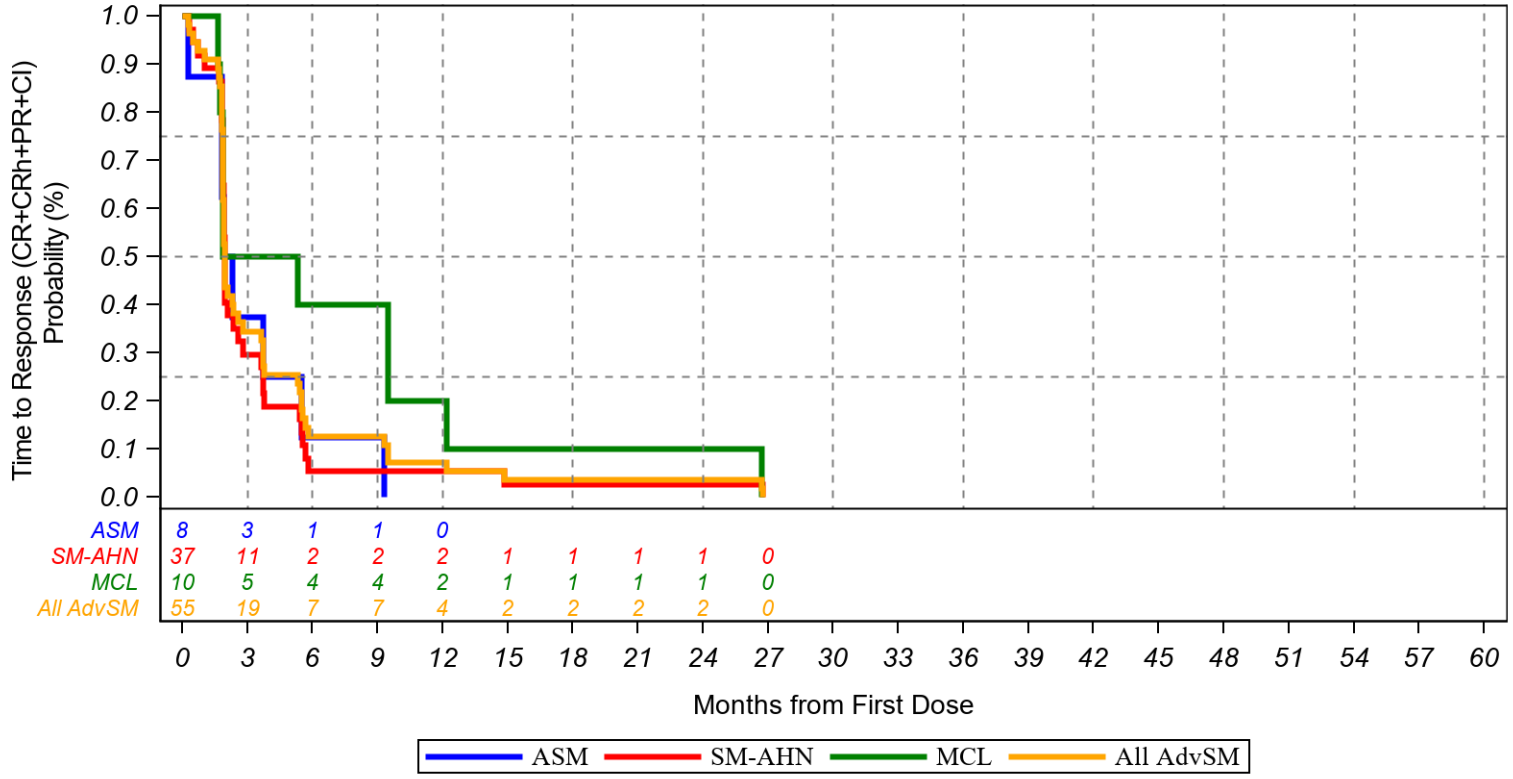

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg

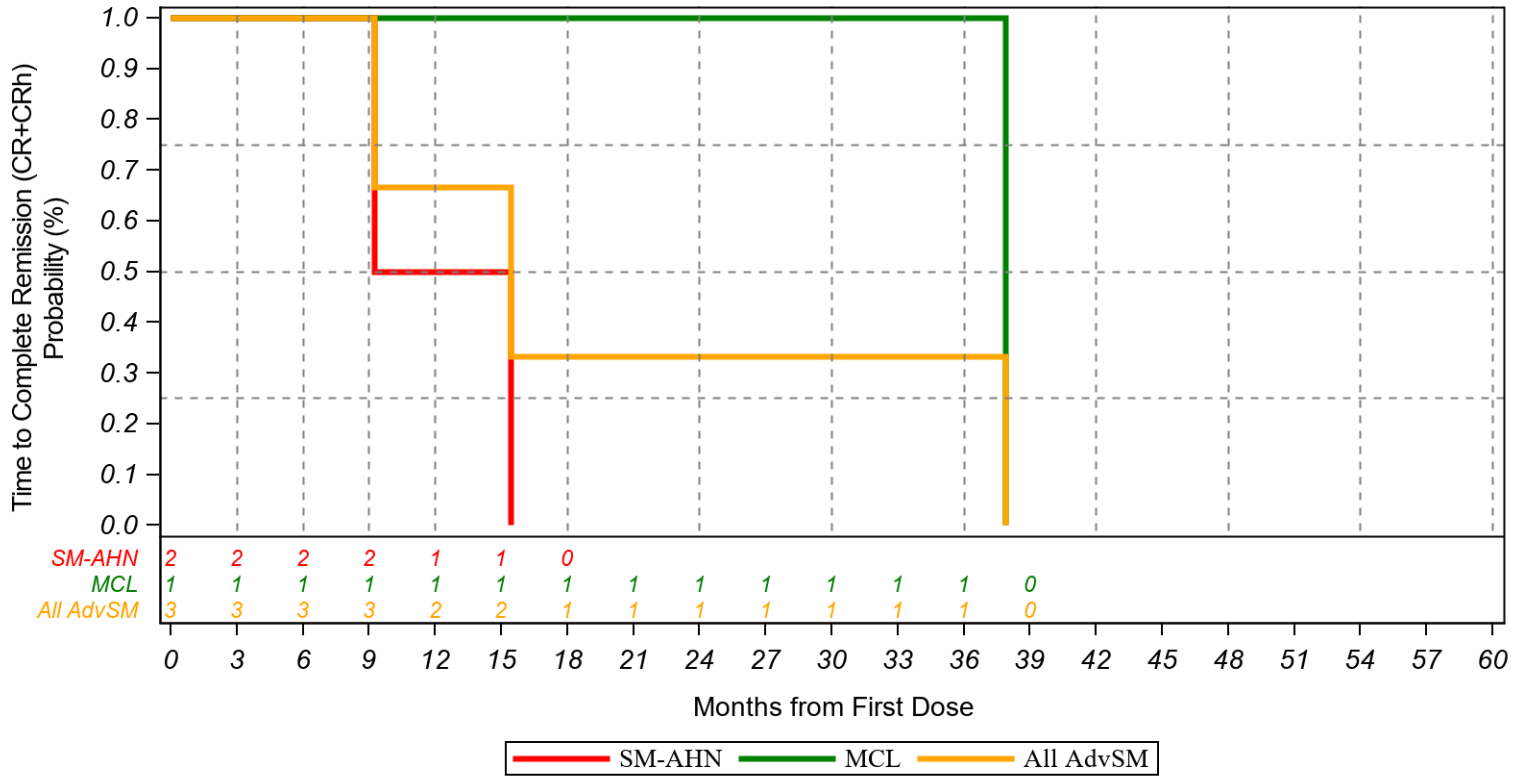

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg

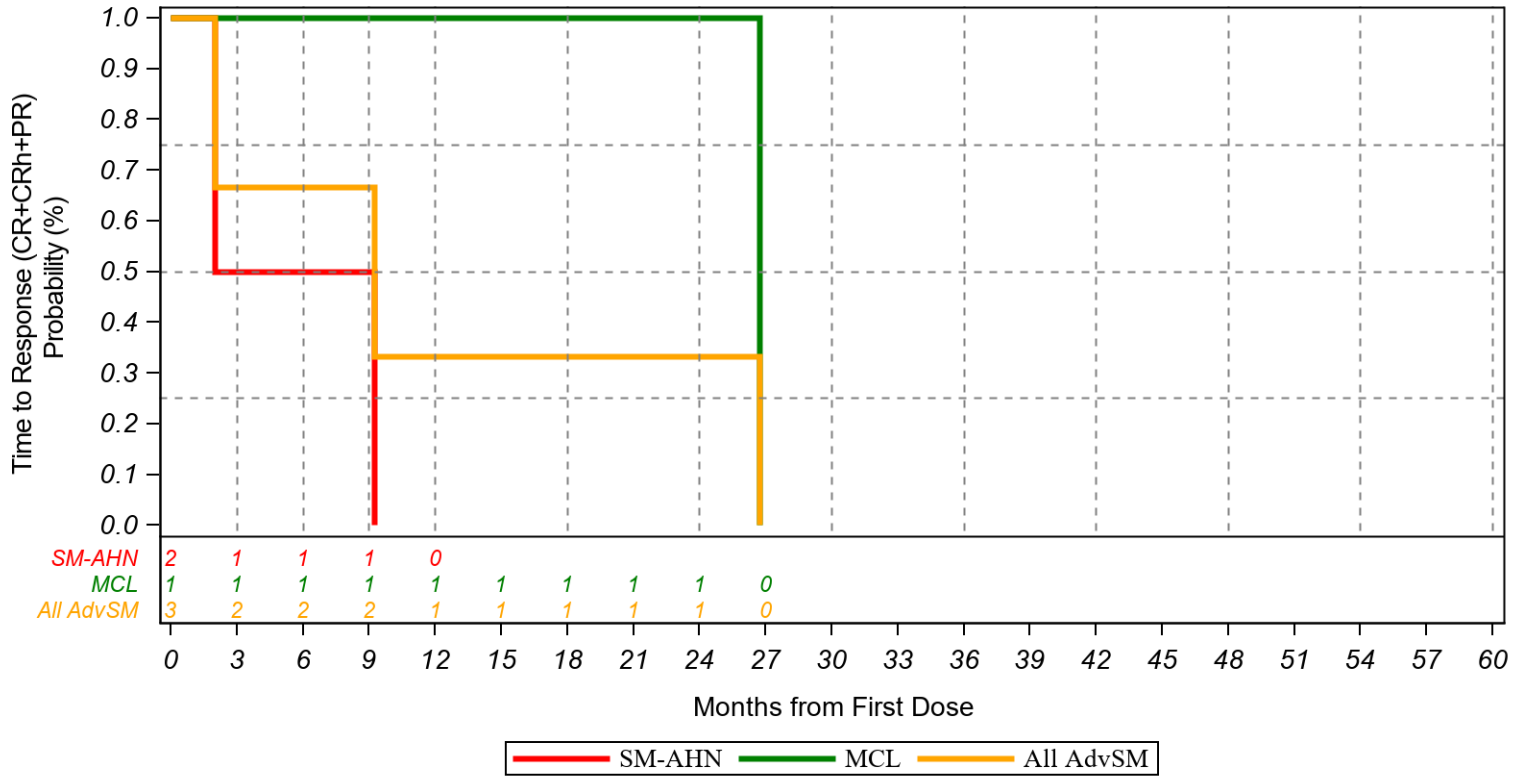

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg

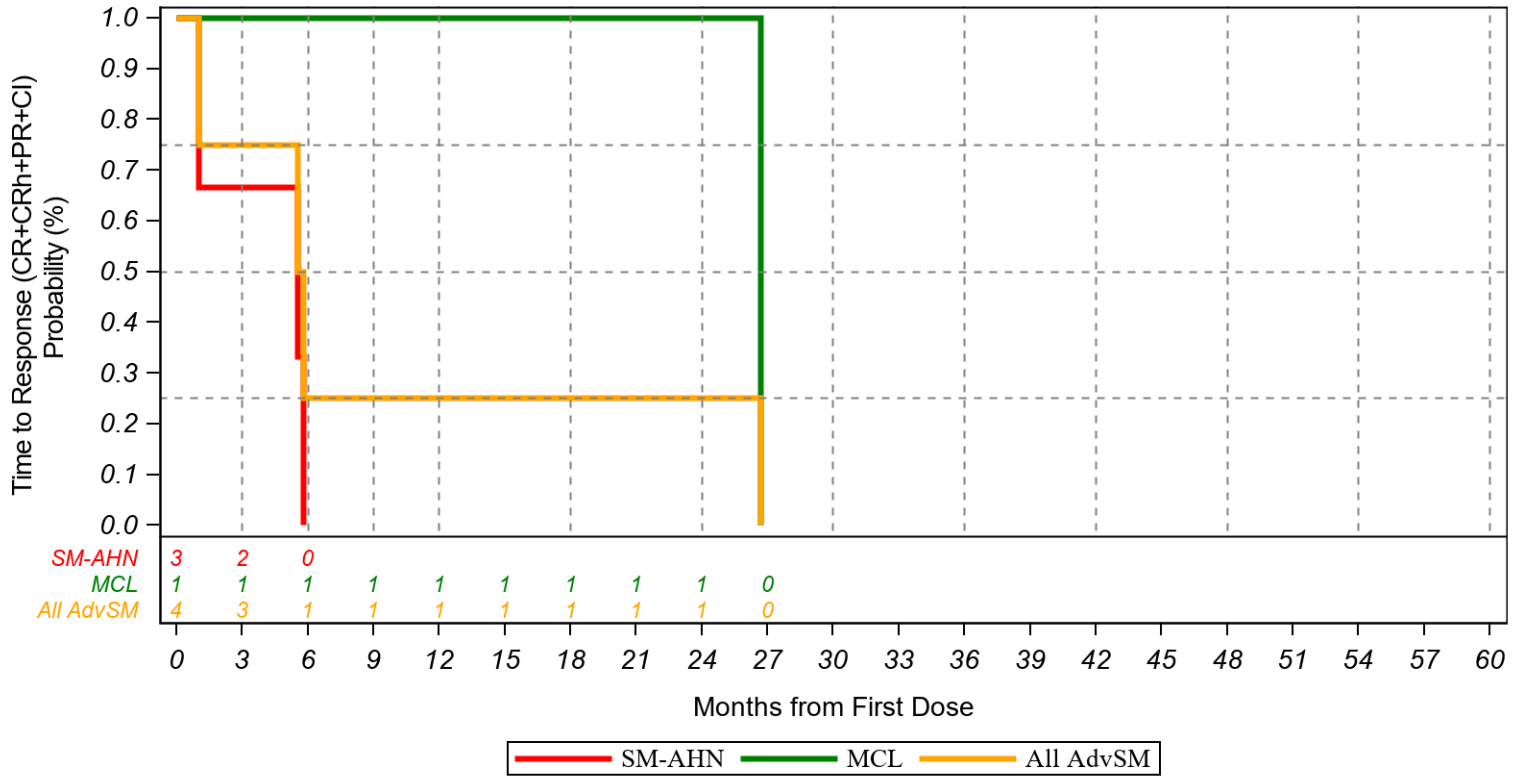

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg

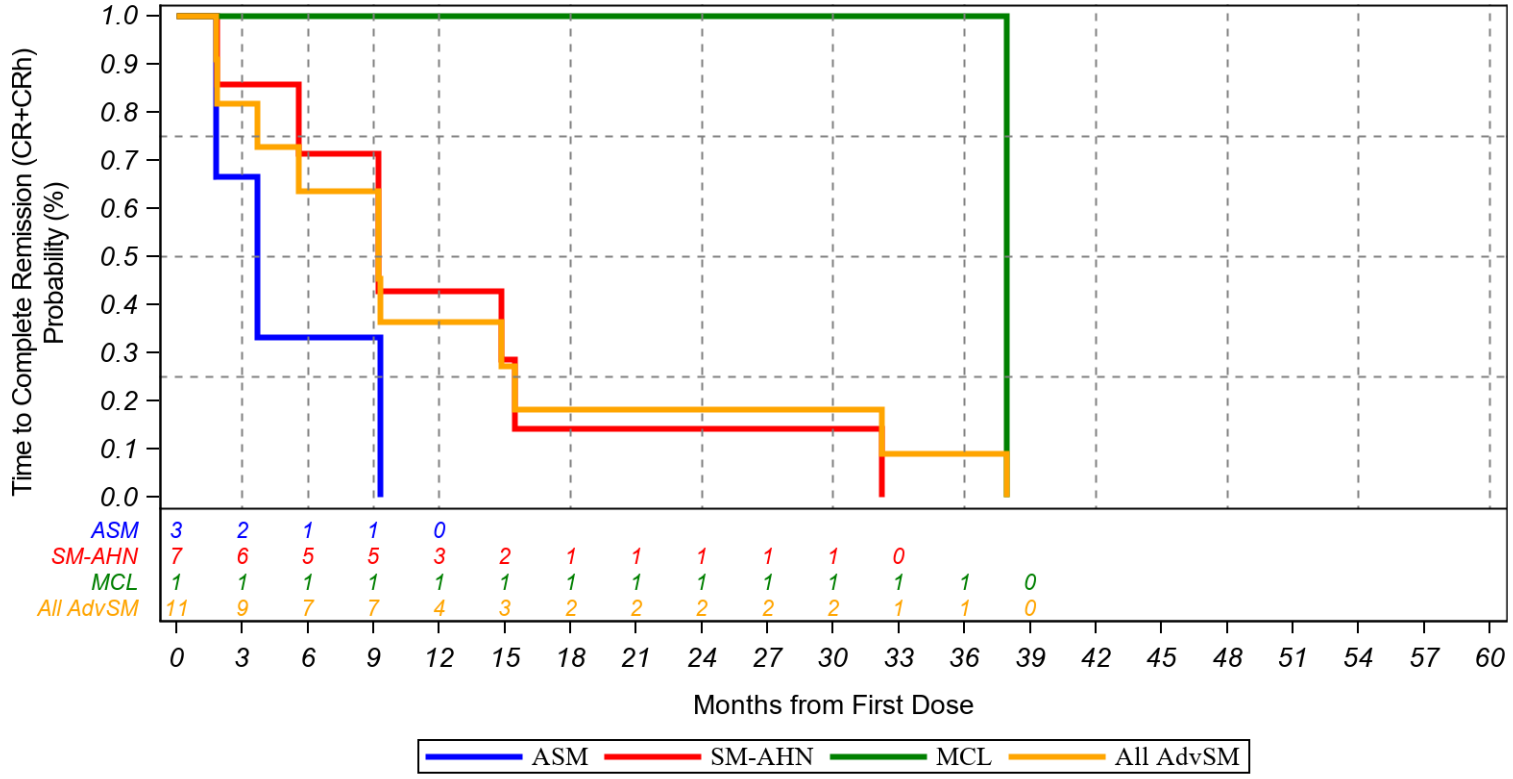

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg

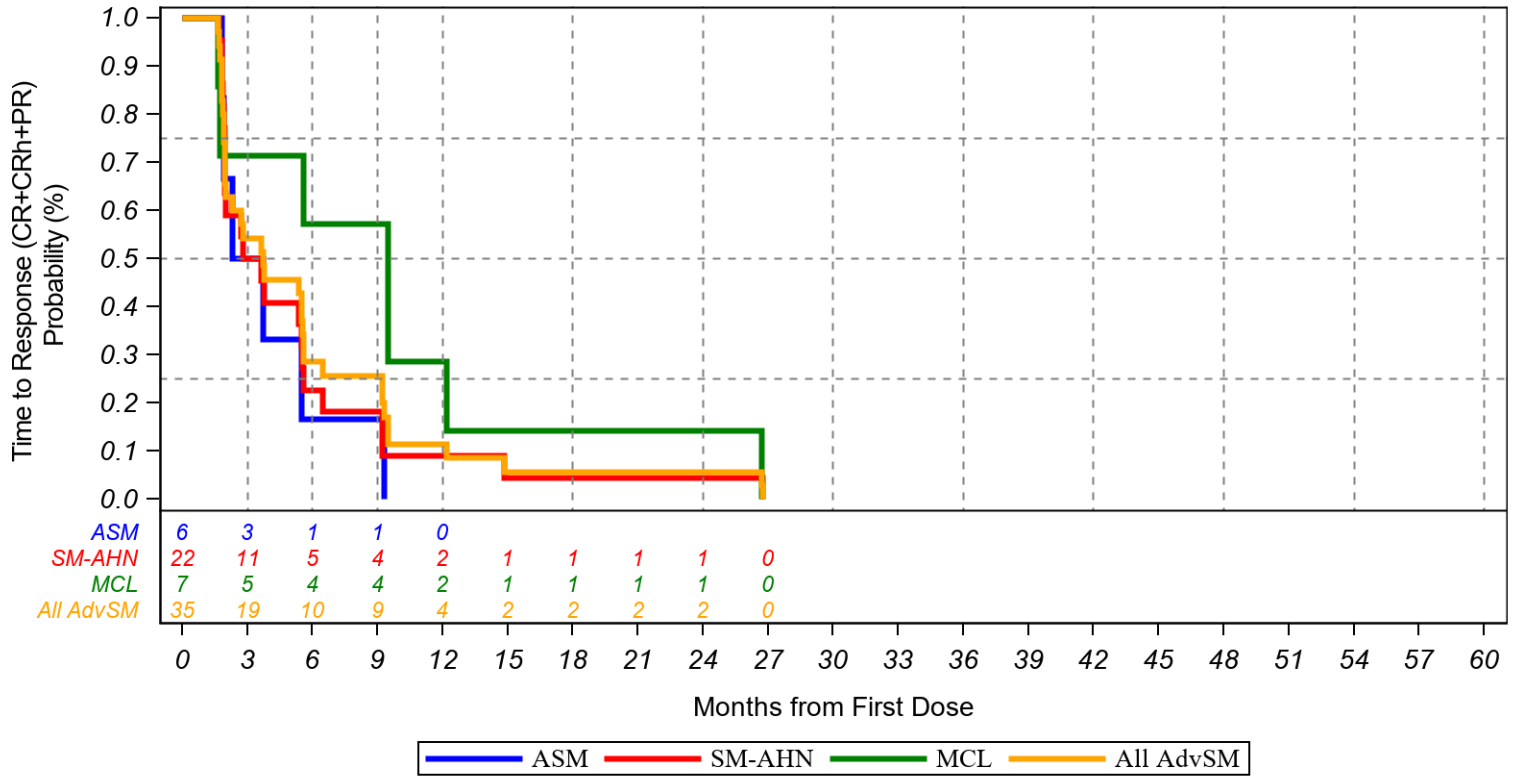

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Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg

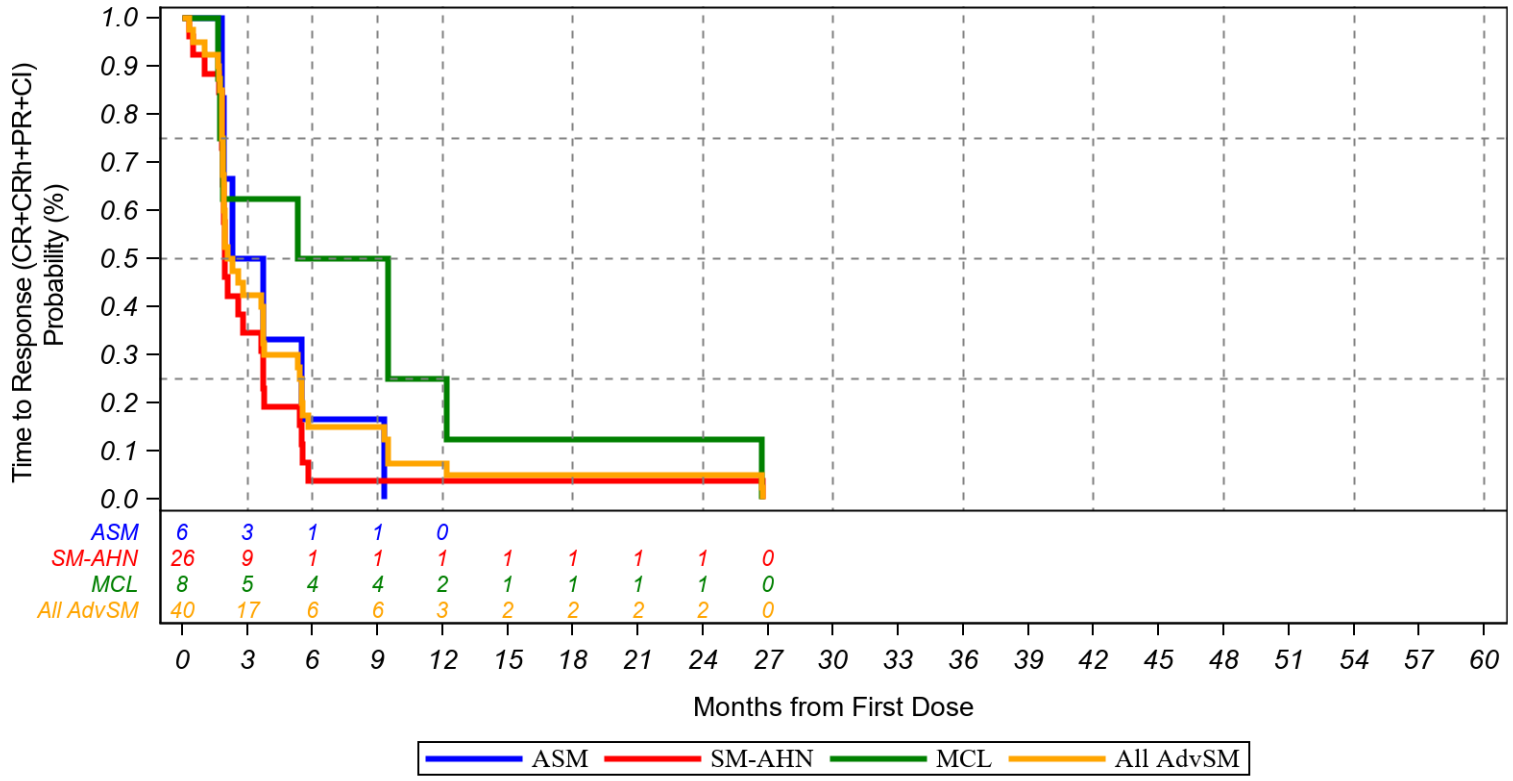

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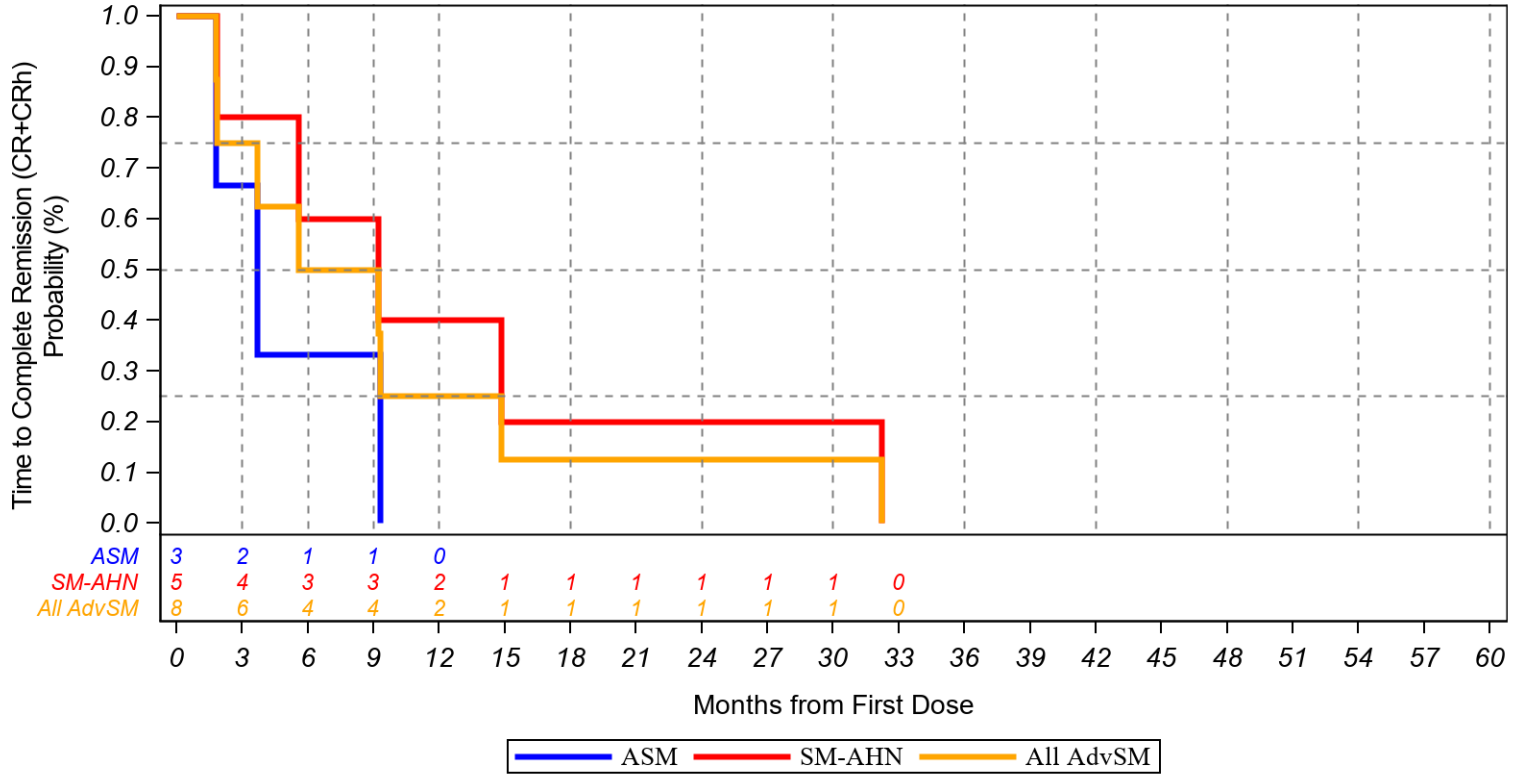
Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg



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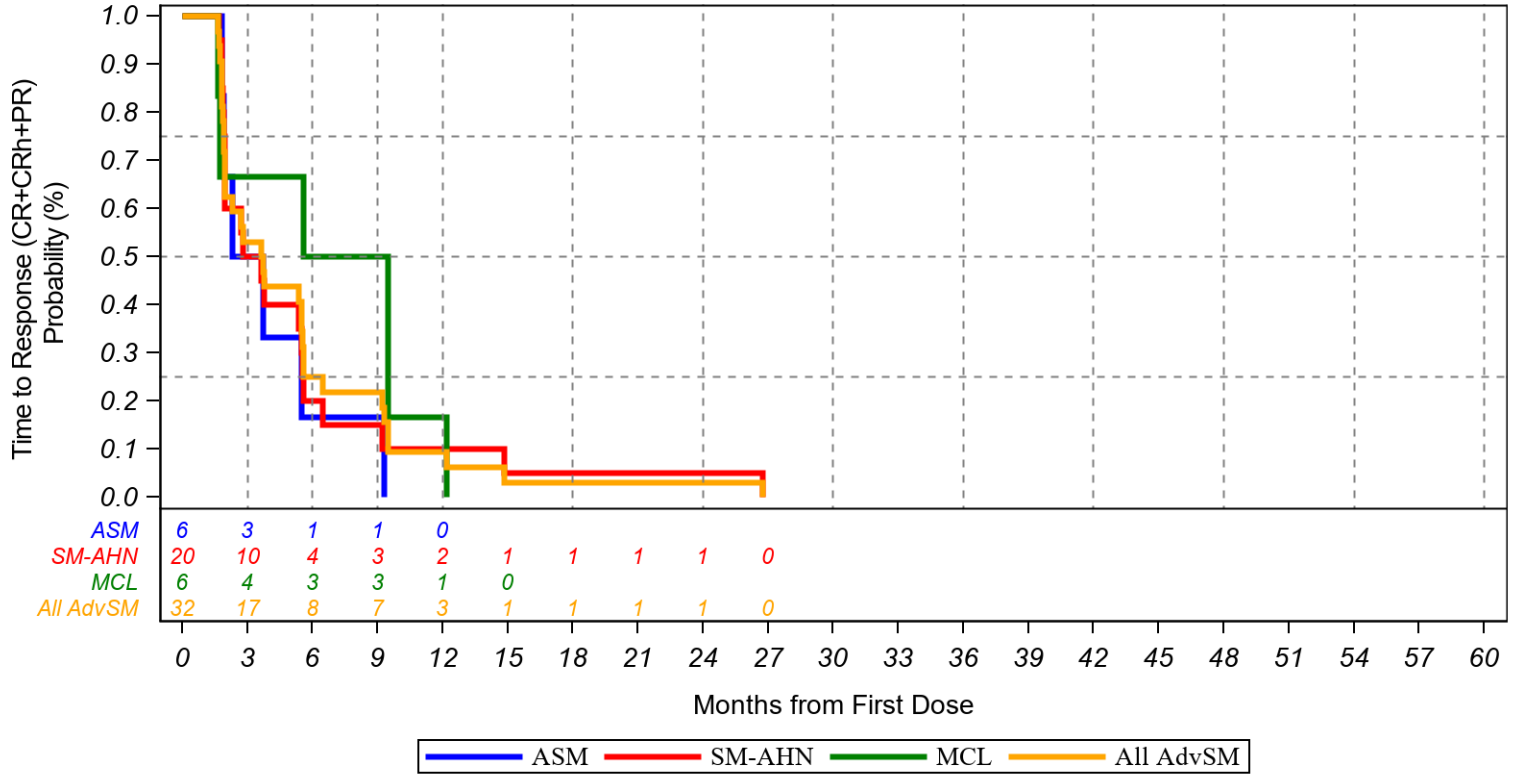
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg



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RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
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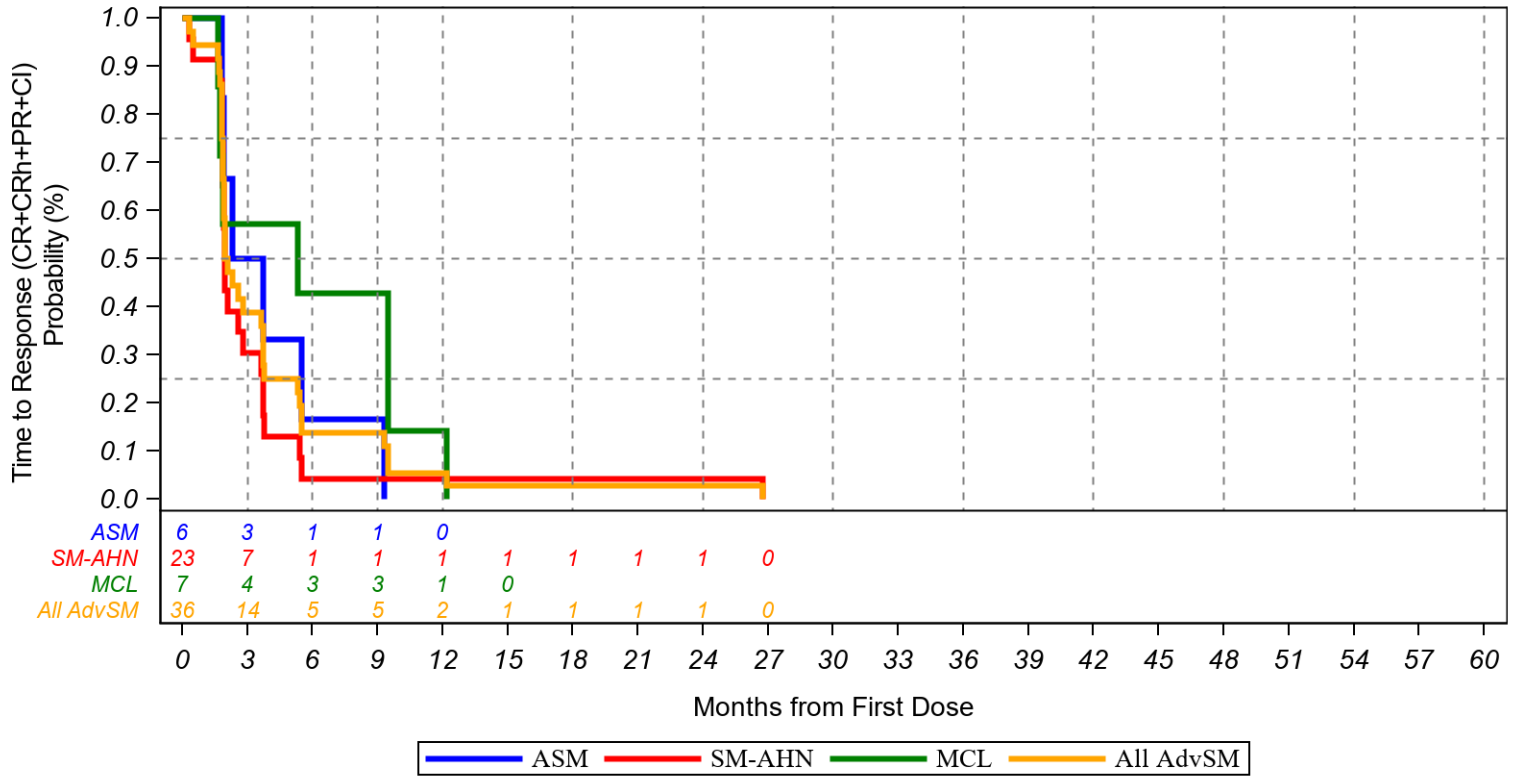

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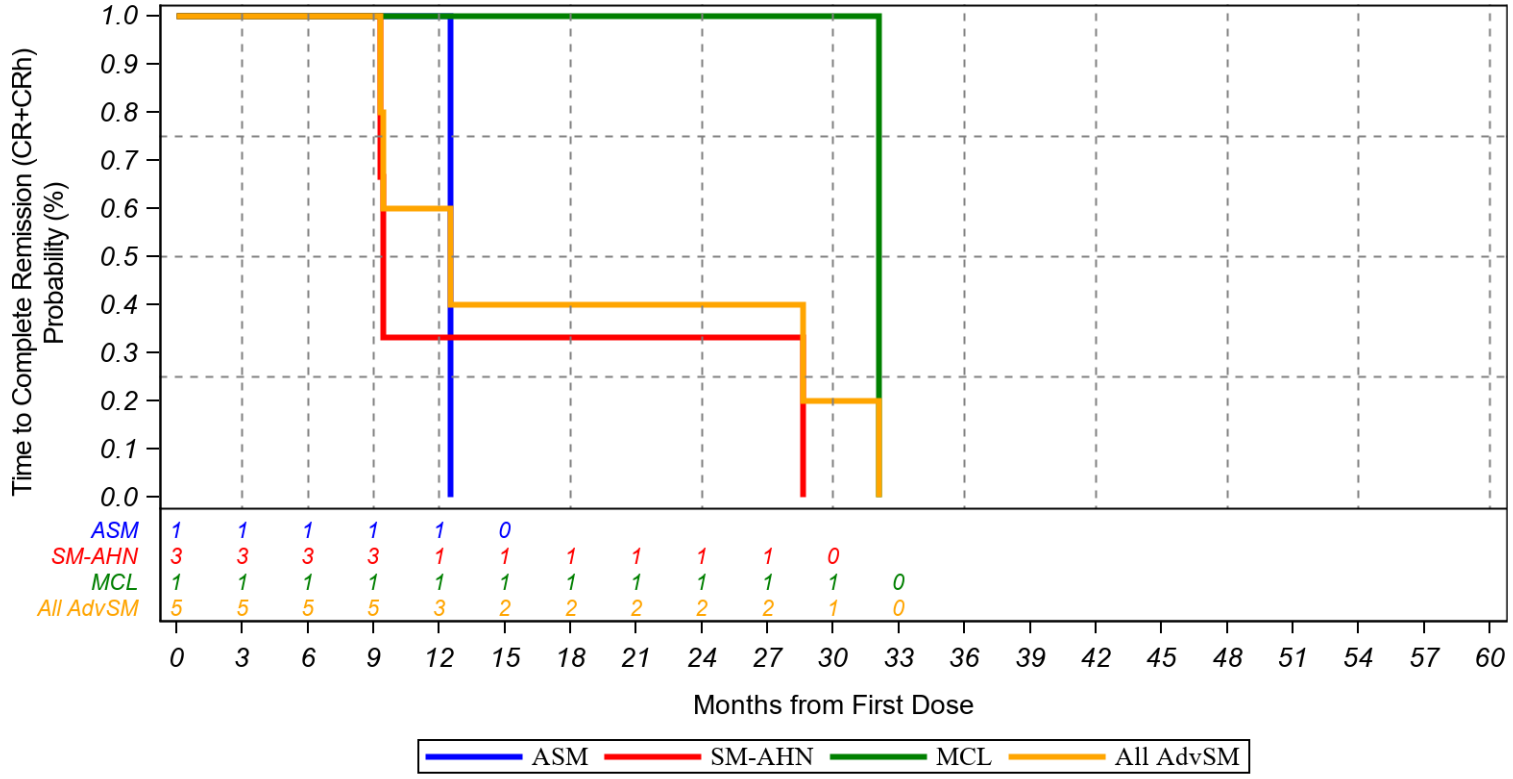
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg



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RAC-RE Population with at least one prior antineoplastic therapy
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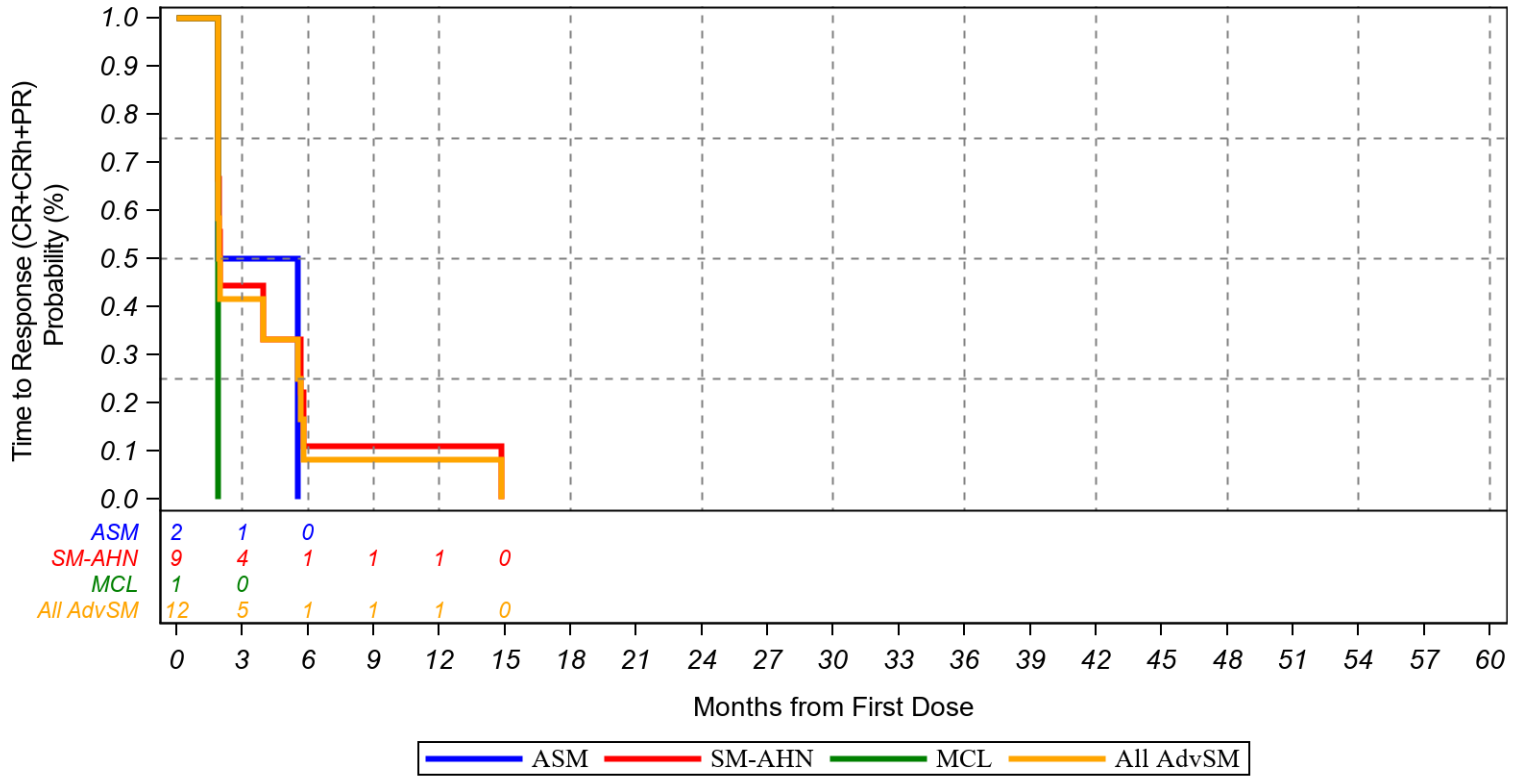

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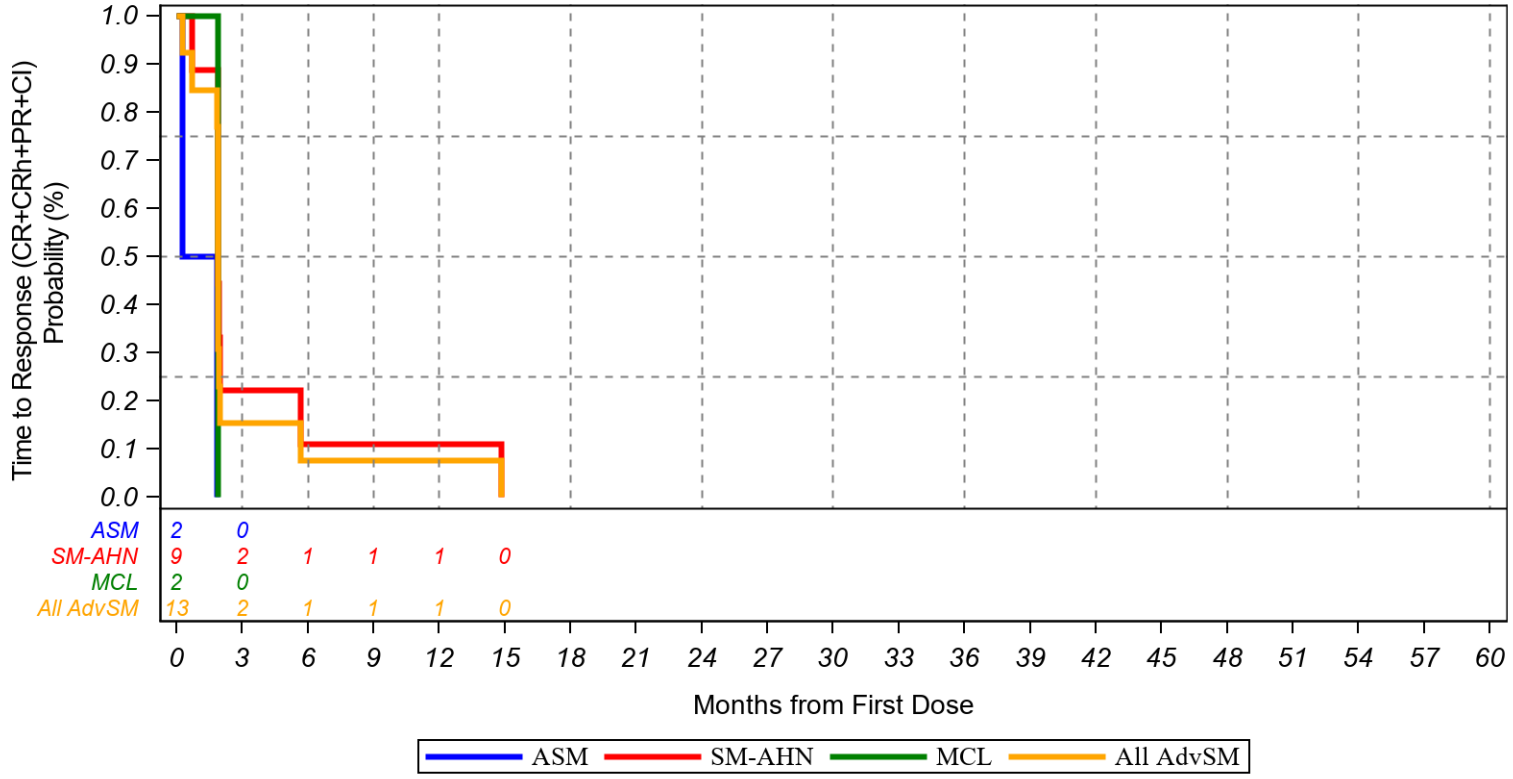
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg



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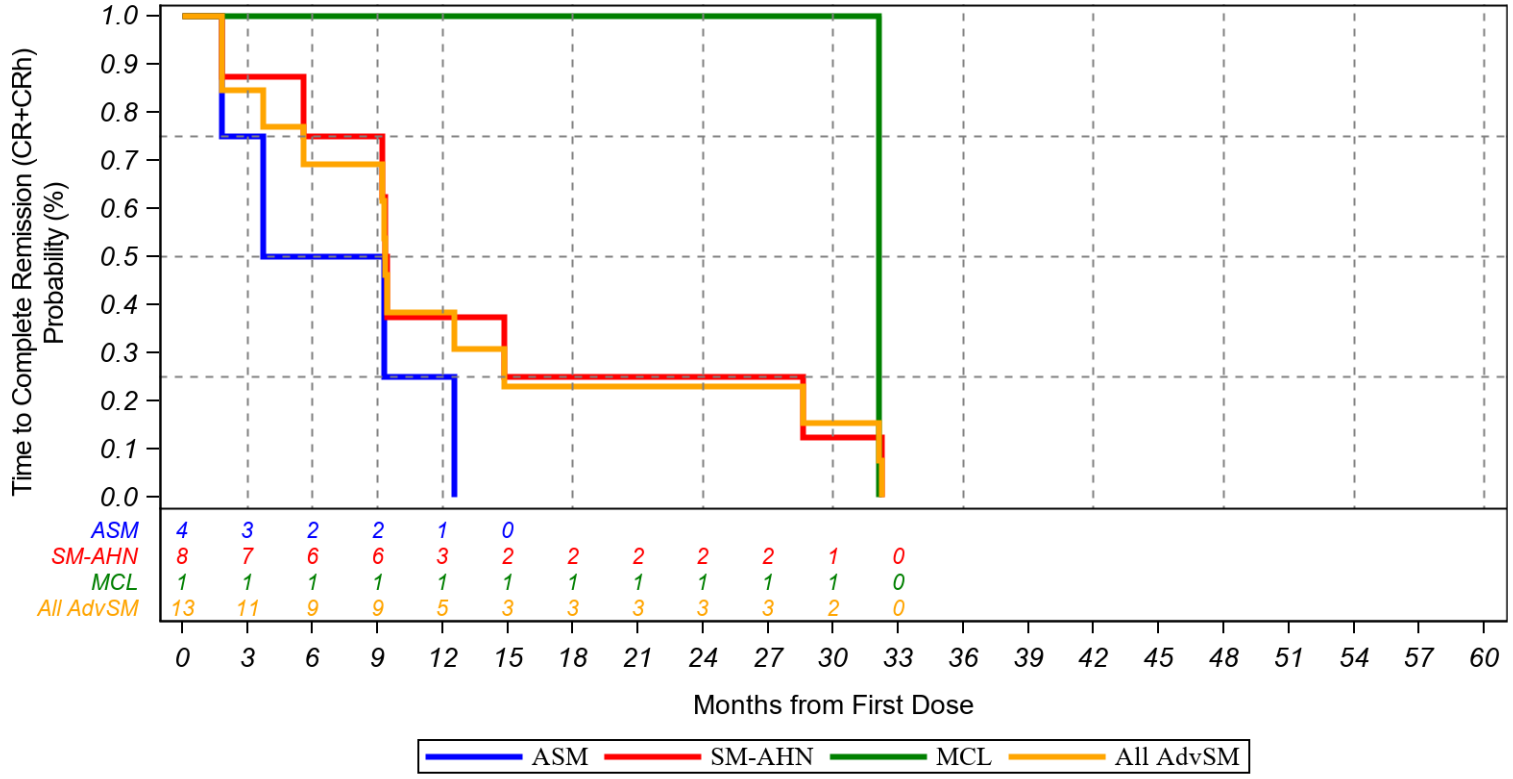
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg



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Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg

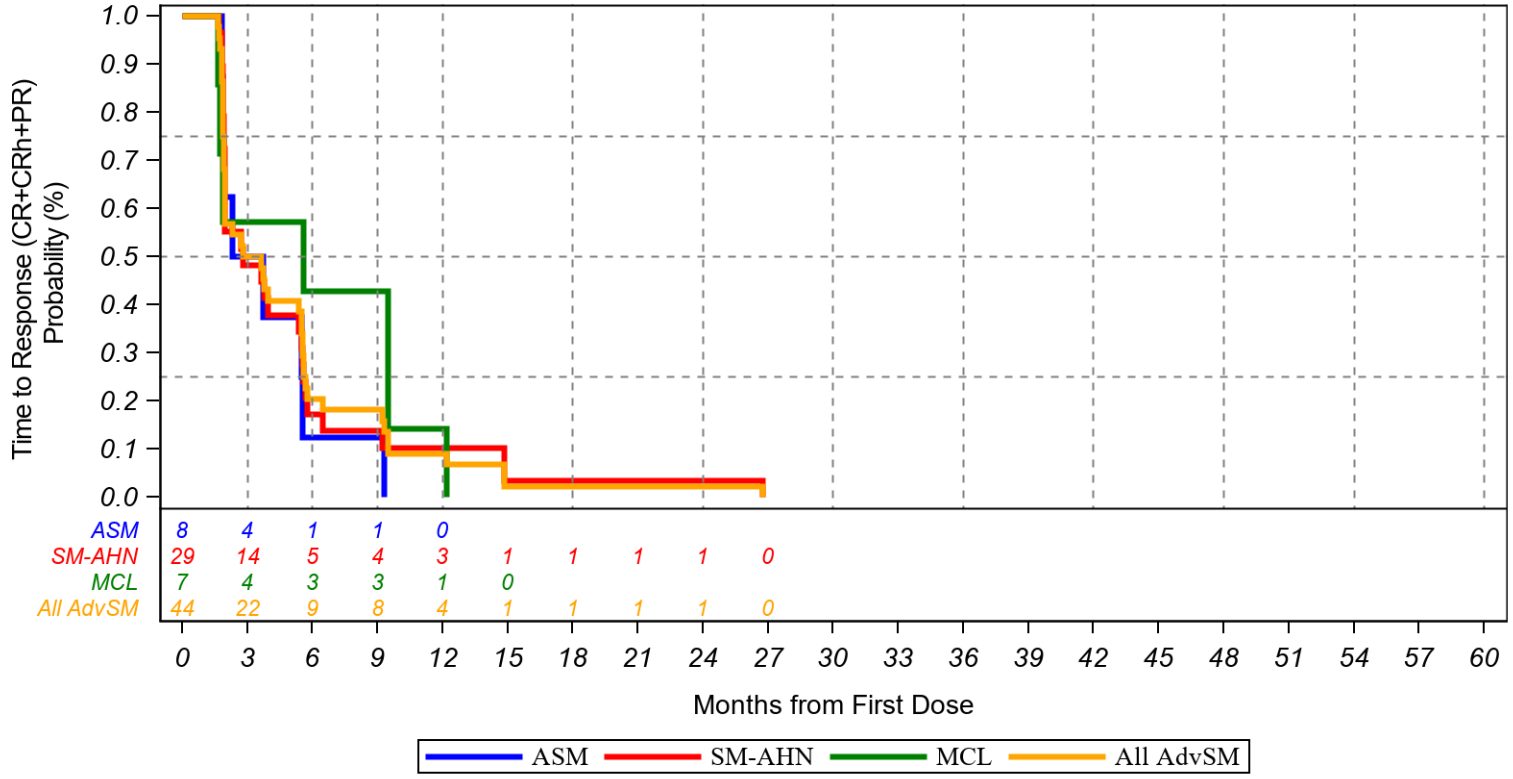

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg

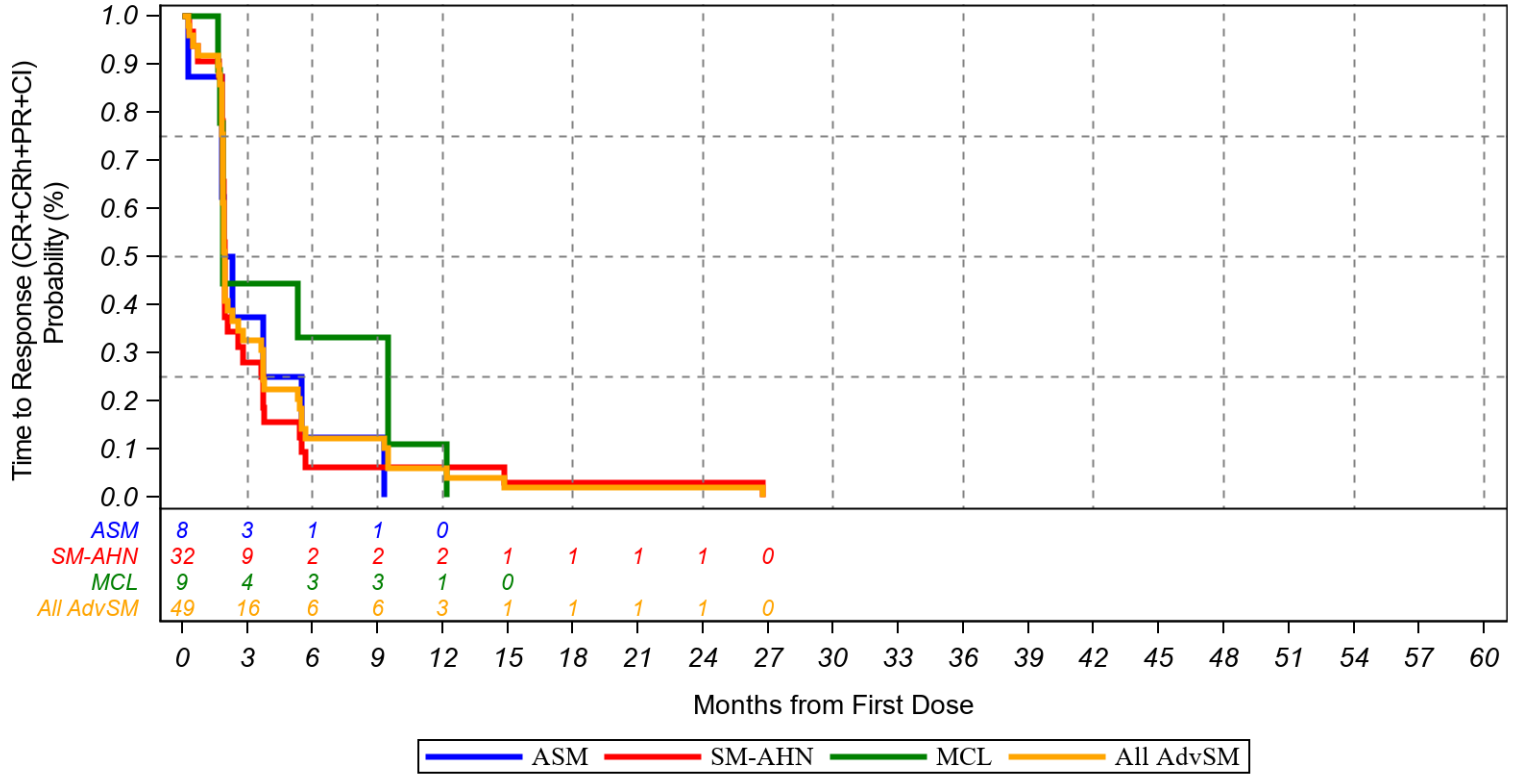

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg

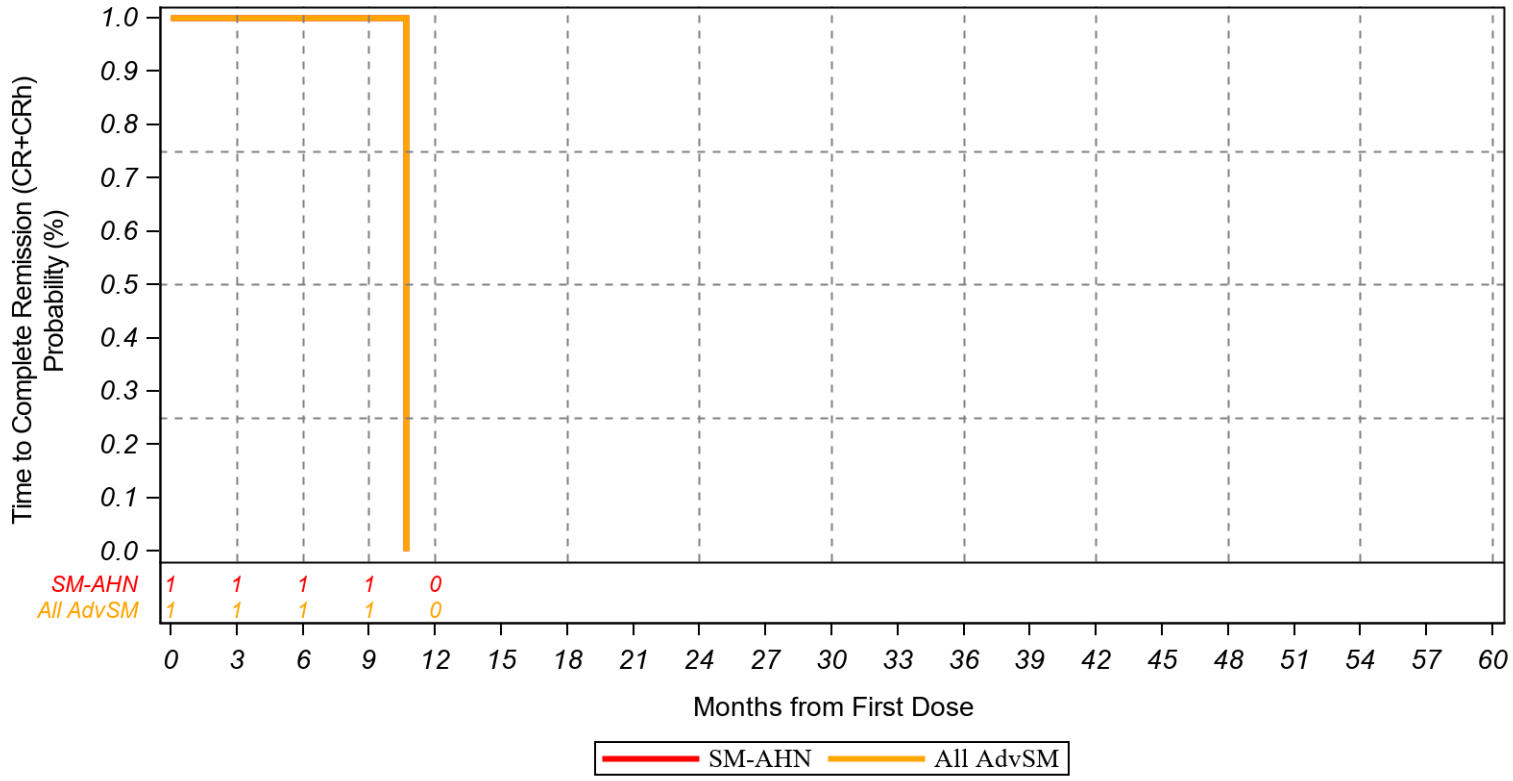

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg

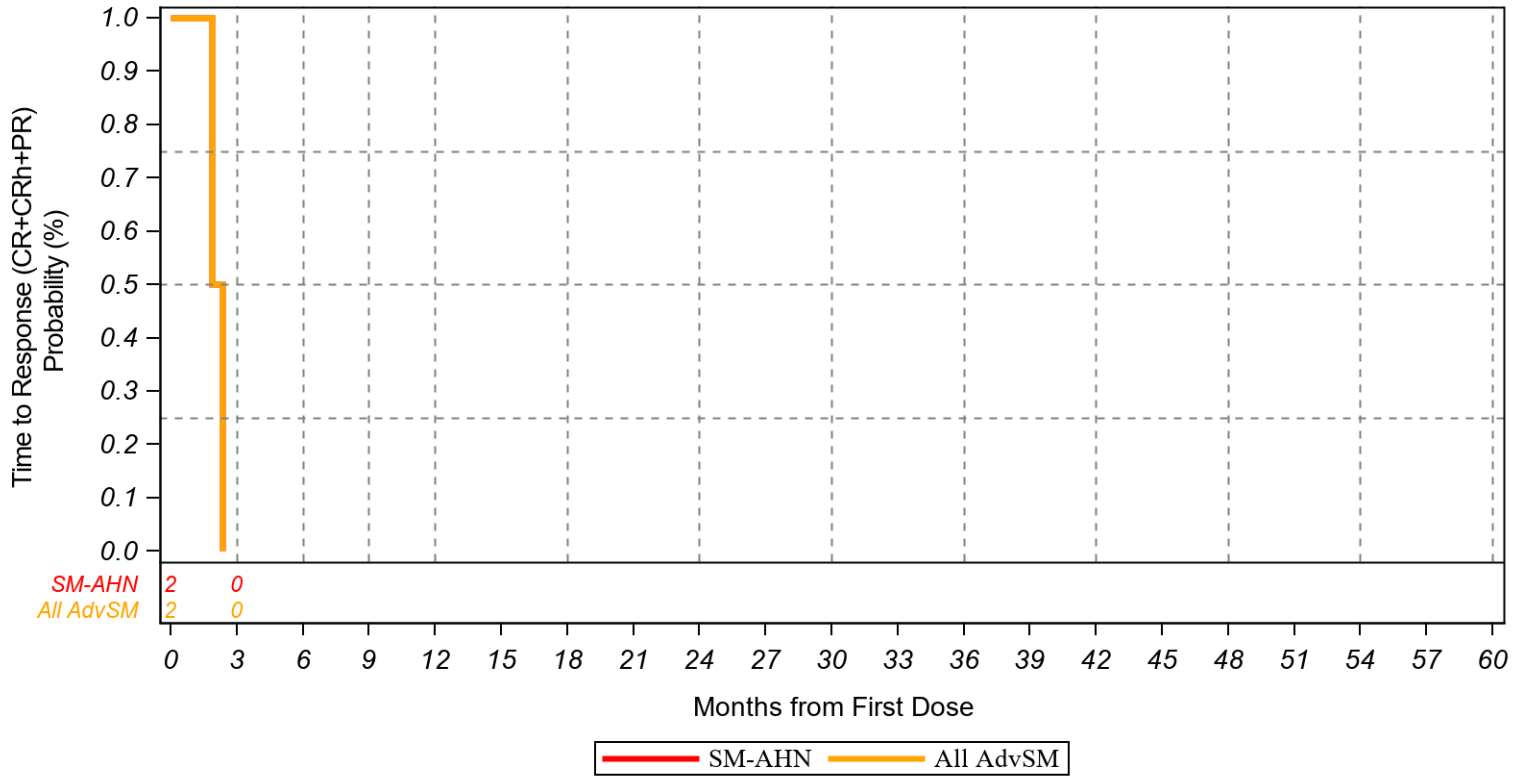

Figure 35.2.2.6
Kaplan-Meier Curves of Adjudicated Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg

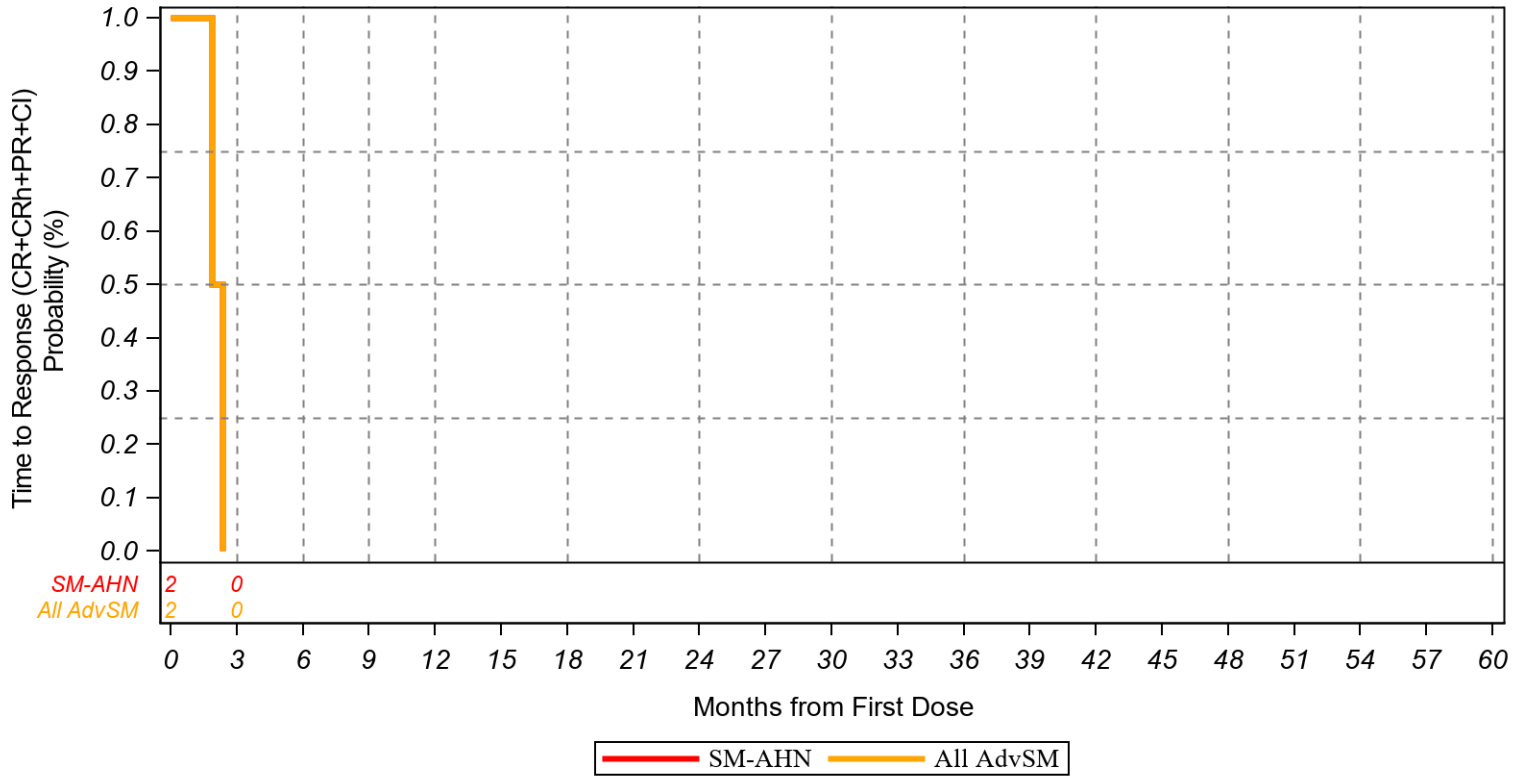

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Study BLU-285-2101
Starting Dose: Overall

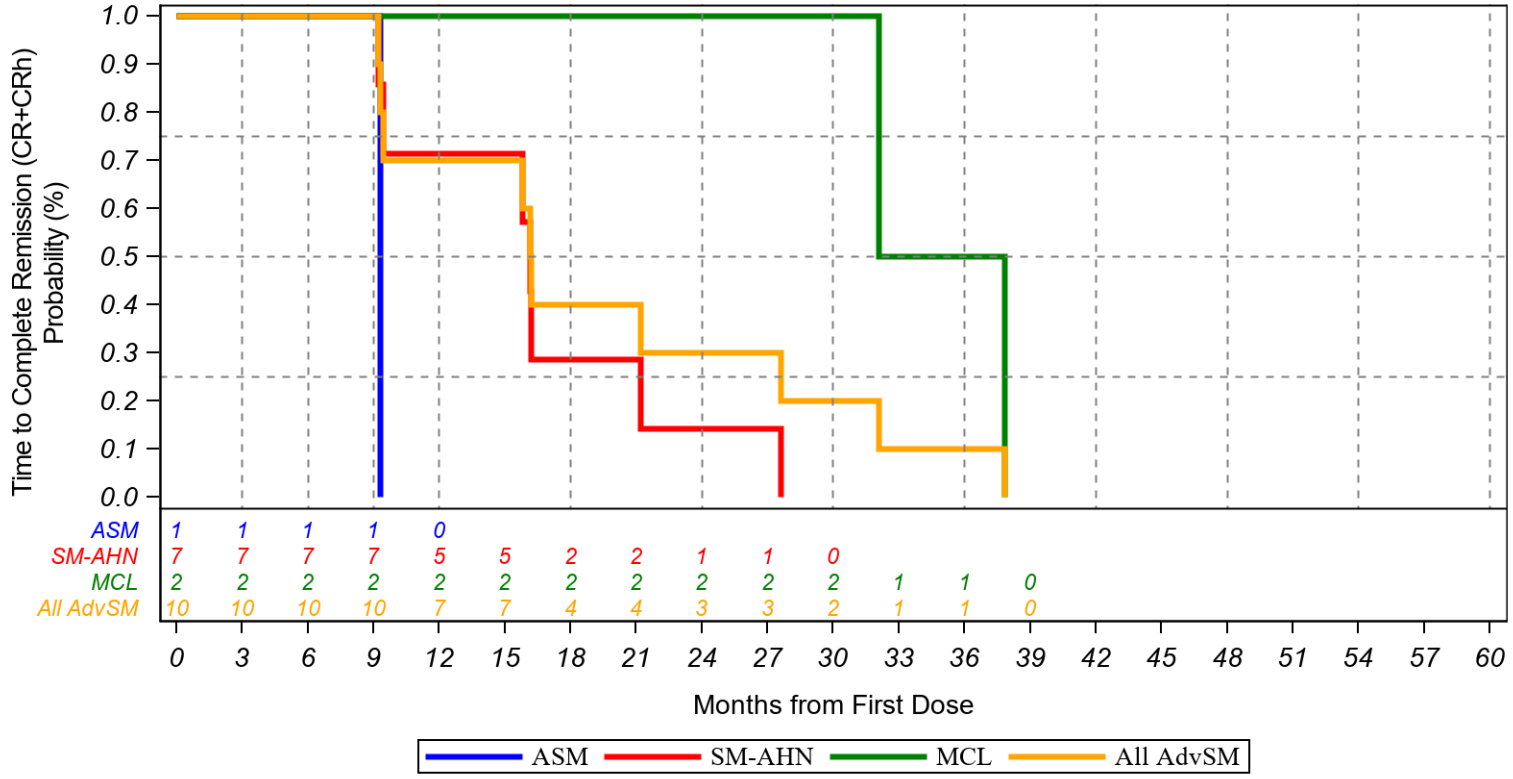

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Study BLU-285-2101
Starting Dose: Overall

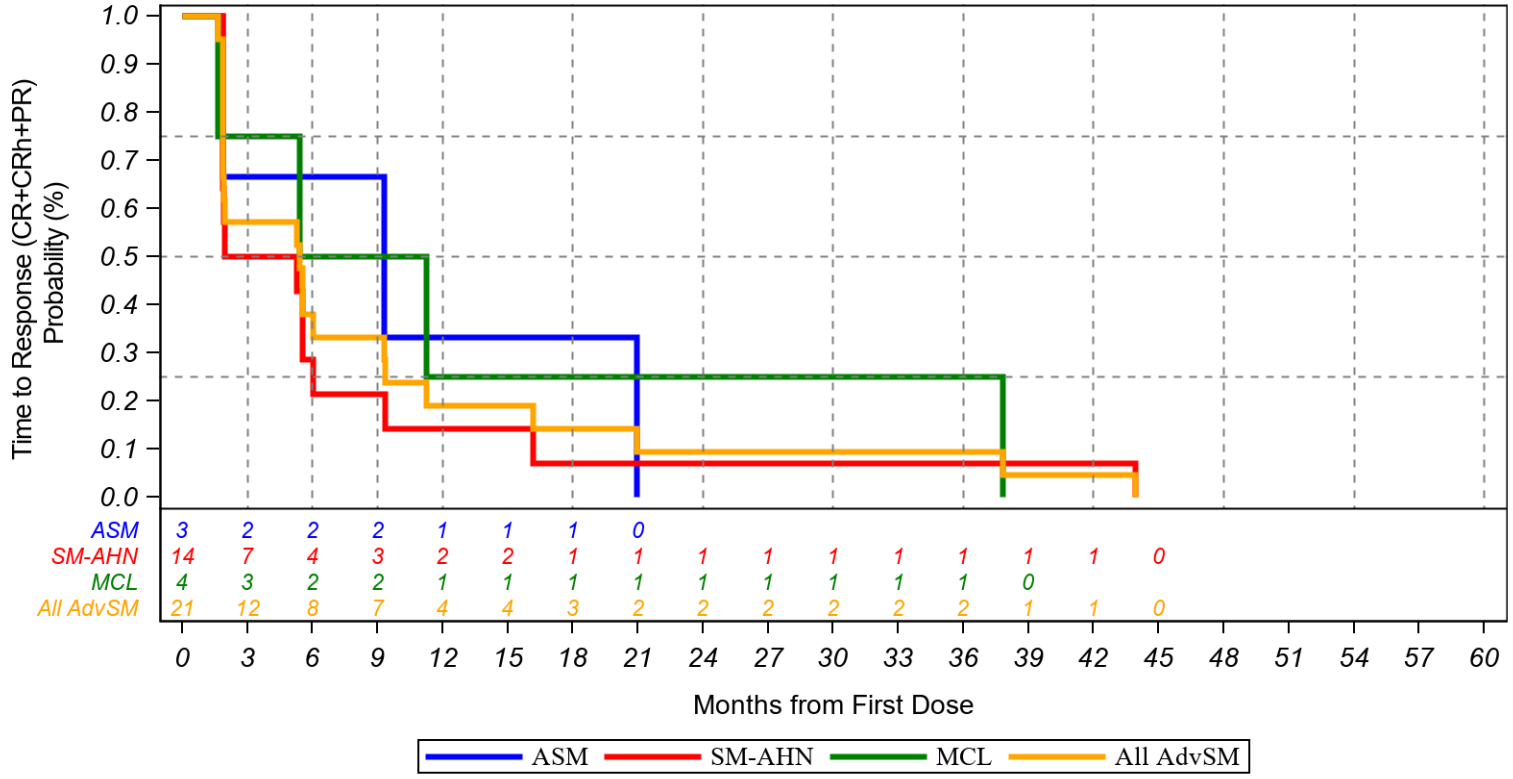

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: Overall

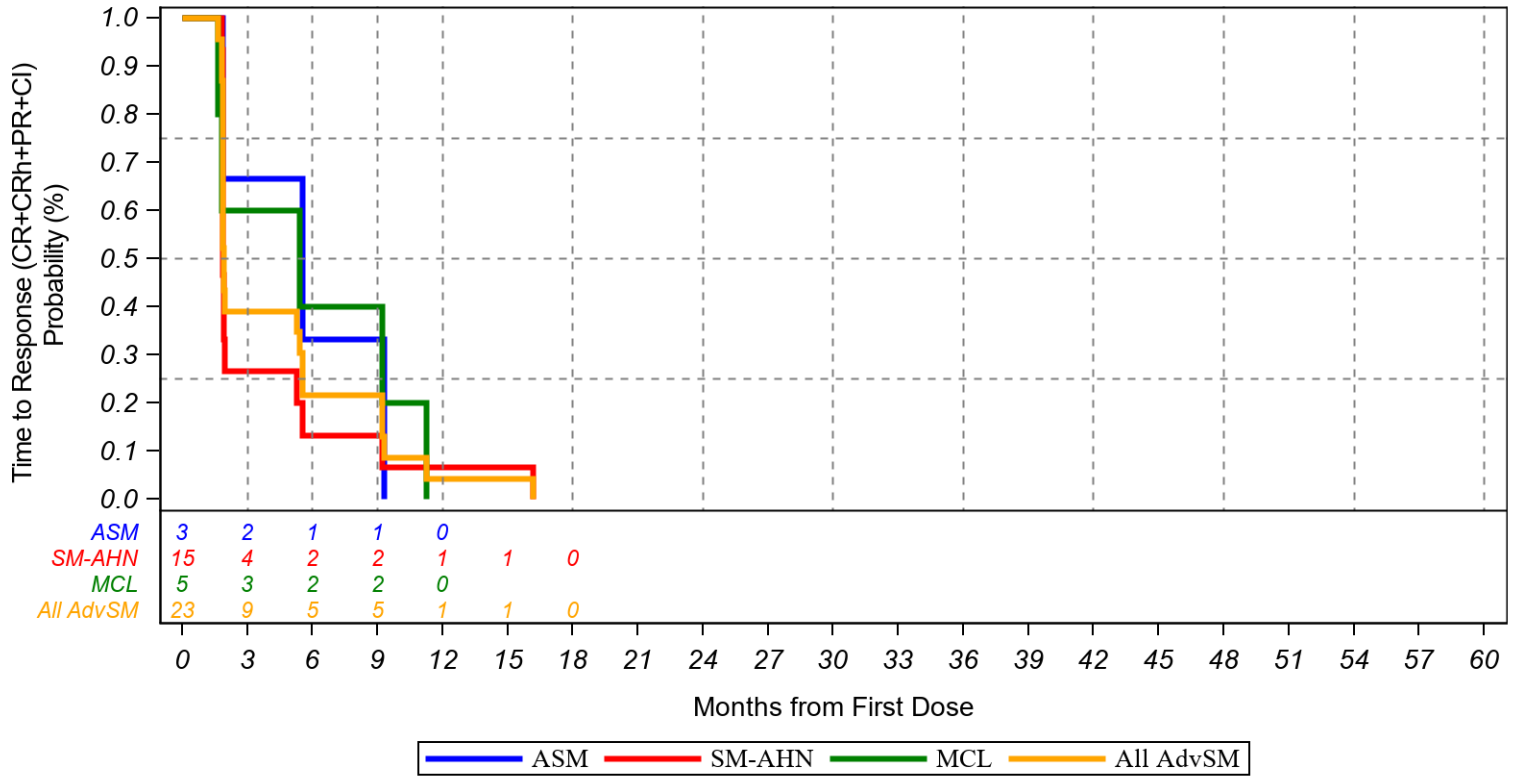

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Study BLU-285-2101
Starting Dose: < 200 mg

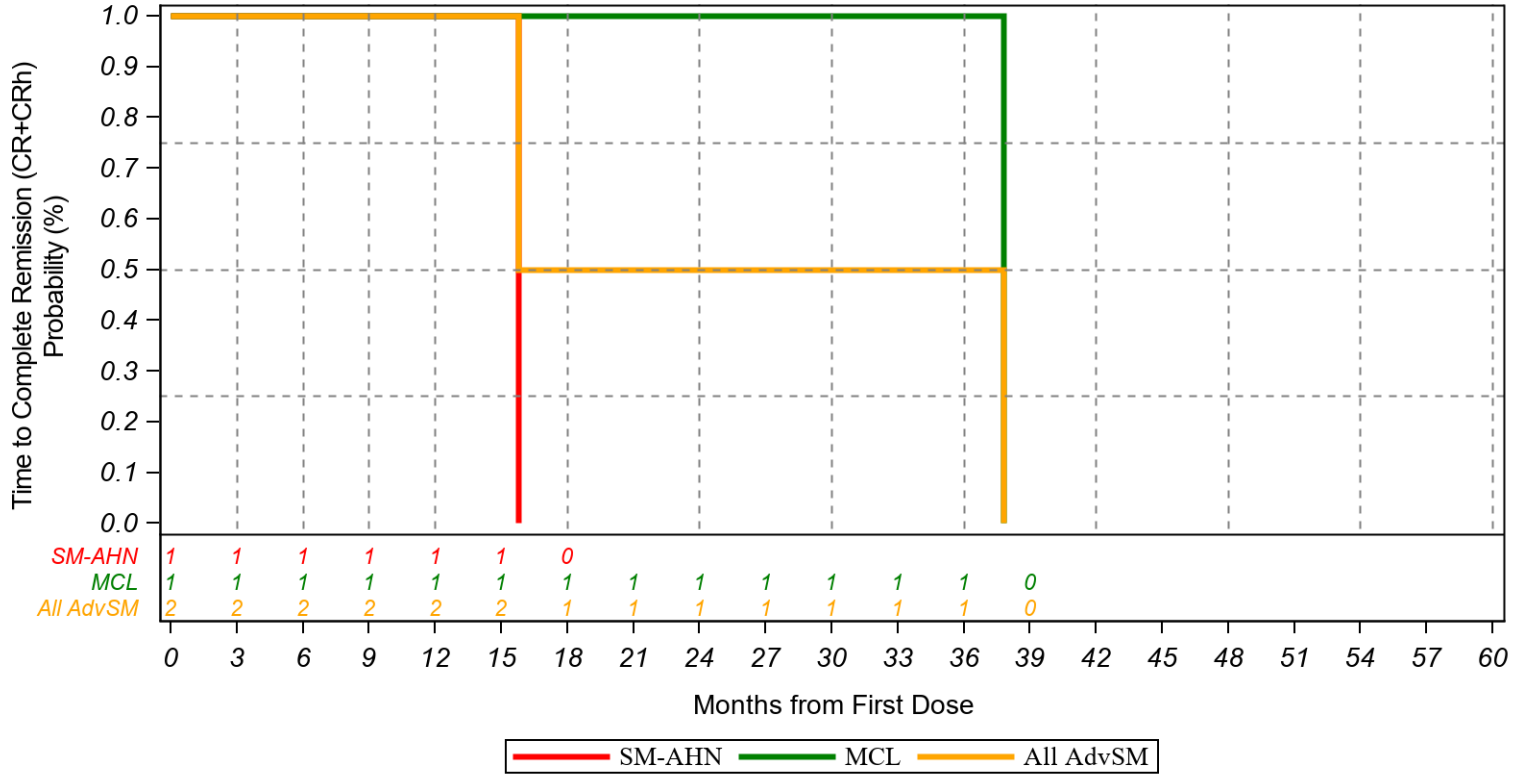

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Study BLU-285-2101
Starting Dose: < 200 mg

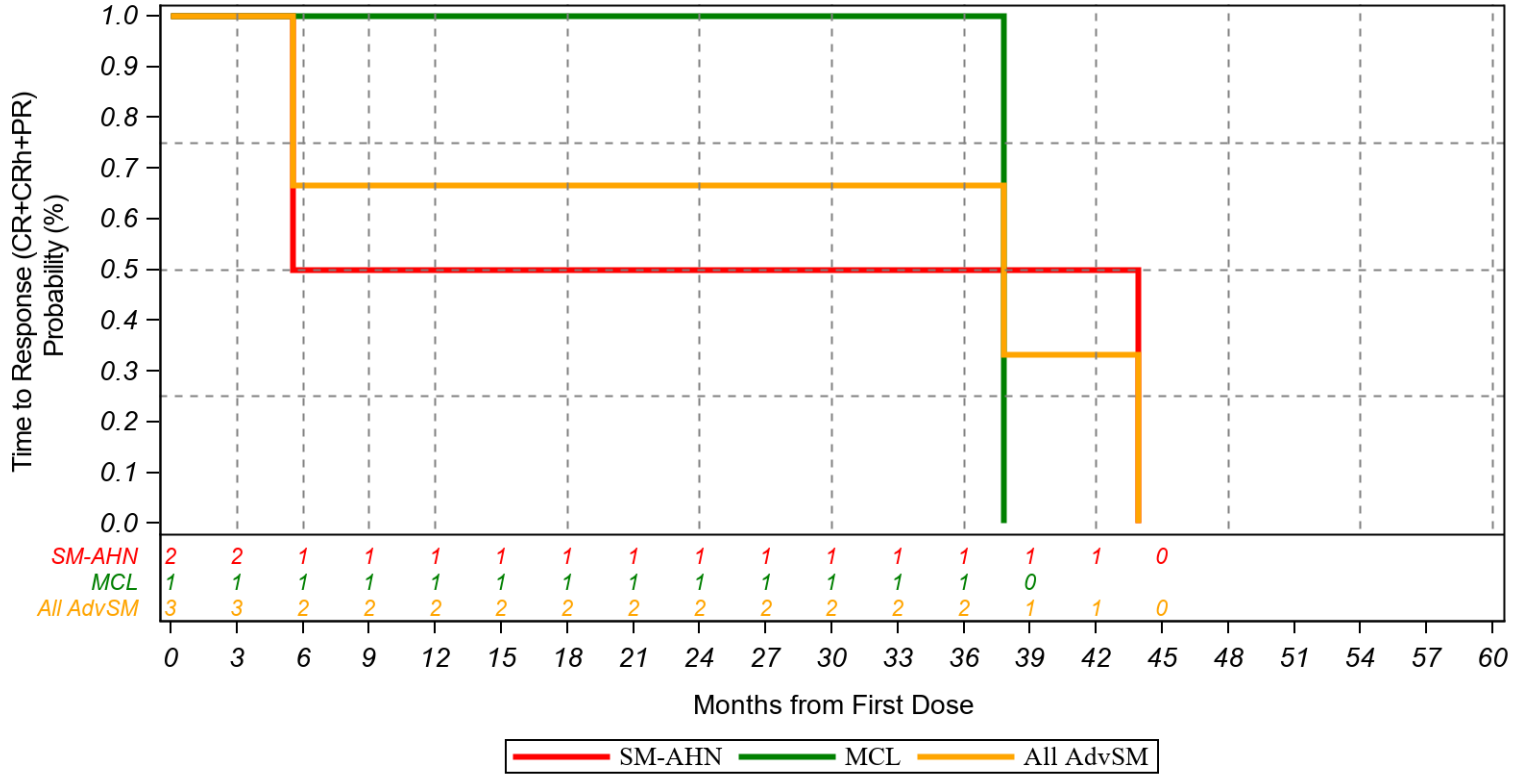

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: < 200 mg

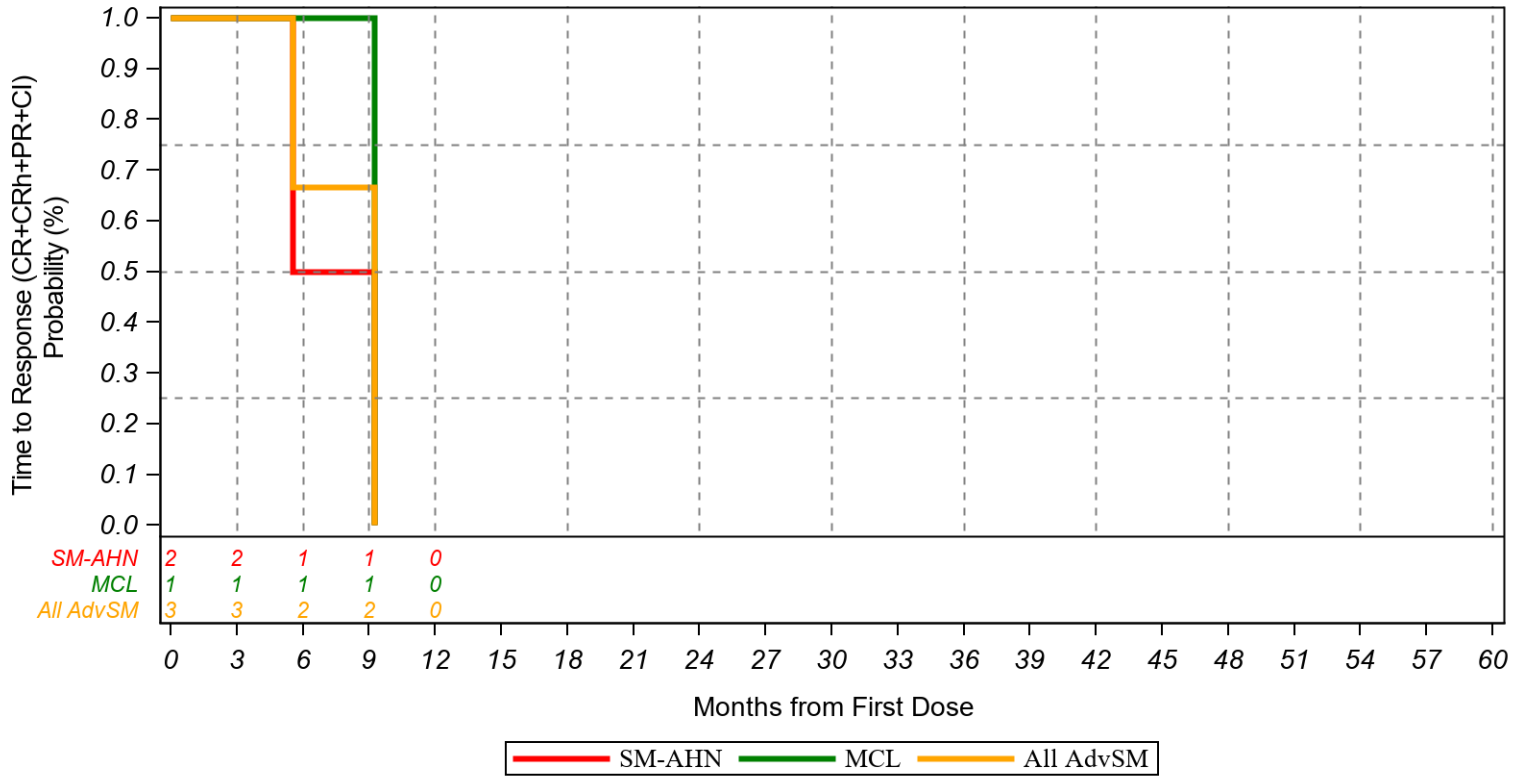

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Study BLU-285-2101
Starting Dose: < 300 mg

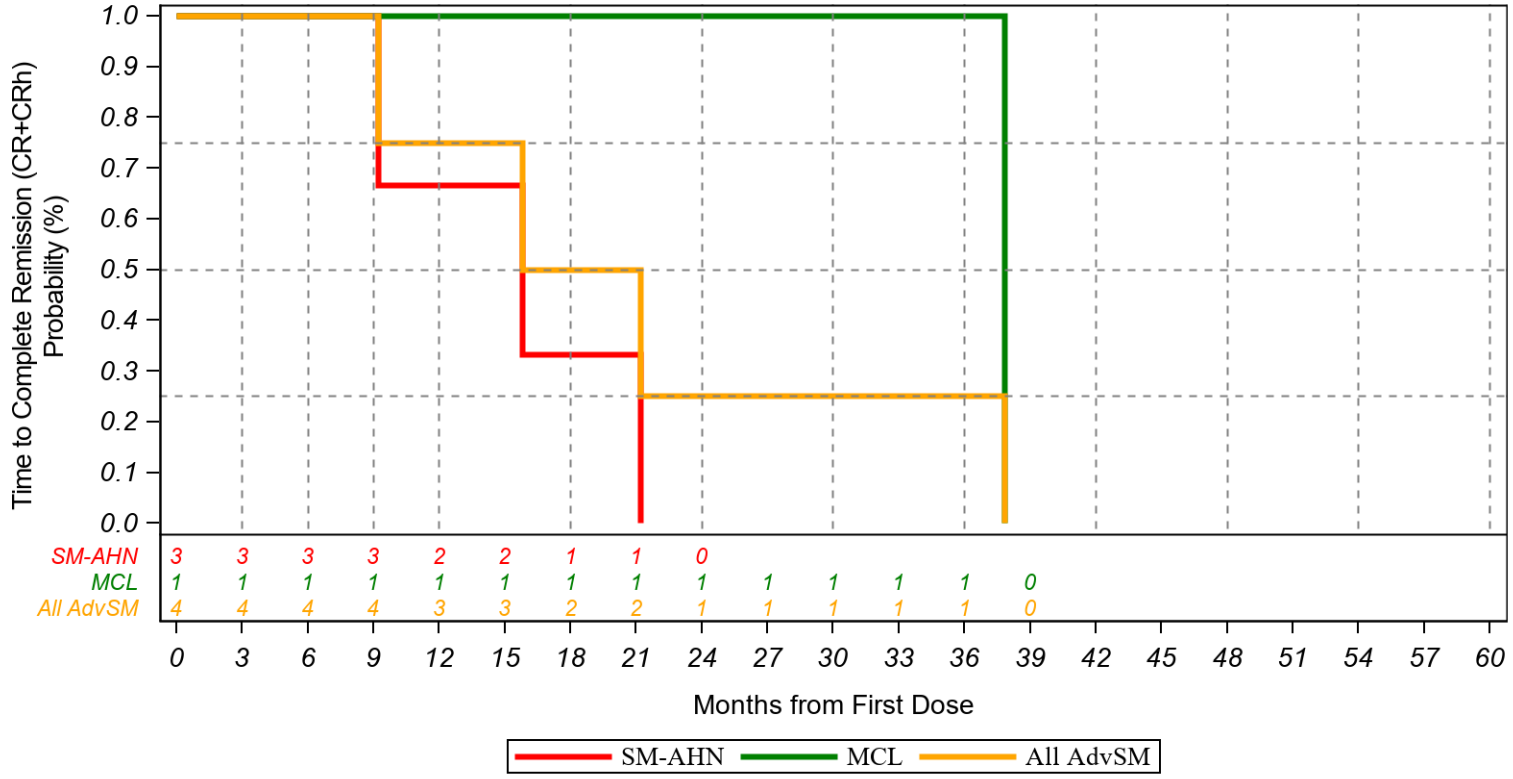

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Study BLU-285-2101
Starting Dose: < 300 mg

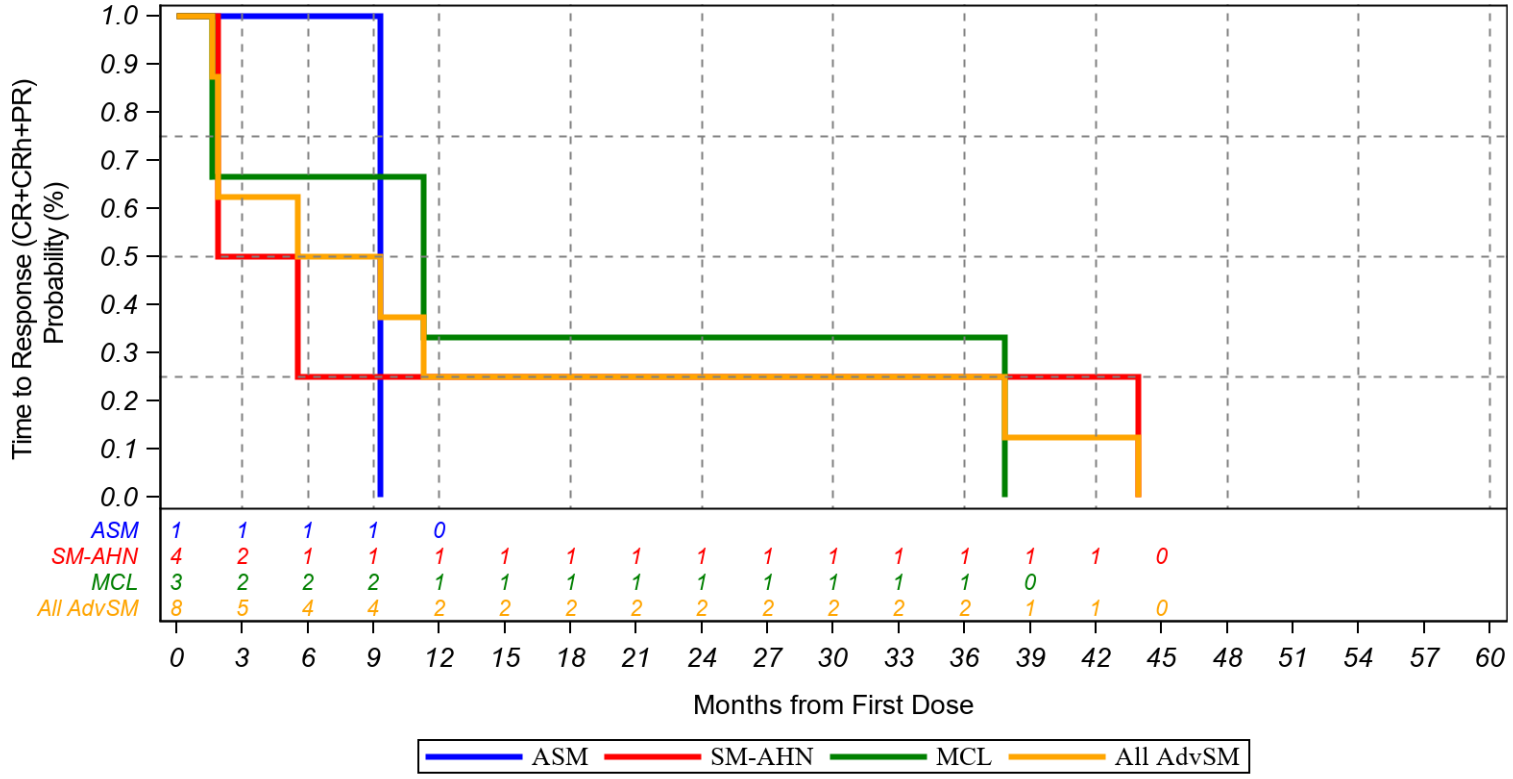

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: < 300 mg

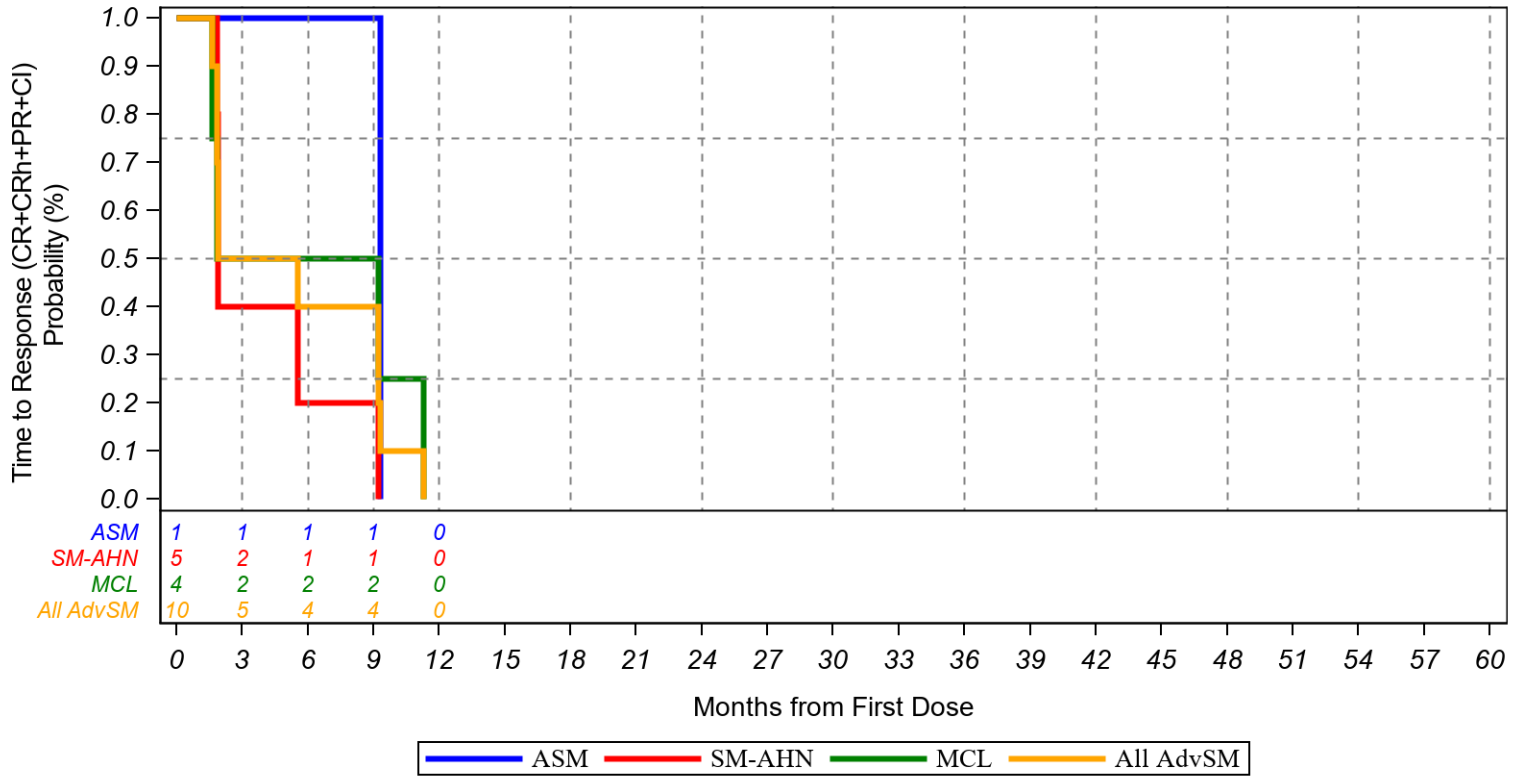

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Study BLU-285-2101
Starting Dose: 200 mg

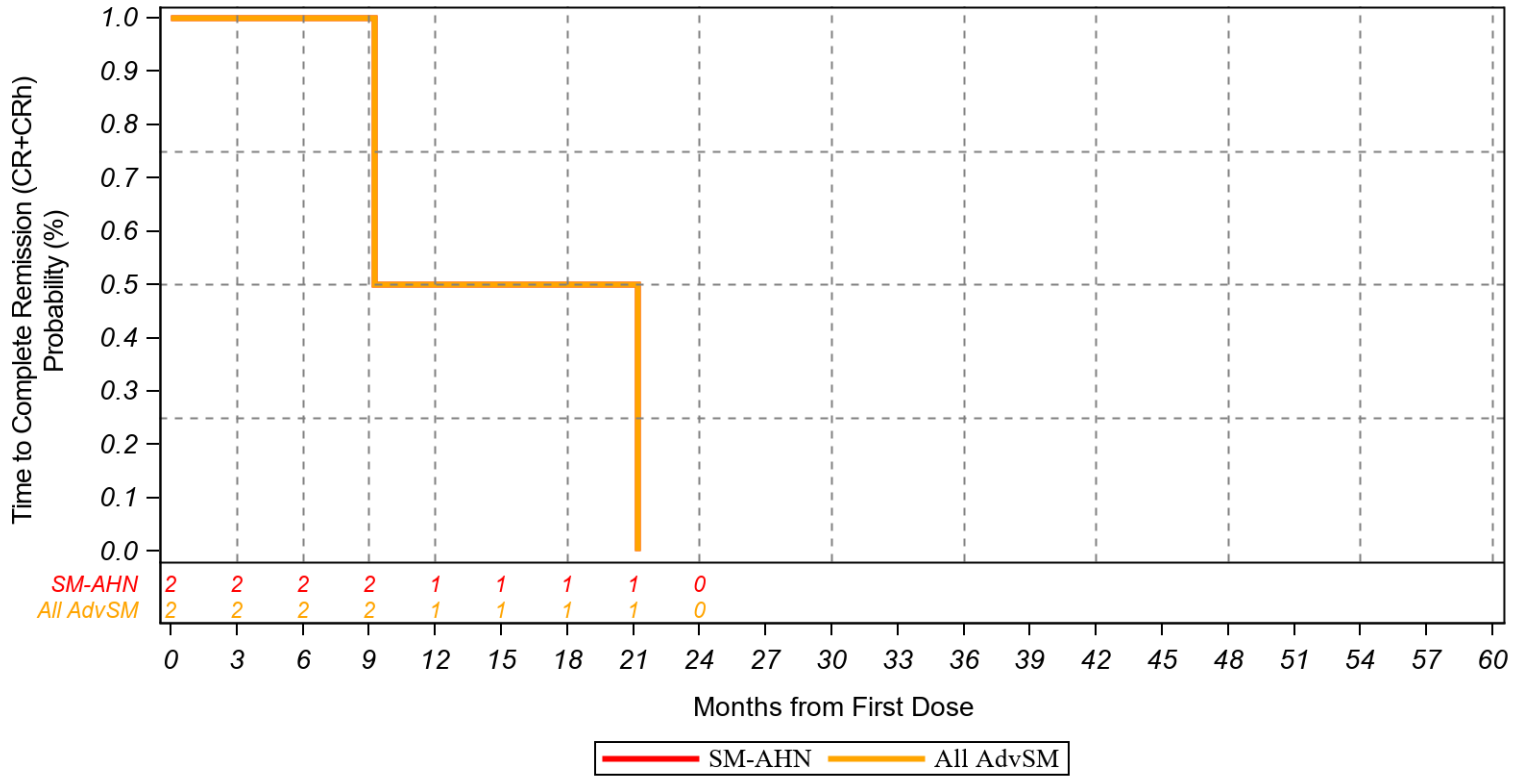

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Study BLU-285-2101
Starting Dose: 200 mg

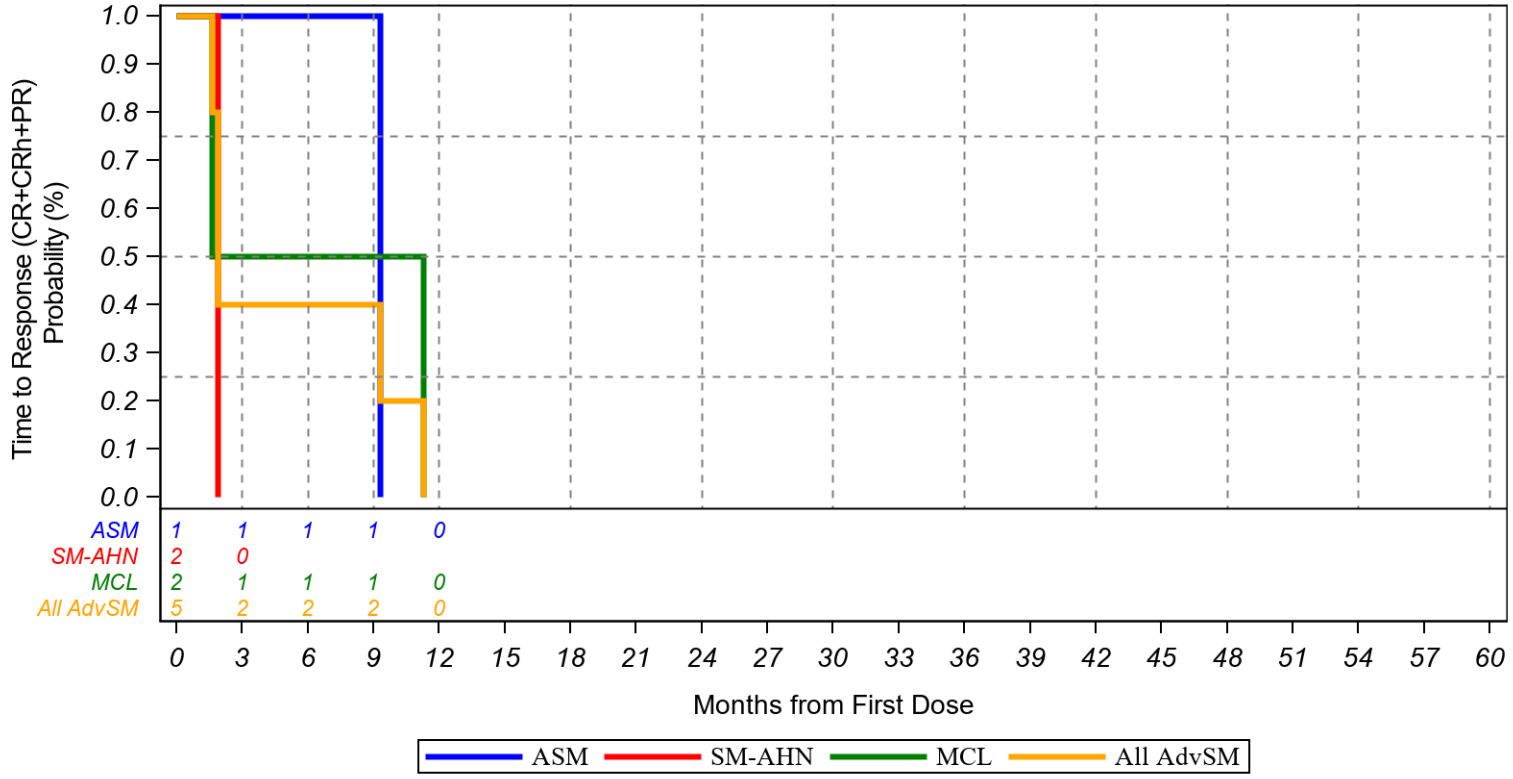

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: 200 mg

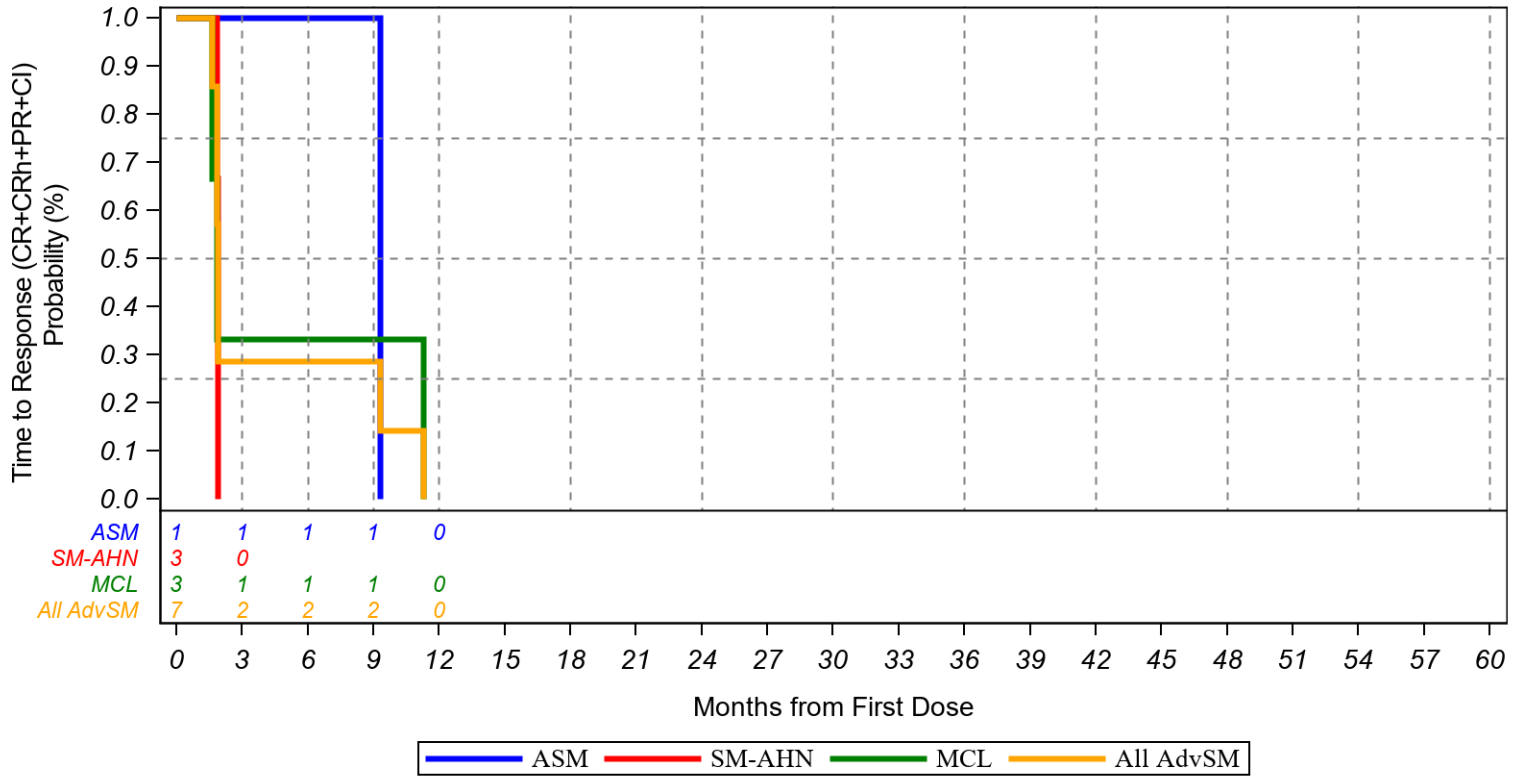

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Study BLU-285-2101
Starting Dose: 300 mg

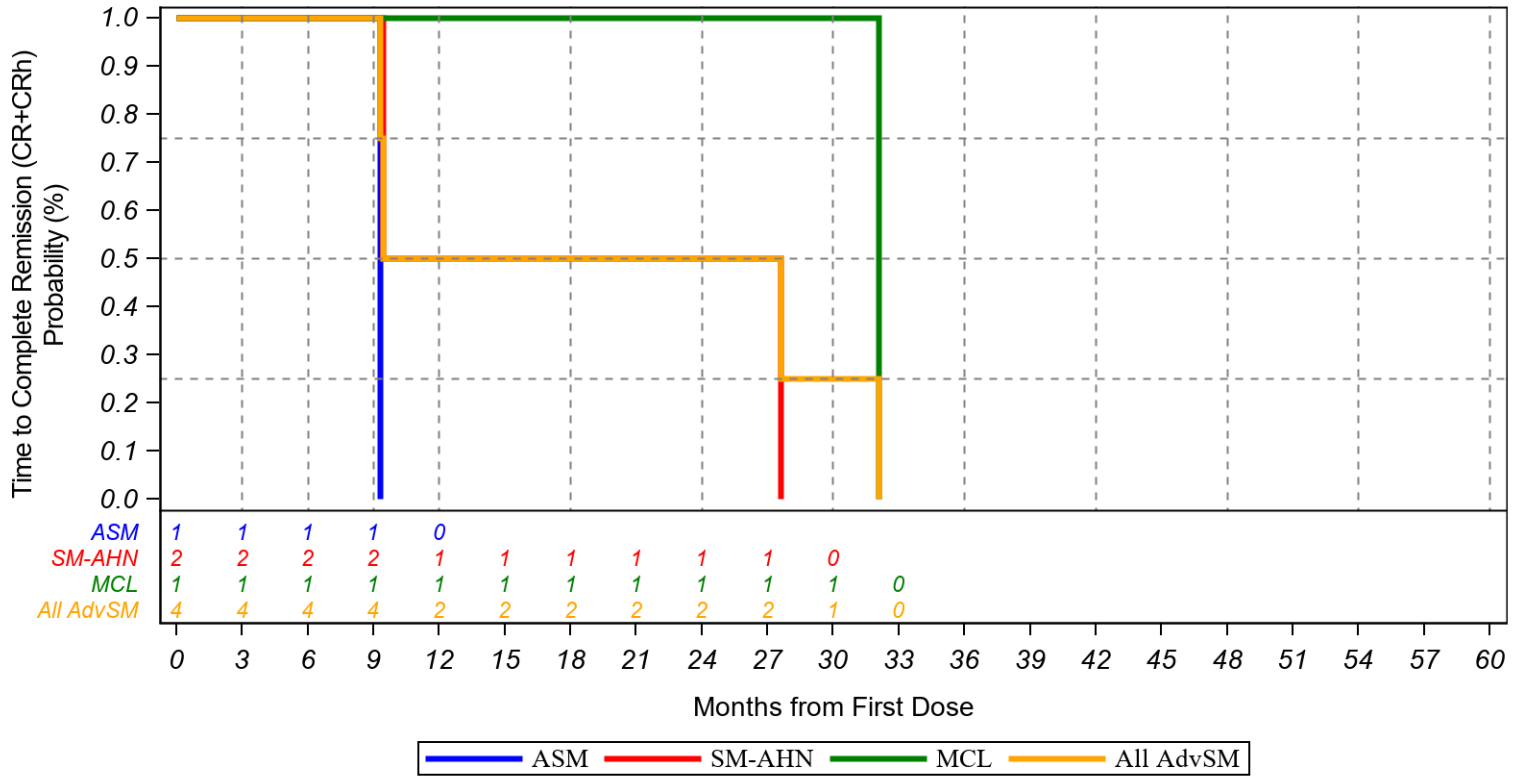

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Study BLU-285-2101
Starting Dose: 300 mg

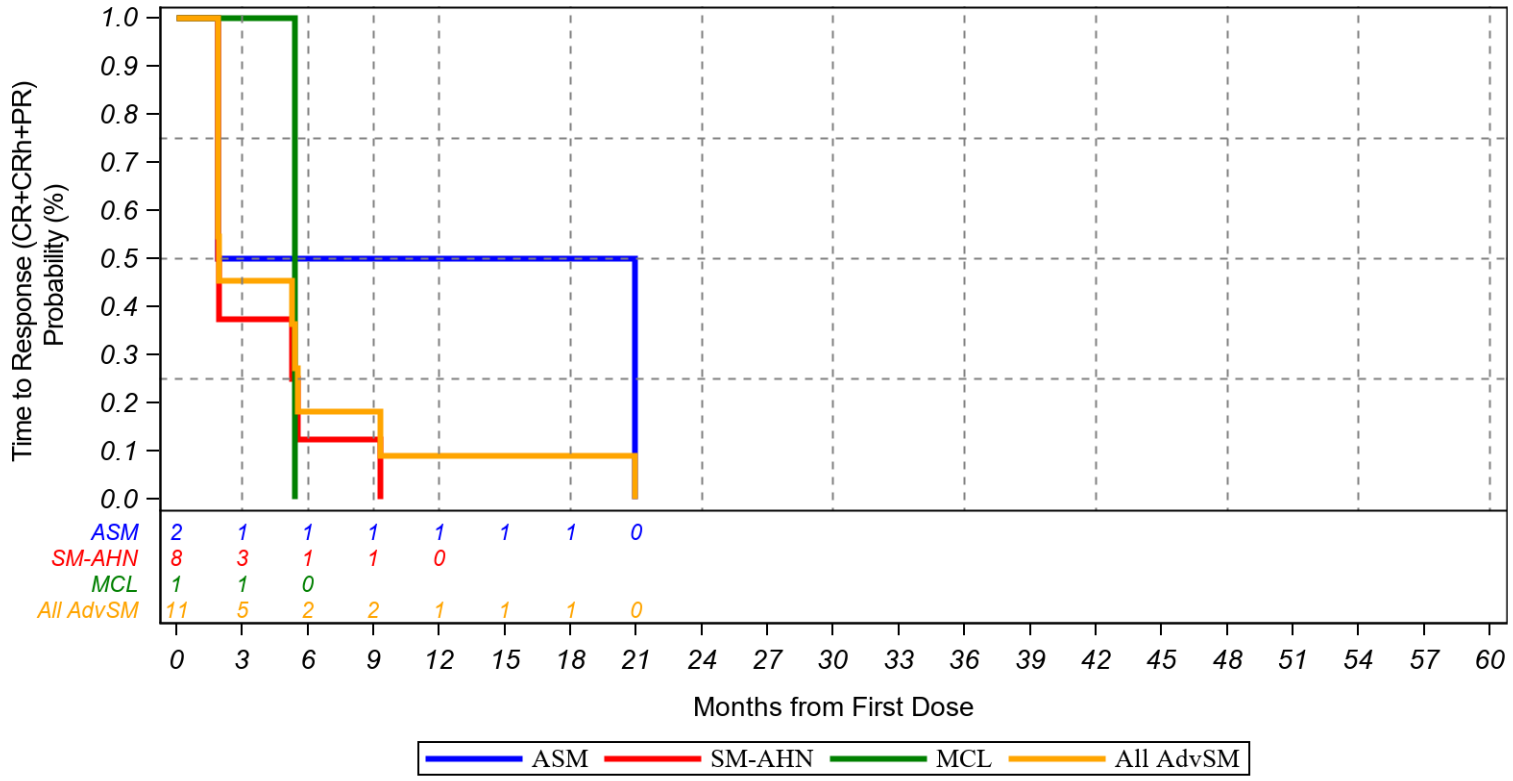

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: 300 mg

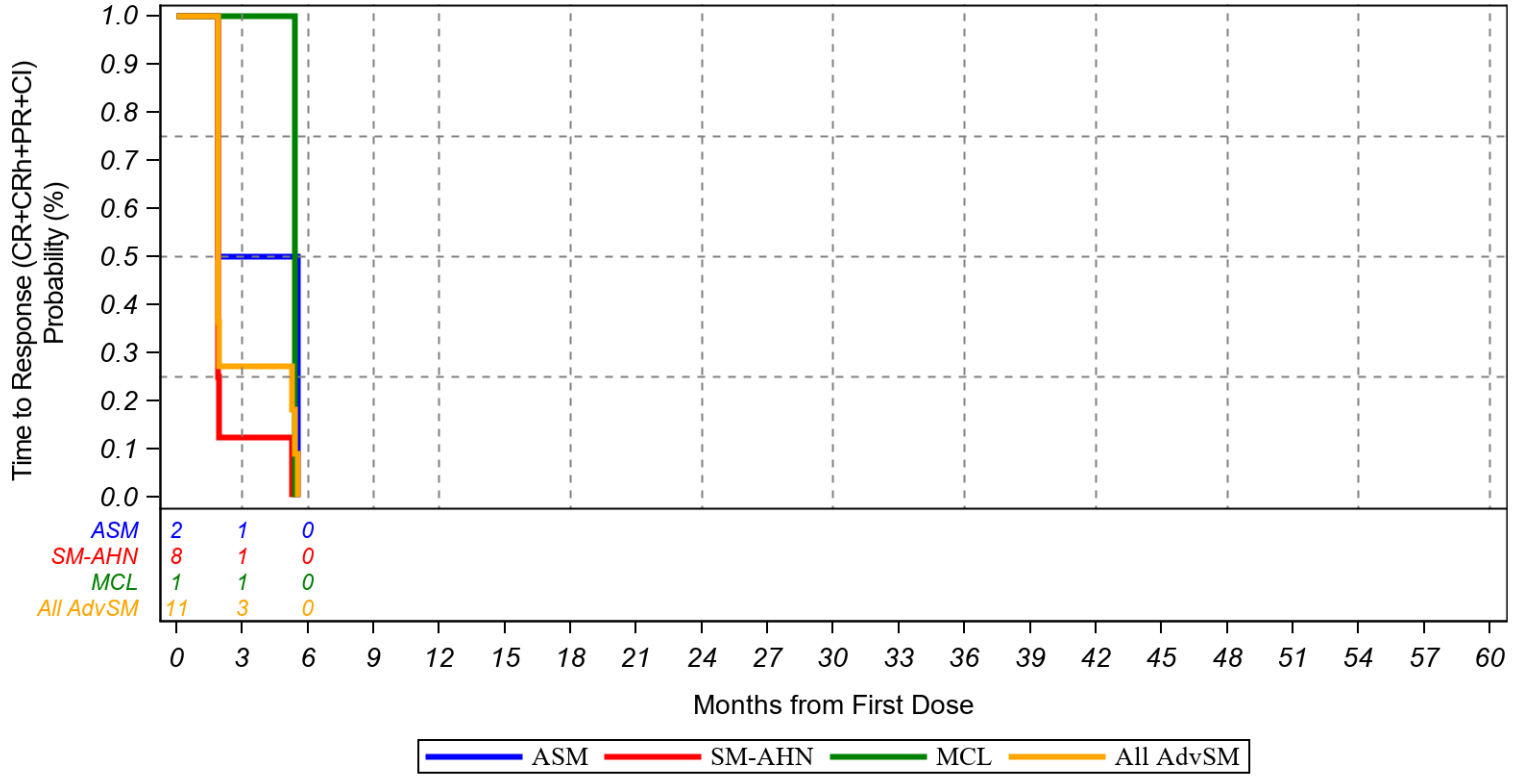

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Study BLU-285-2101
Starting Dose: 200 mg and 300 mg

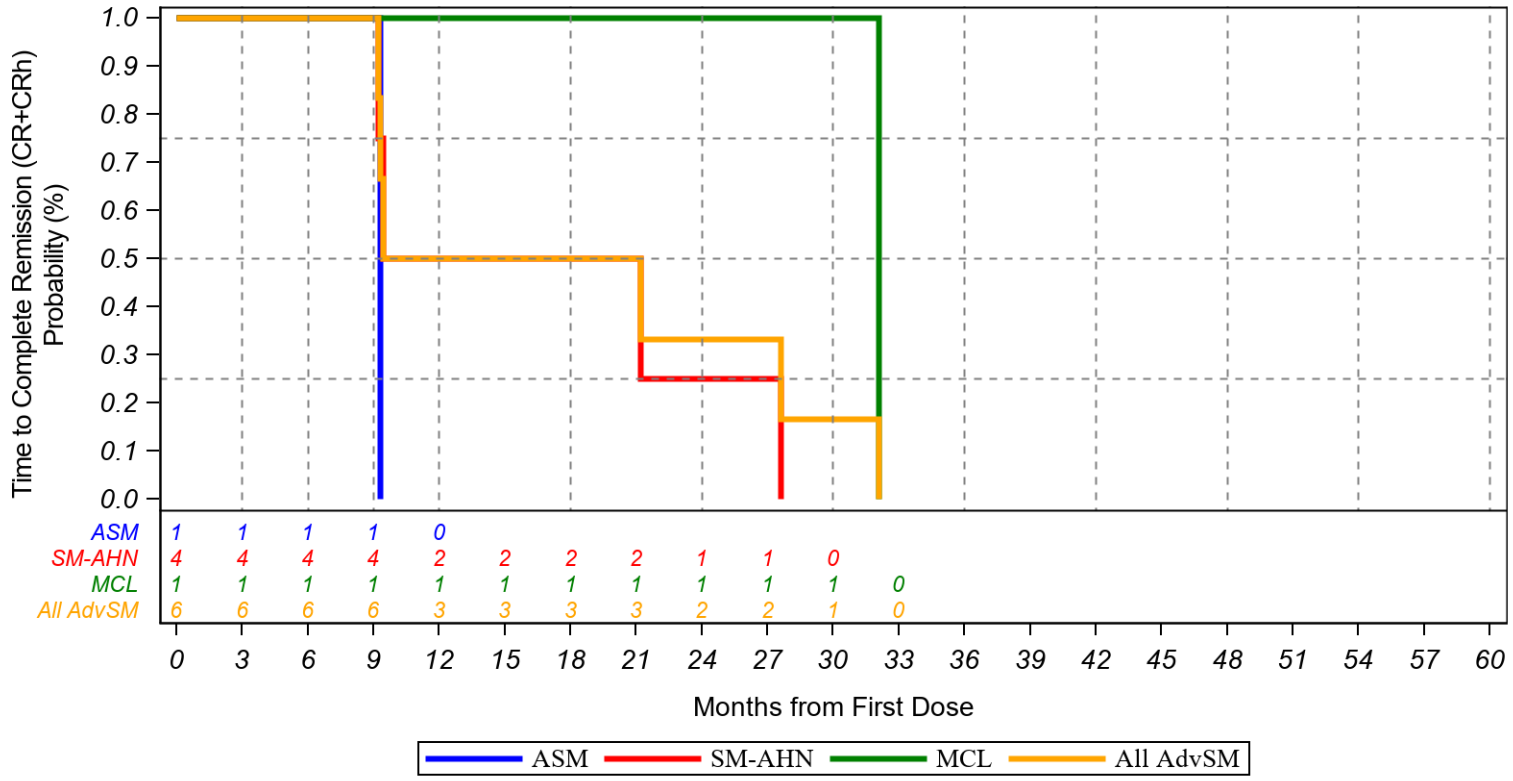

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Study BLU-285-2101
Starting Dose: 200 mg and 300 mg

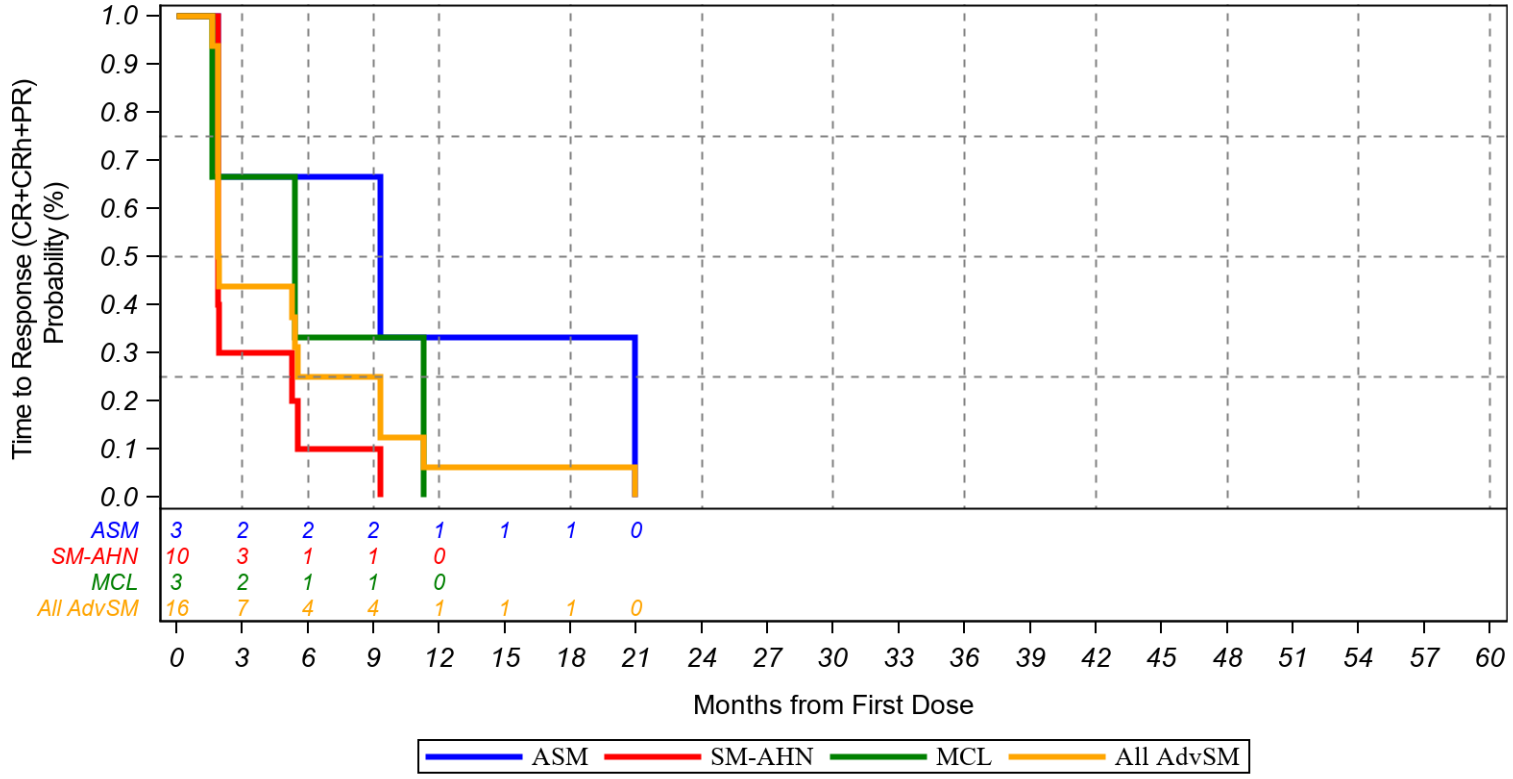

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: 200 mg and 300 mg

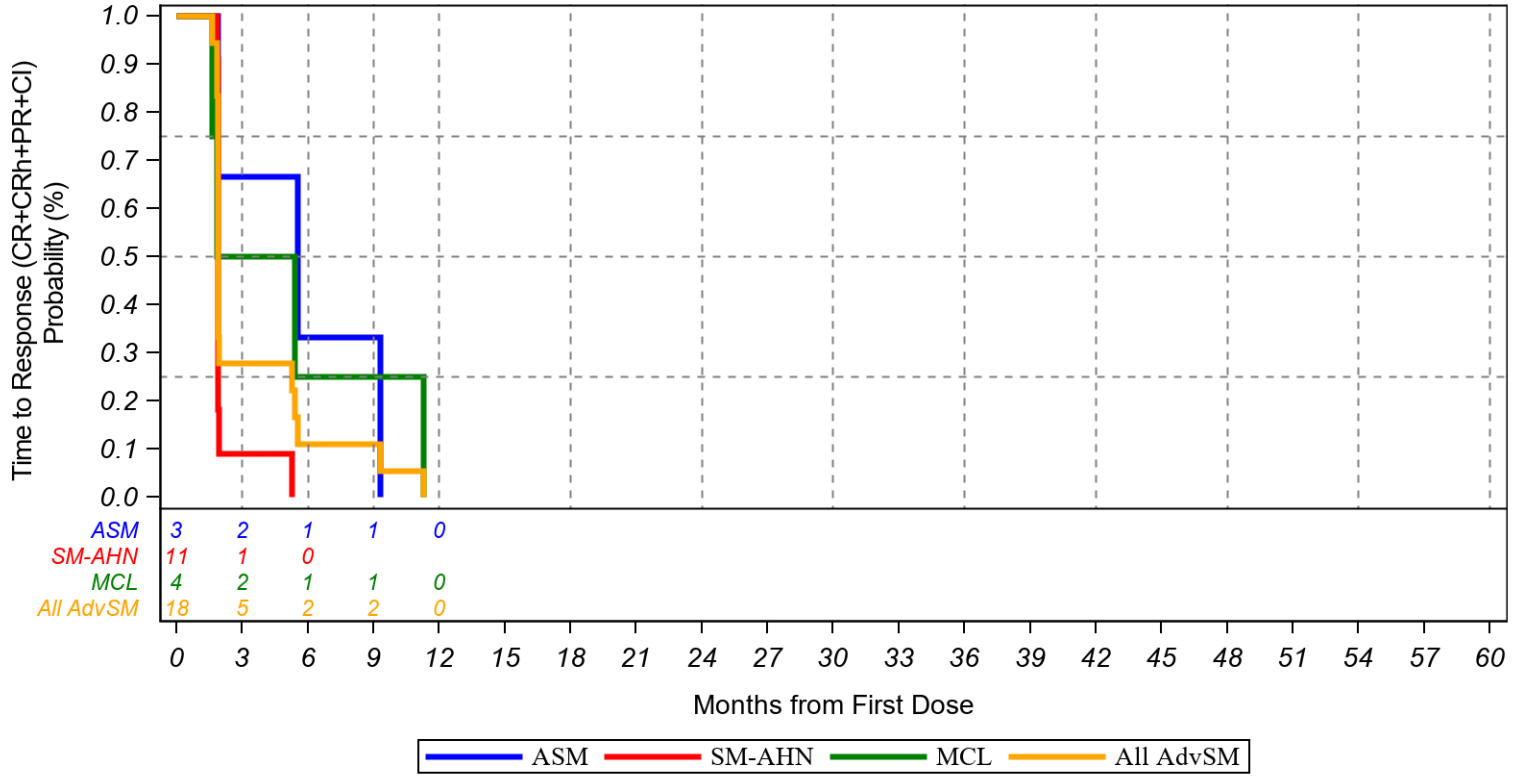

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Study BLU-285-2101
Starting Dose: 400 mg

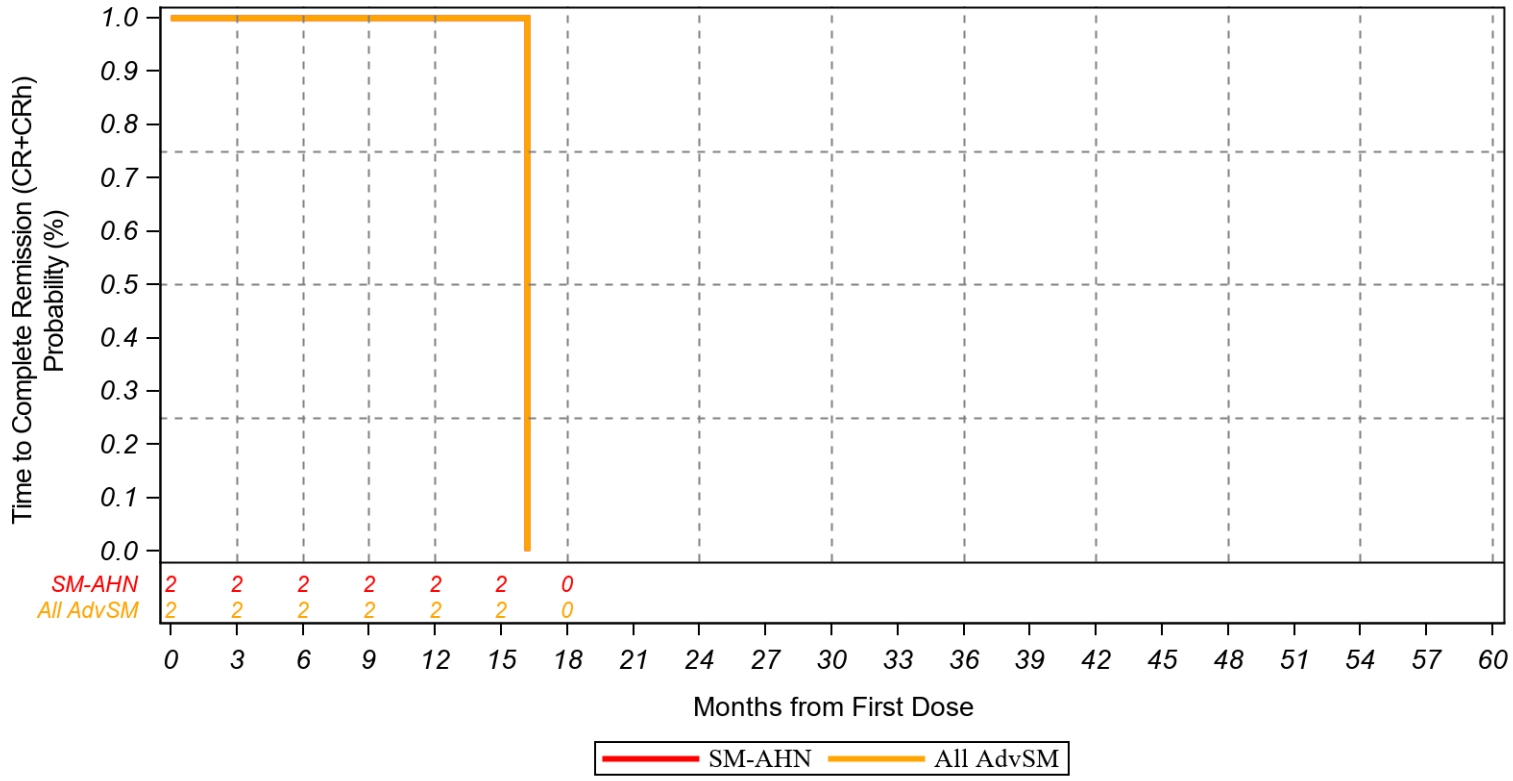

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Study BLU-285-2101
Starting Dose: 400 mg

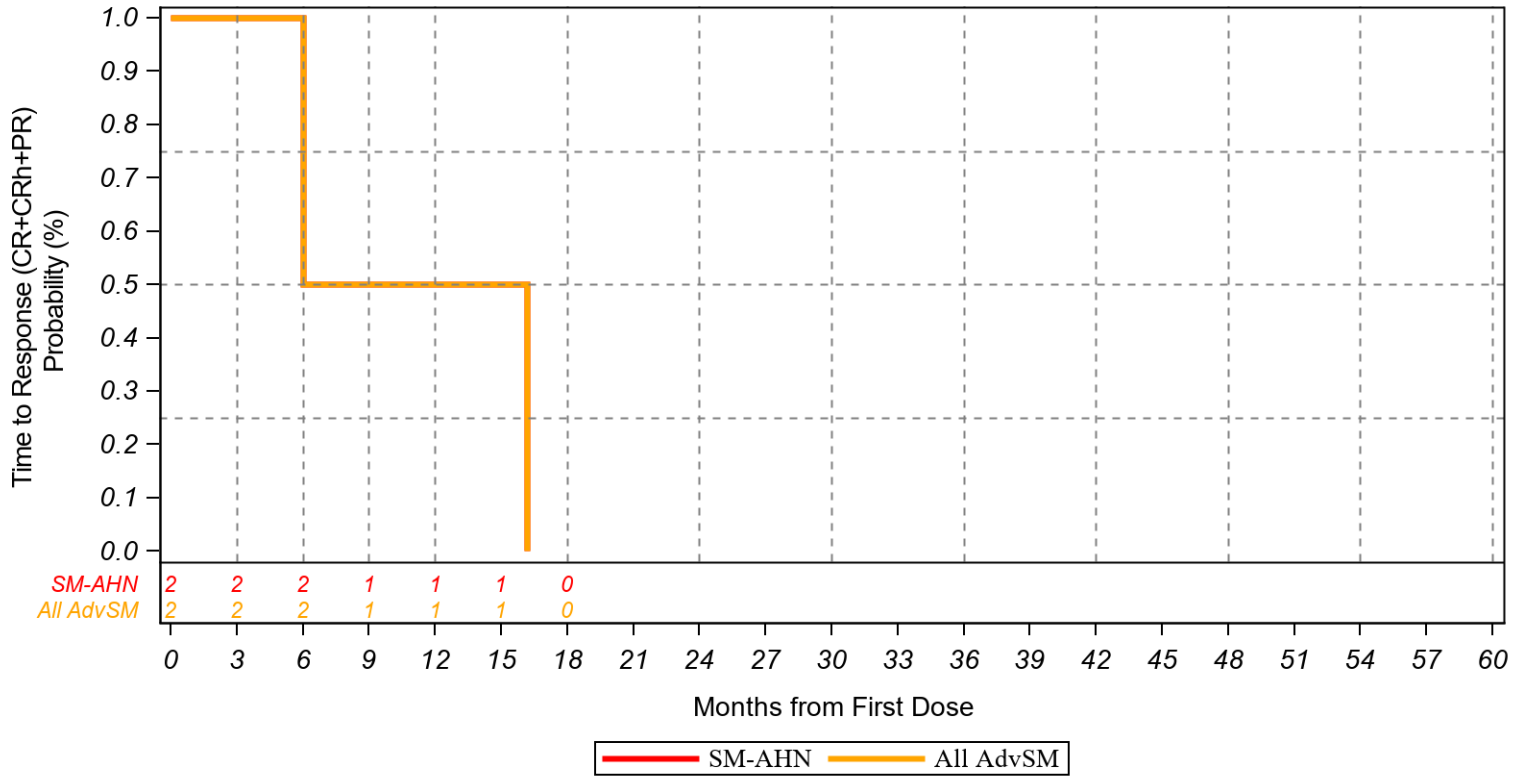

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Study BLU-285-2101
Starting Dose: 400 mg

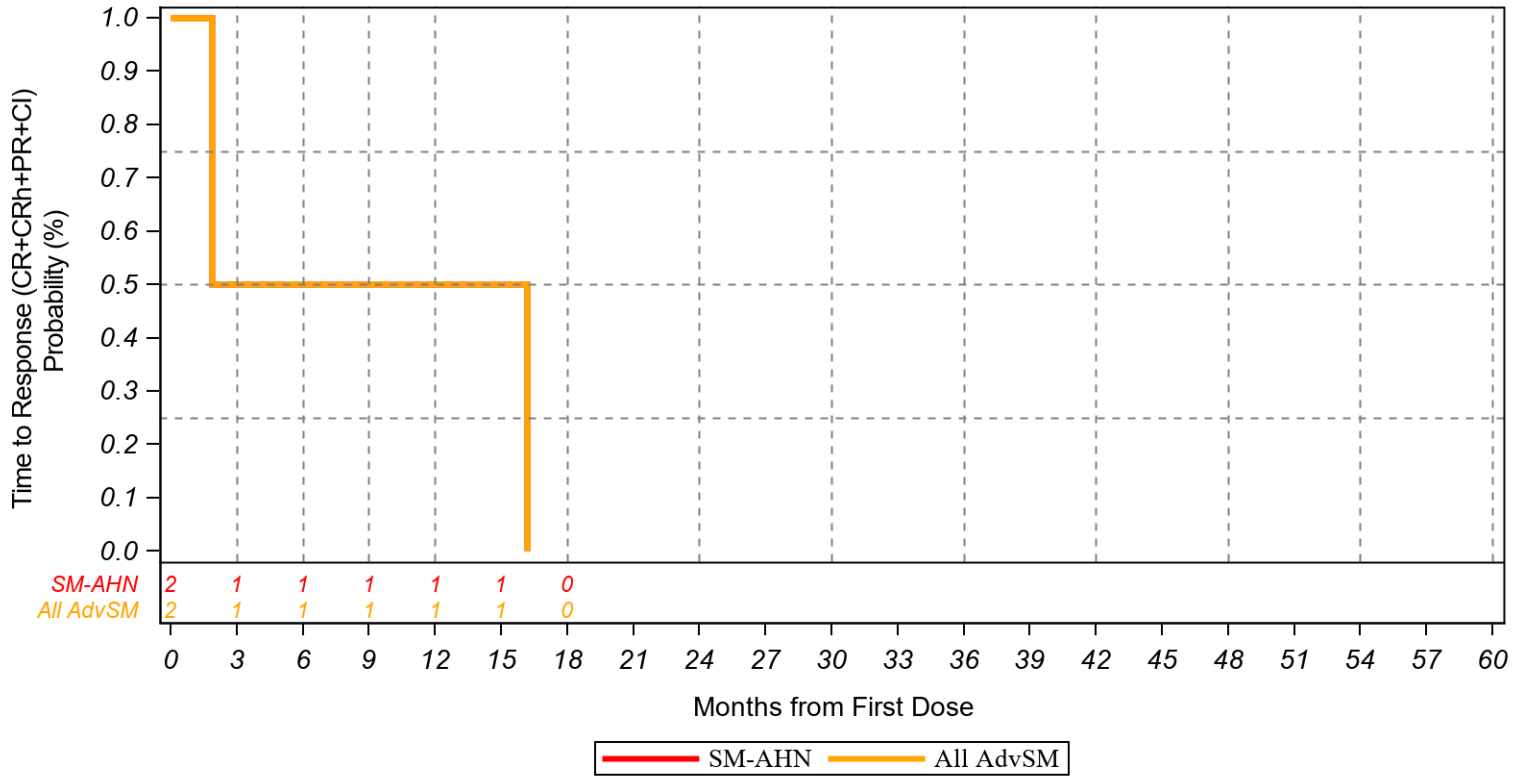

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Study BLU-285-2202
Starting Dose: Overall

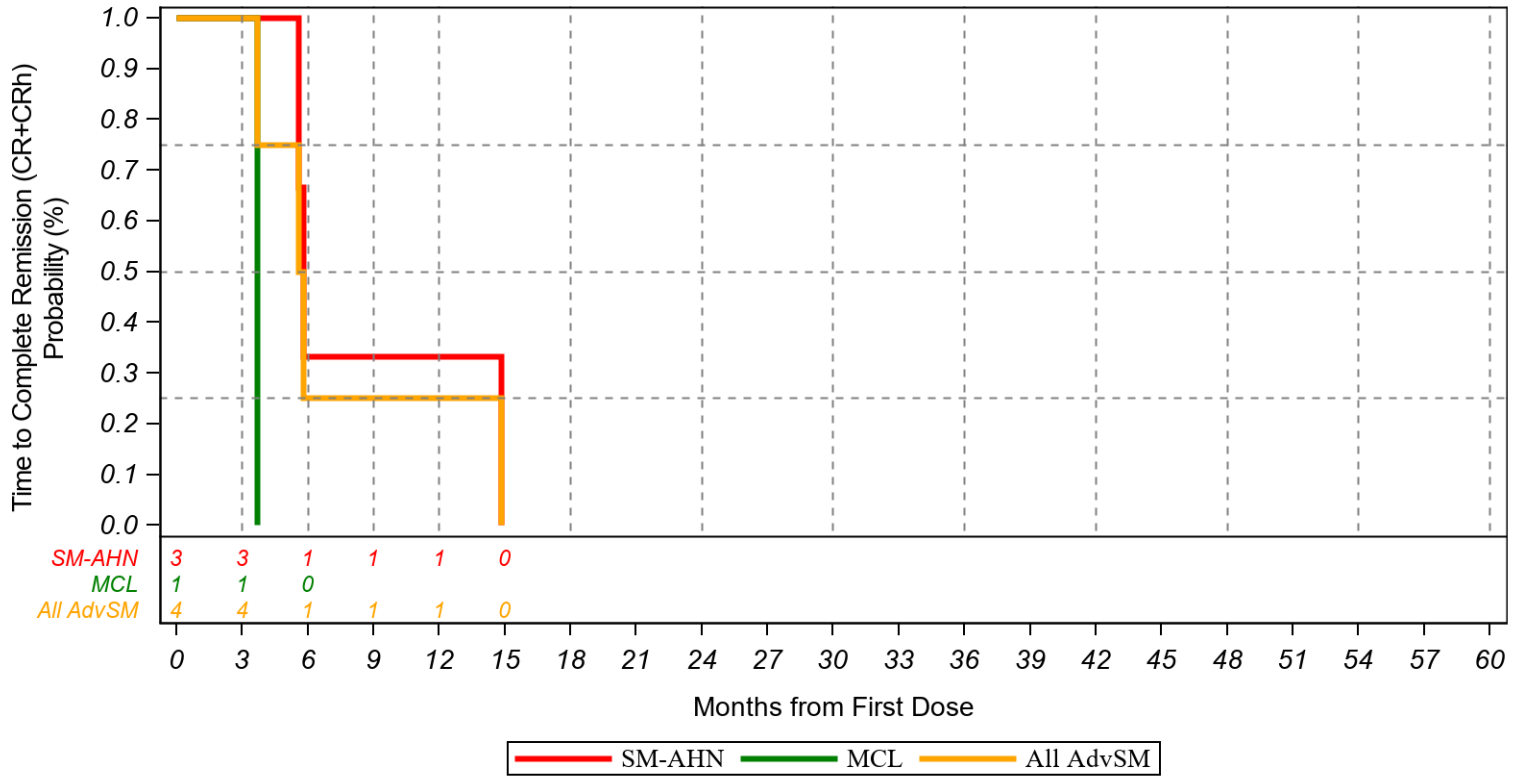

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Study BLU-285-2202
Starting Dose: Overall

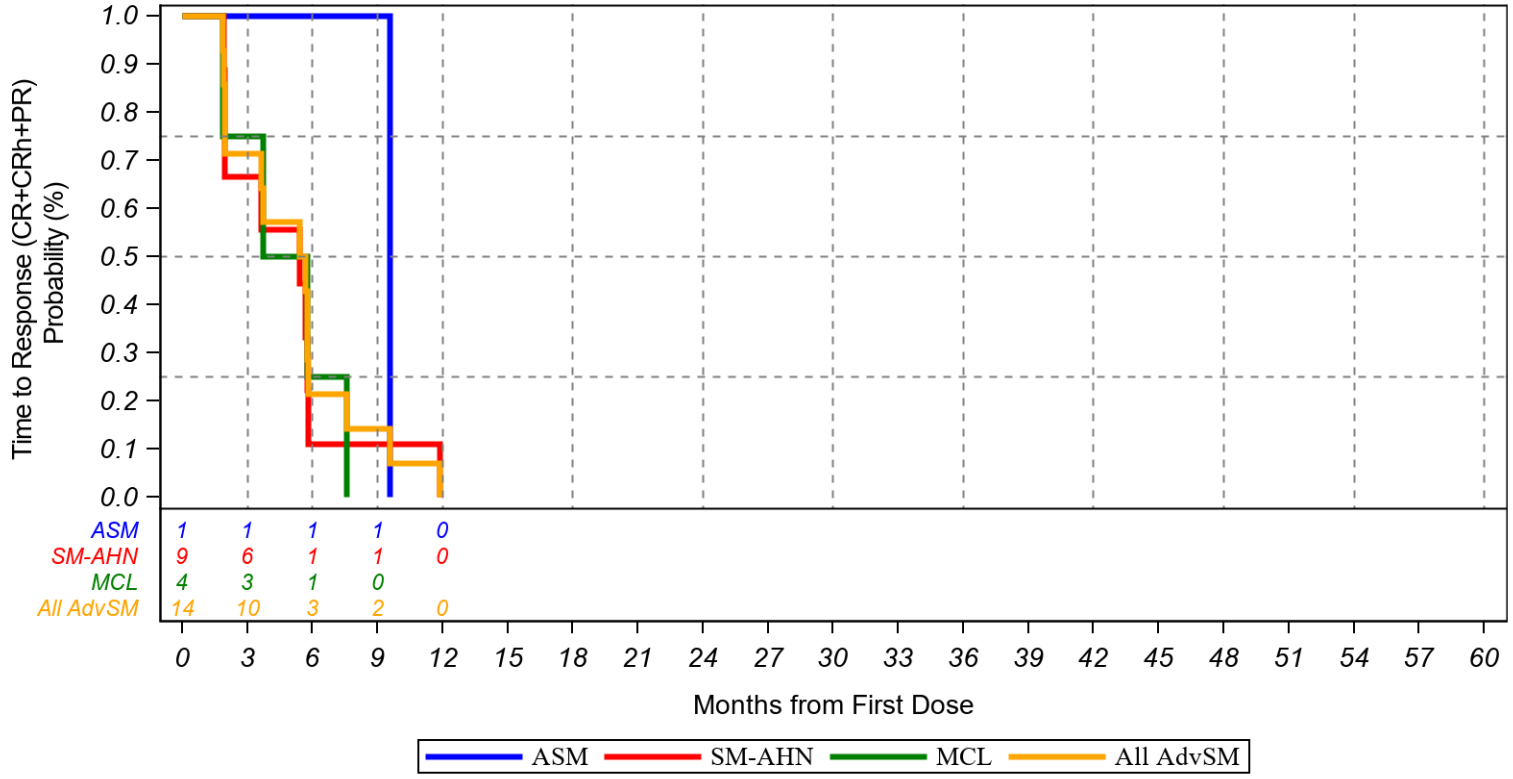

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Study BLU-285-2202
Starting Dose: Overall

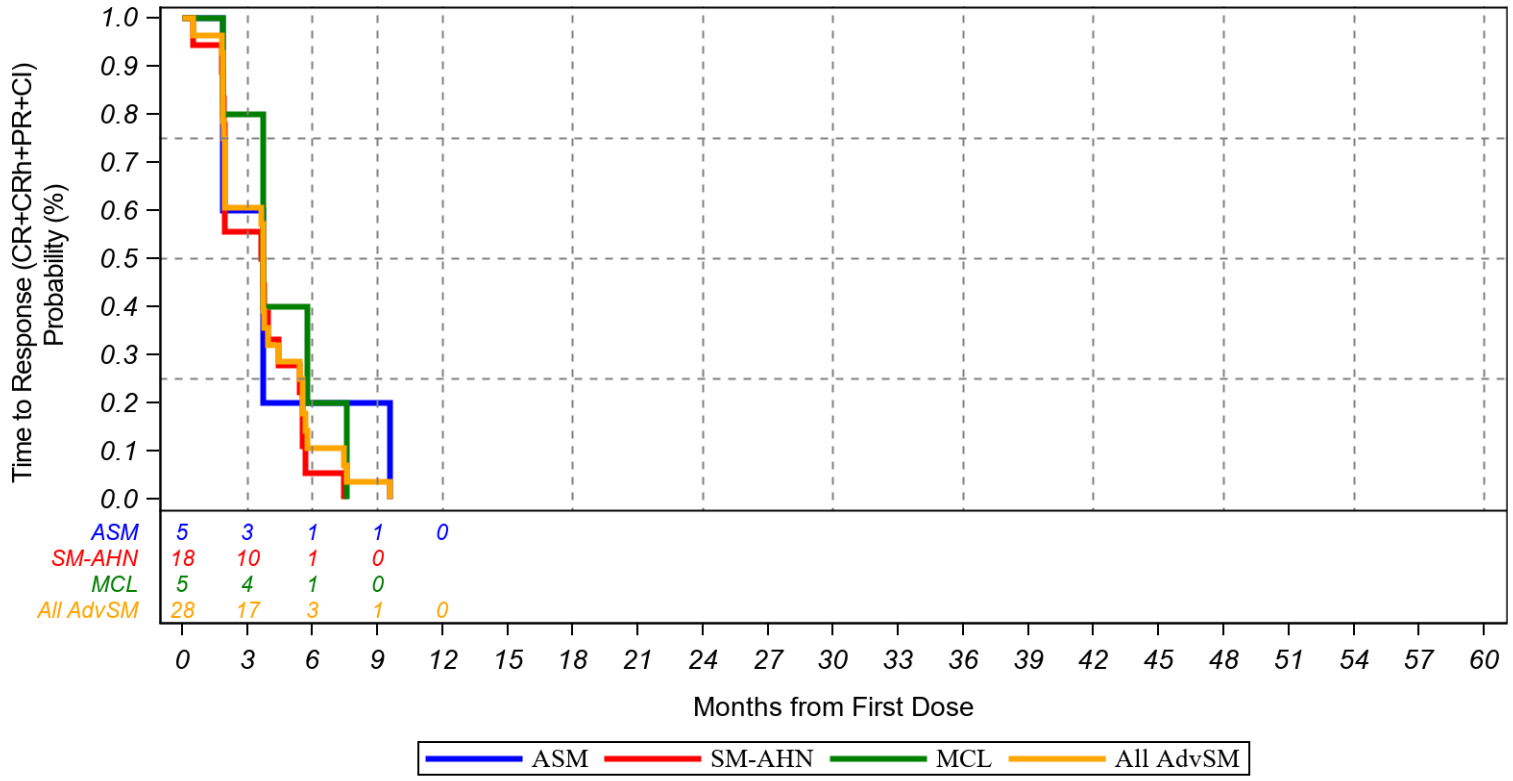

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Study BLU-285-2202
Starting Dose: 200 mg

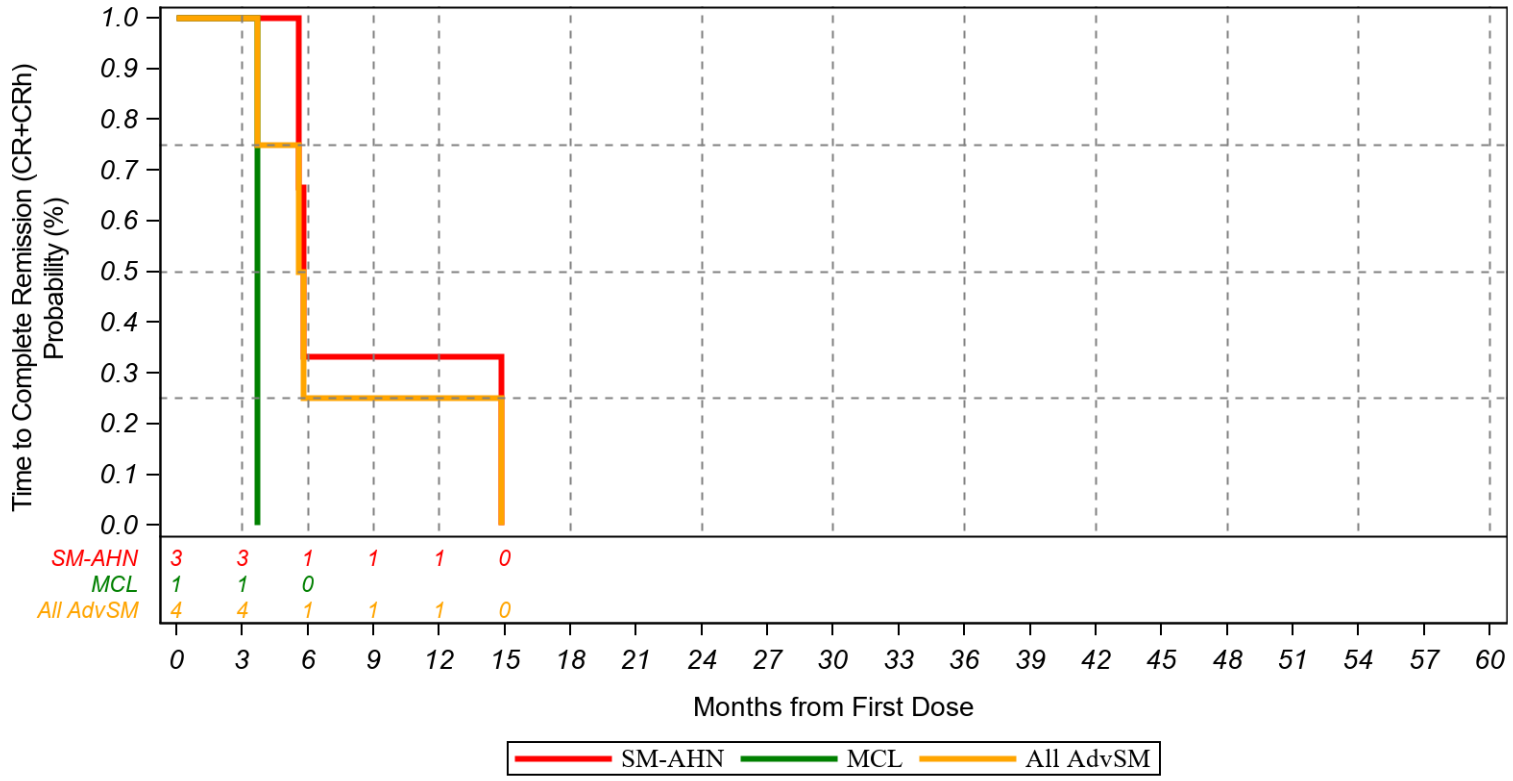

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Study BLU-285-2202
Starting Dose: 200 mg

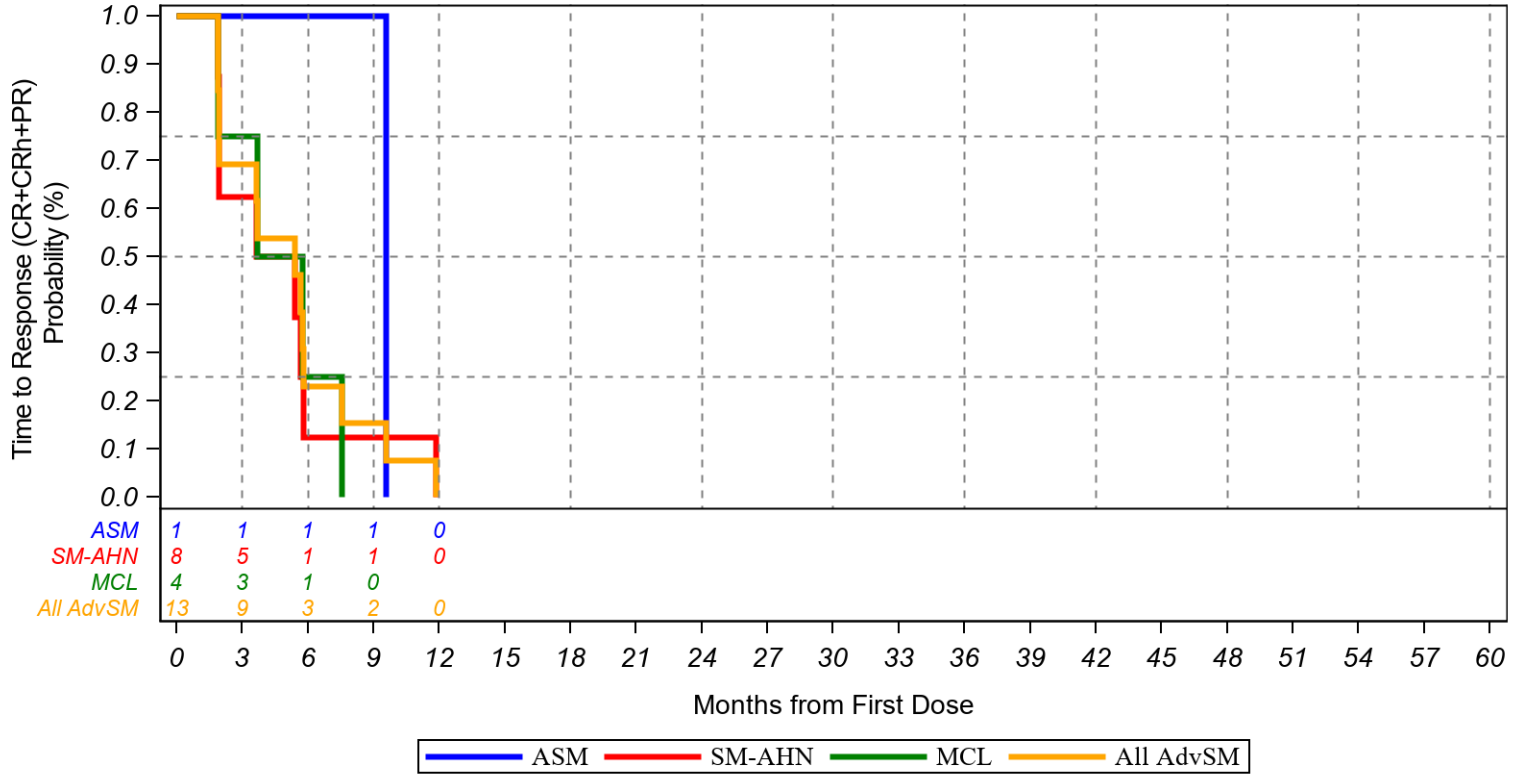

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Study BLU-285-2202
Starting Dose: 200 mg

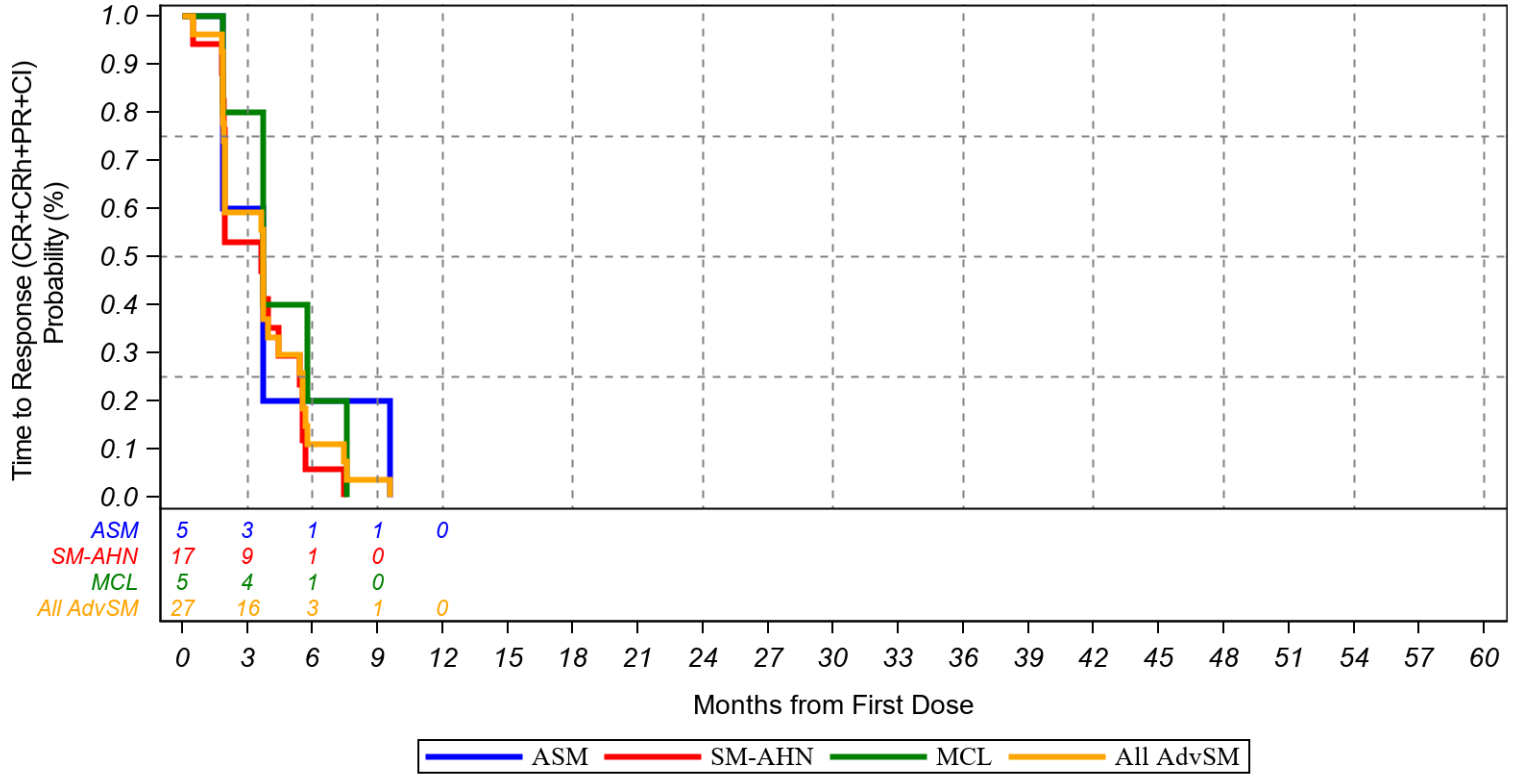

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall

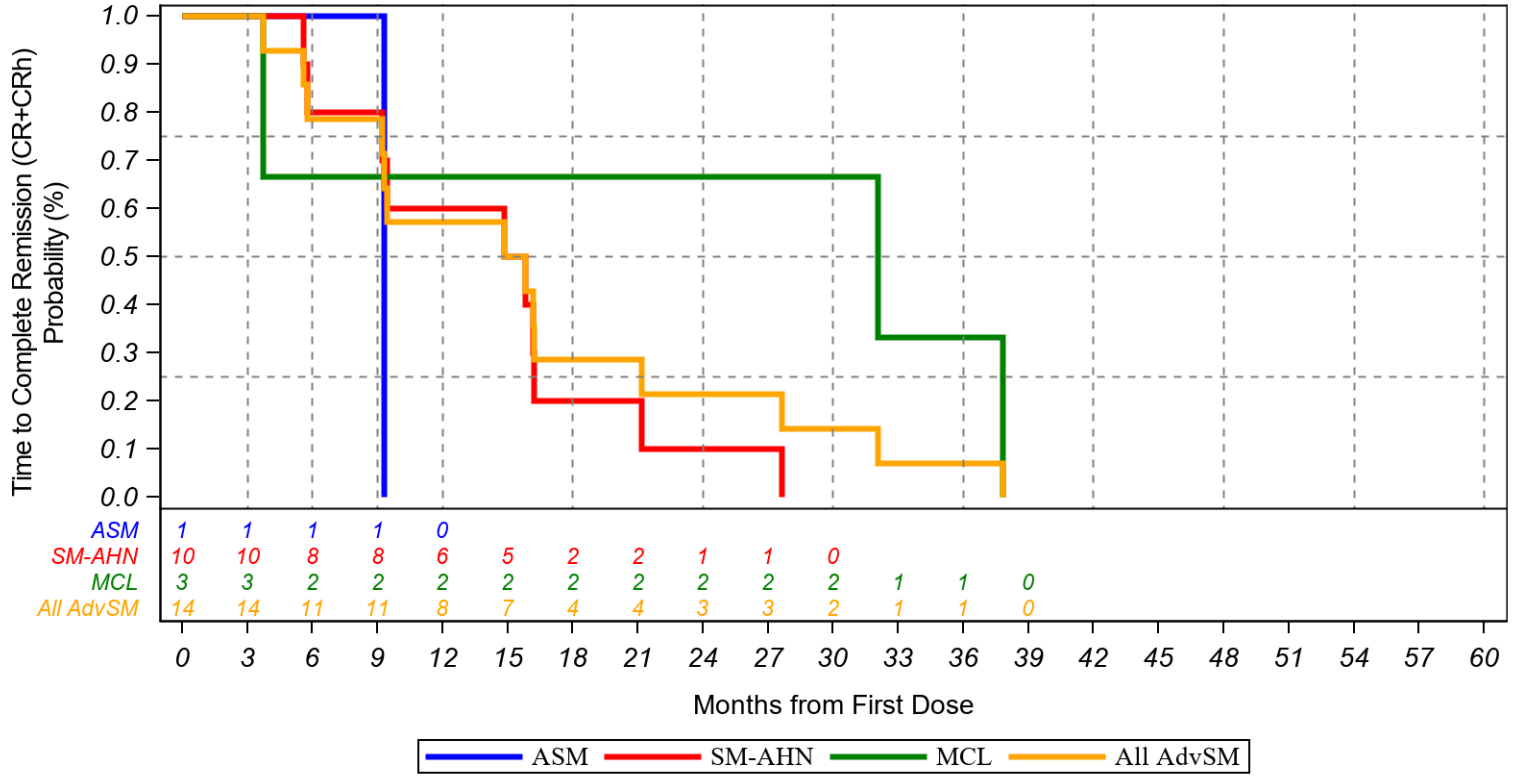

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall

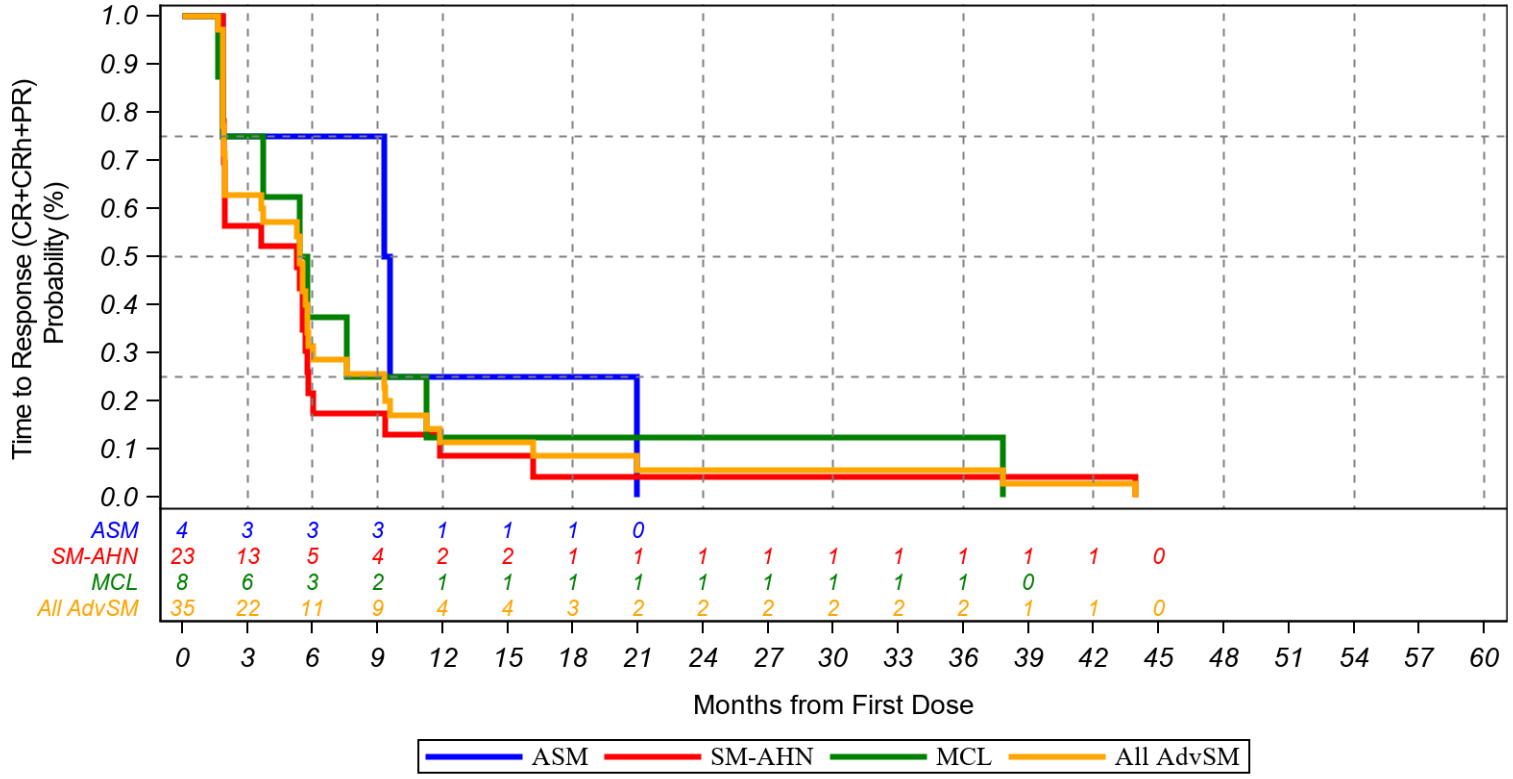

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall

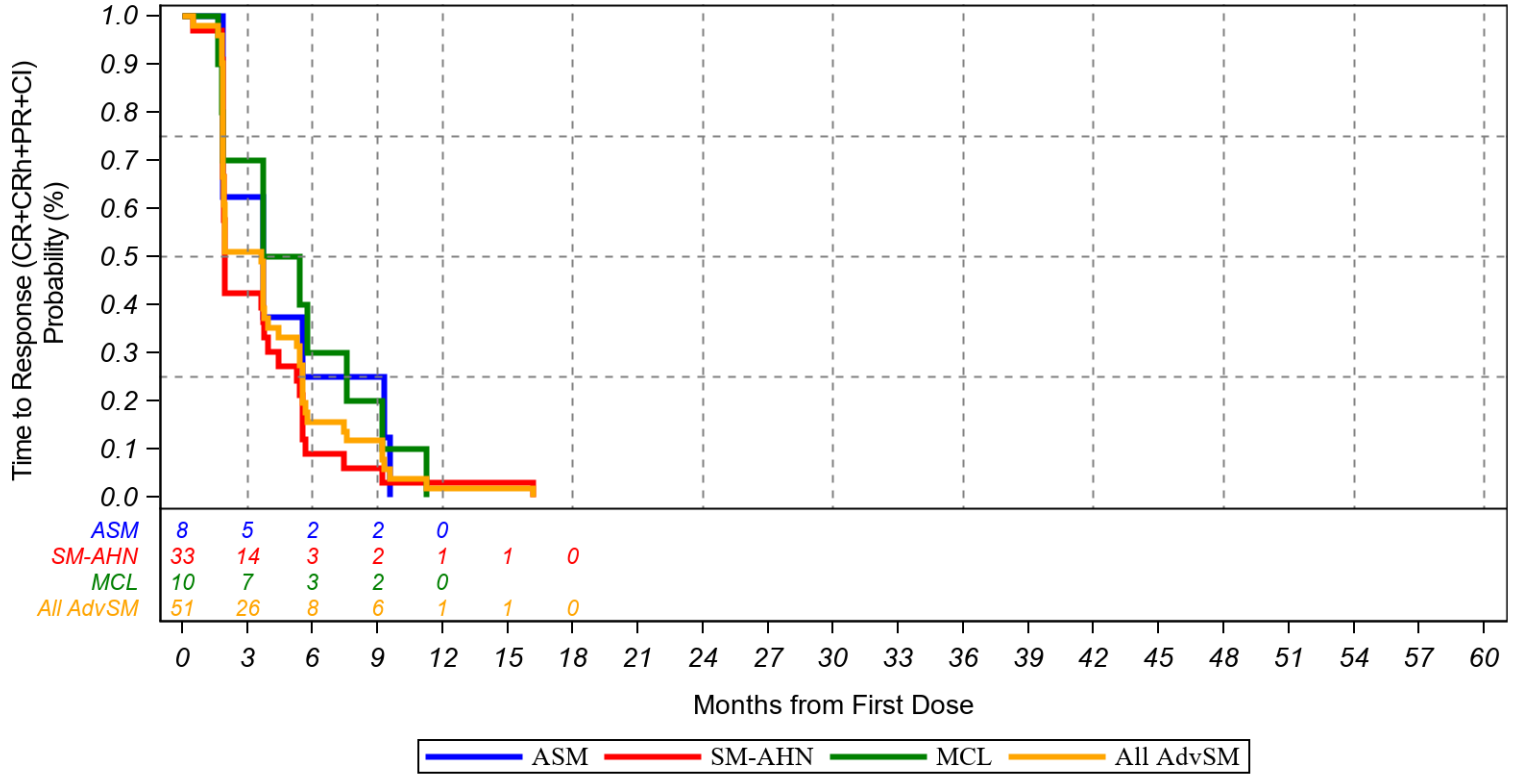

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg

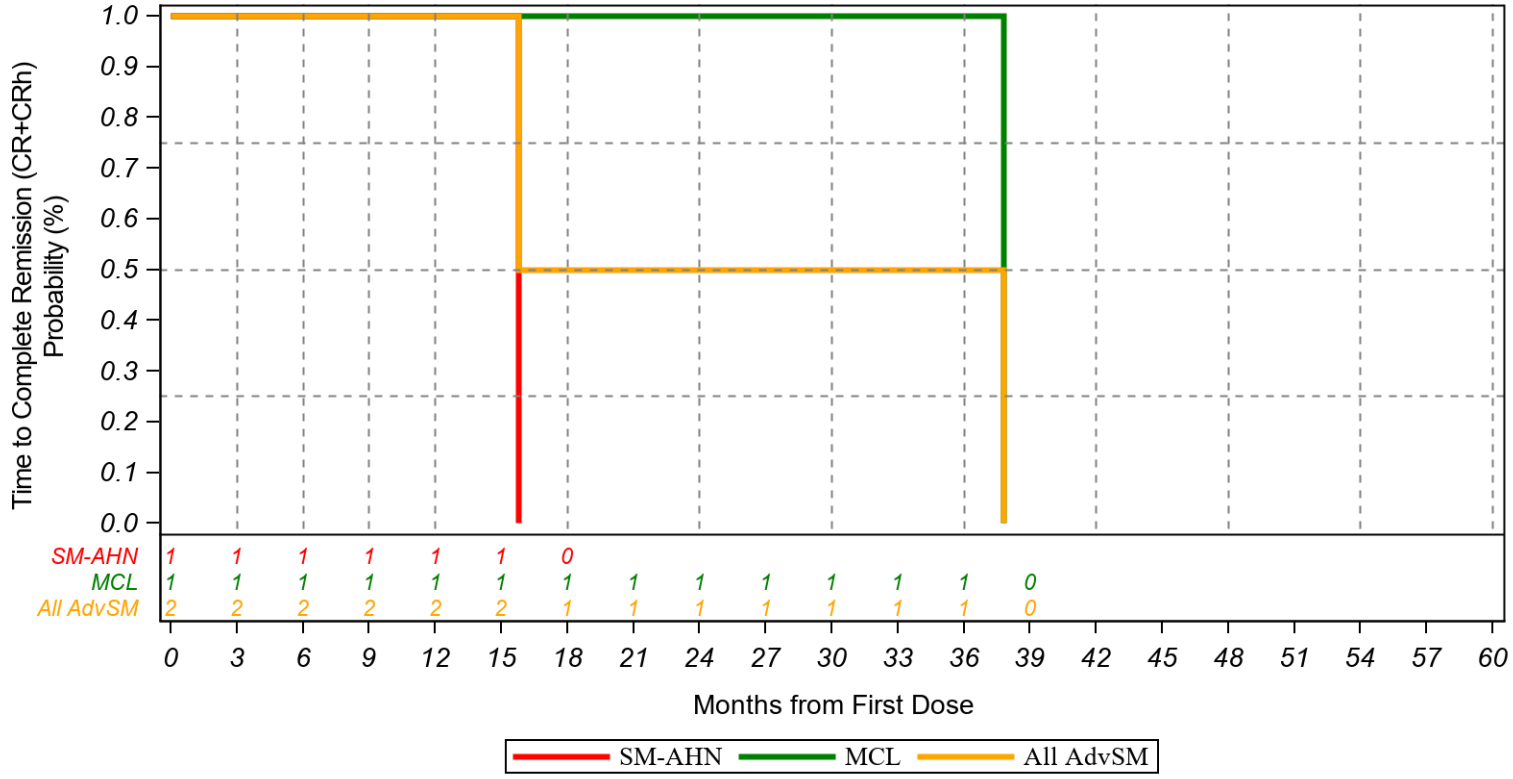

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg

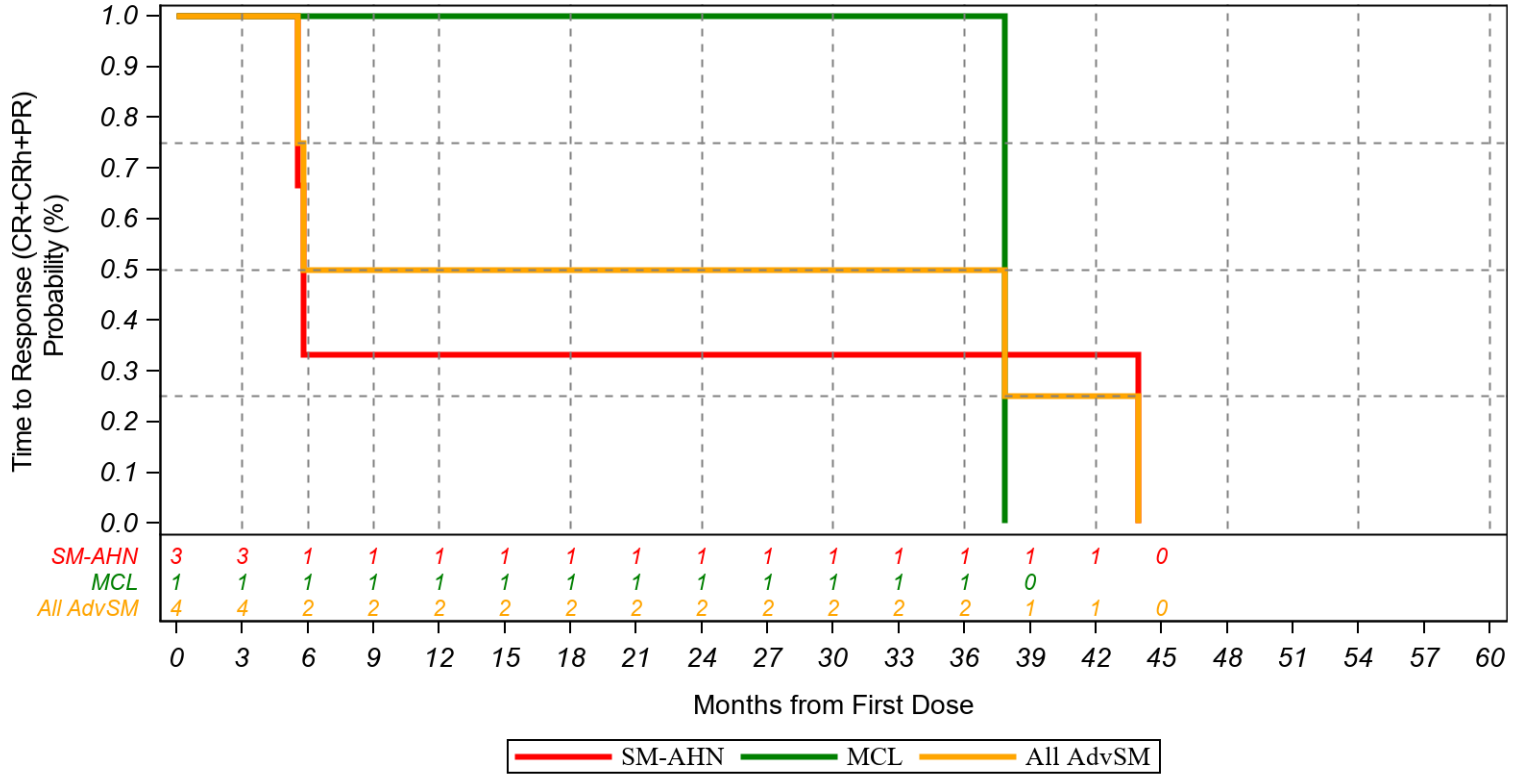

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg

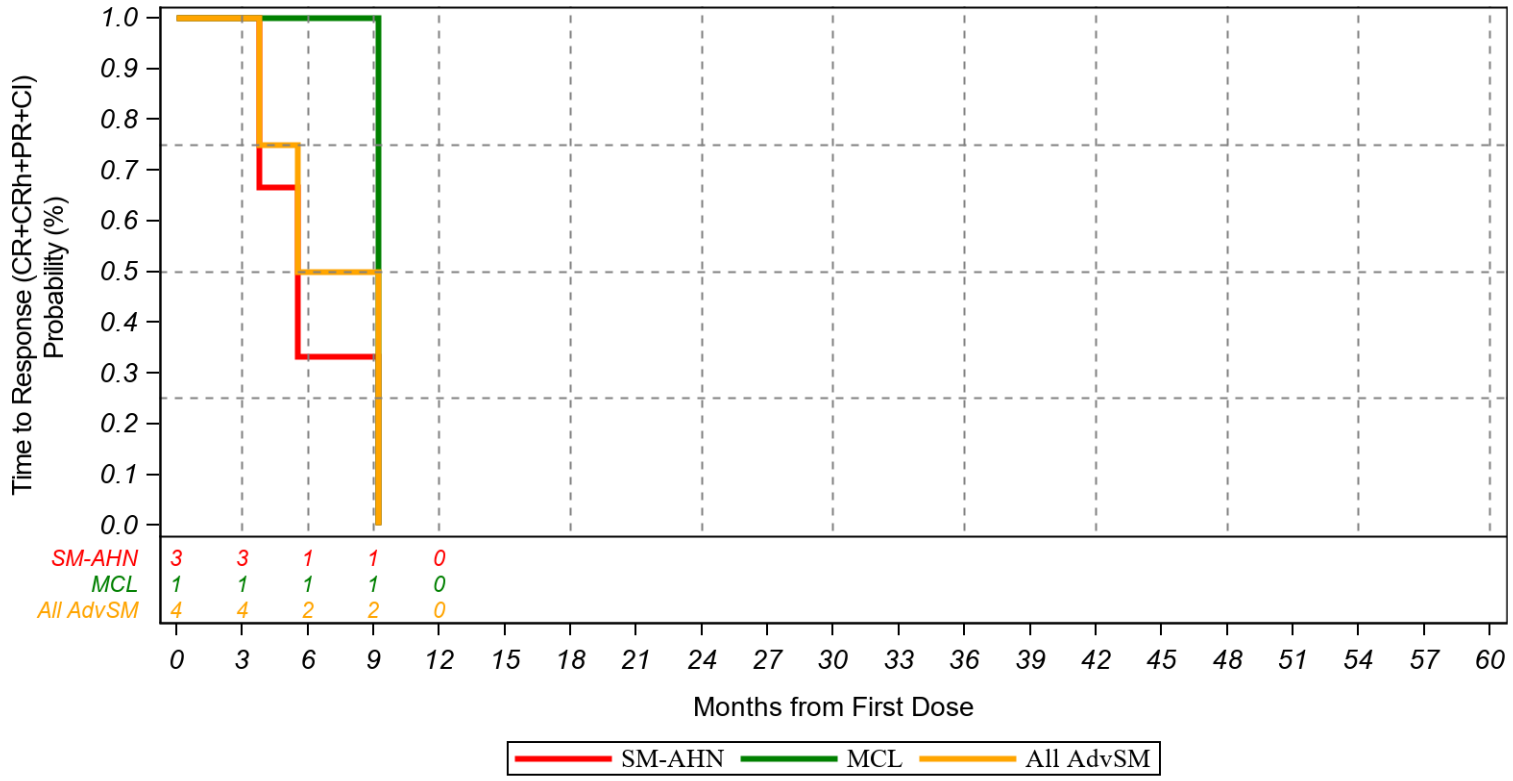

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg

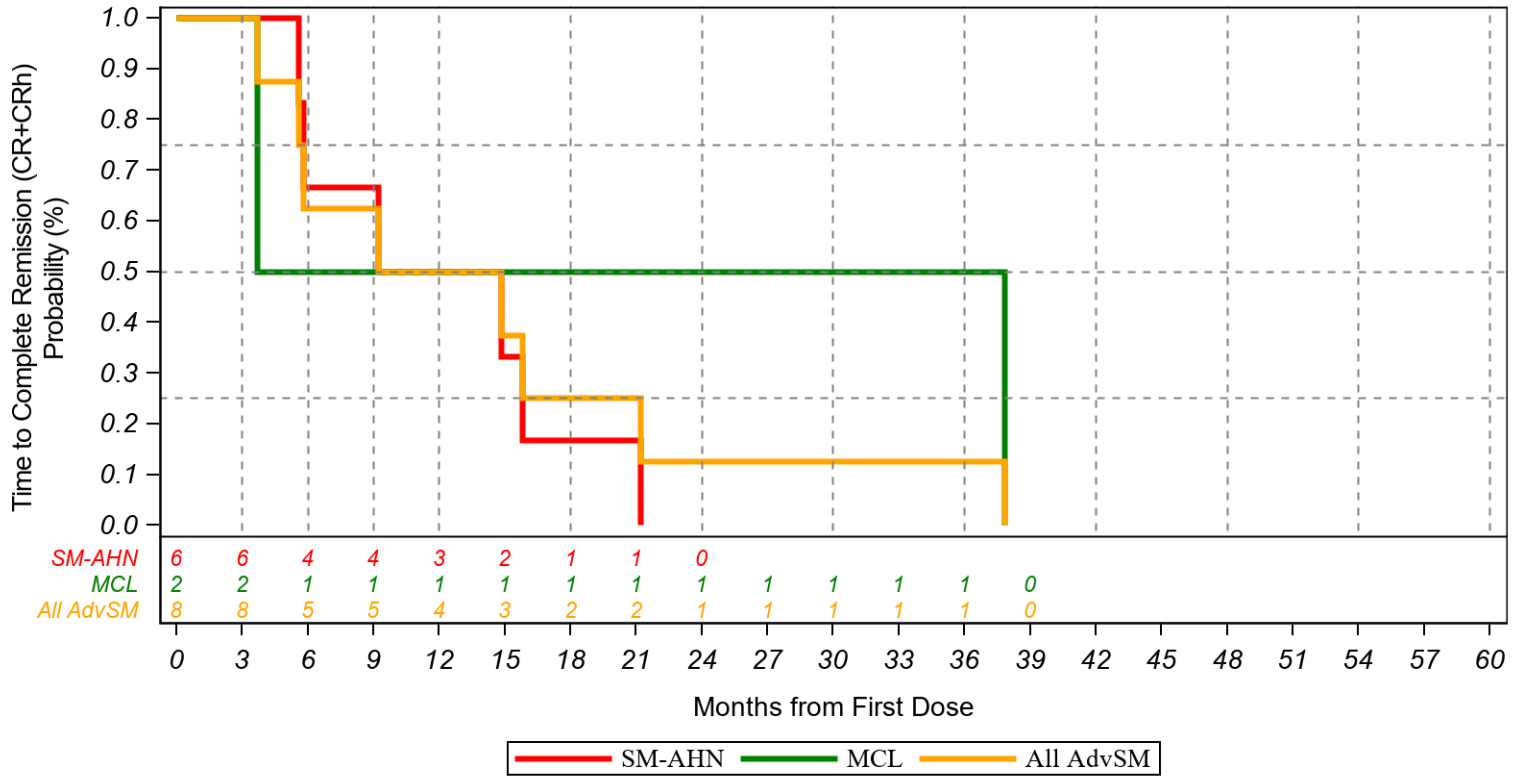

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg

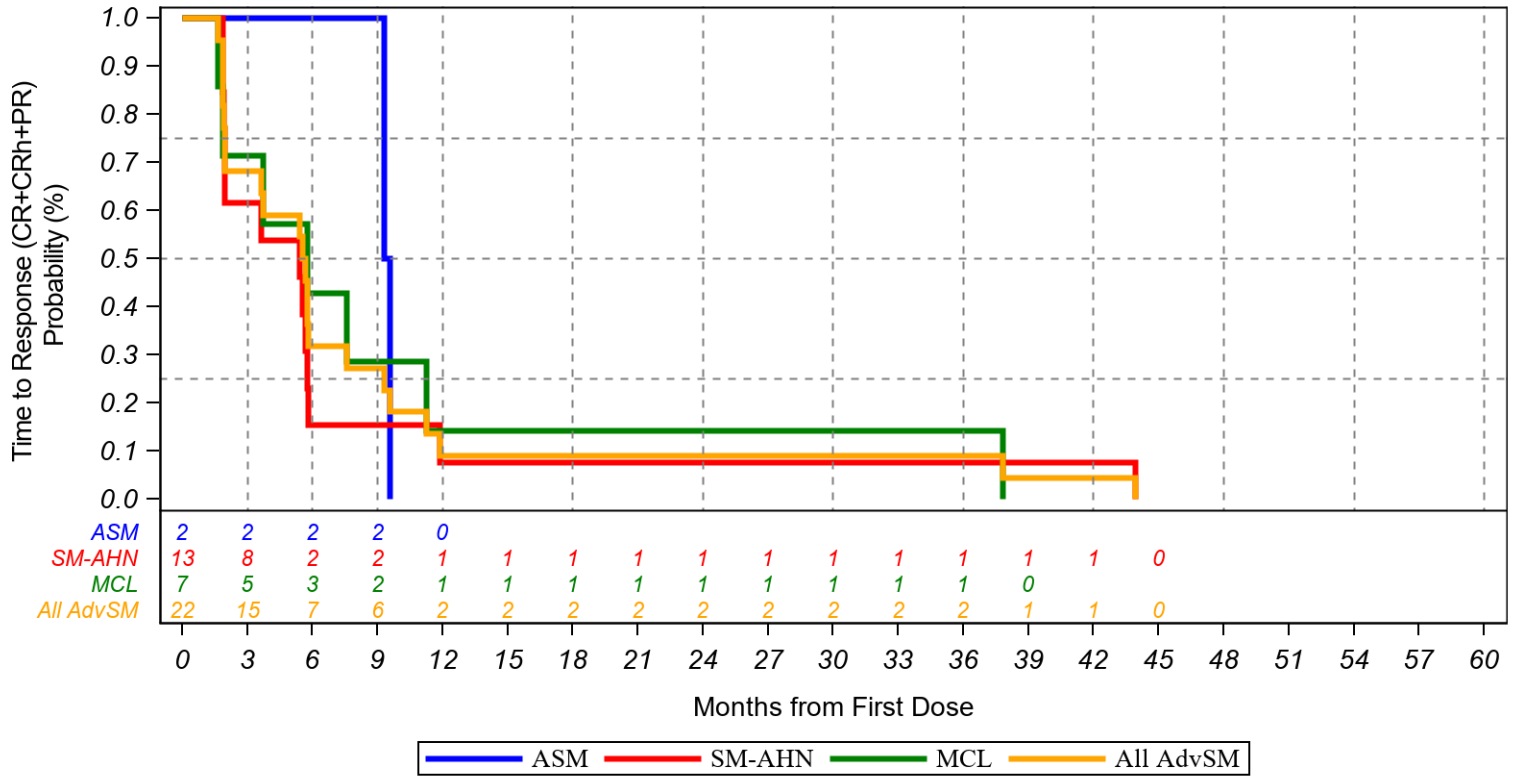

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg

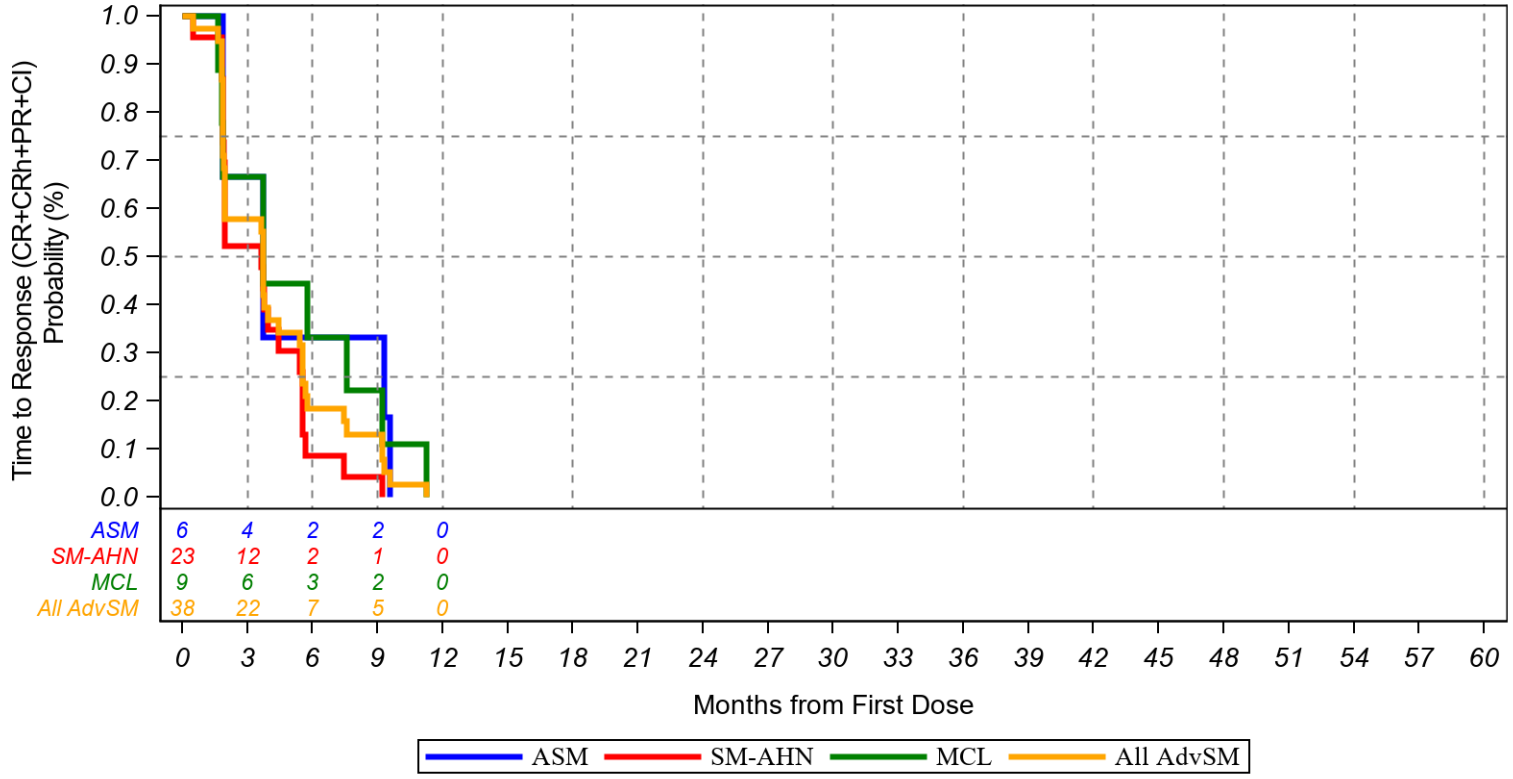

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg

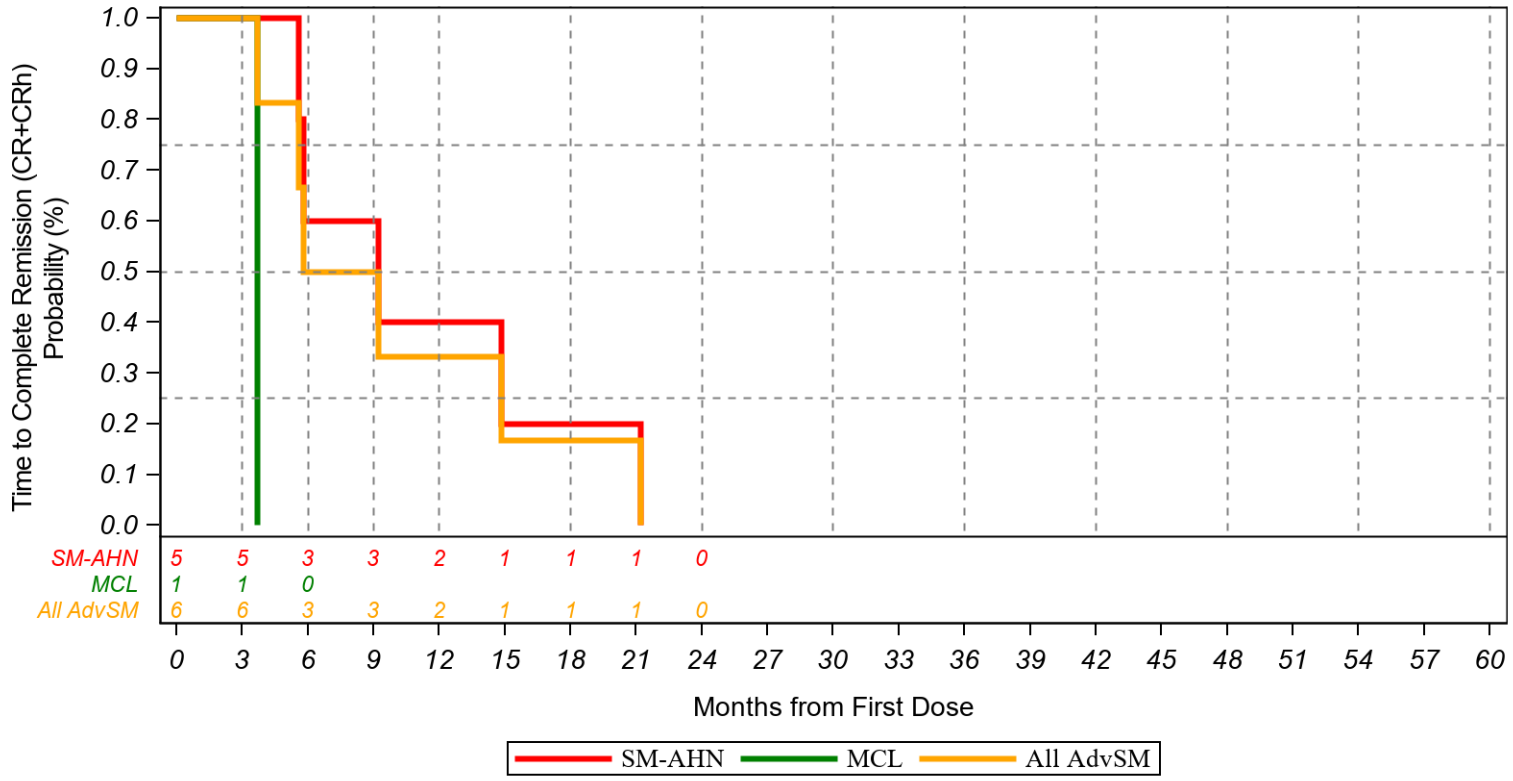

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Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg

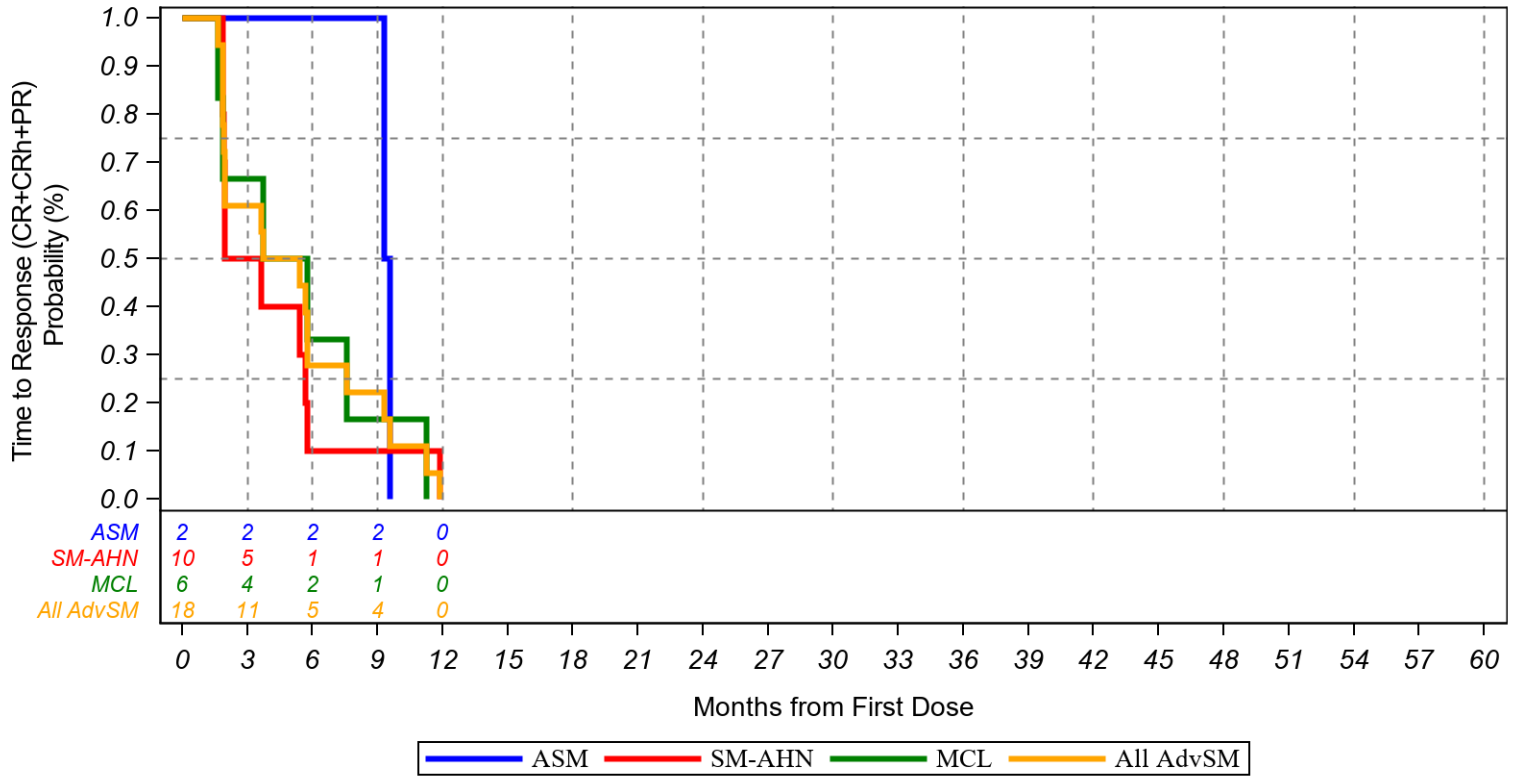

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Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg

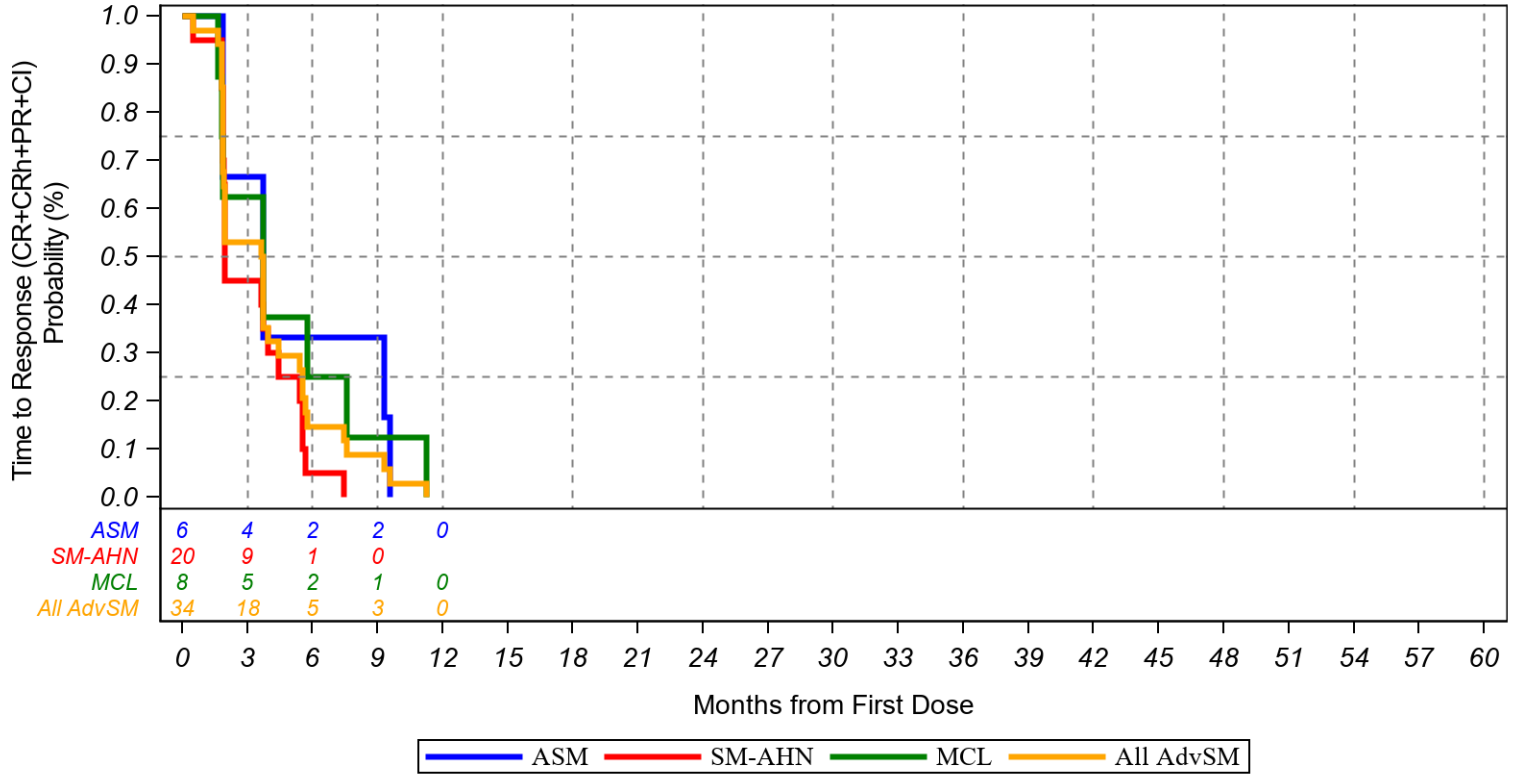

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg

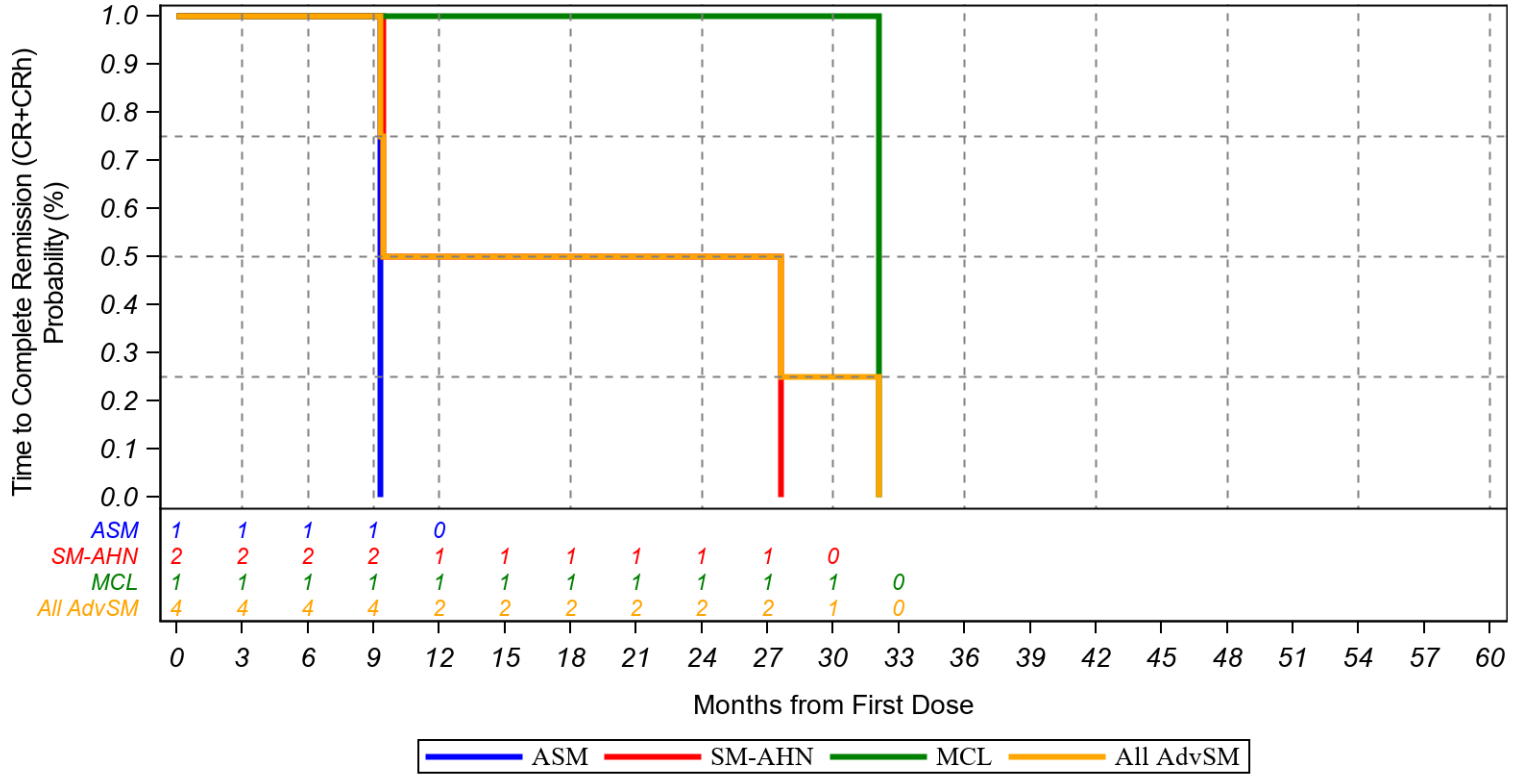

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg

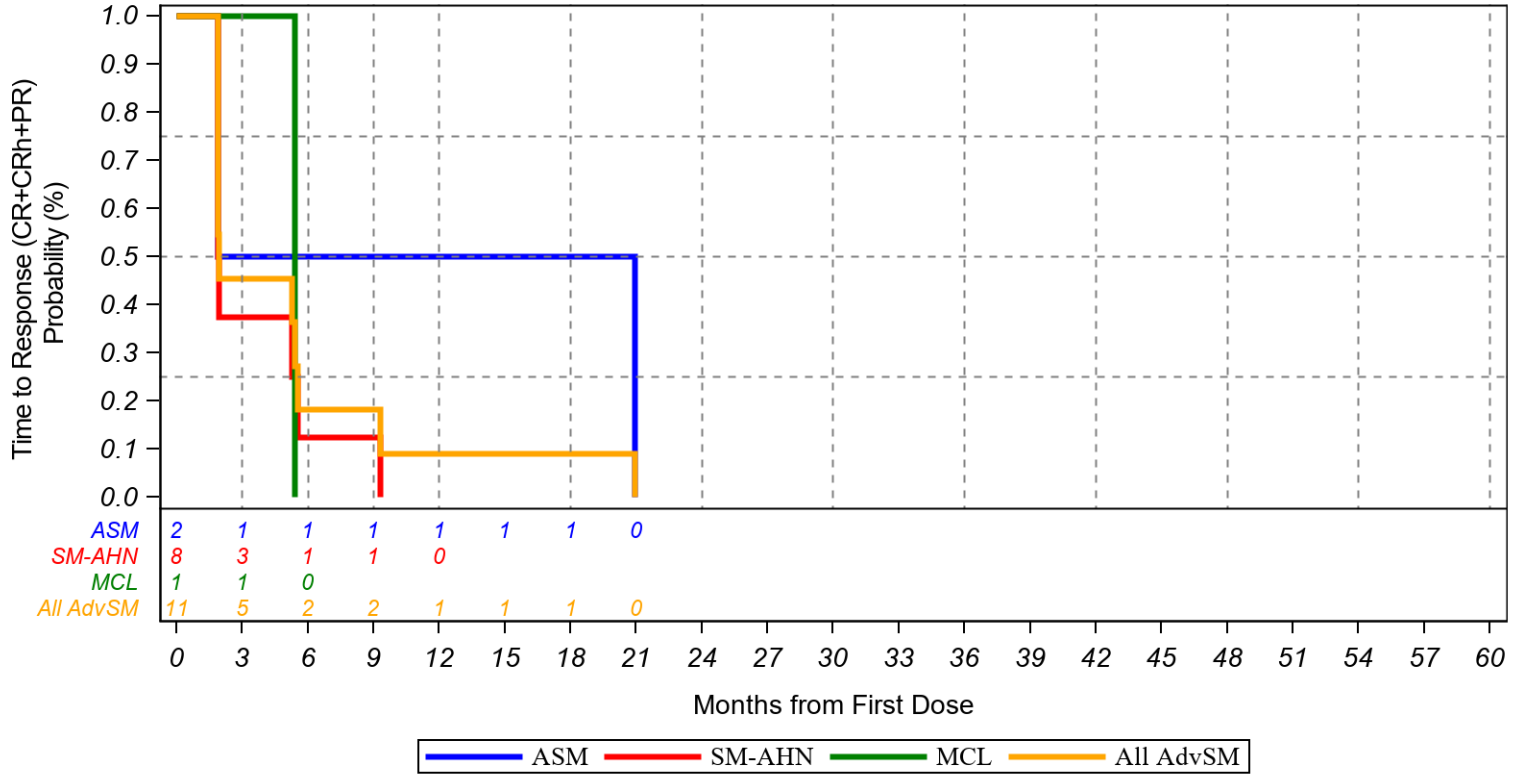

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg

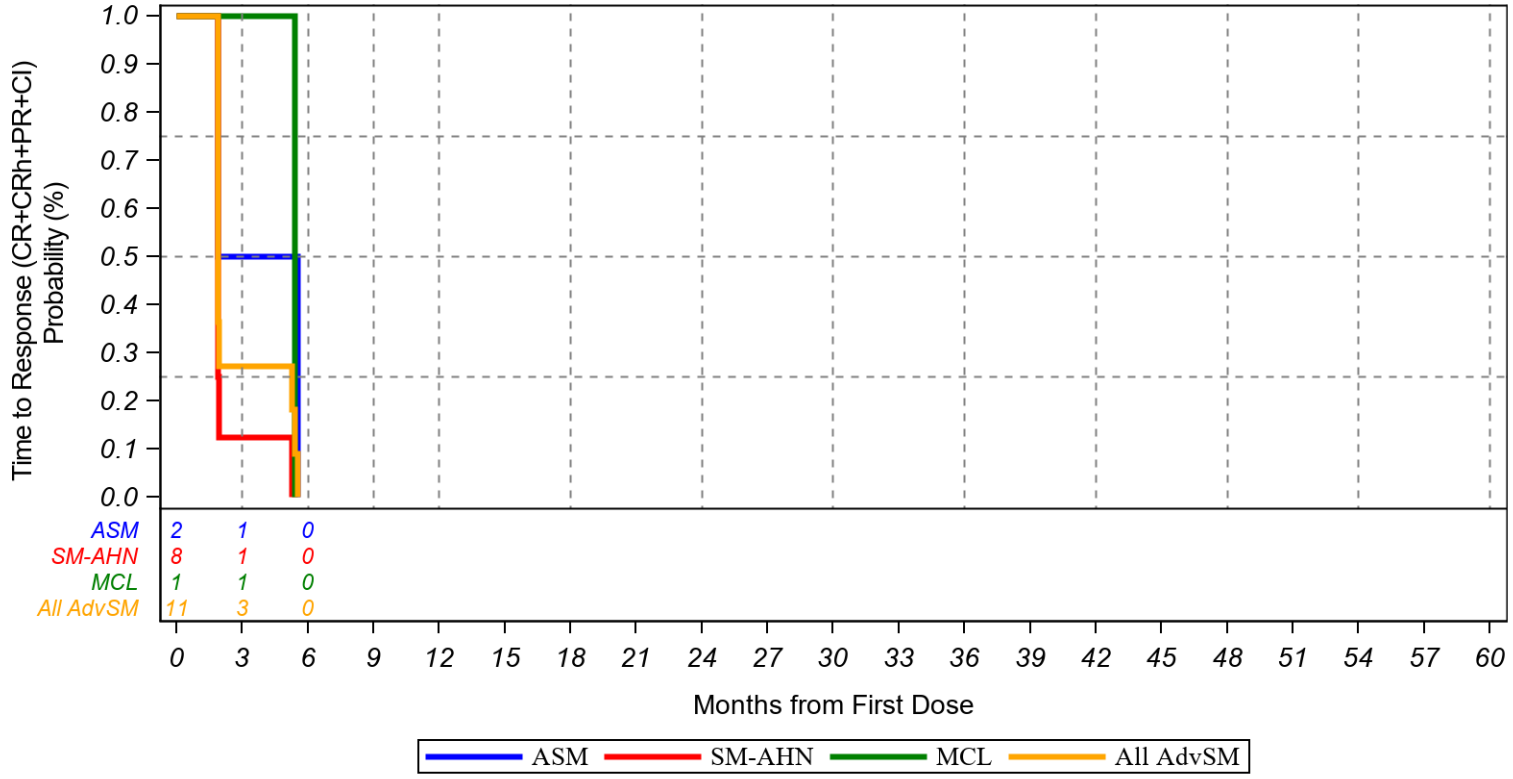

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg

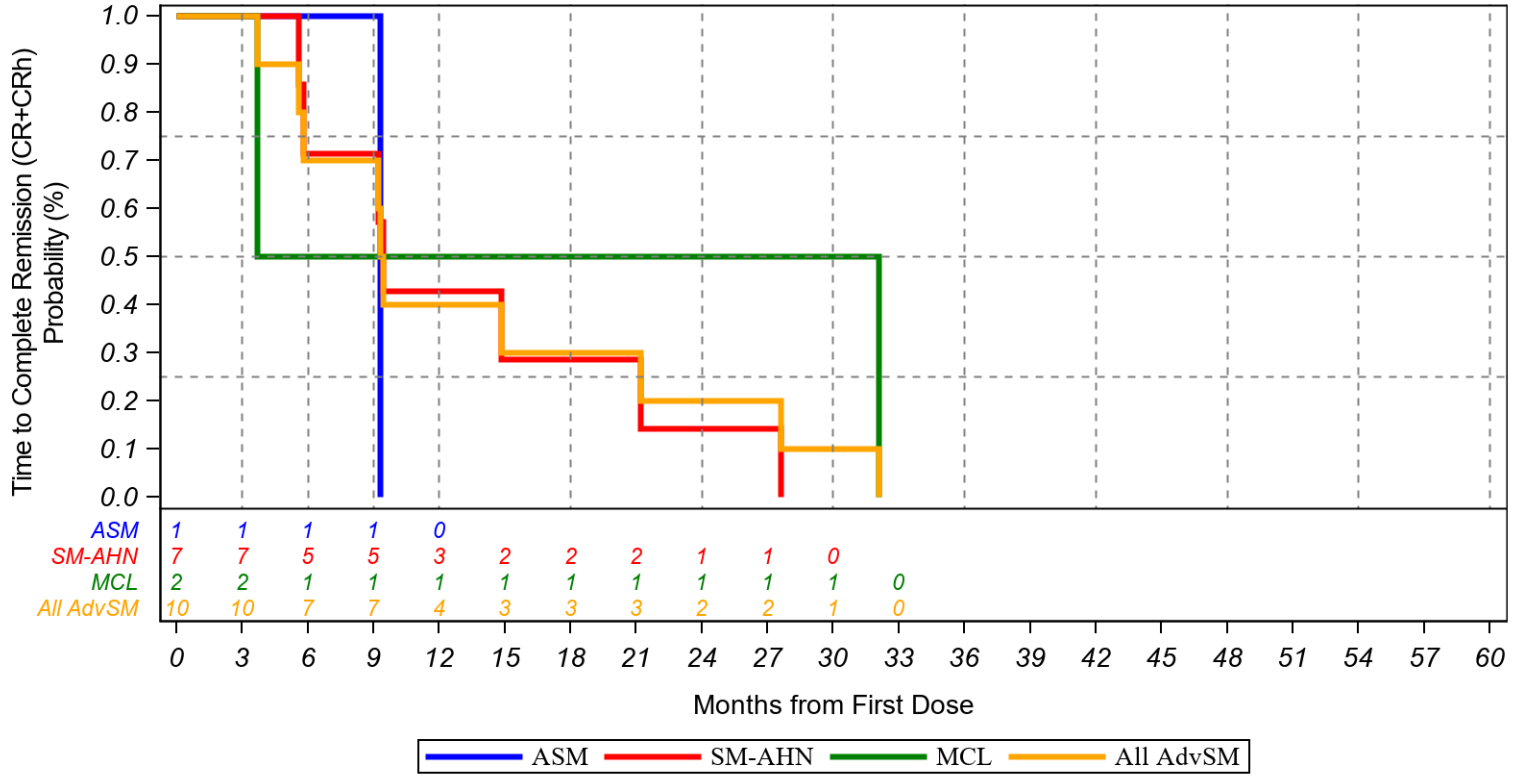

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg

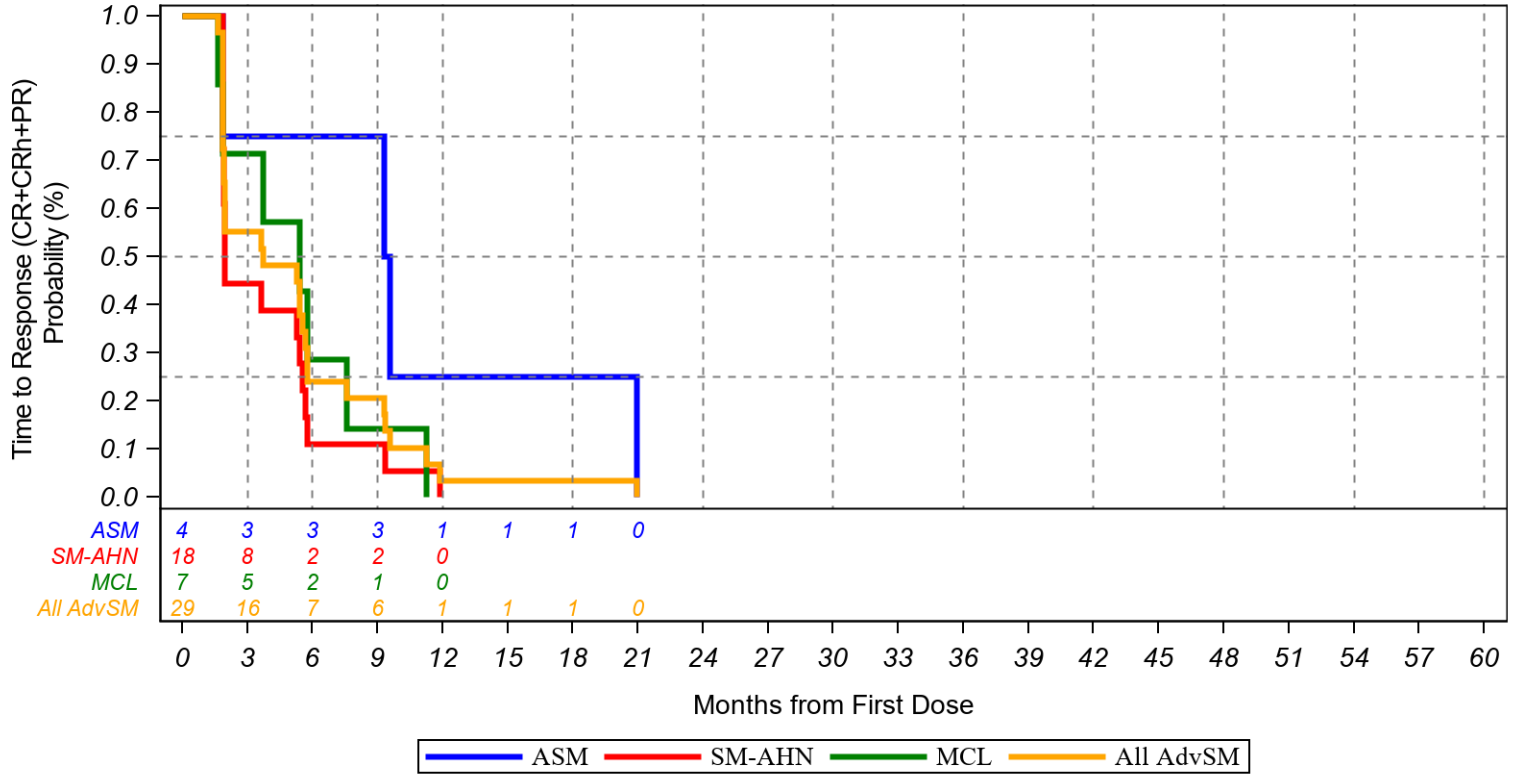

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg

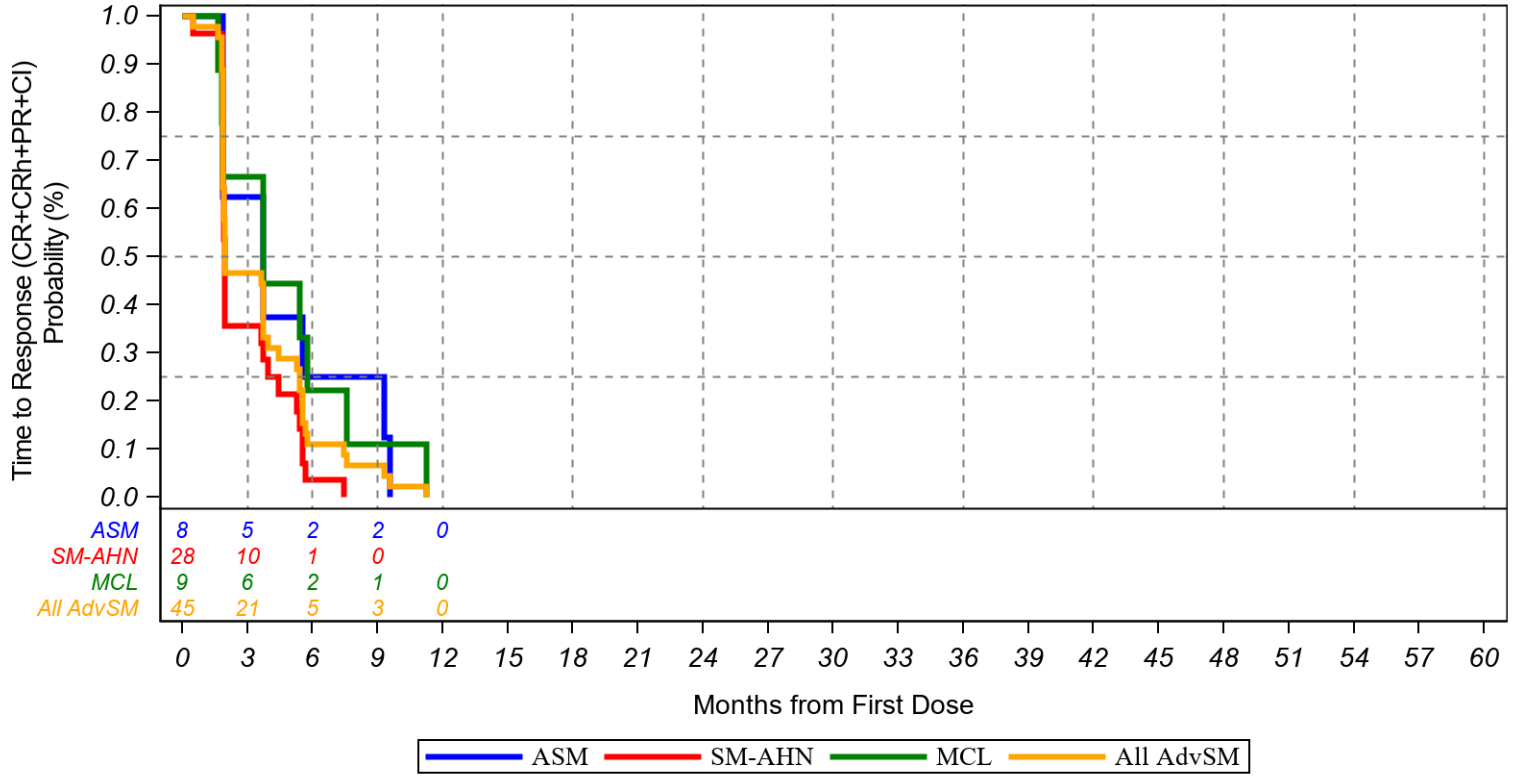

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg

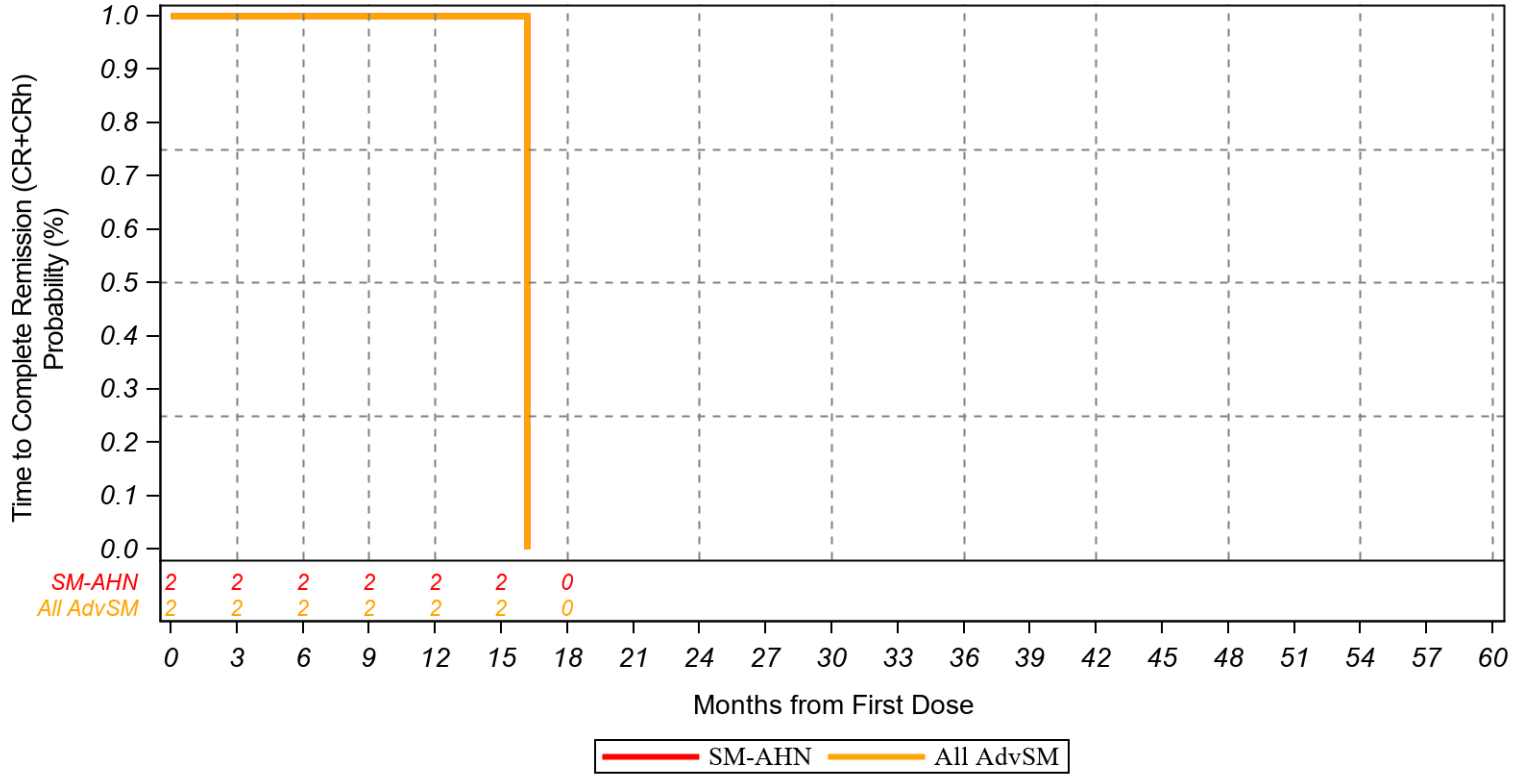

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg

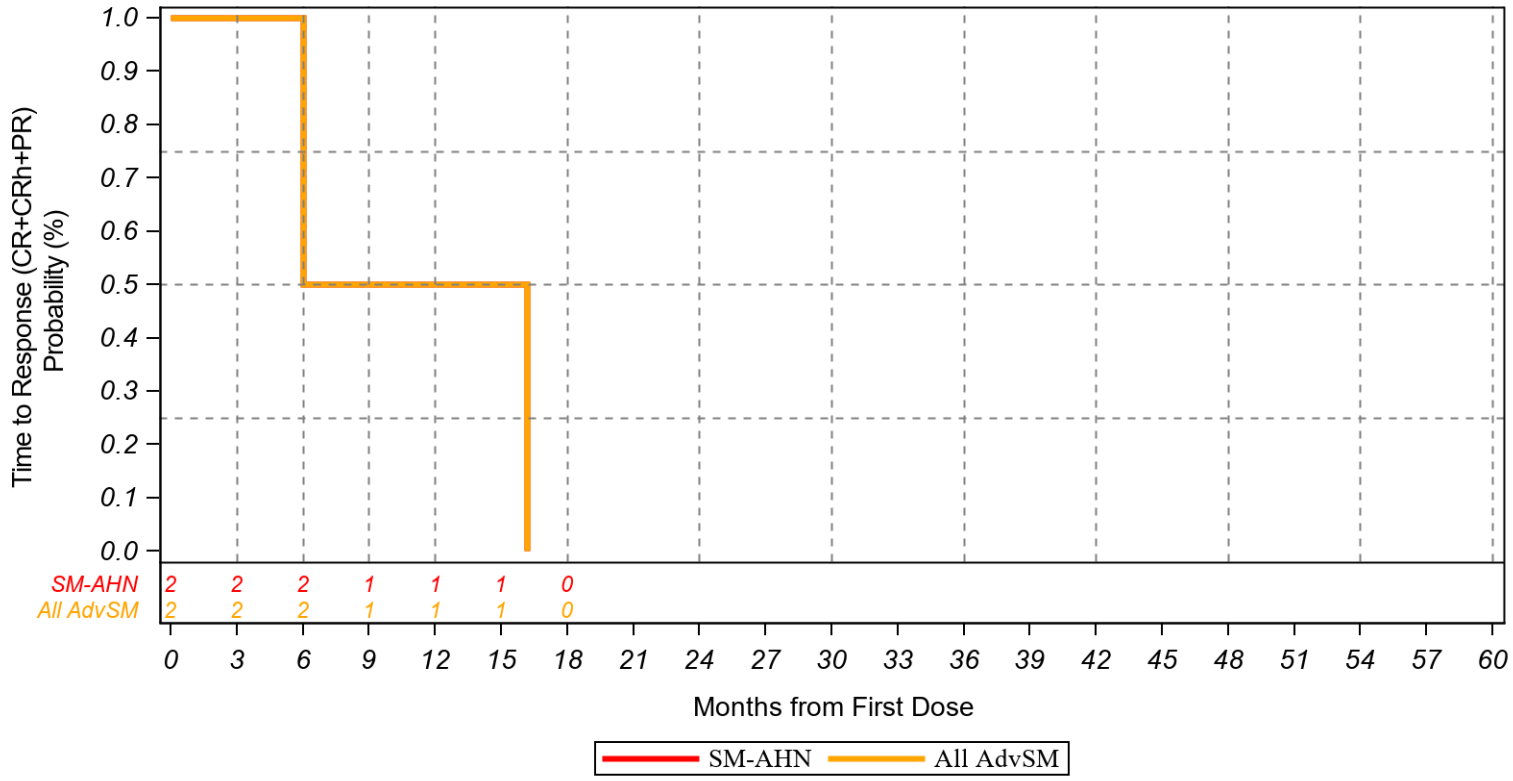

Figure 35.2.2.7
Kaplan-Meier Curves of Investigator Assessed Time to Response & Time to Complete Remission by mIWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+CRh+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg

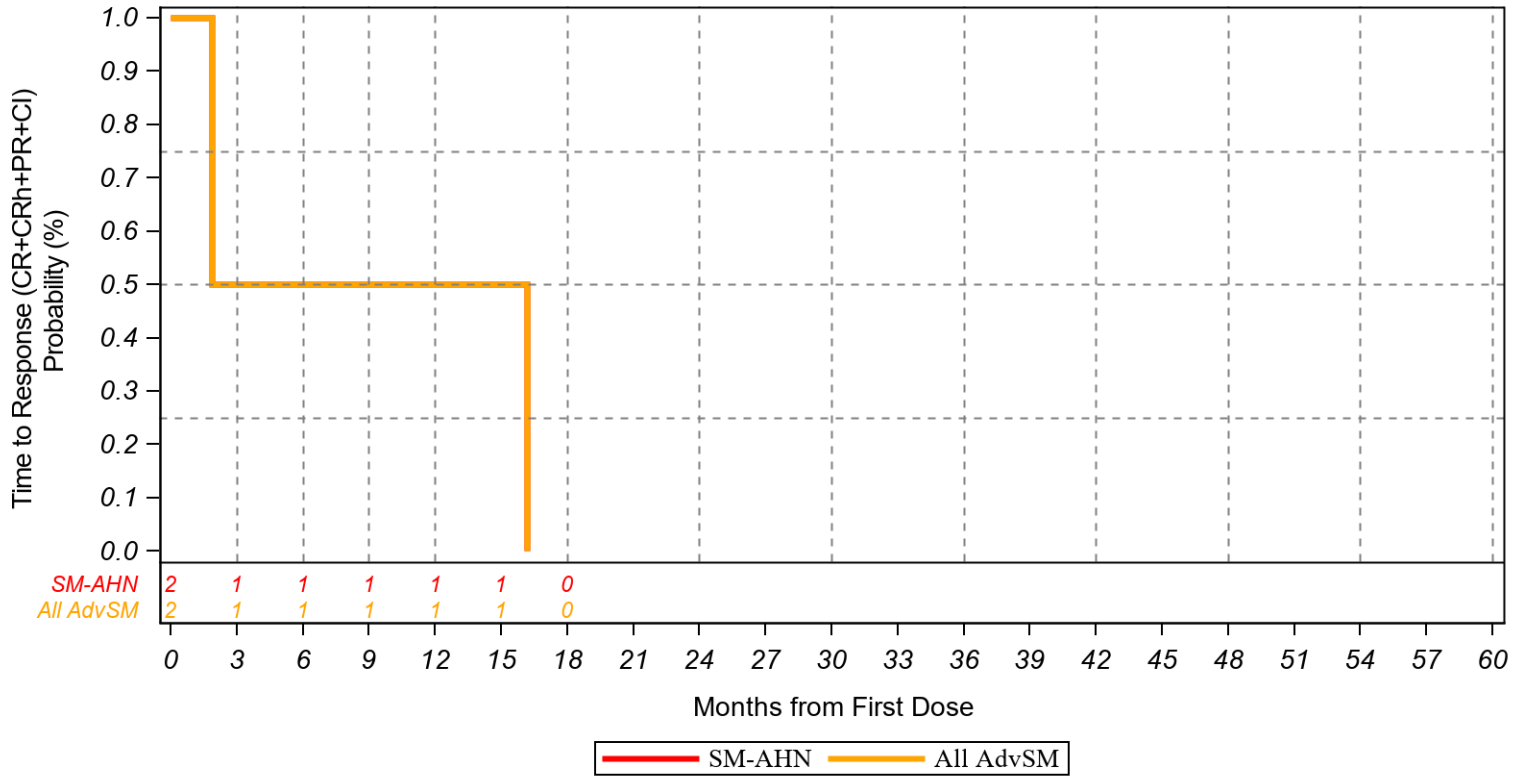

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Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR)
Study BLU-285-2101
Starting Dose: Overall

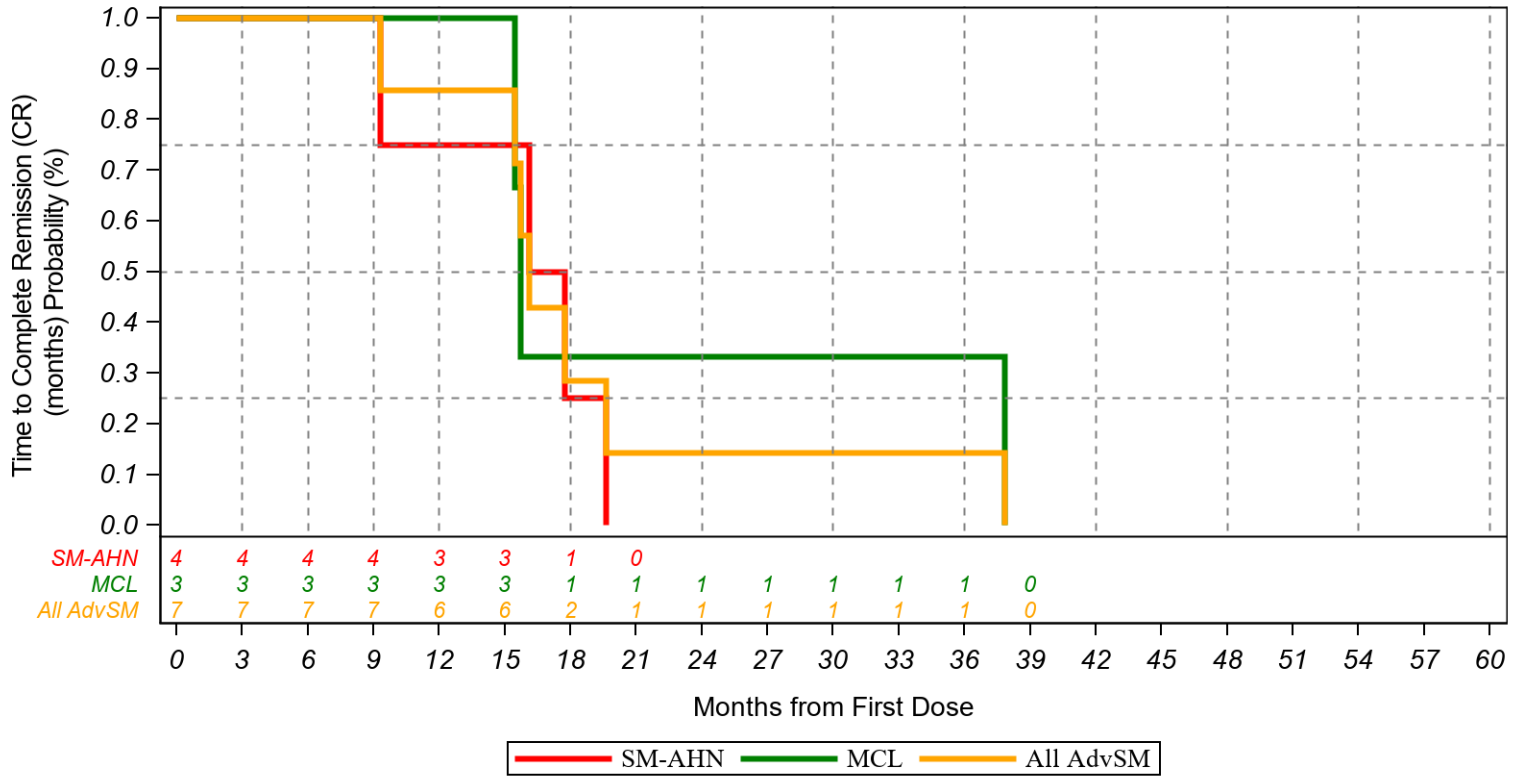

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Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR)
Study BLU-285-2101
Starting Dose: Overall

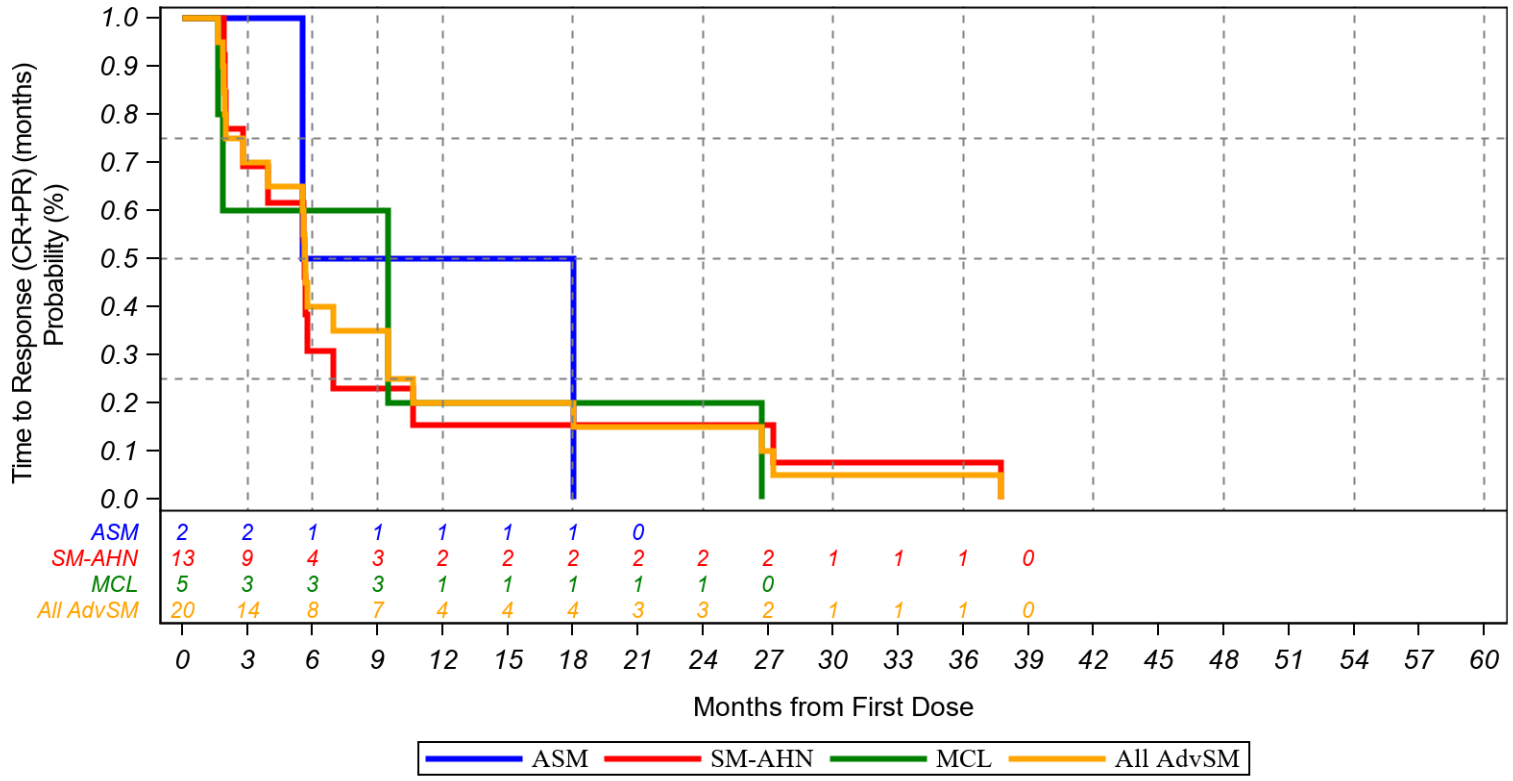


Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR+CI)
Study BLU-285-2101
Starting Dose: Overall

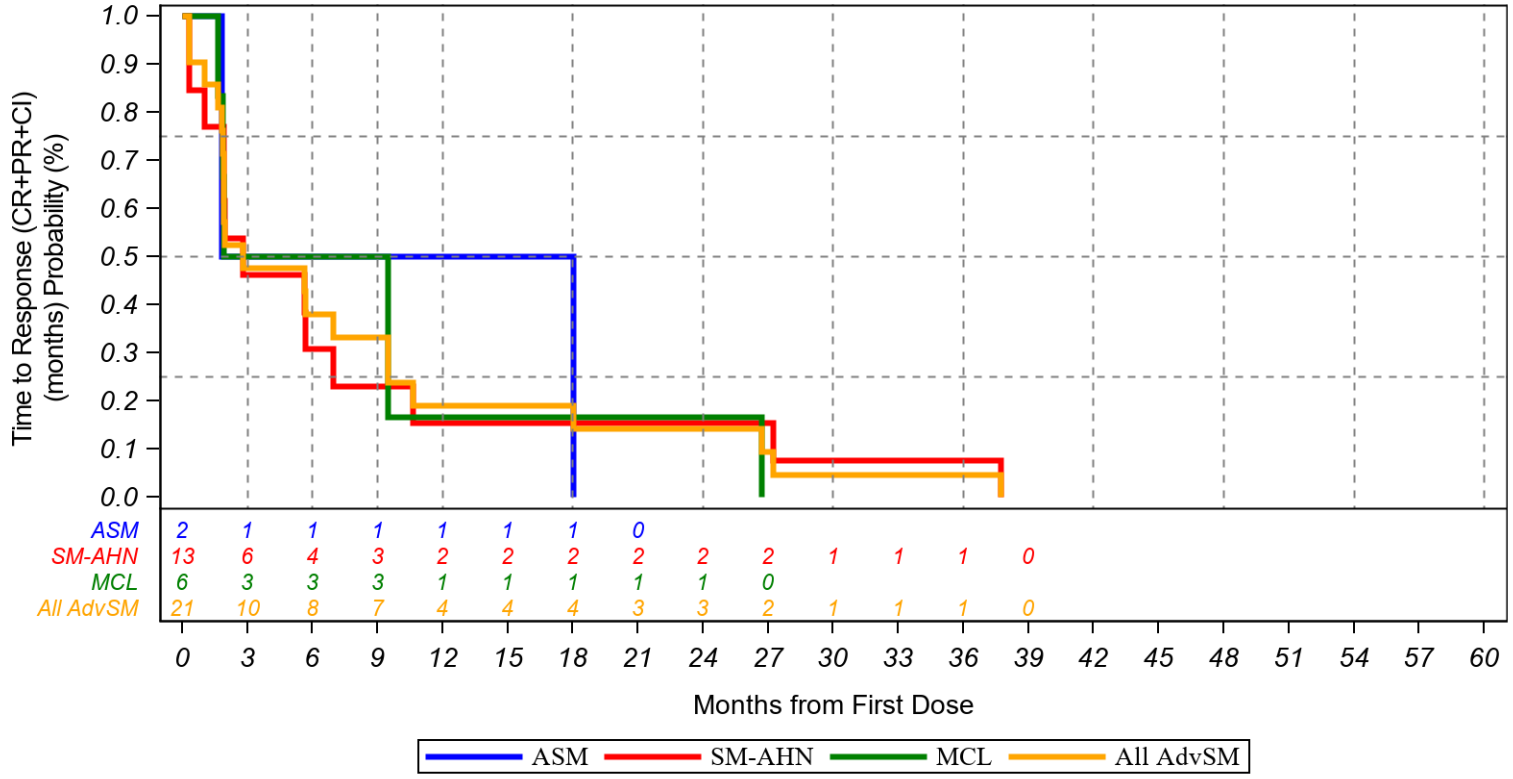


Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR)
Study BLU-285-2101
Starting Dose: < 200 mg

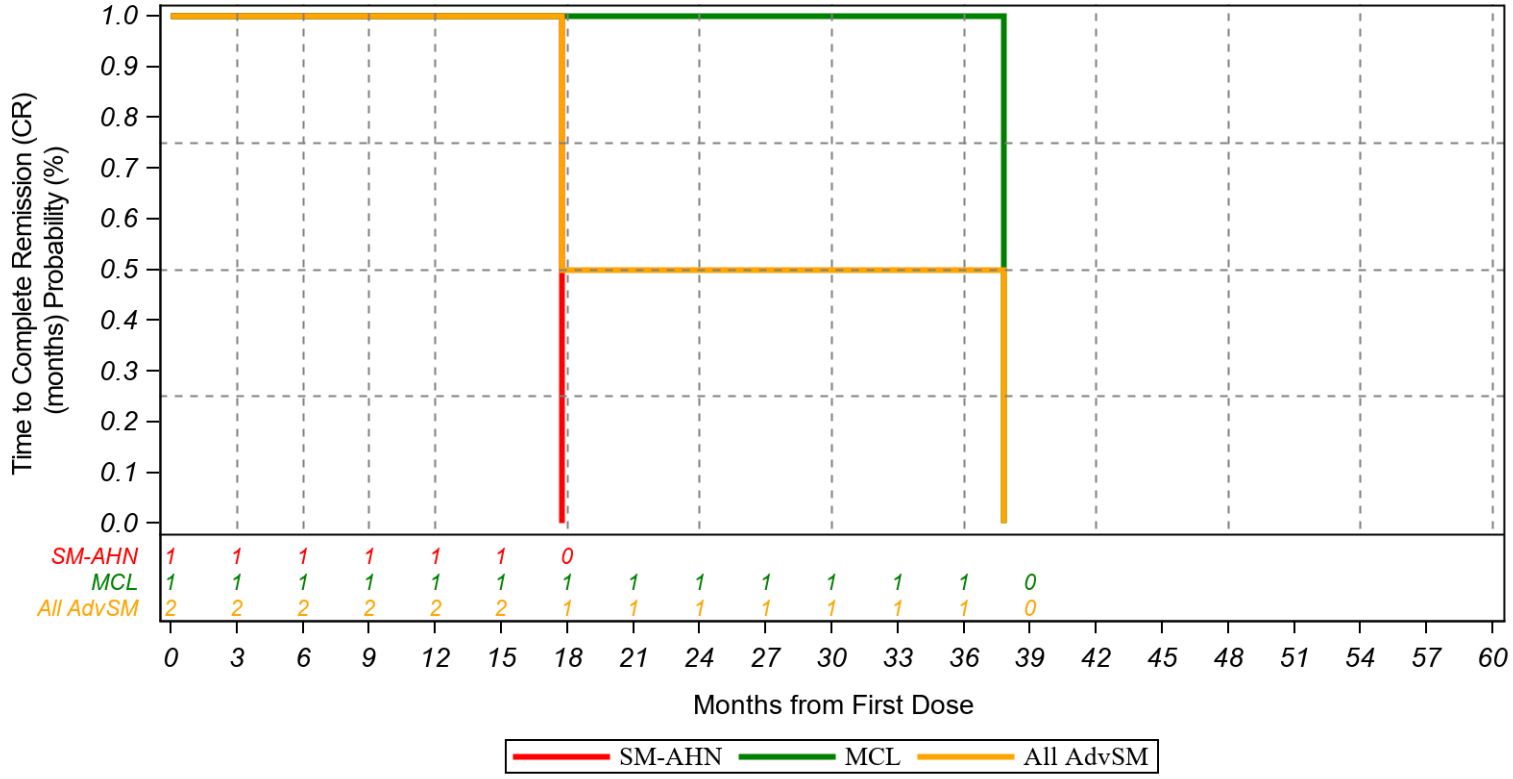


Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR)
Study BLU-285-2101
Starting Dose: < 200 mg

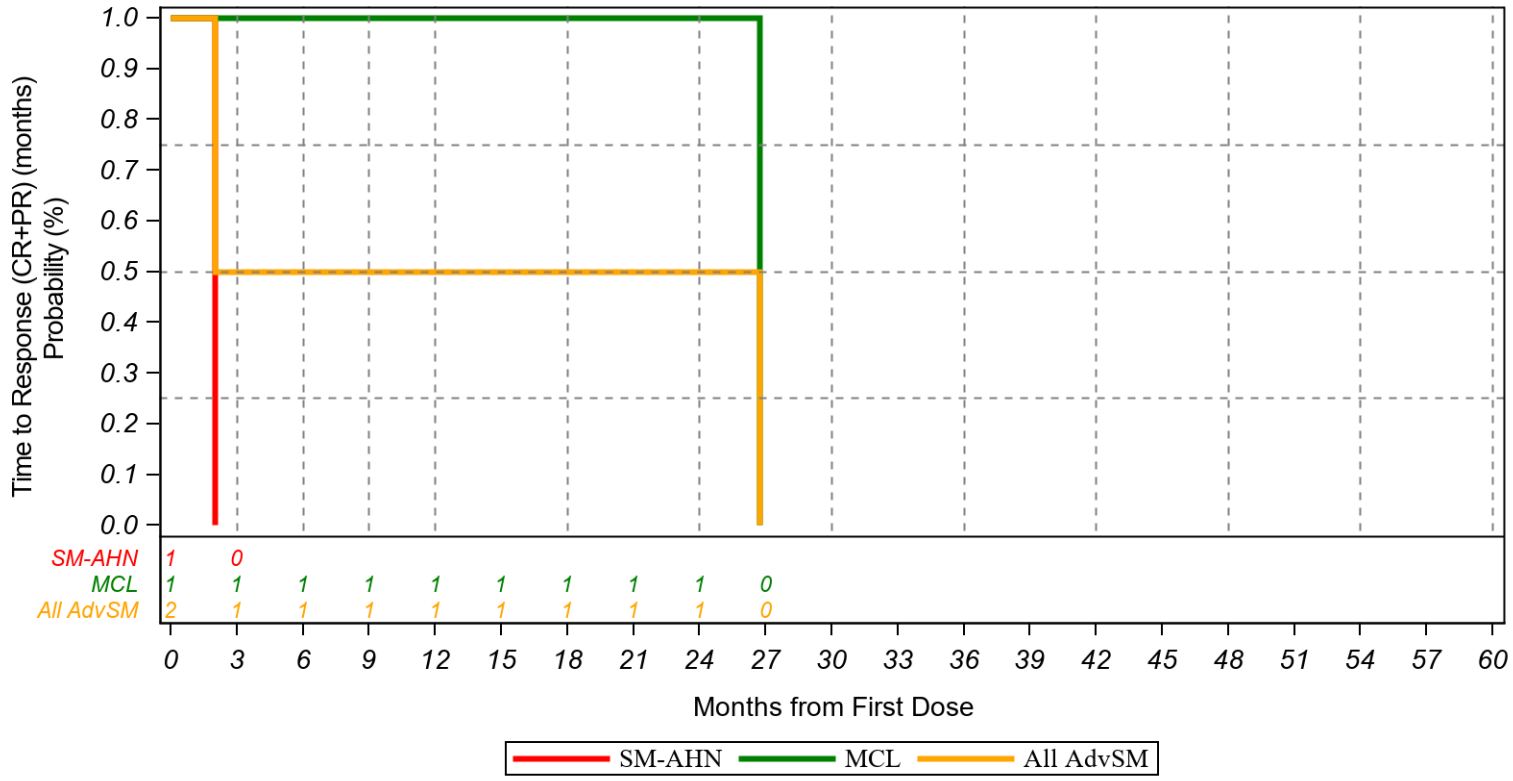


Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR+CI)
Study BLU-285-2101
Starting Dose: < 200 mg

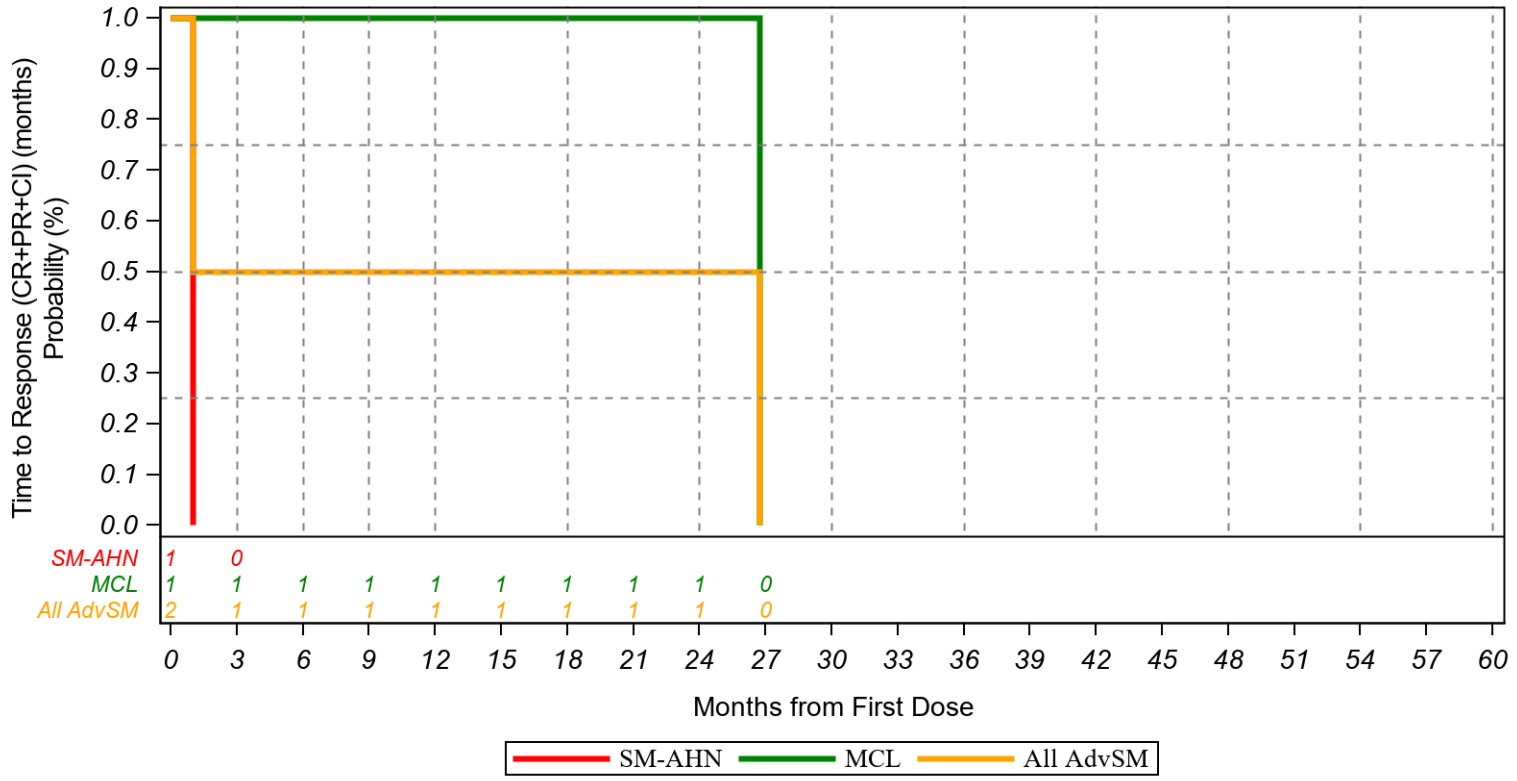


Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR)
Study BLU-285-2101
Starting Dose: < 300 mg

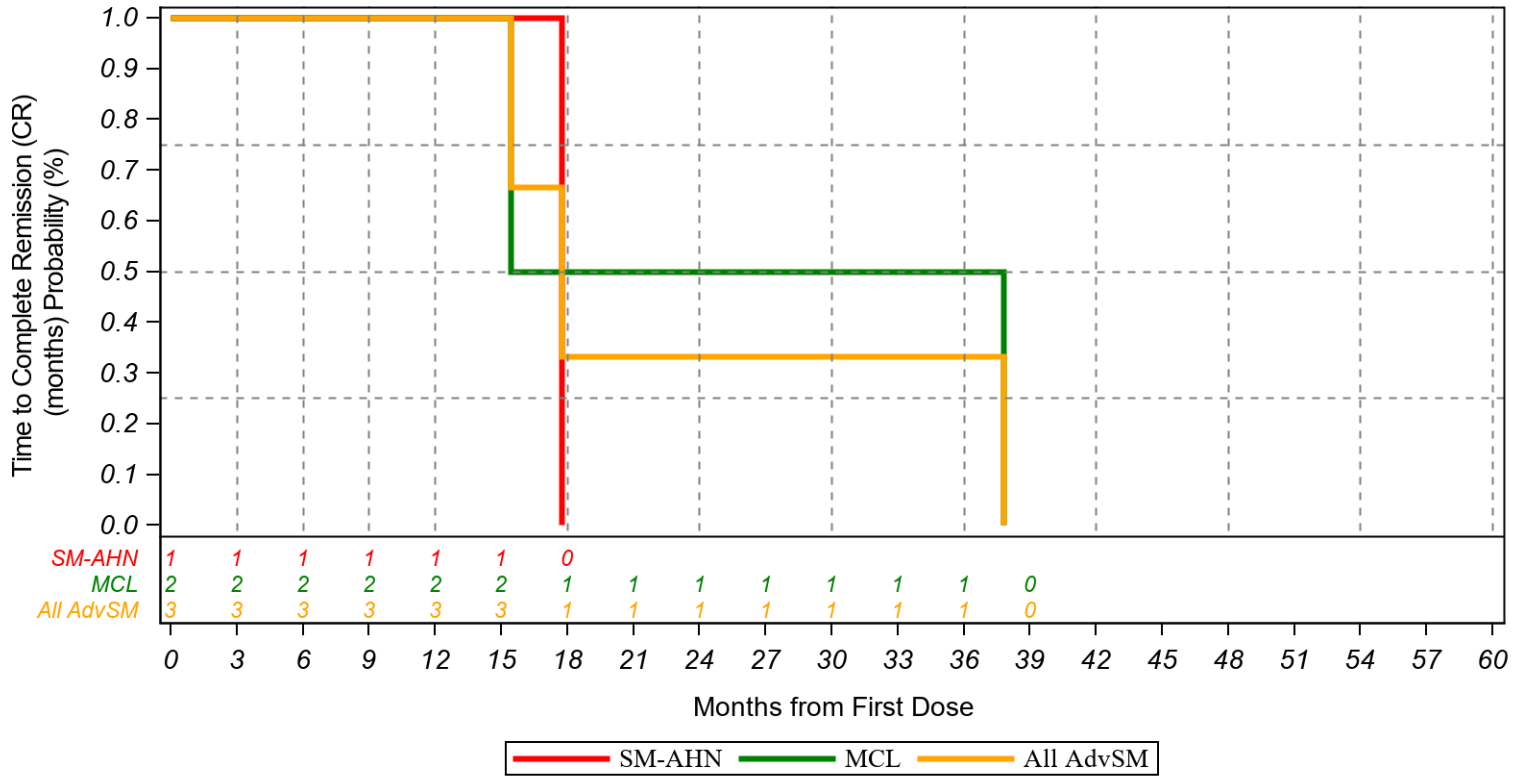


Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR)
Study BLU-285-2101
Starting Dose: < 300 mg

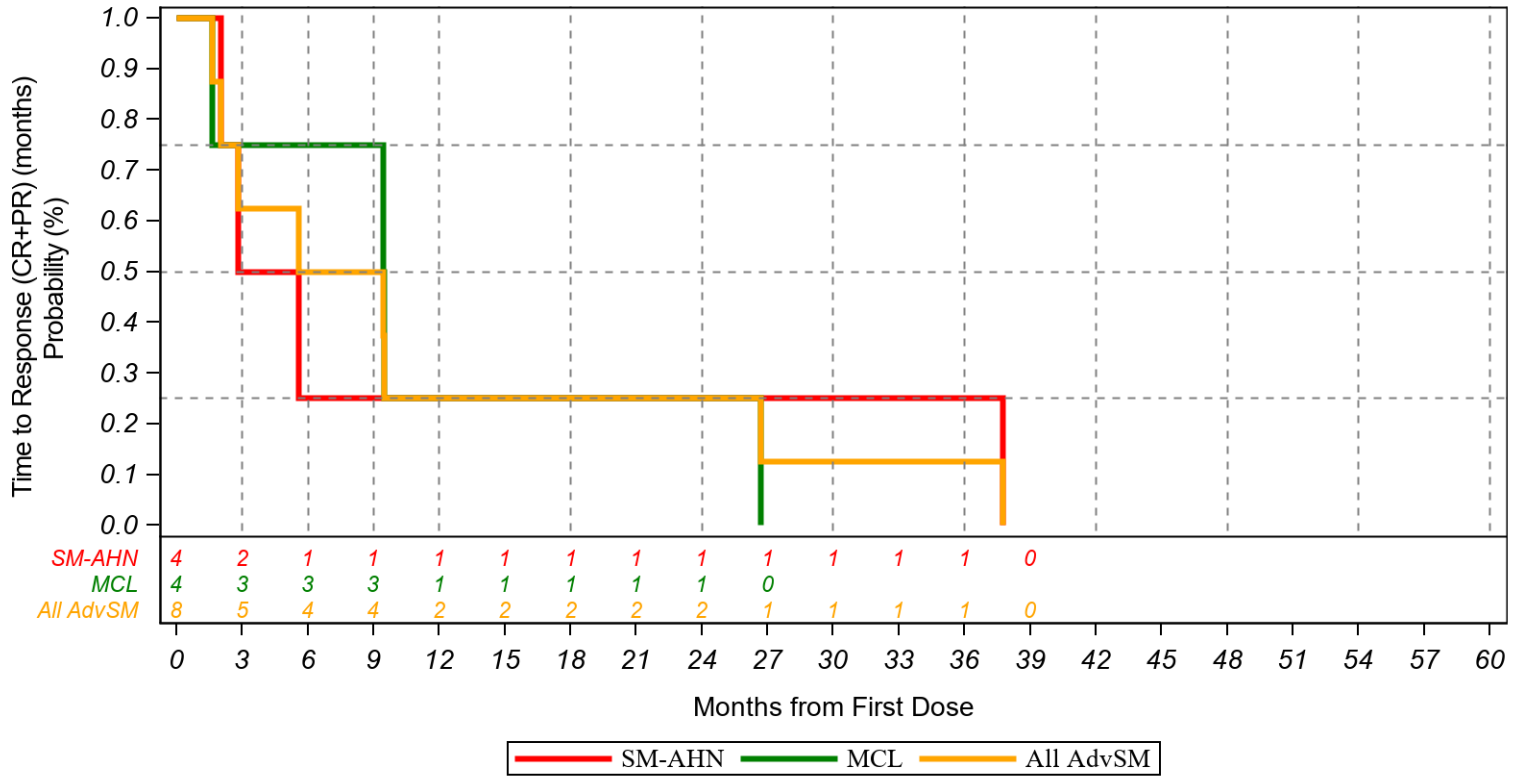


Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR+CI)
Study BLU-285-2101
Starting Dose: < 300 mg

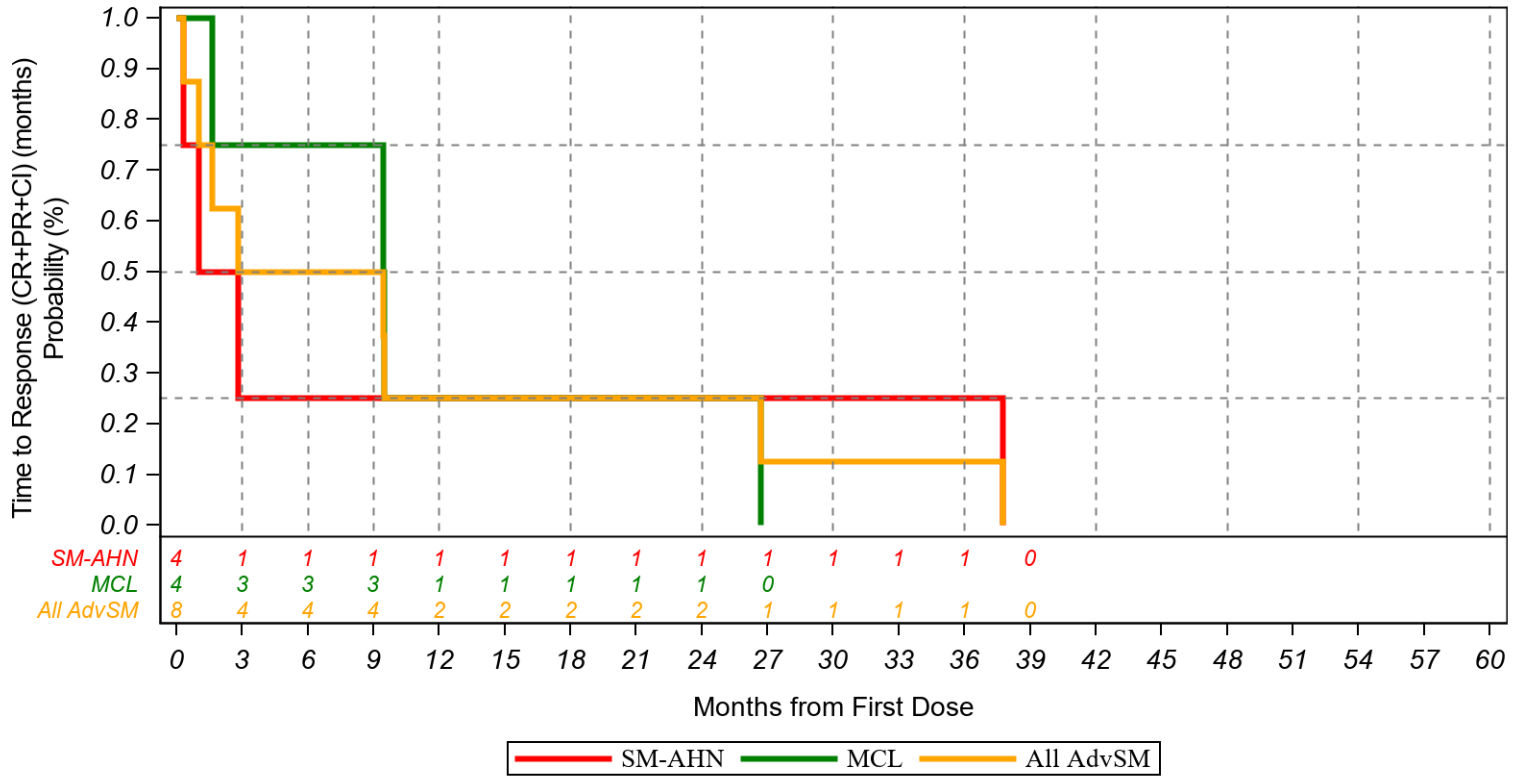


Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR)
Study BLU-285-2101
Starting Dose: 200 mg

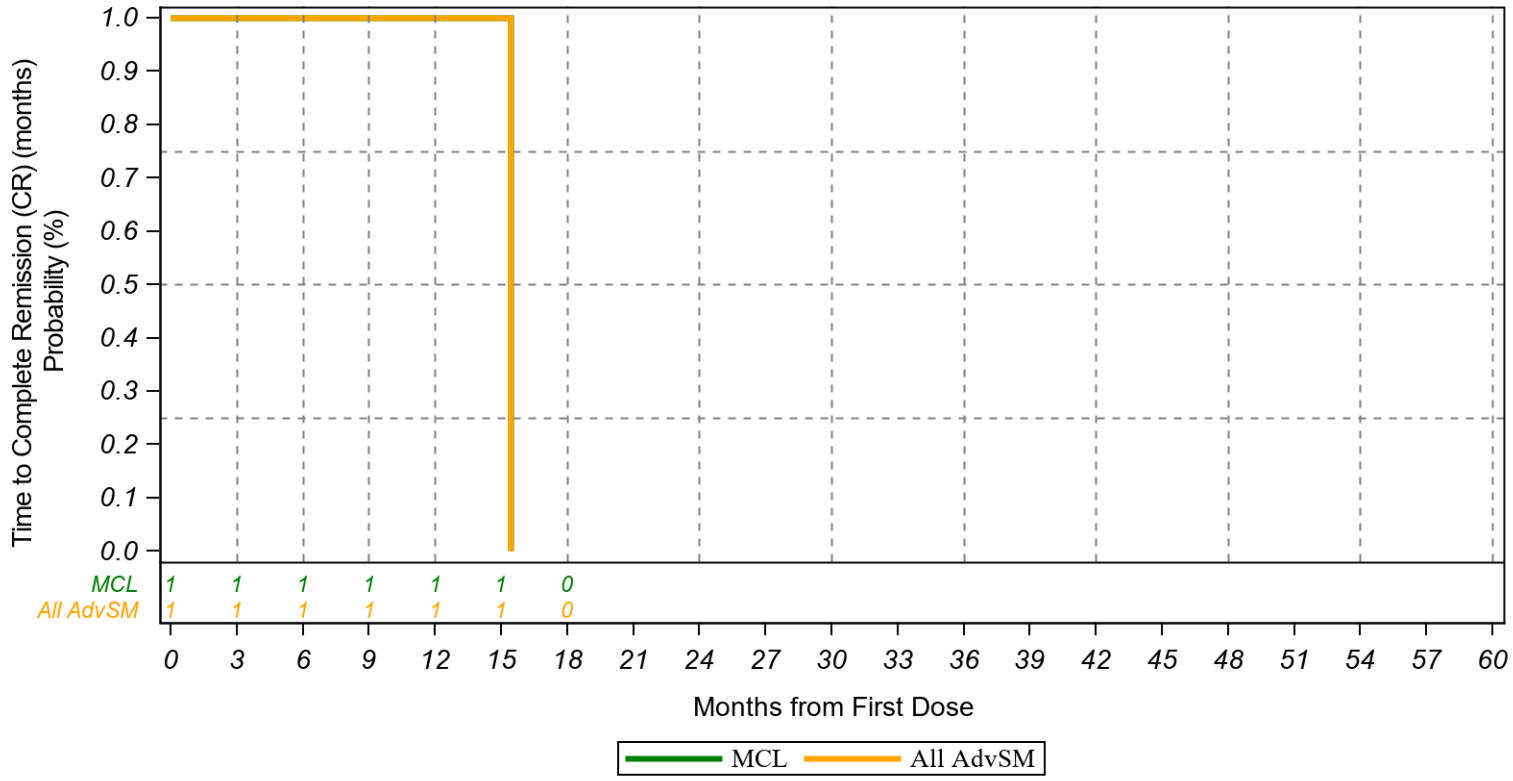


Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR)
Study BLU-285-2101
Starting Dose: 200 mg

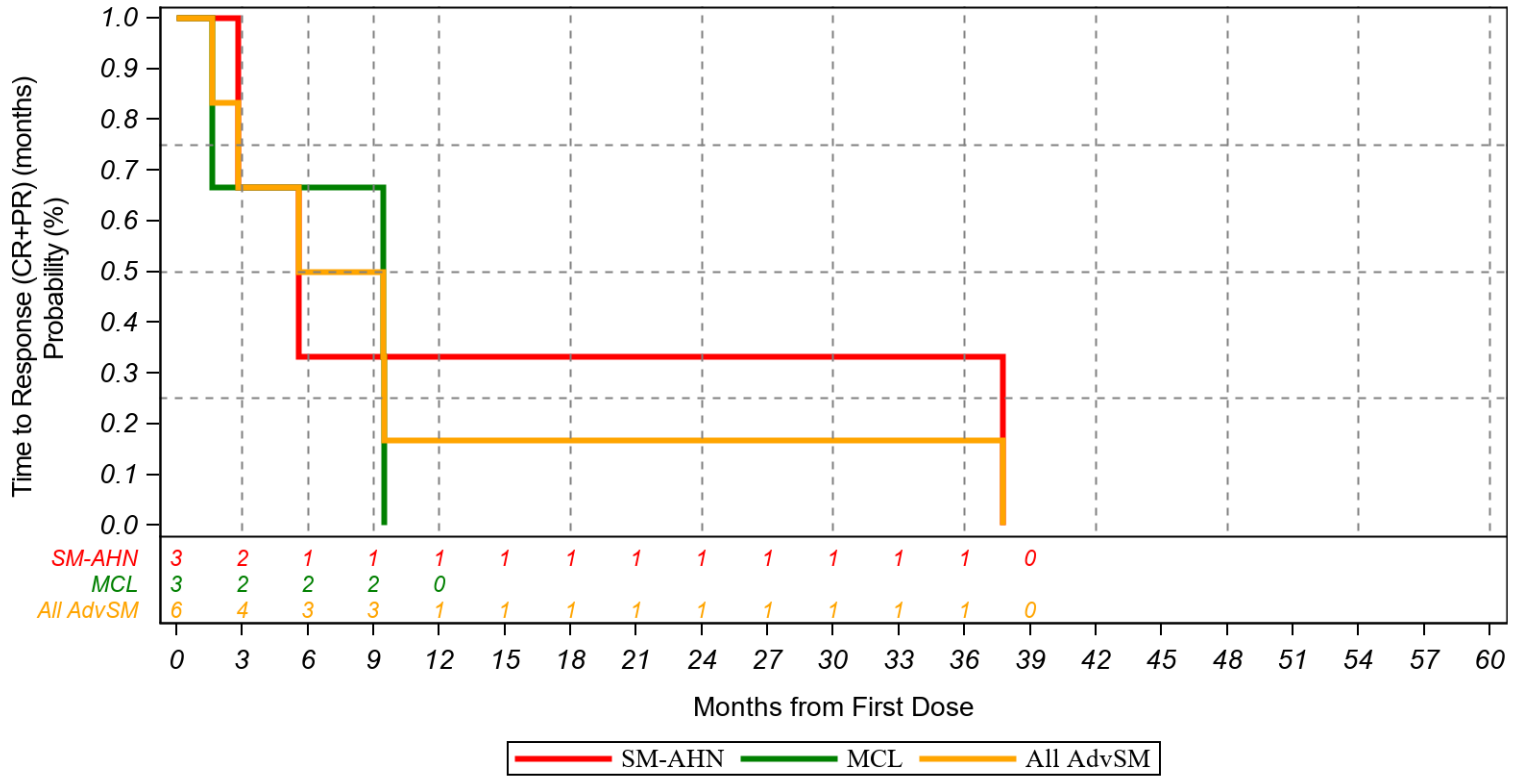


Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR+CI)
Study BLU-285-2101
Starting Dose: 200 mg

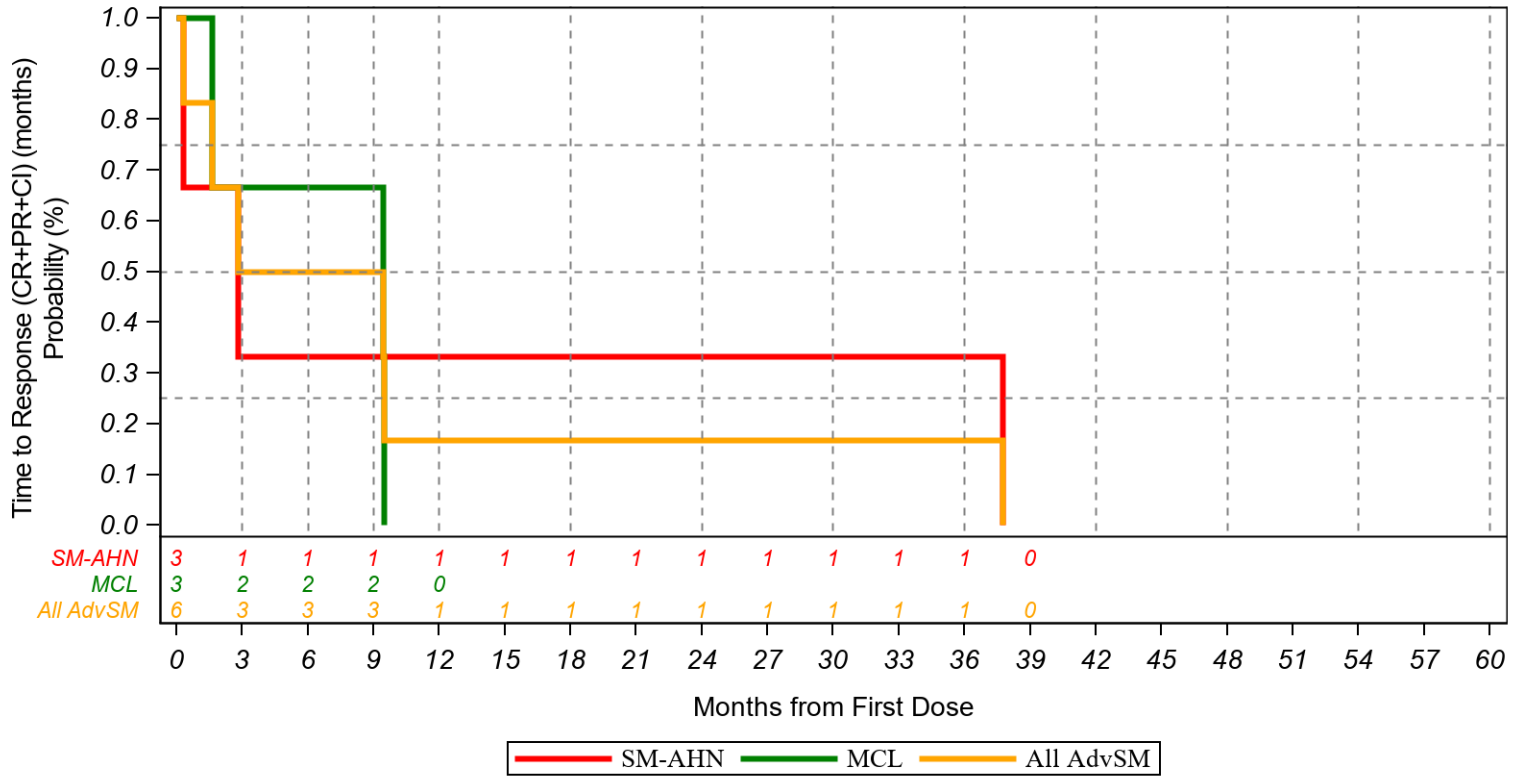


Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR)
Study BLU-285-2101
Starting Dose: 300 mg

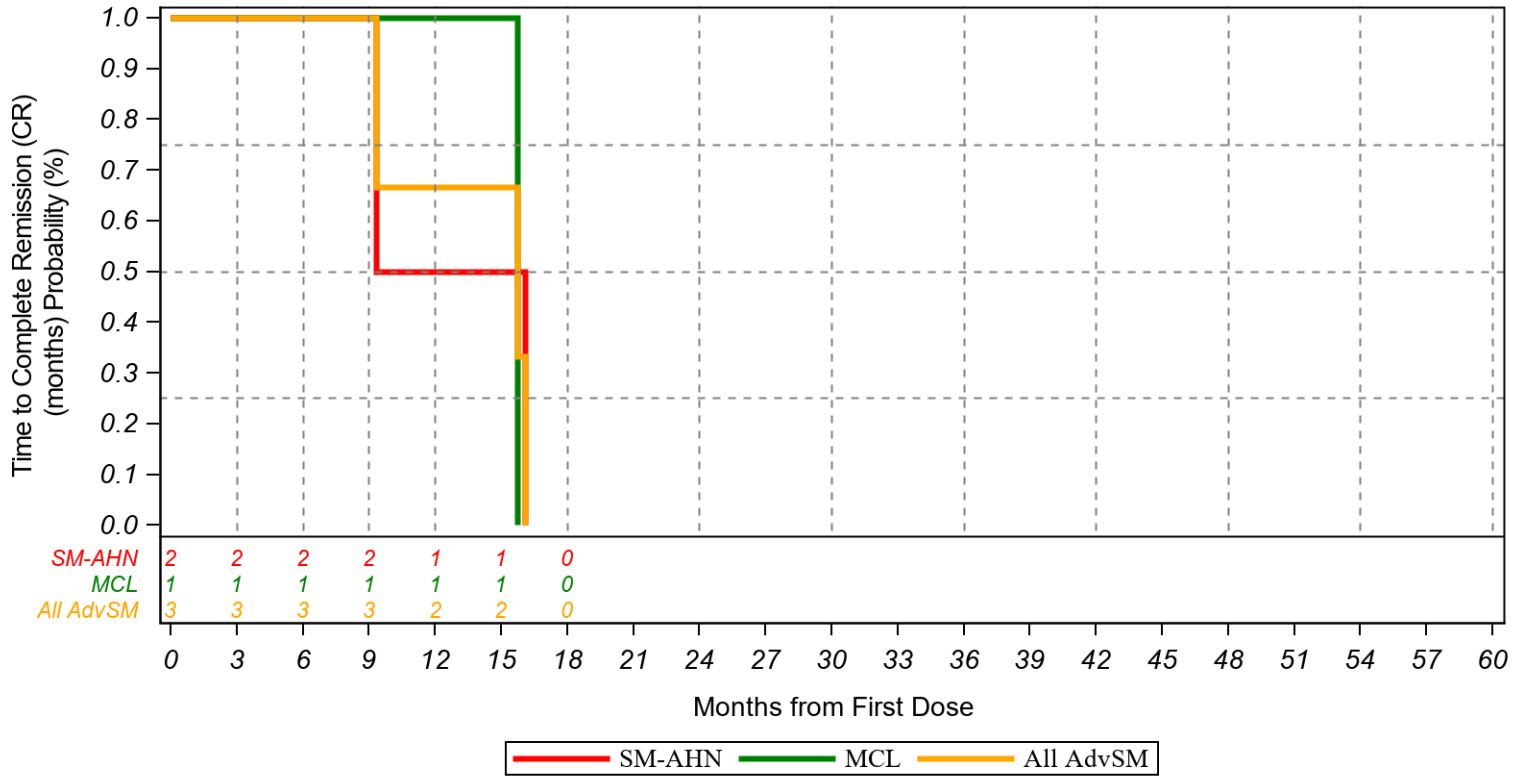


Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR)
Study BLU-285-2101
Starting Dose: 300 mg

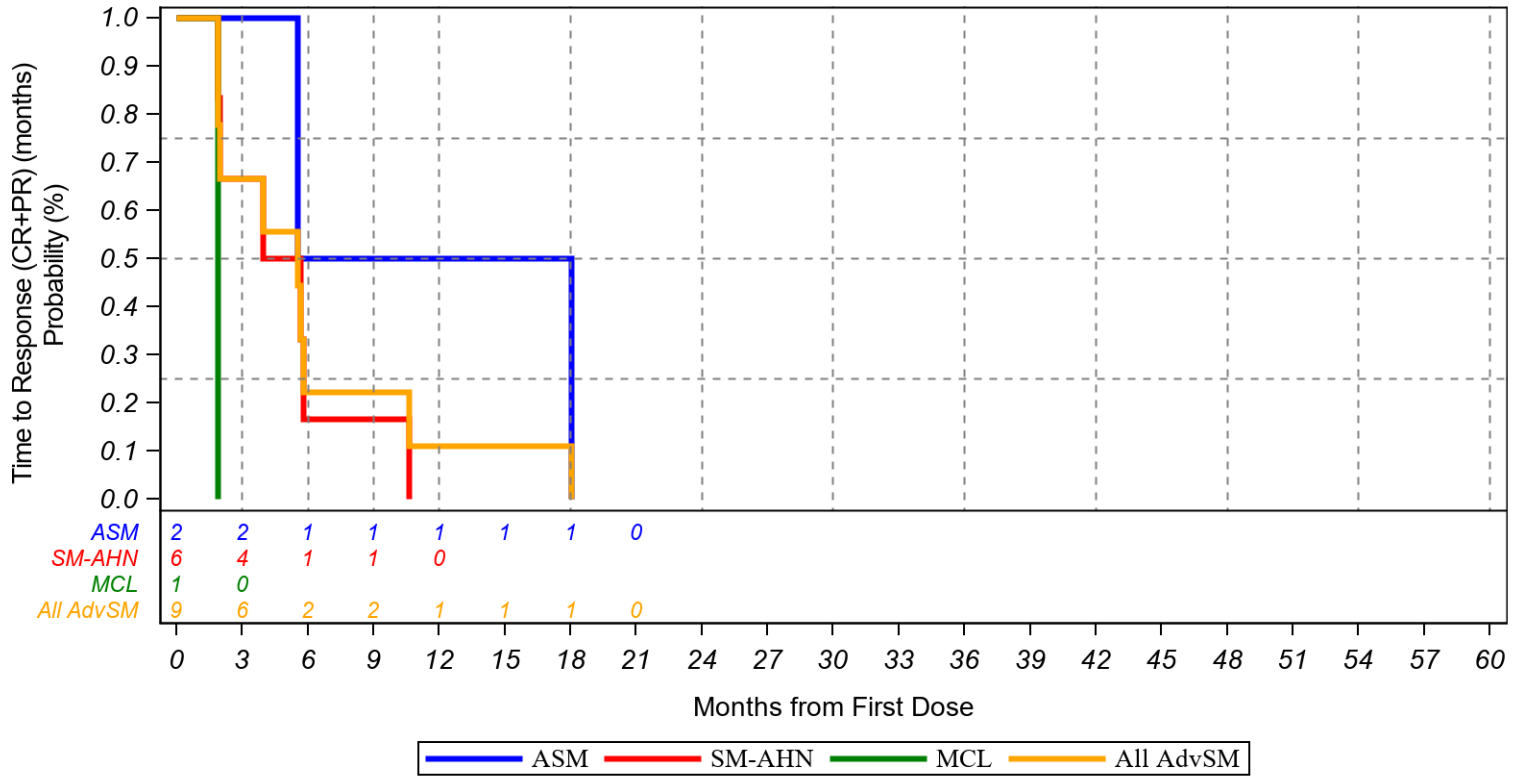


Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR+CI)
Study BLU-285-2101
Starting Dose: 300 mg

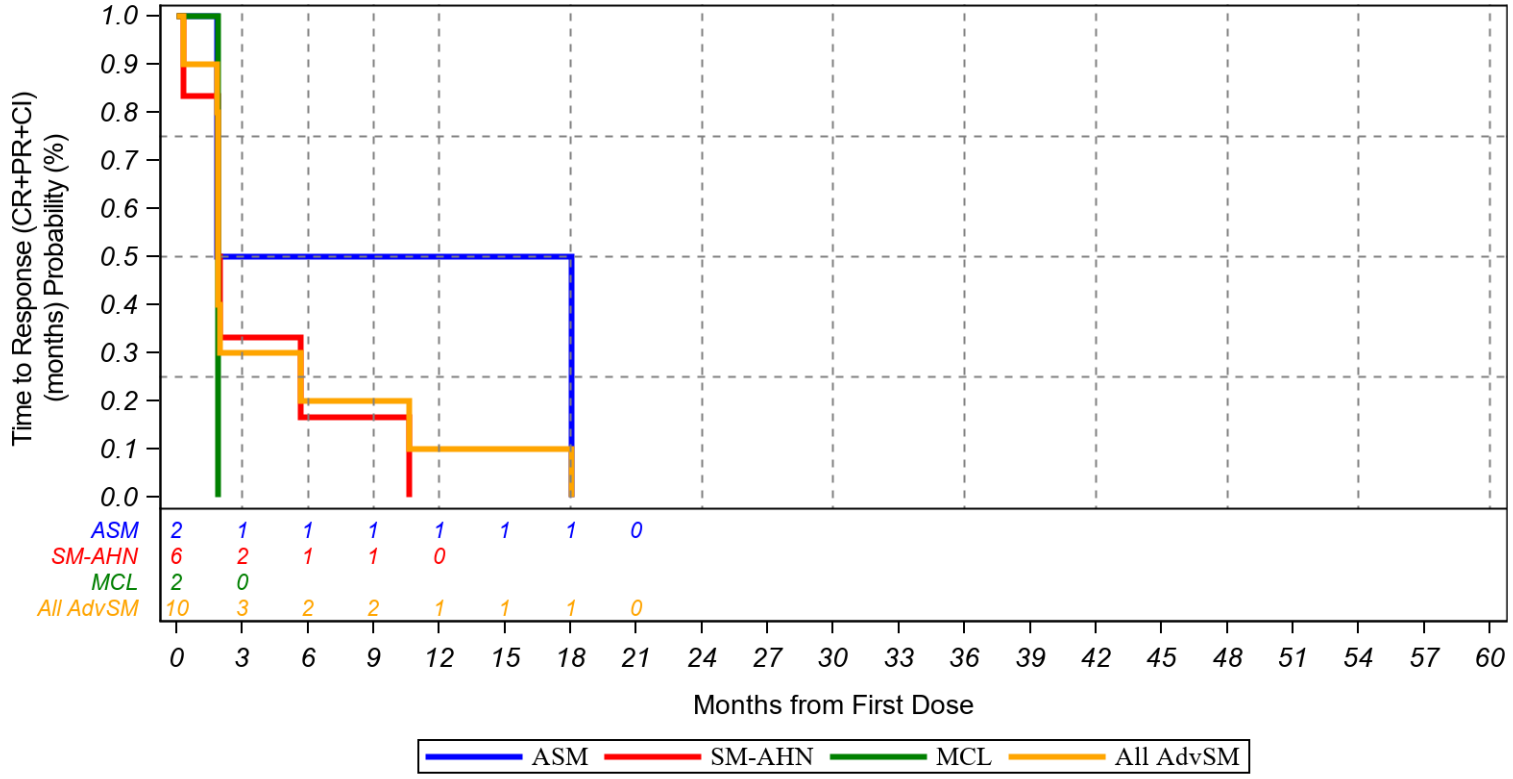


Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR)
Study BLU-285-2101
Starting Dose: 200 mg and 300 mg

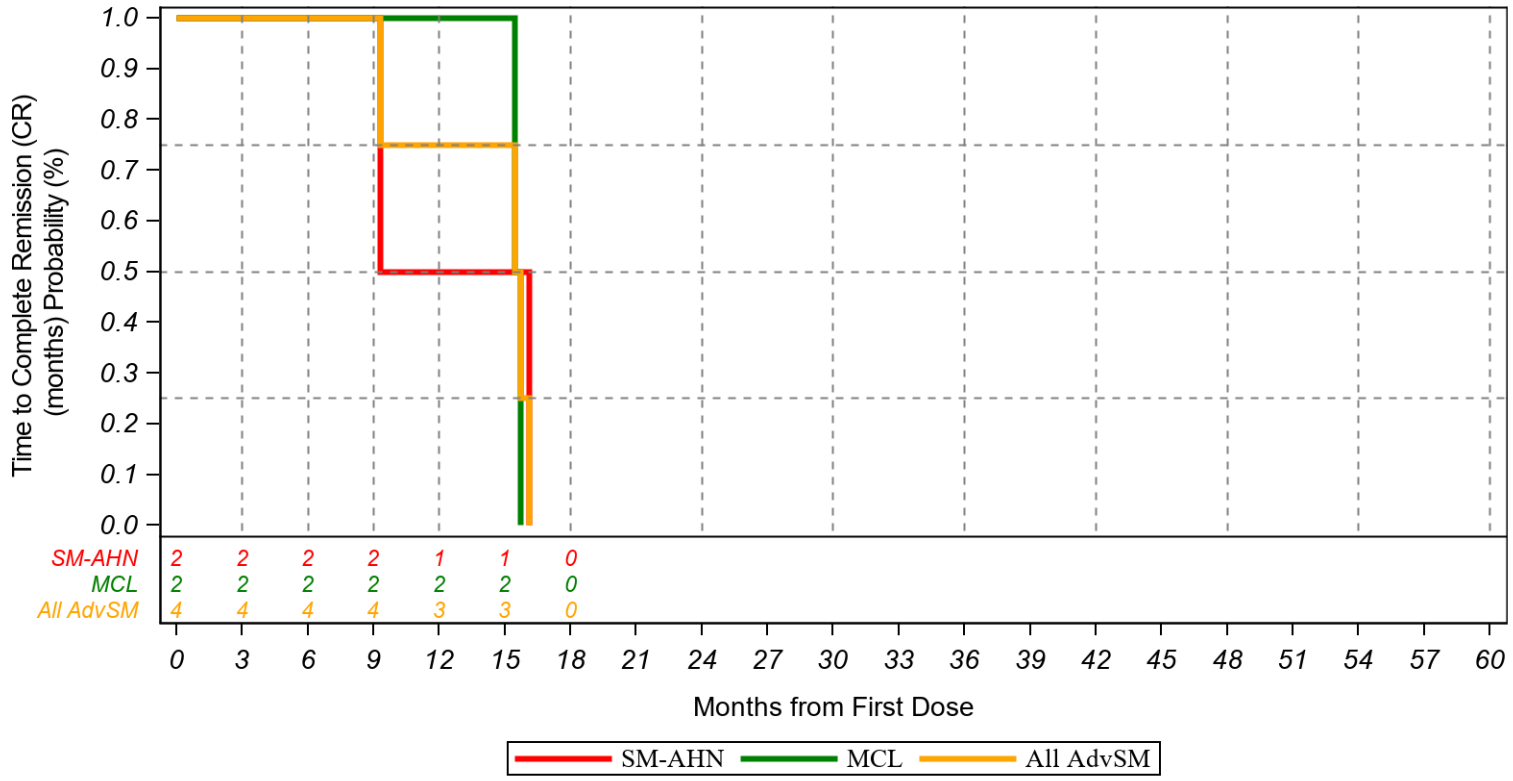


Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR)
Study BLU-285-2101
Starting Dose: 200 mg and 300 mg

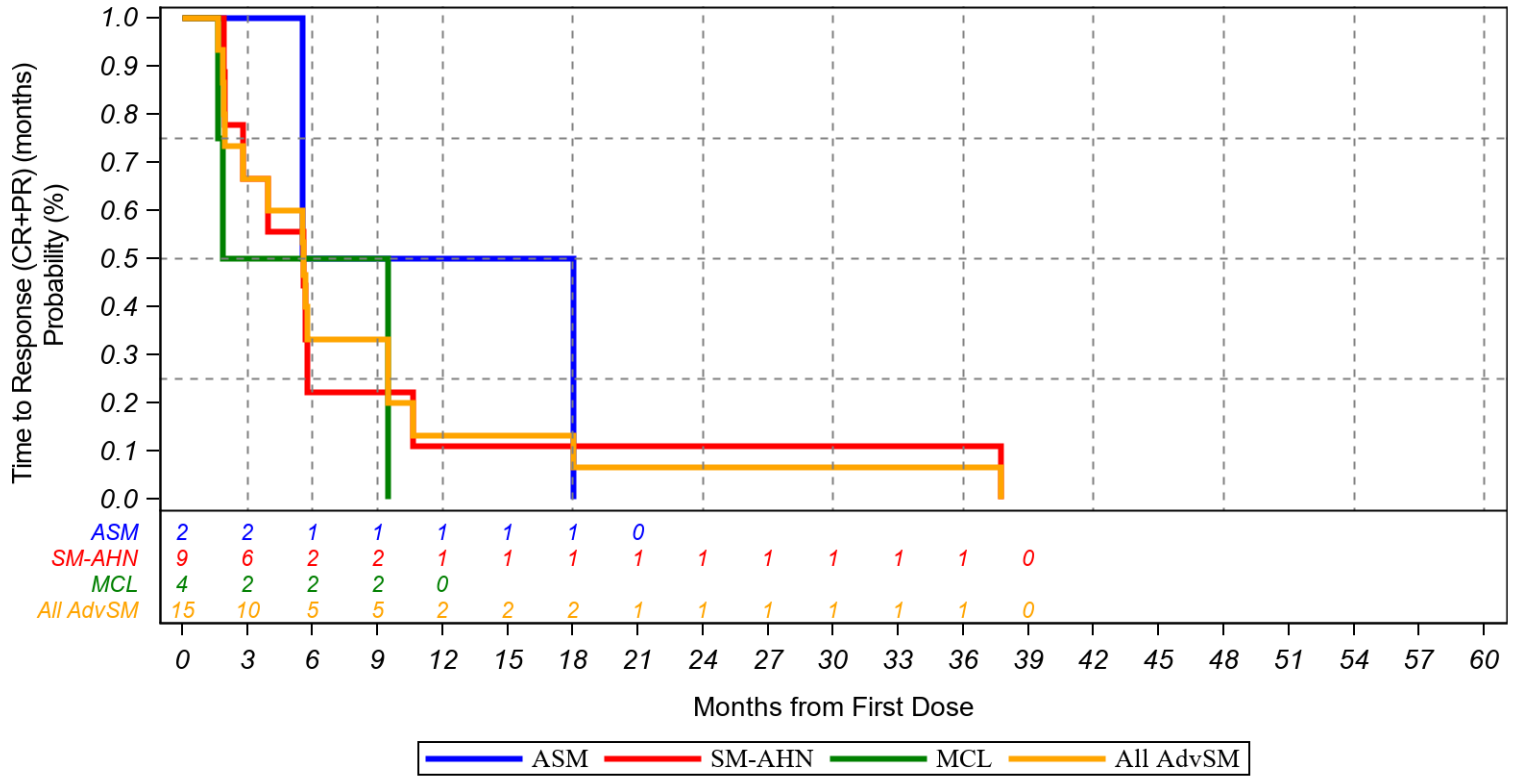


Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR+CI)
Study BLU-285-2101
Starting Dose: 200 mg and 300 mg

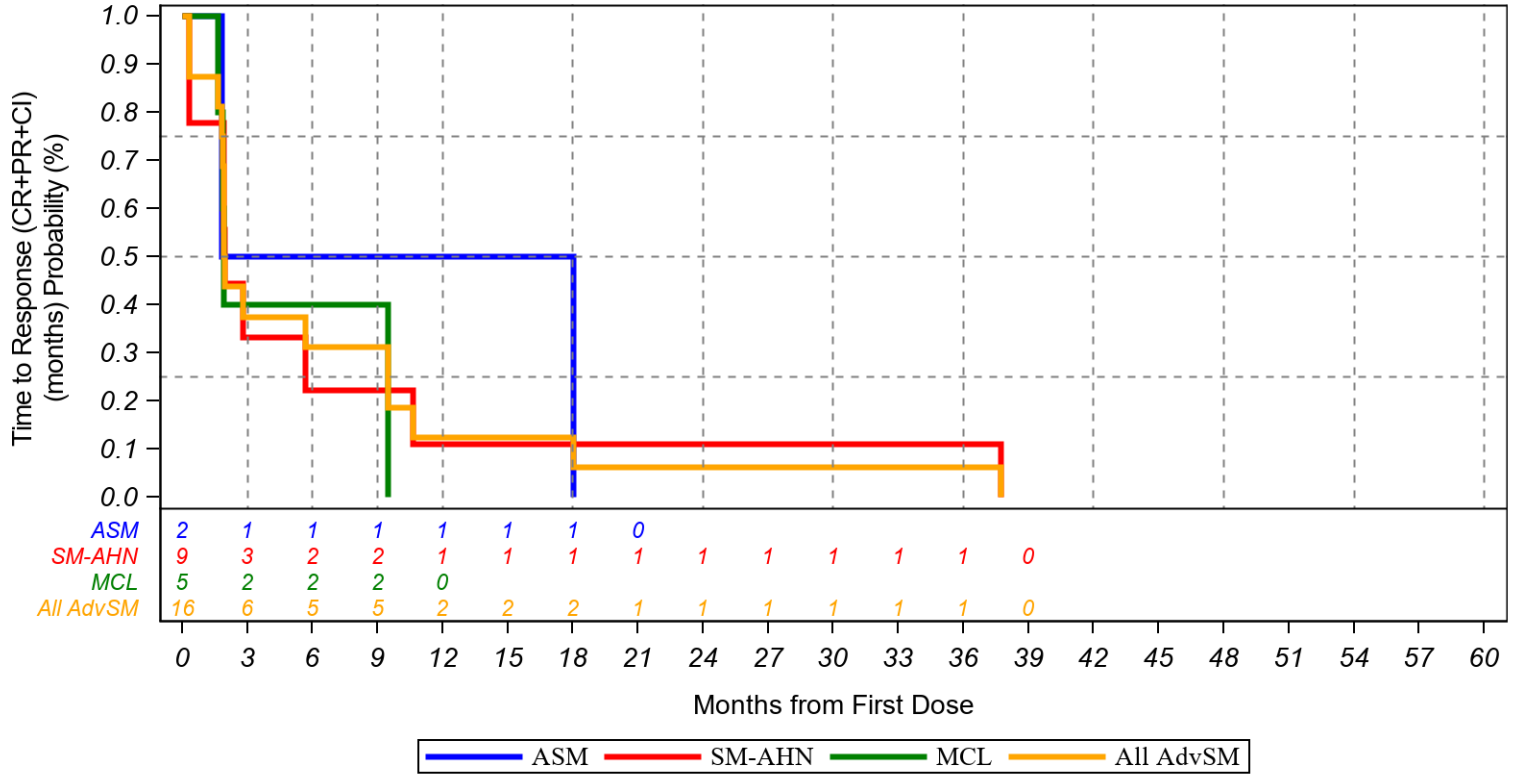


Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR)
Study BLU-285-2101
Starting Dose: 400 mg

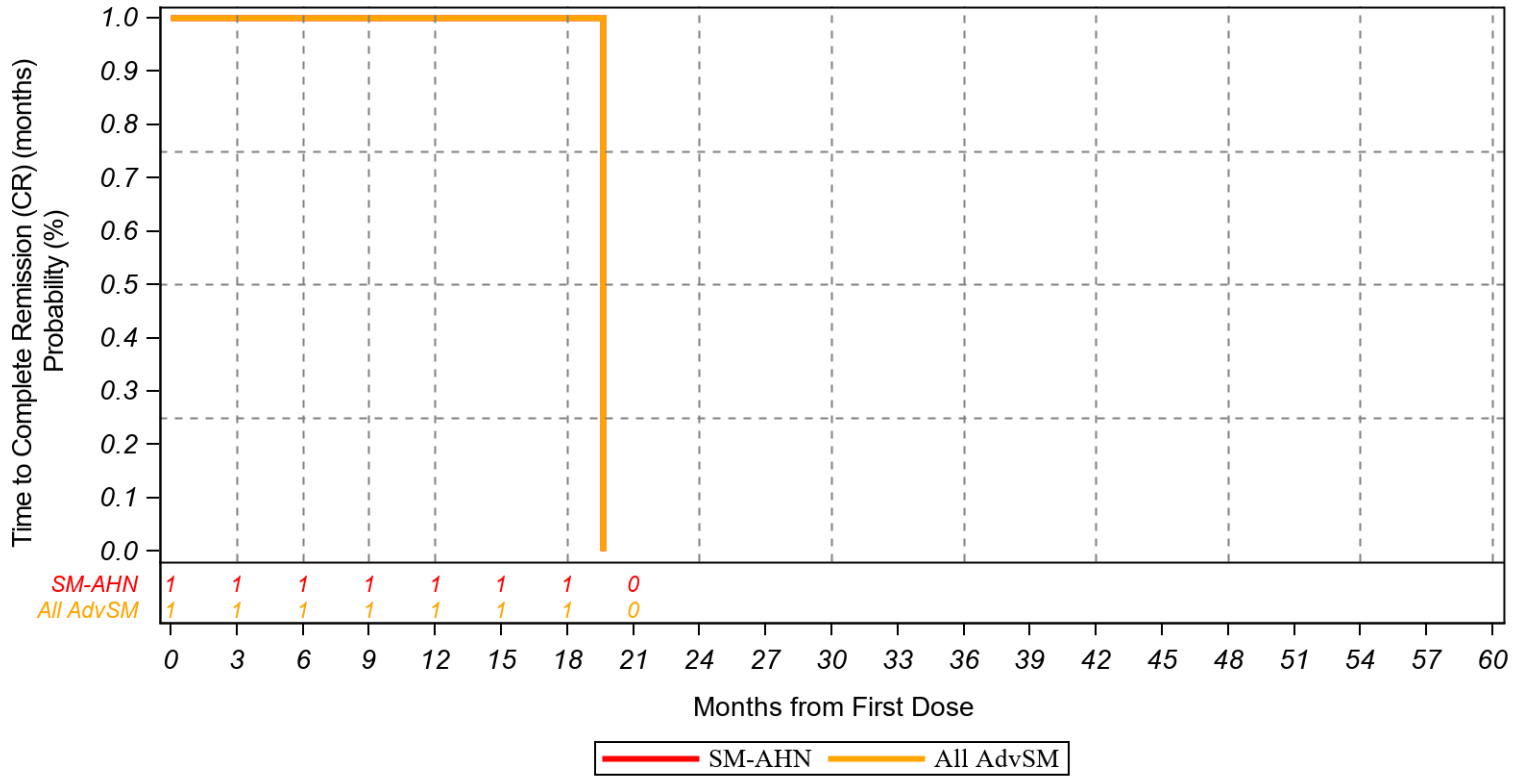


Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR)
Study BLU-285-2101
Starting Dose: 400 mg

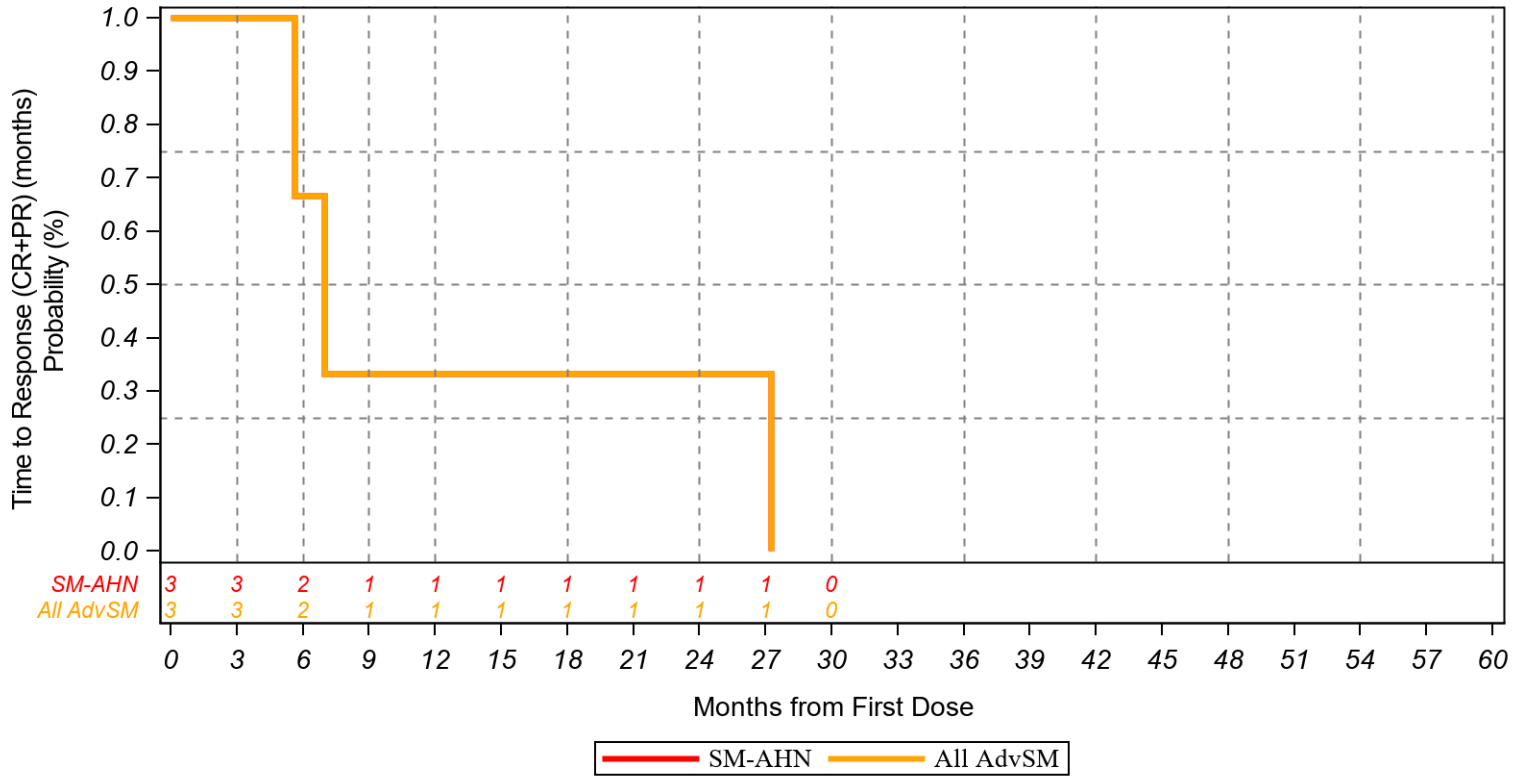


Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR+CI)
Study BLU-285-2101
Starting Dose: 400 mg

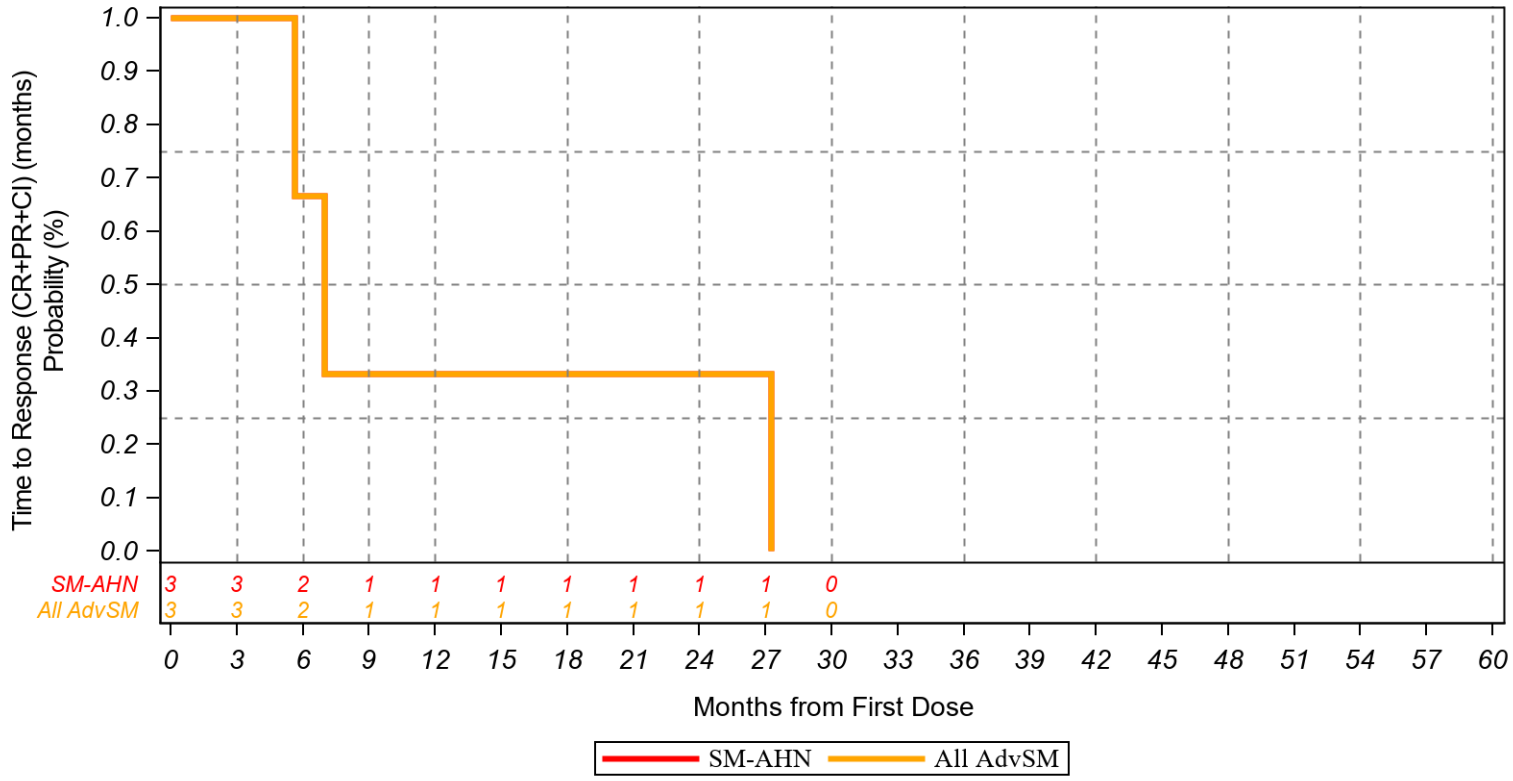


Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR)
Study BLU-285-2202
Starting Dose: Overall

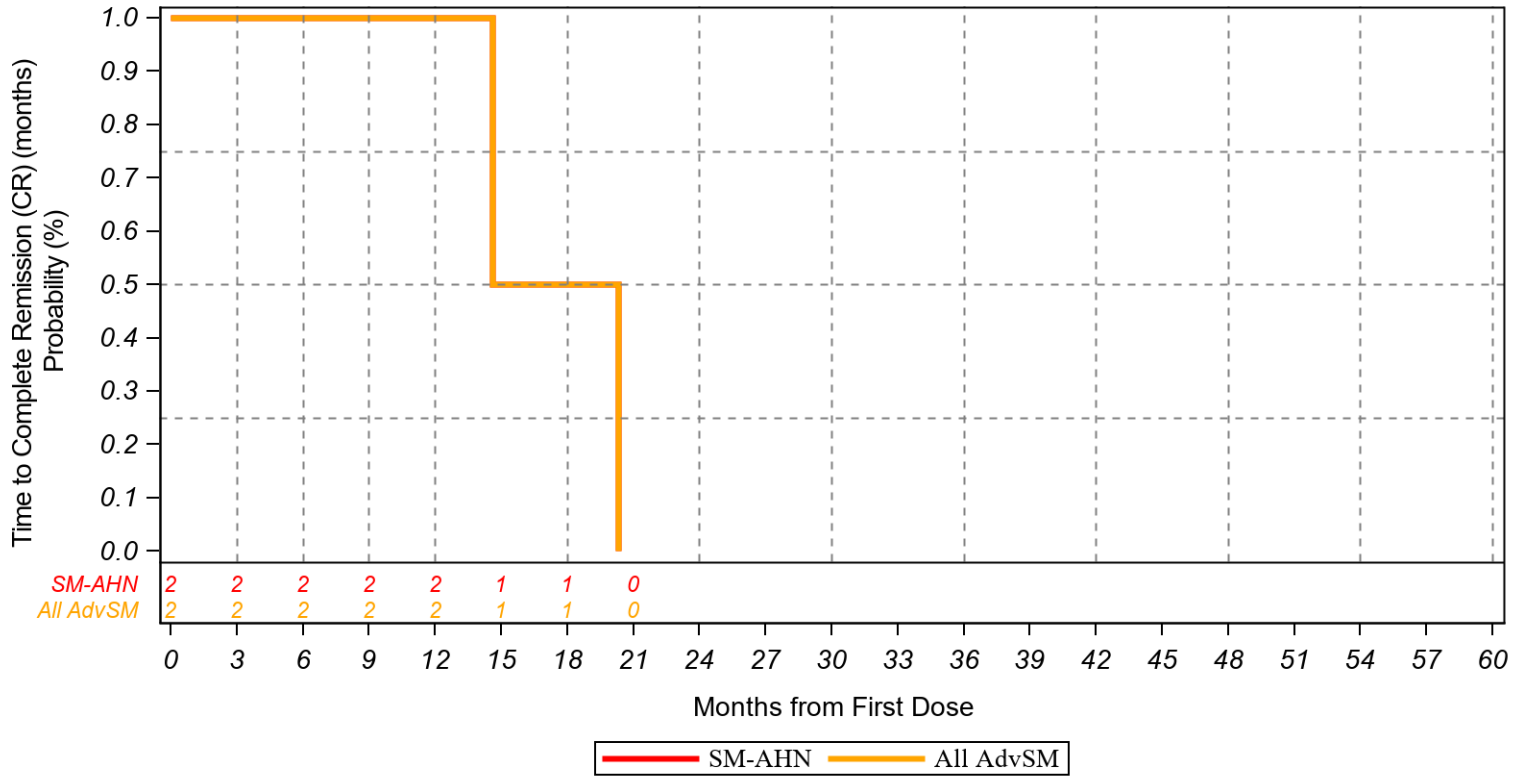


Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR)
Study BLU-285-2202
Starting Dose: Overall

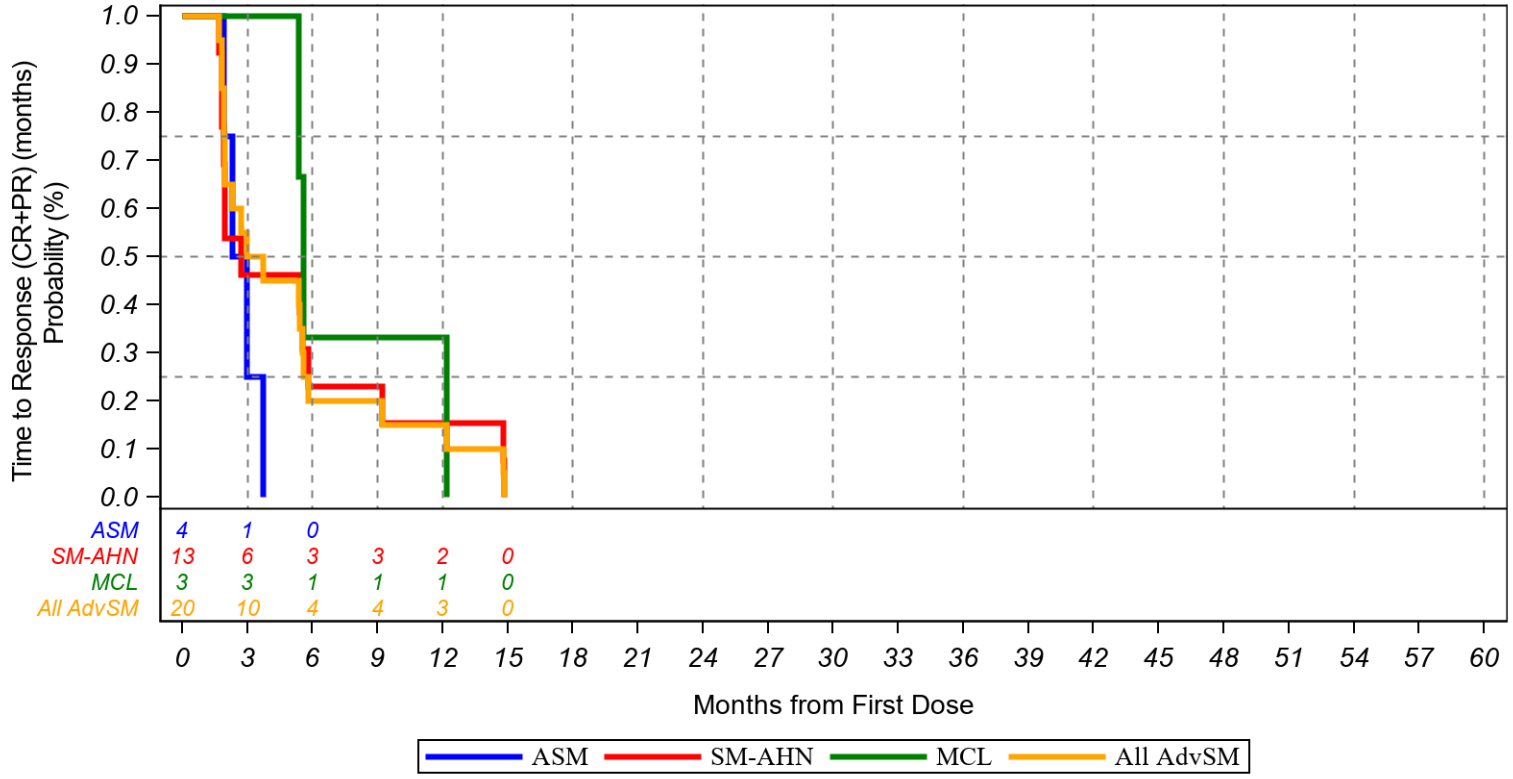


Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR+CI)
Study BLU-285-2202
Starting Dose: Overall

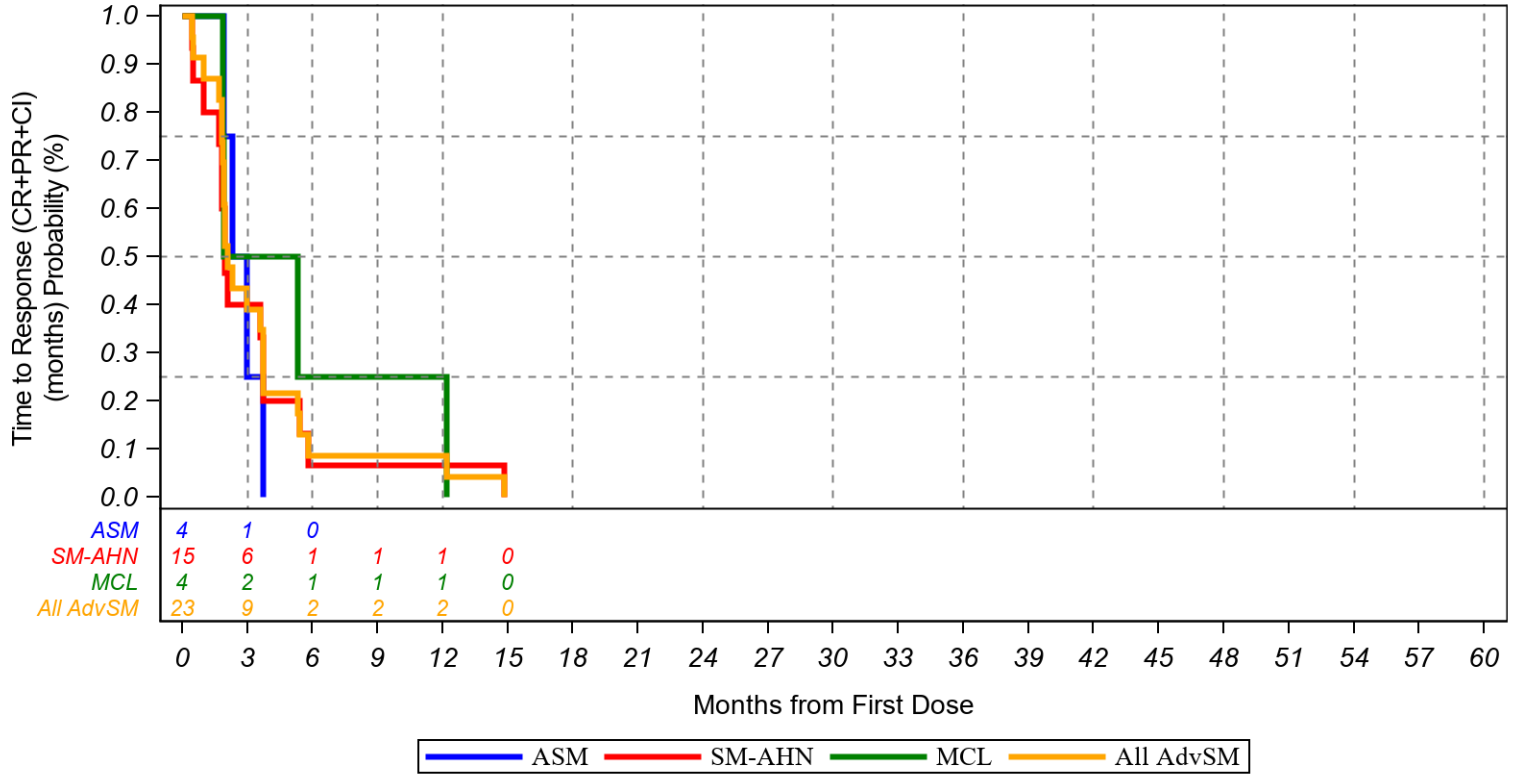


Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR)
Study BLU-285-2202
Starting Dose: 200 mg

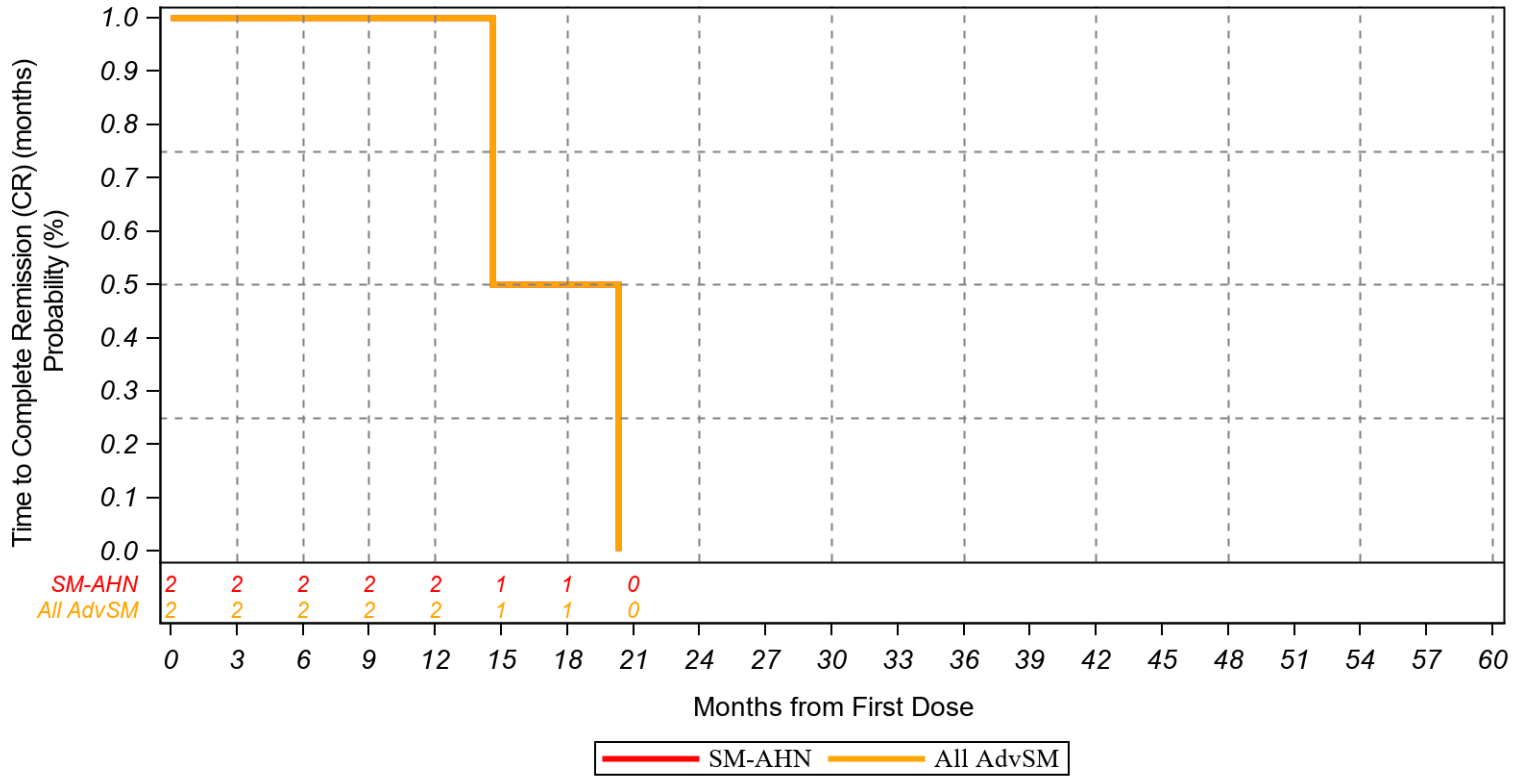


Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR)
Study BLU-285-2202
Starting Dose: 200 mg

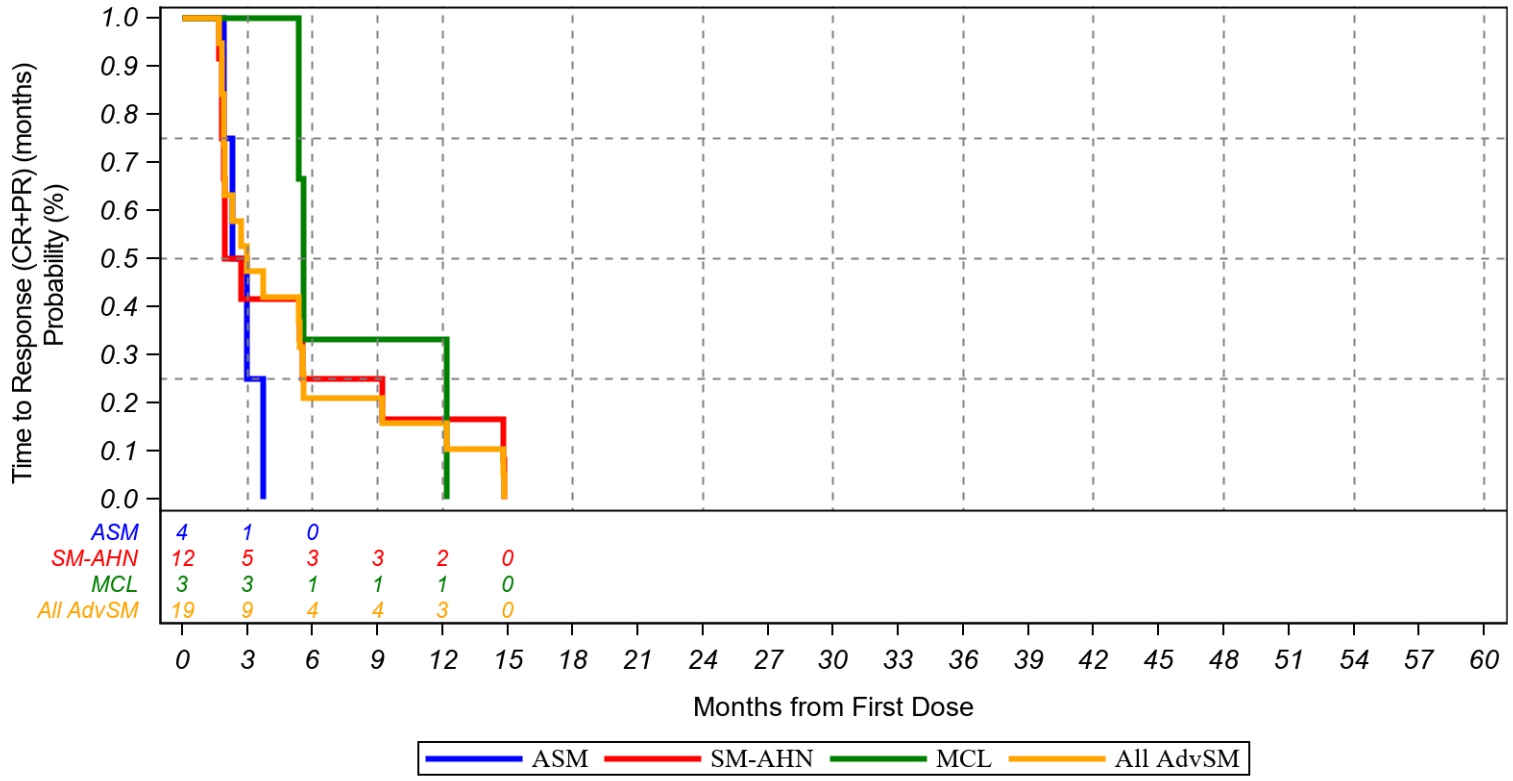


Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR+CI)
Study BLU-285-2202
Starting Dose: 200 mg

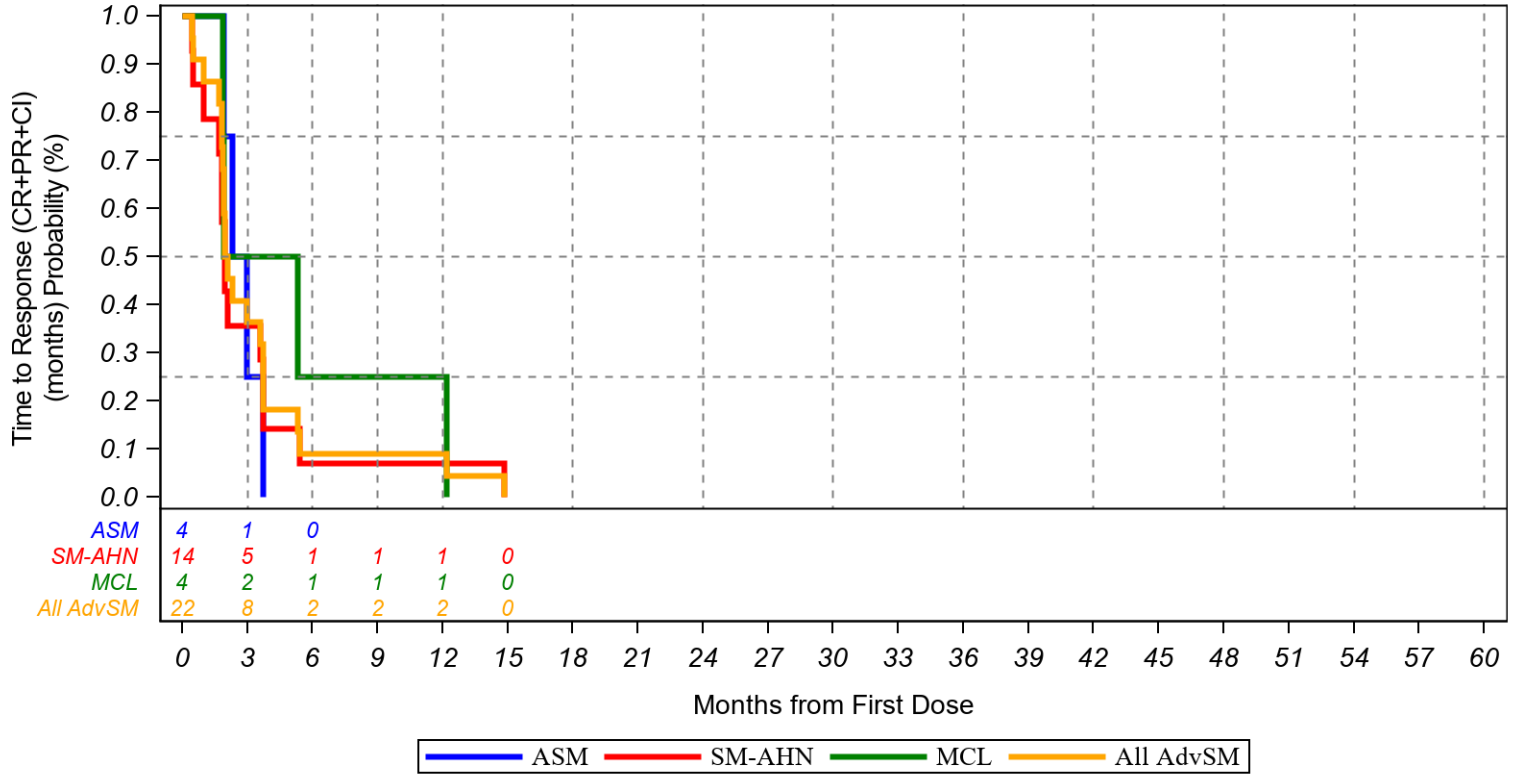


Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall

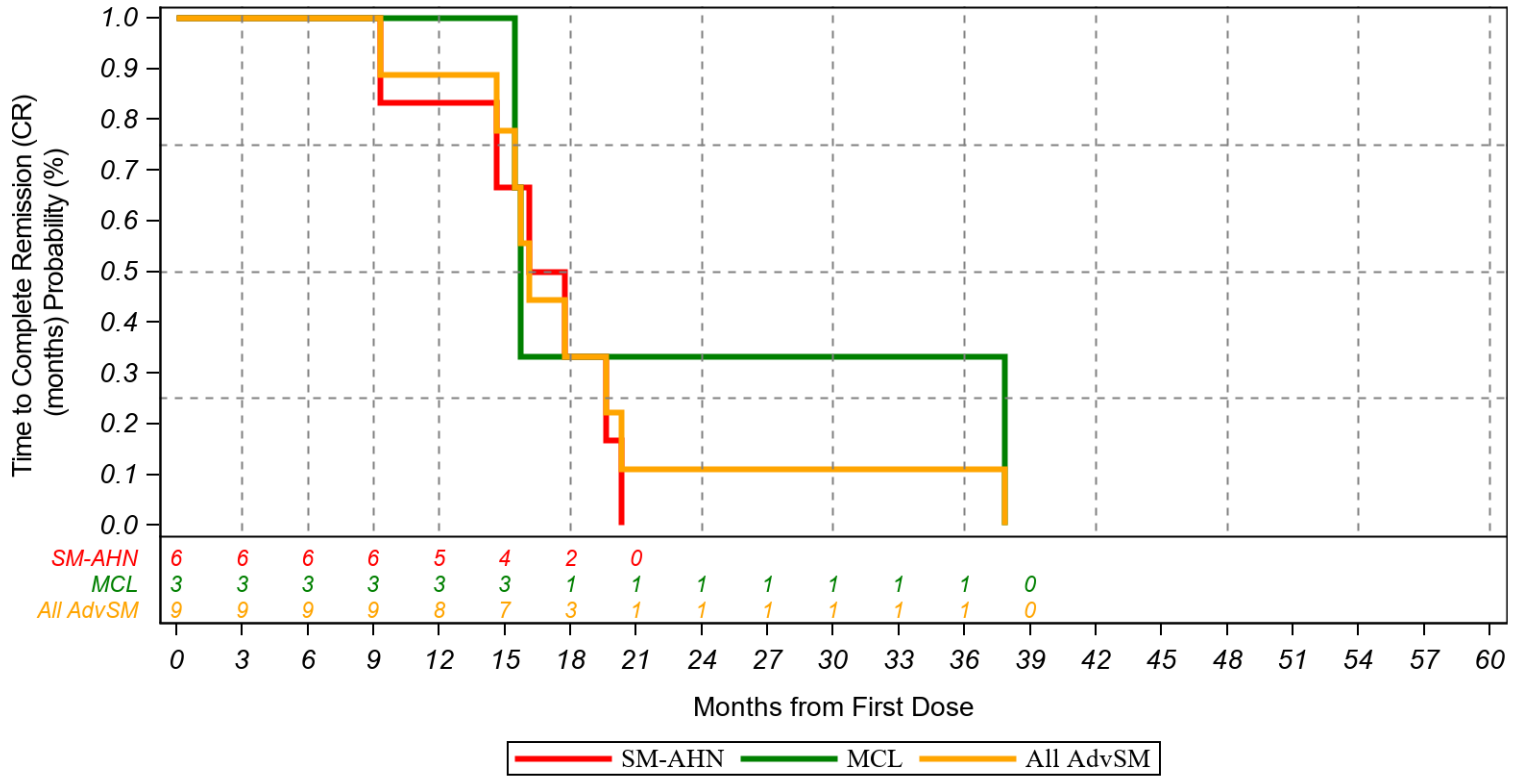


Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall

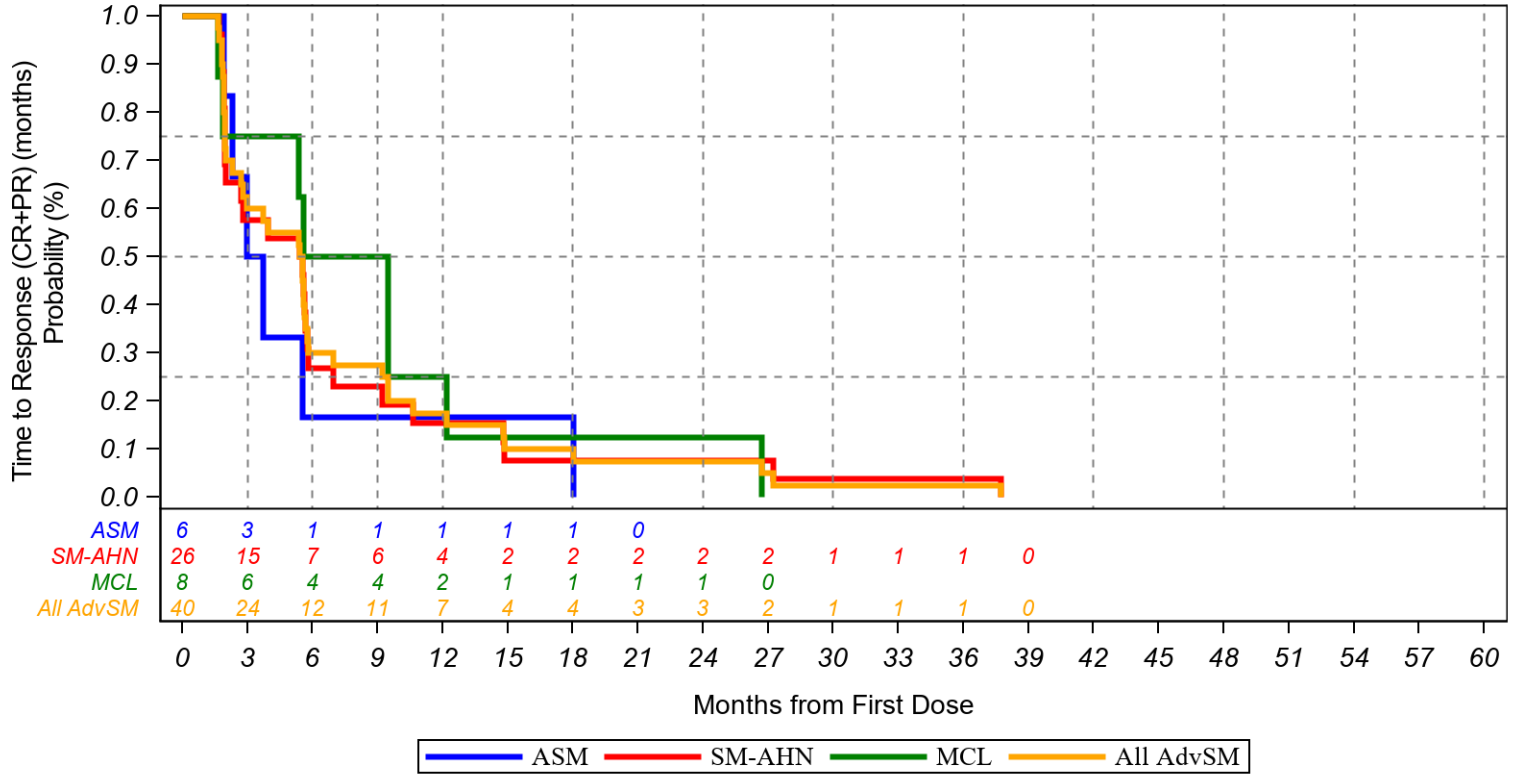


Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall

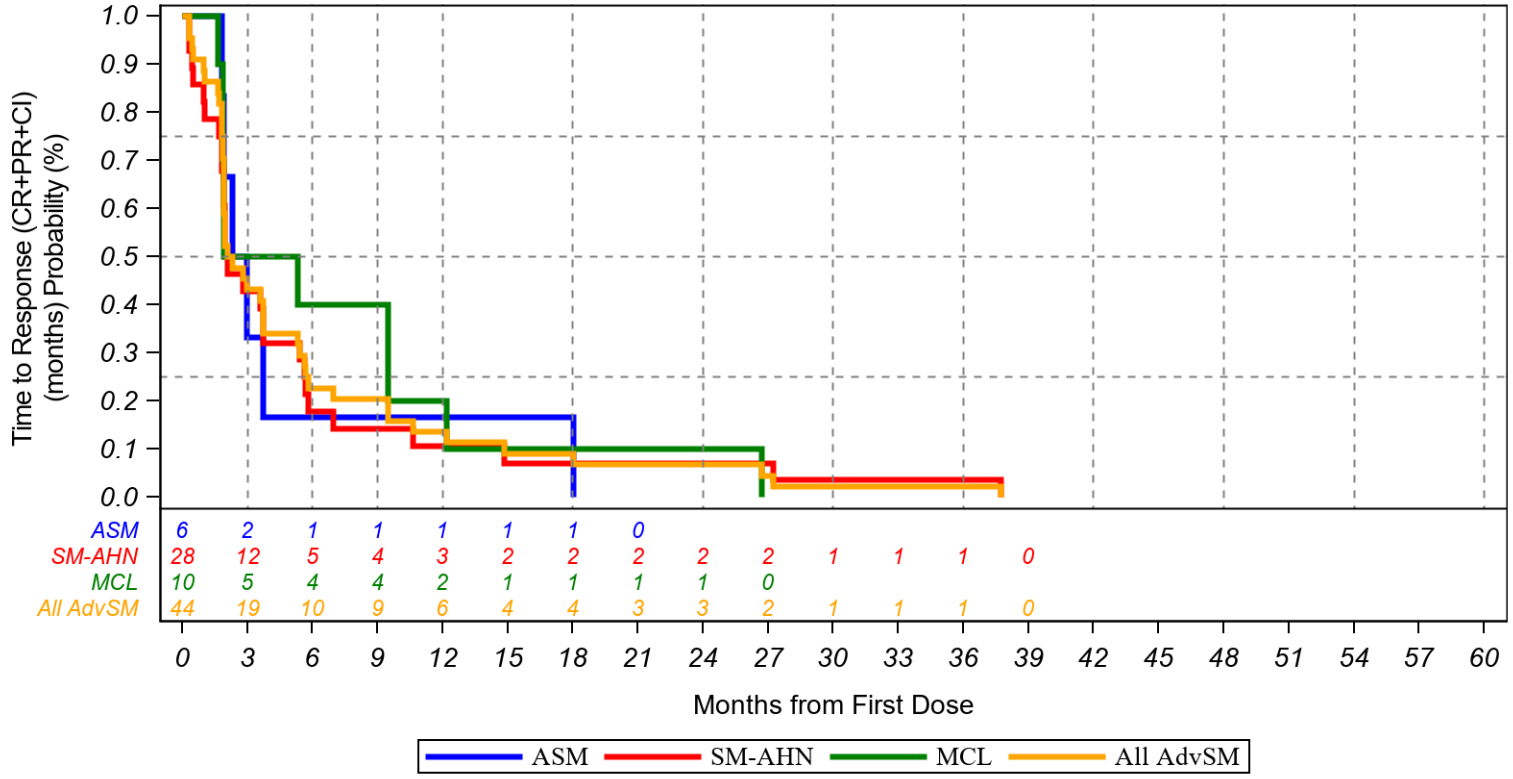


Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg

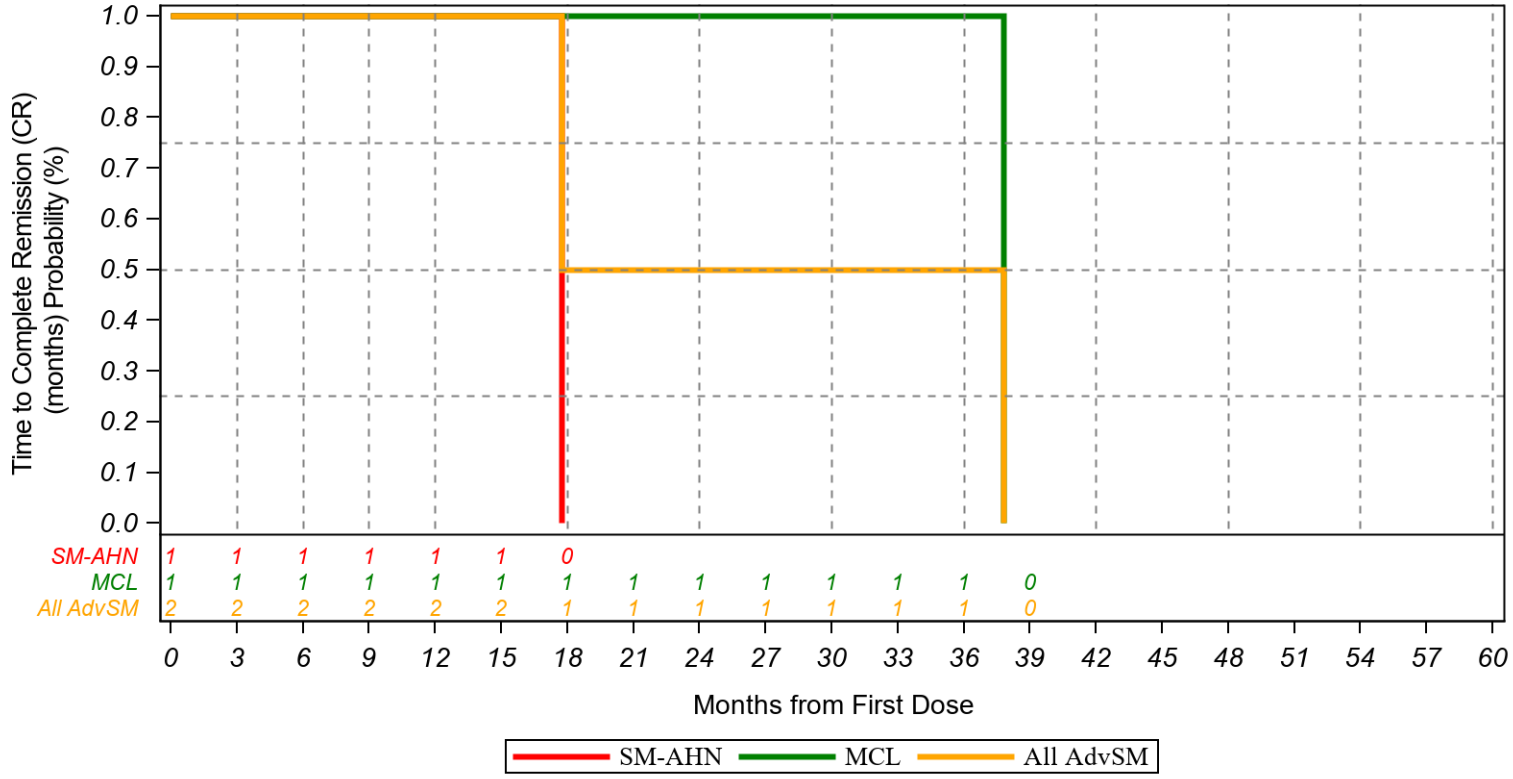


Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg

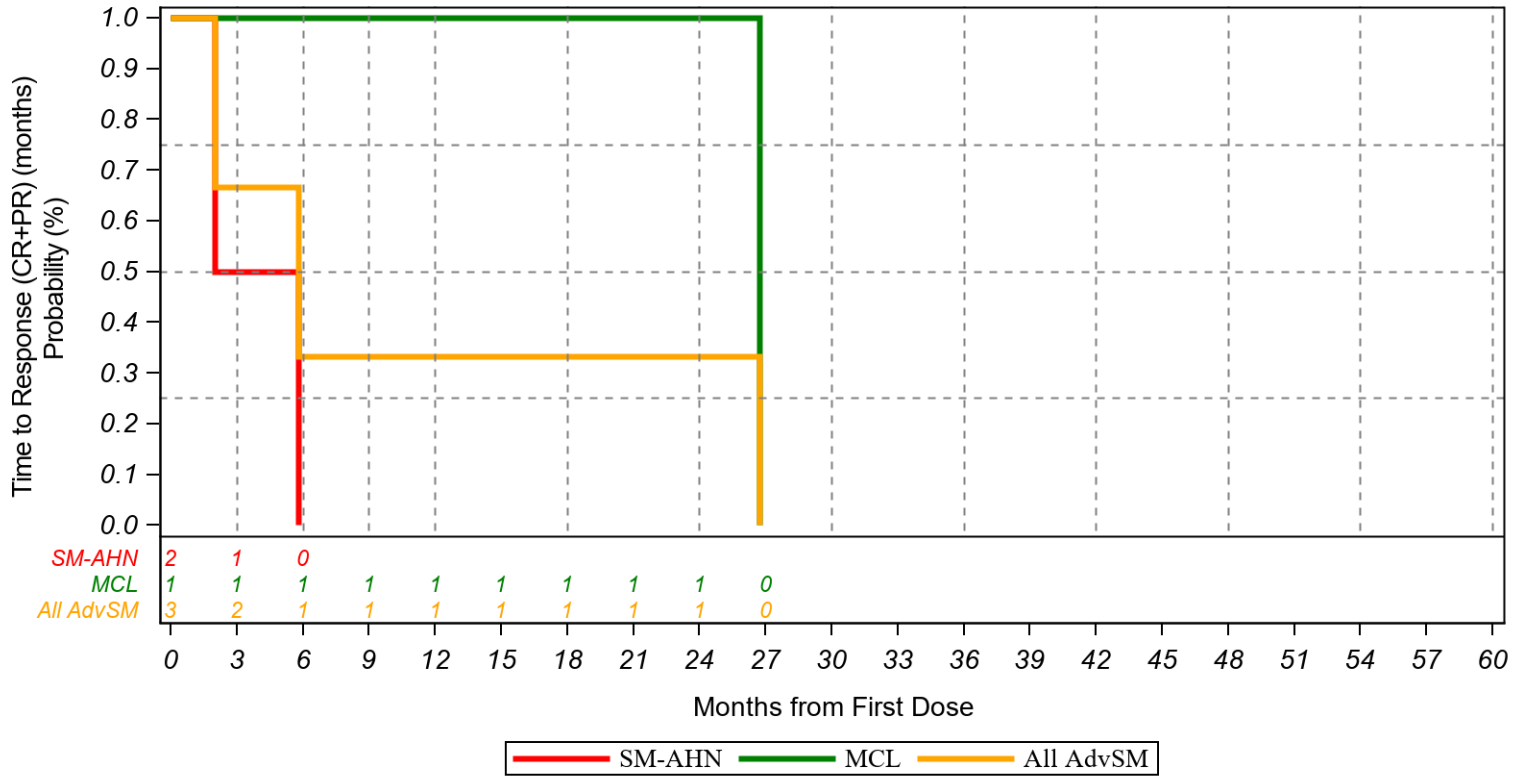


Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg

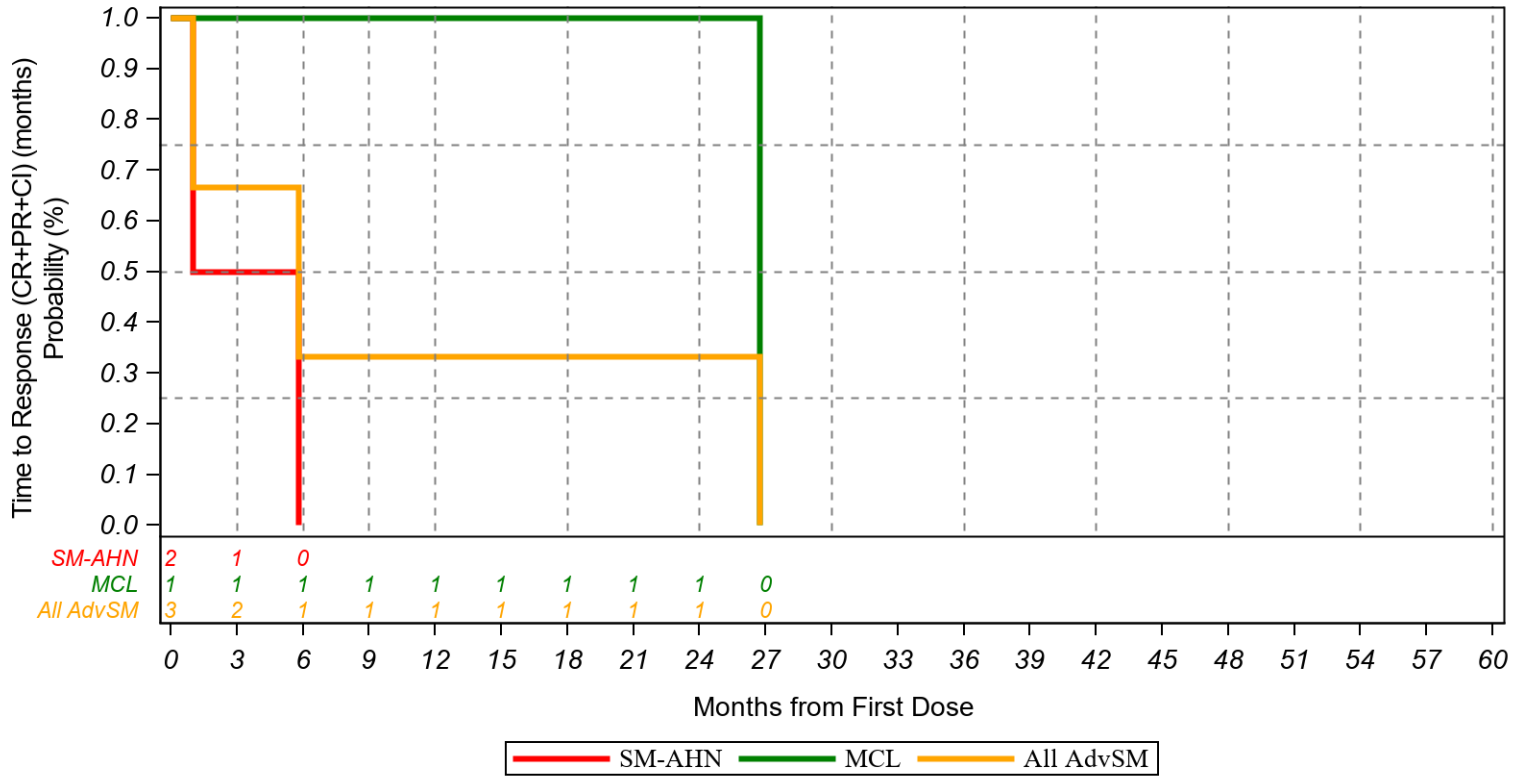


Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg

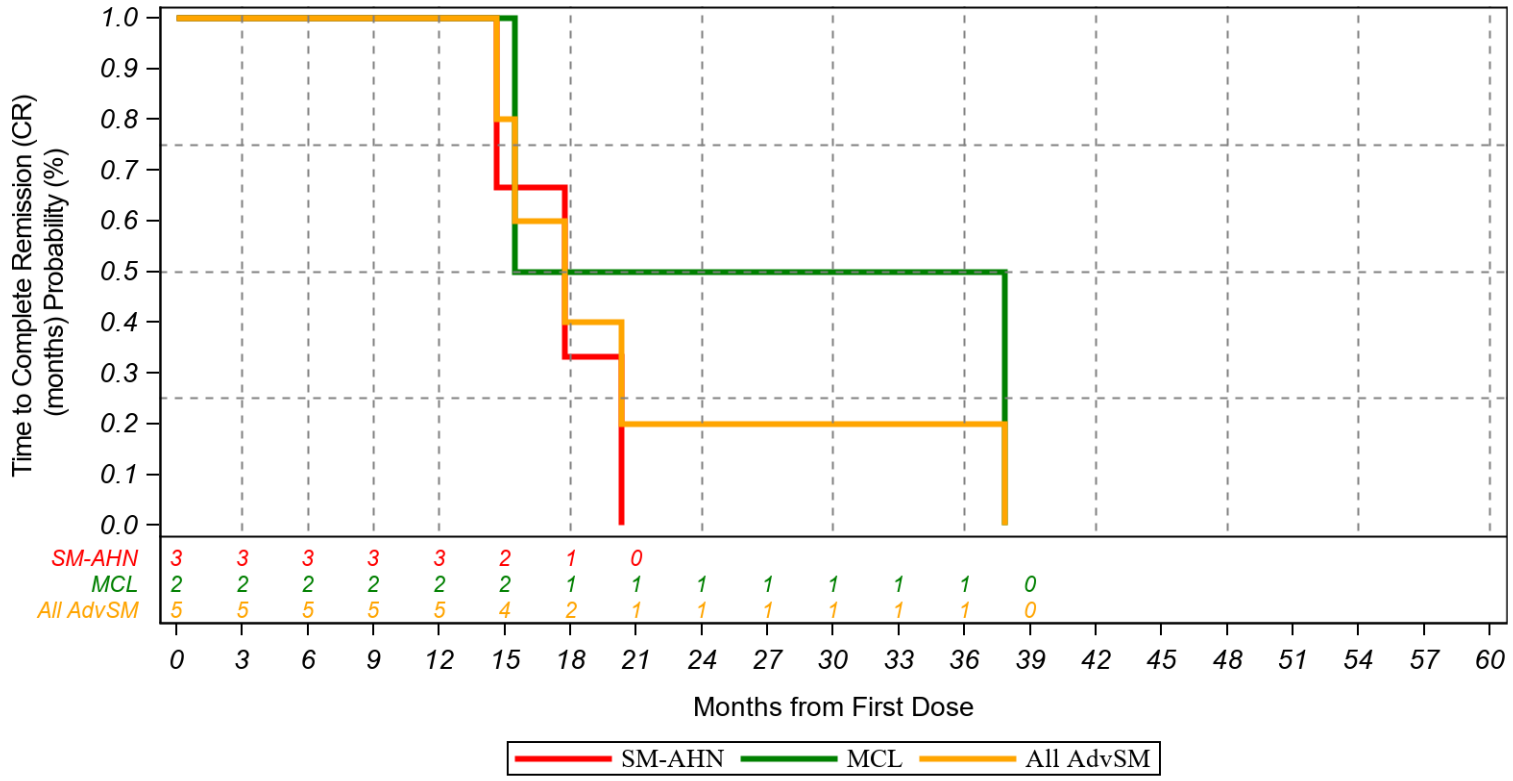
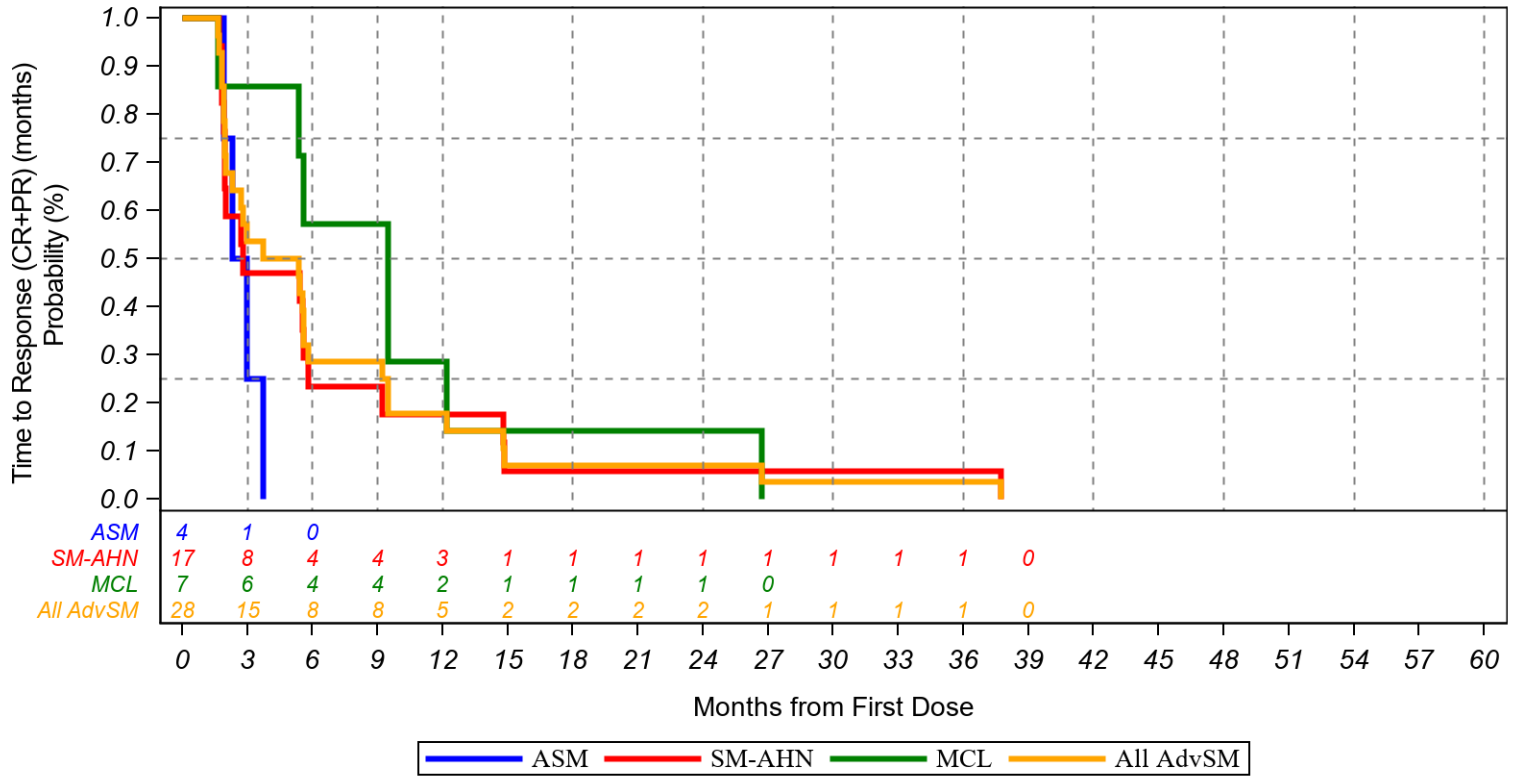


Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg



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BLU-285 SM Germany HTA Analysis
Cutoff date: 20apr2021

Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg

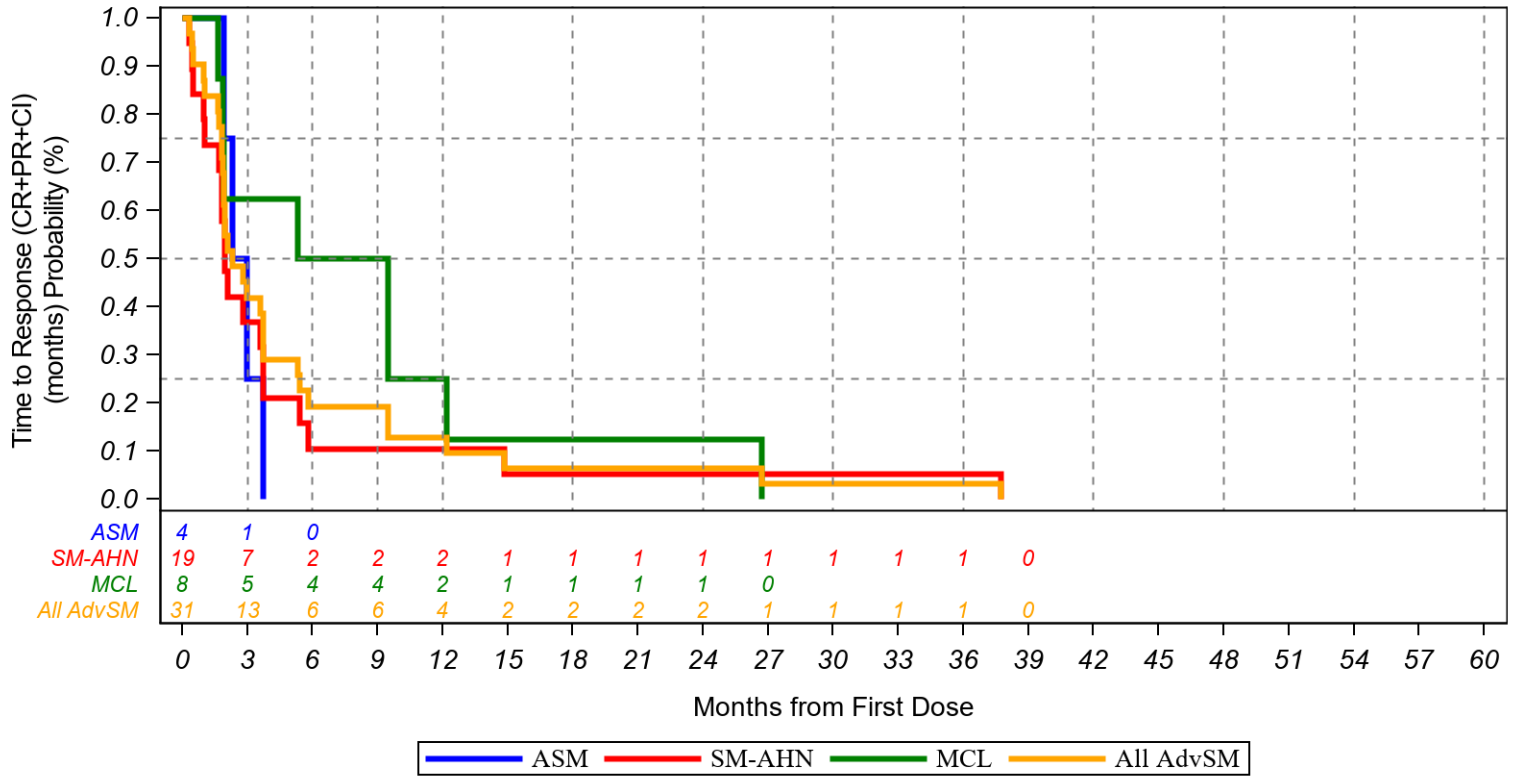

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Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg

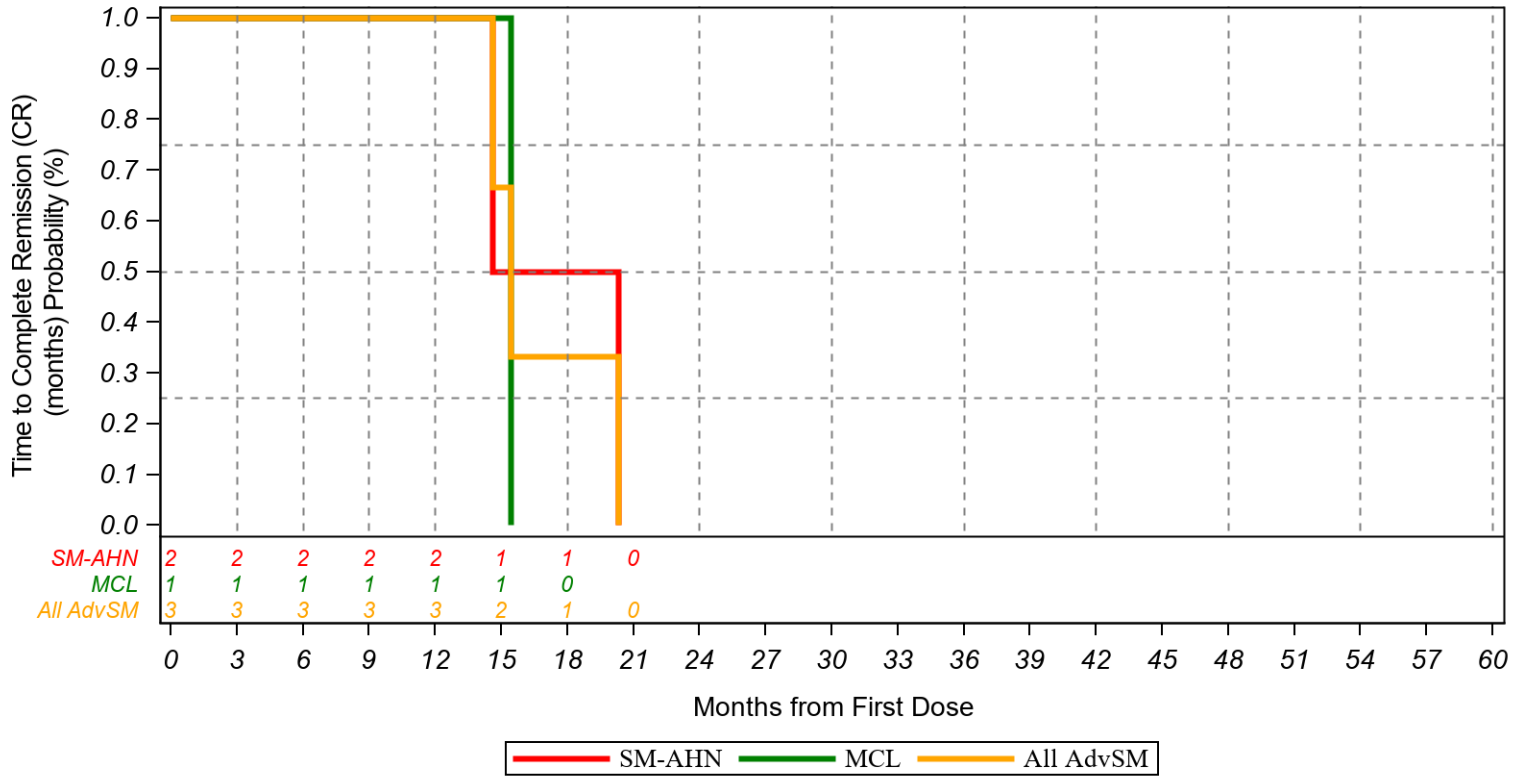

Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg

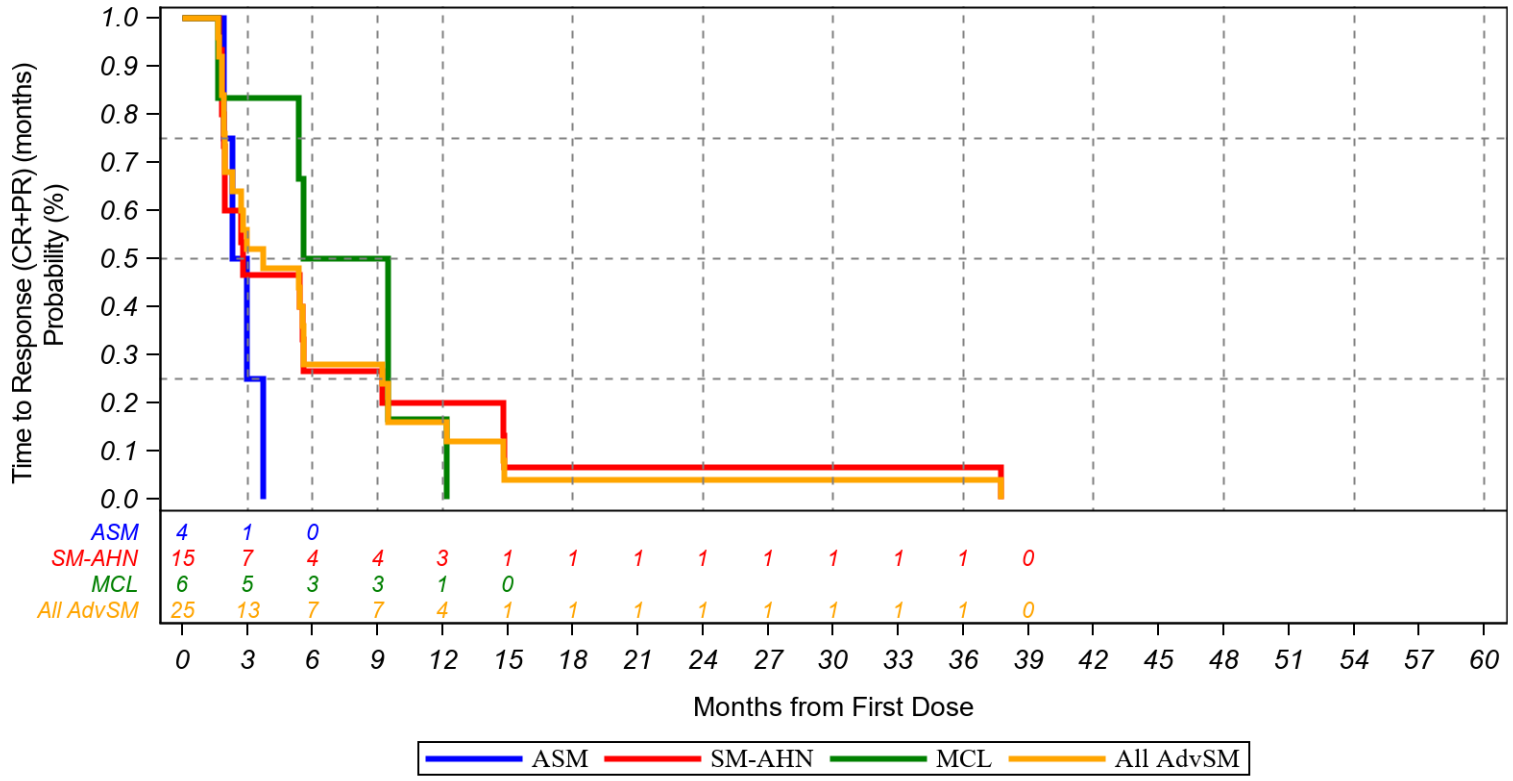

Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg

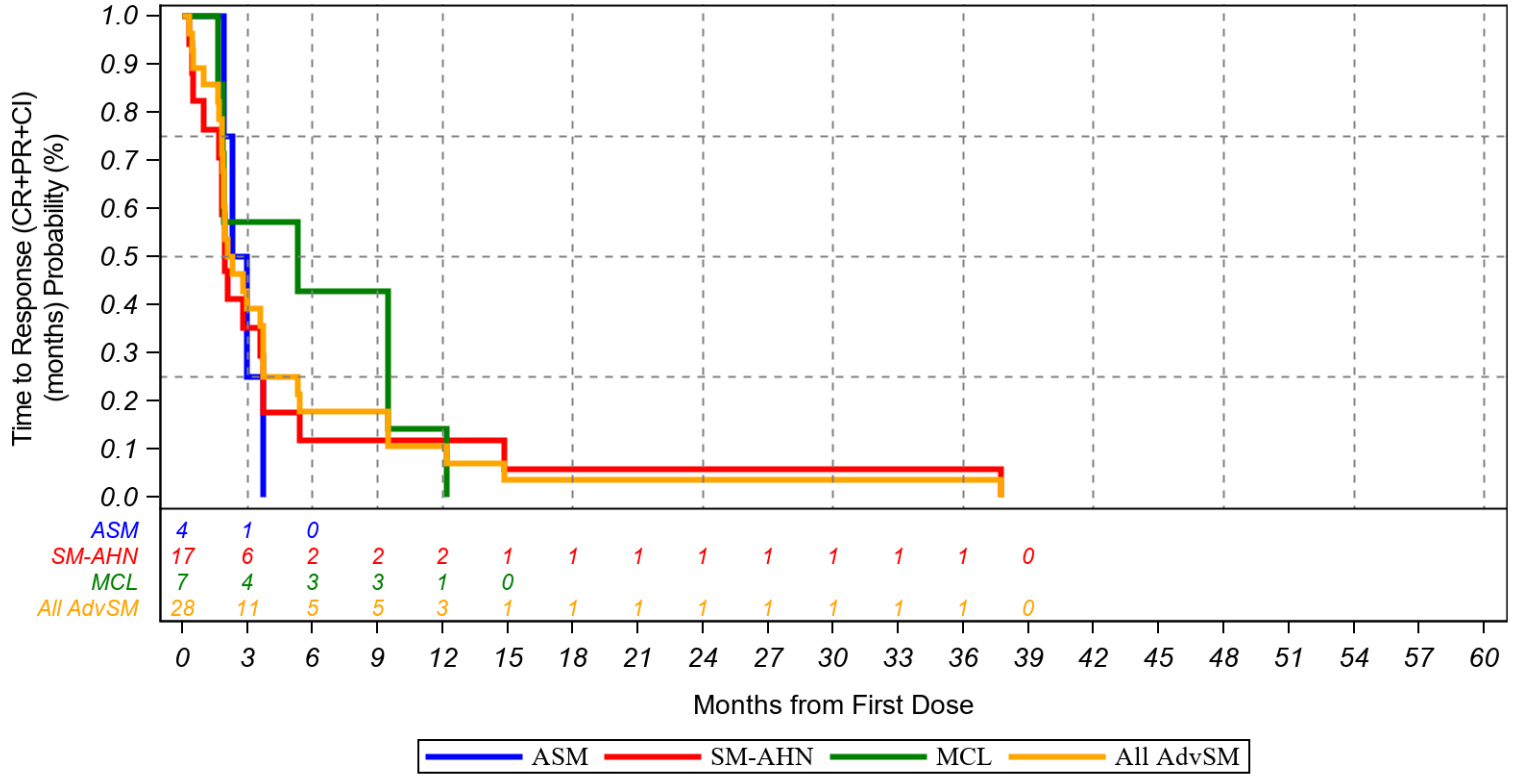

Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg

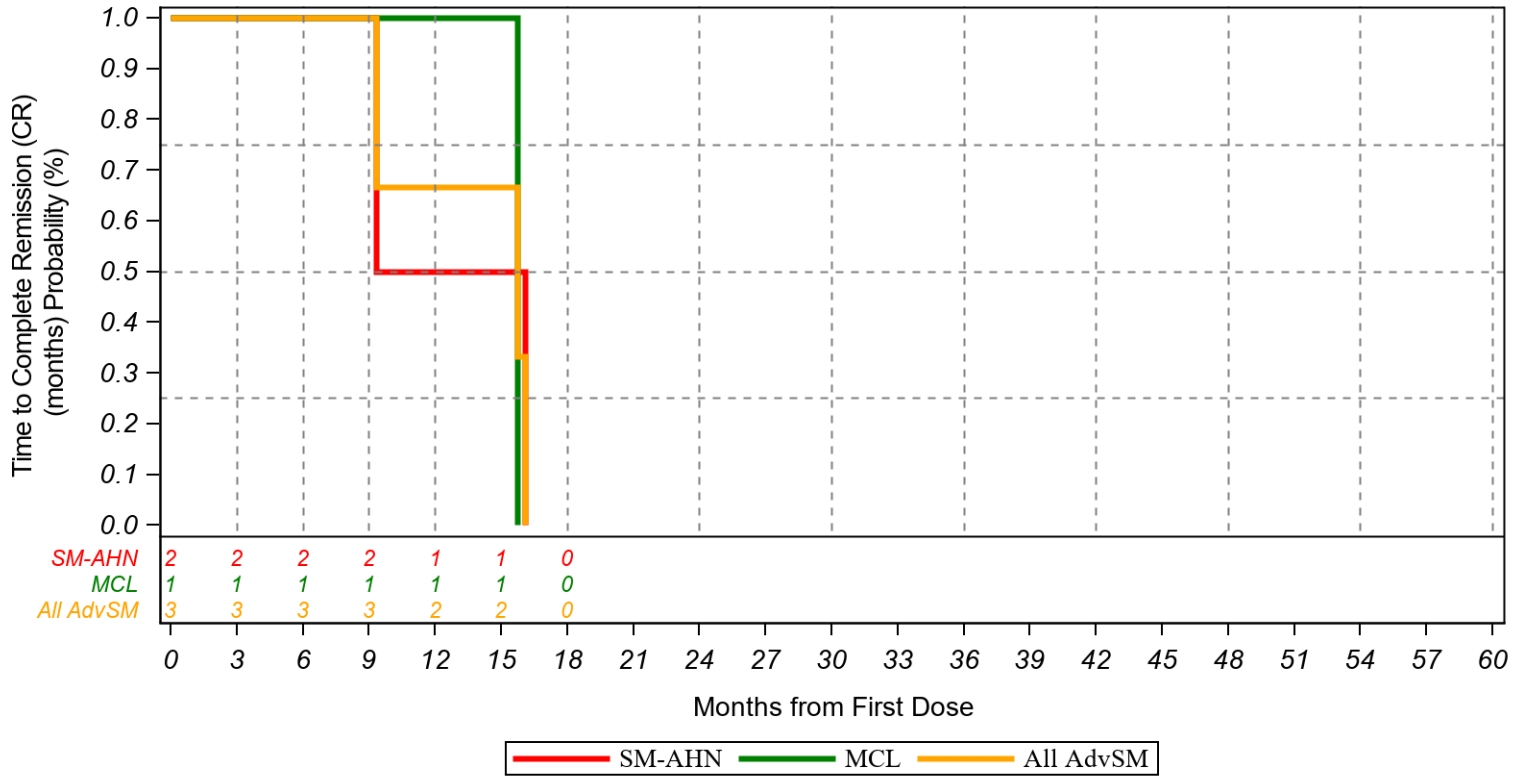

Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg

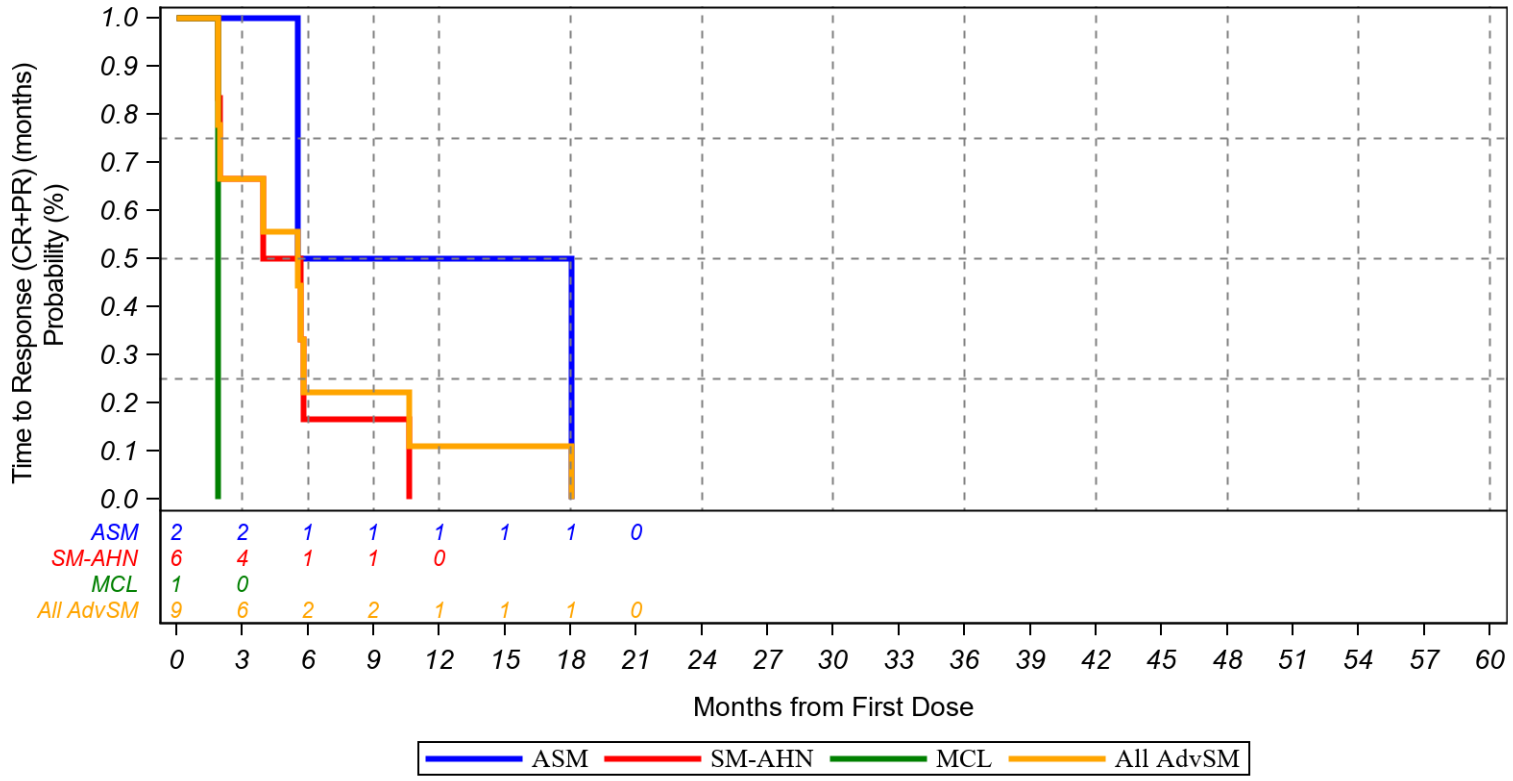

Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg

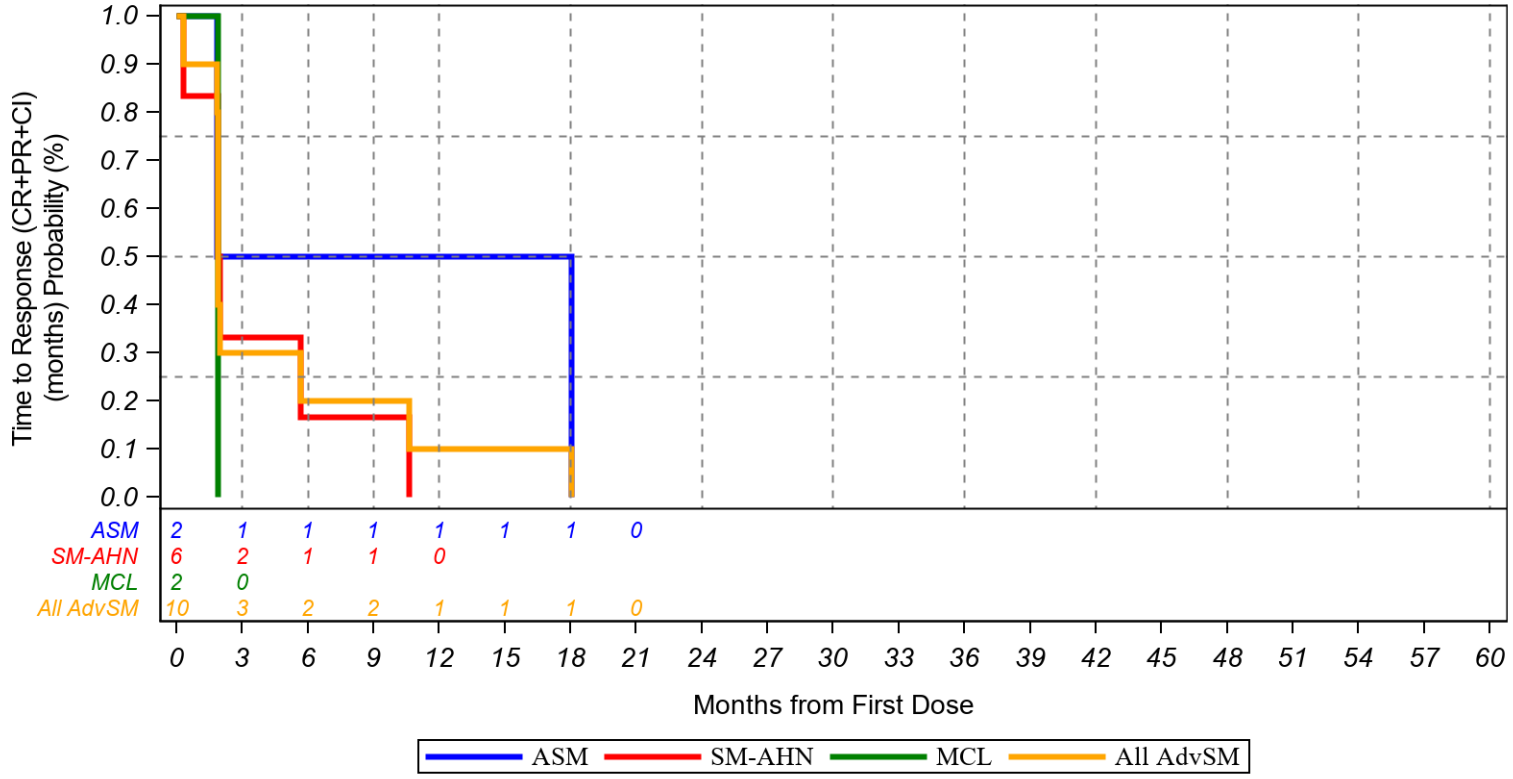

Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg

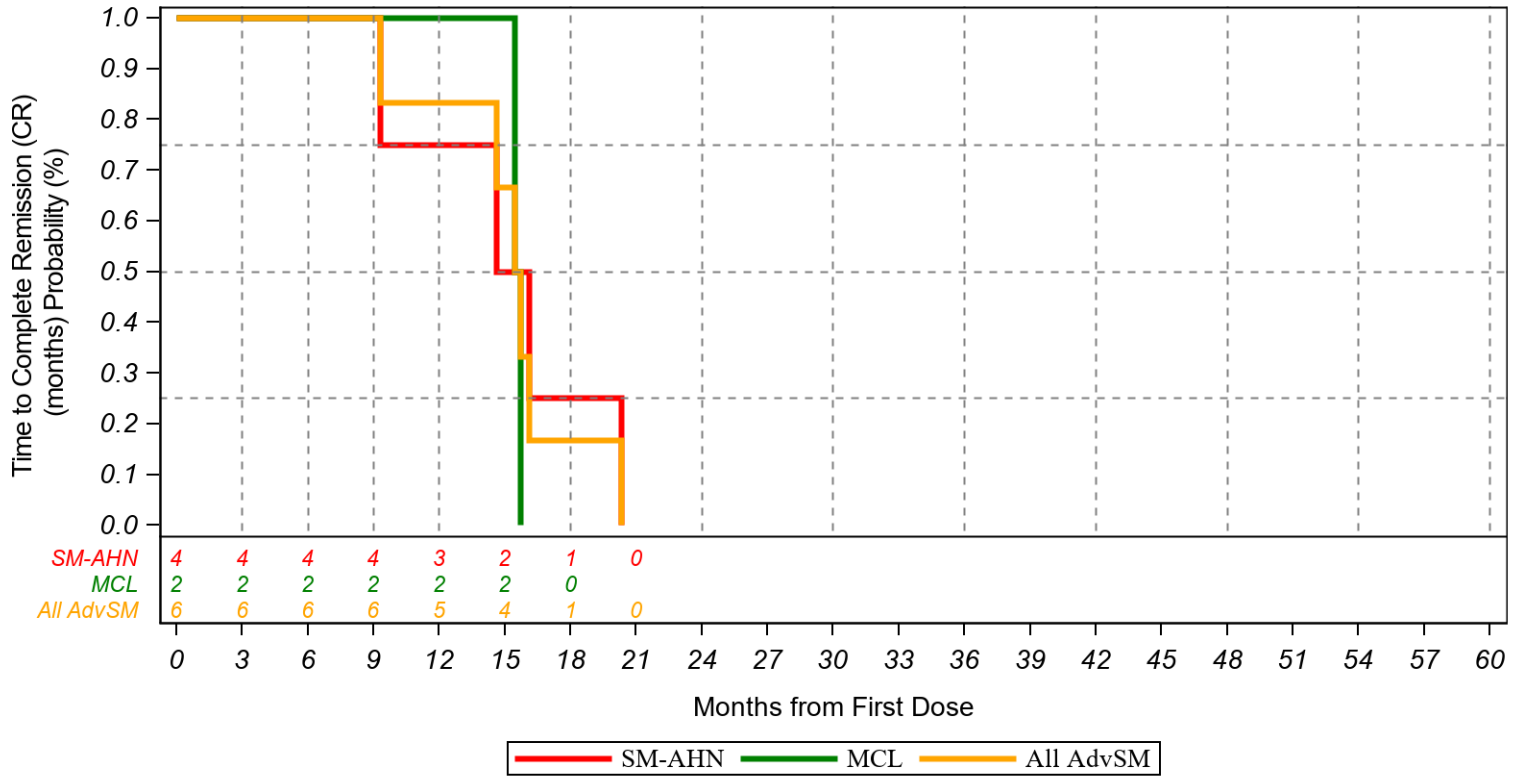

Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg

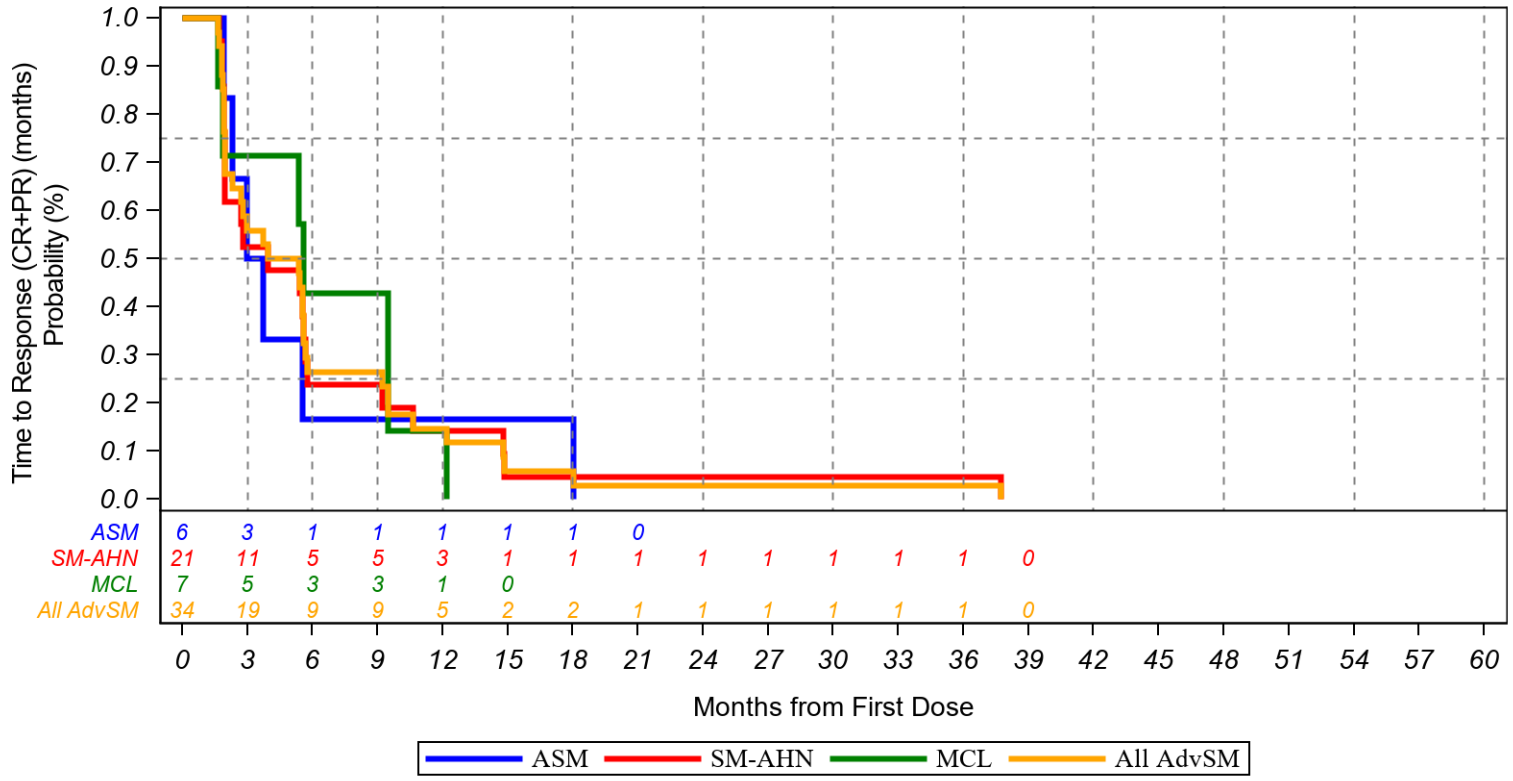

Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg

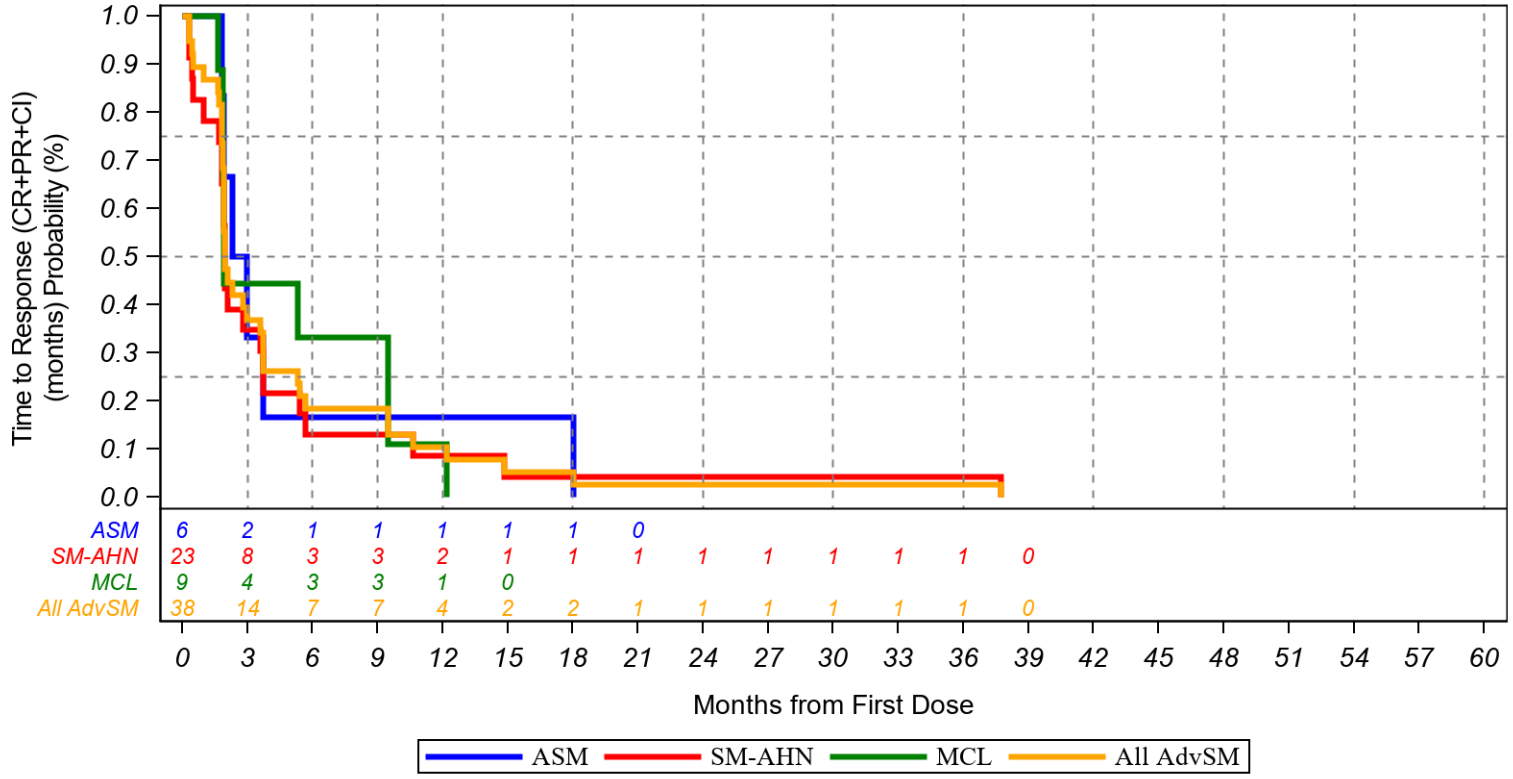

Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg

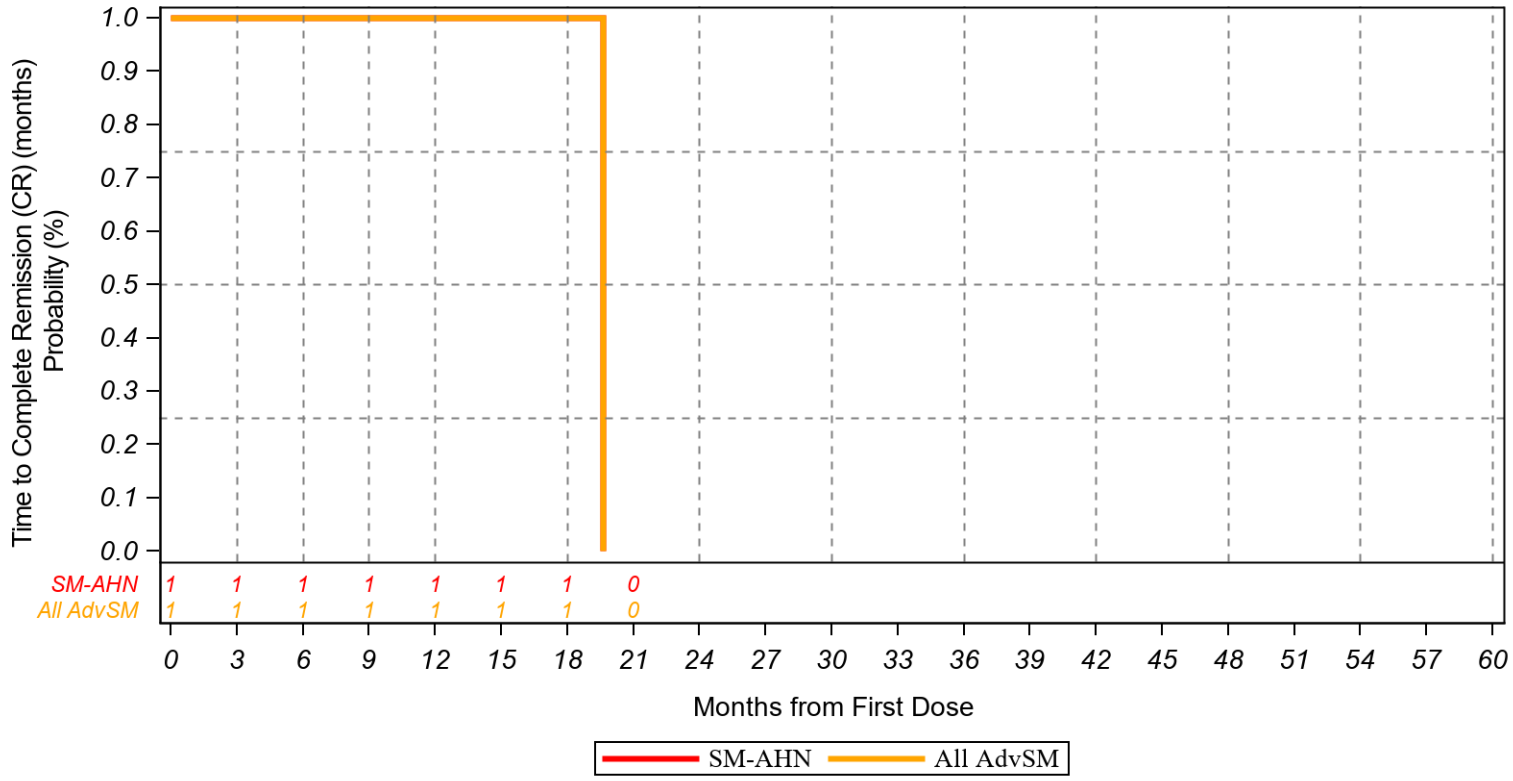

Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg

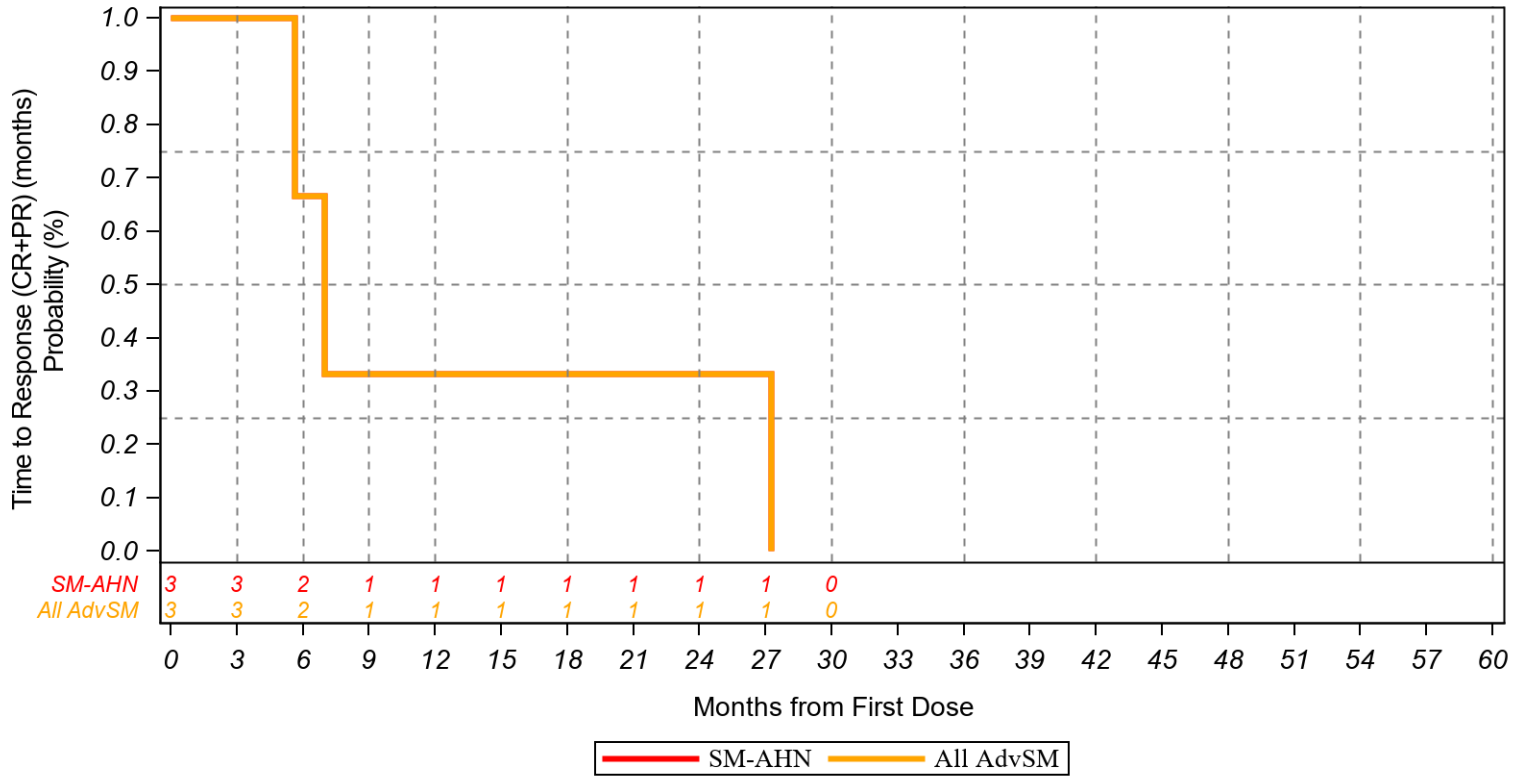

Figure 35.2.2.9
Kaplan-Meier Curves of Algorithm Time to Response & Time to Complete Remission by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Responders (CR+PR+CI)
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg

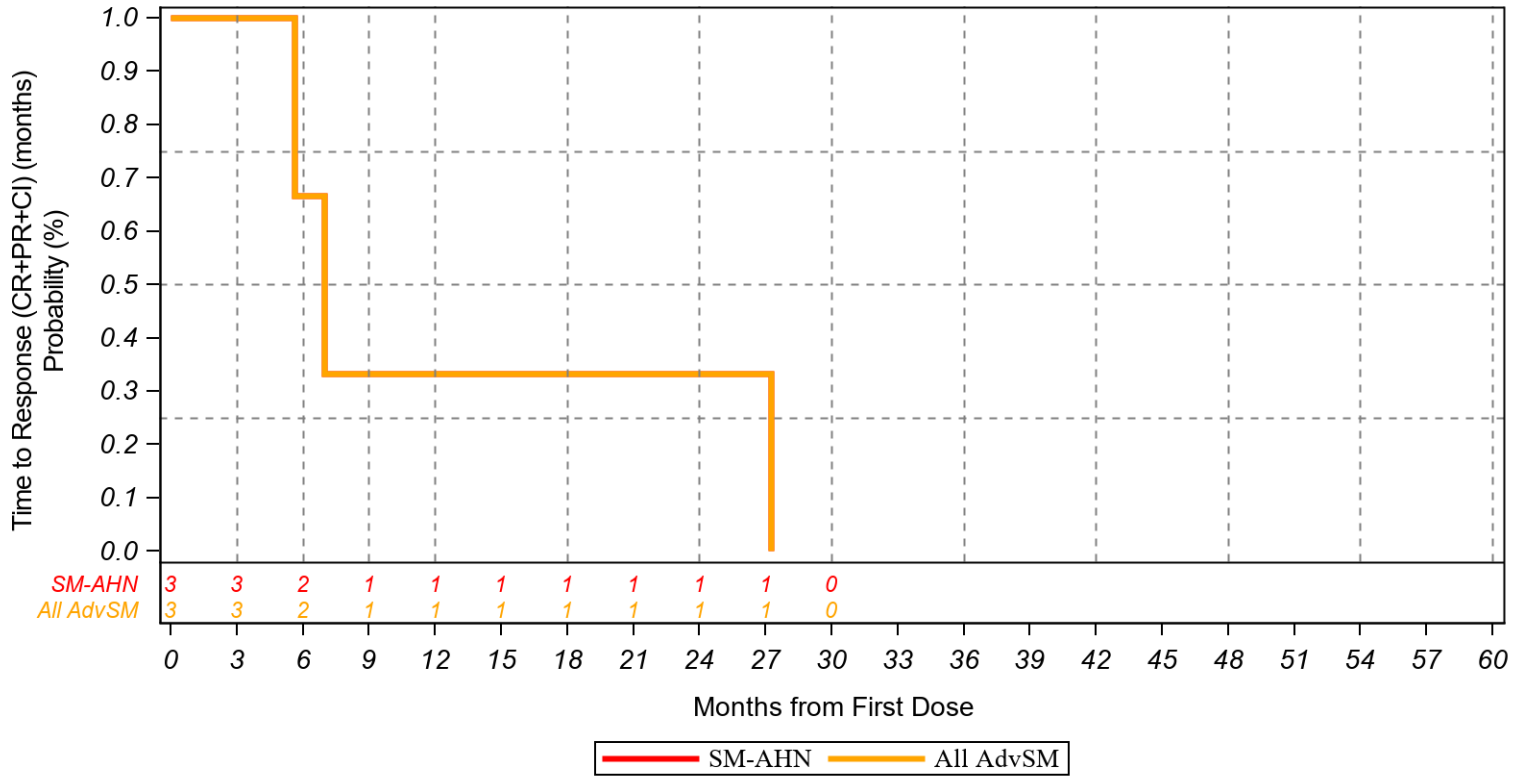

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Figure 99.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: Overall & Prior antineoplastic therapy = Yes

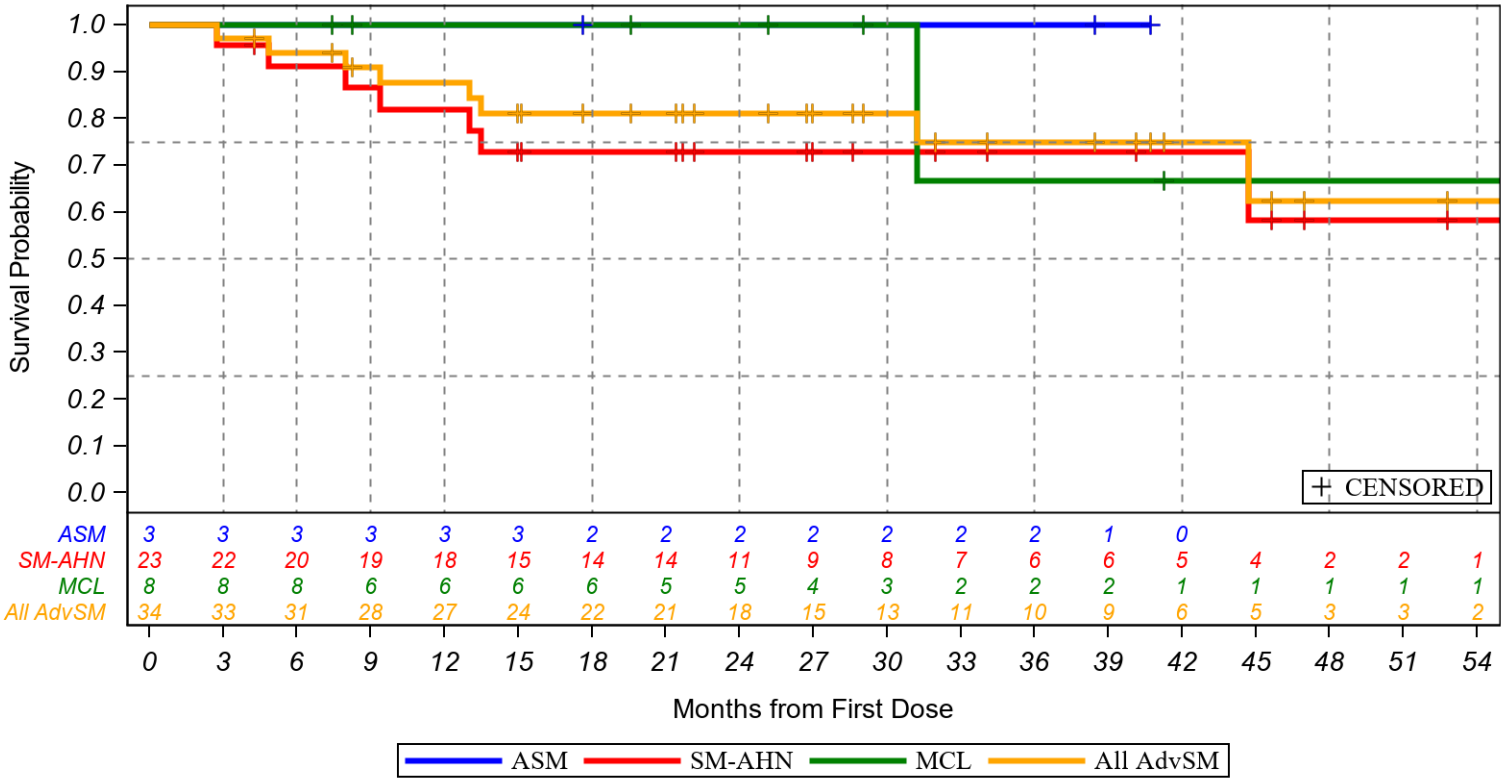

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Figure 99.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: < 200 mg & Prior antineoplastic therapy = Yes

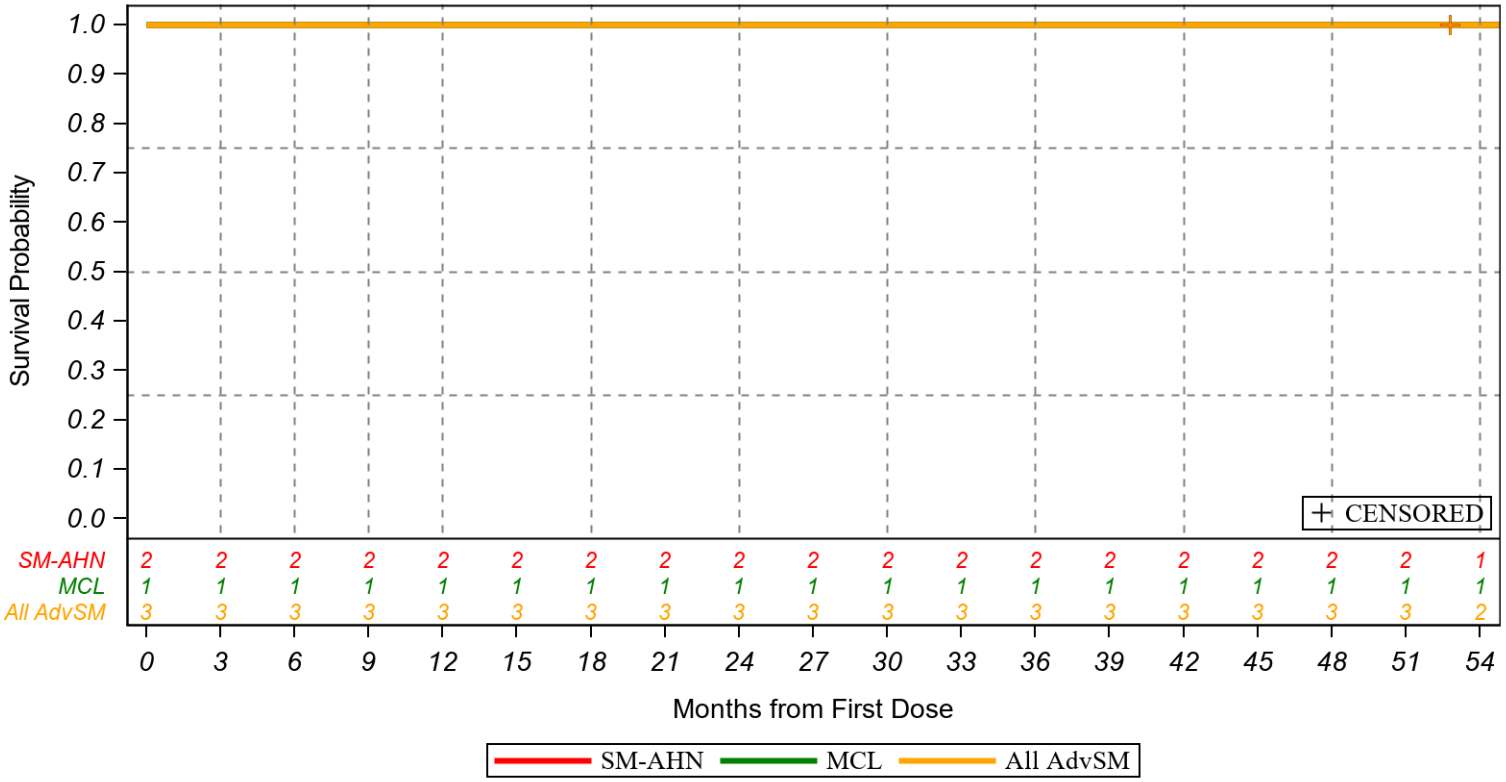

Figure 99.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: < 300 mg & Prior antineoplastic therapy = Yes

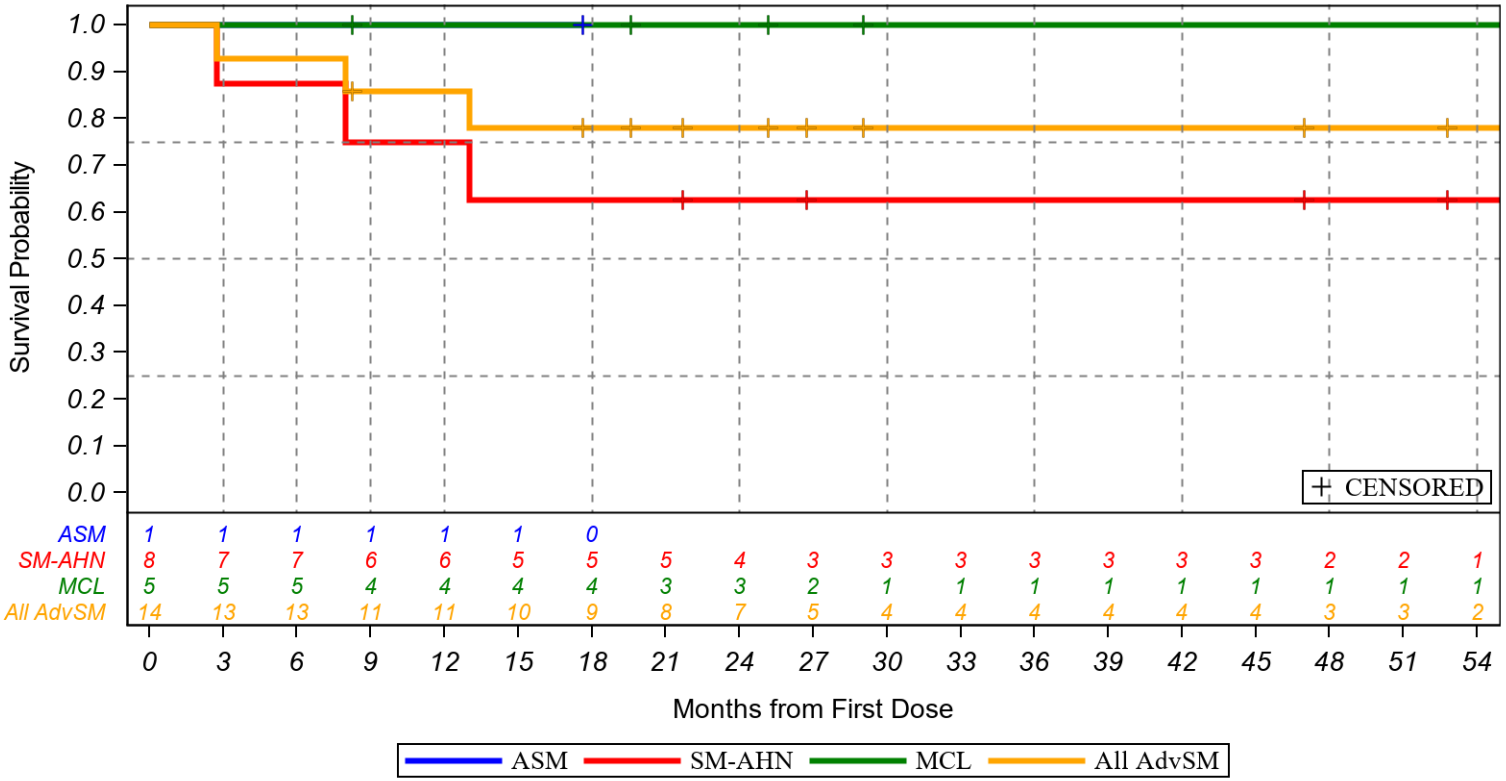

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Figure 99.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: 200 mg & Prior antineoplastic therapy = Yes

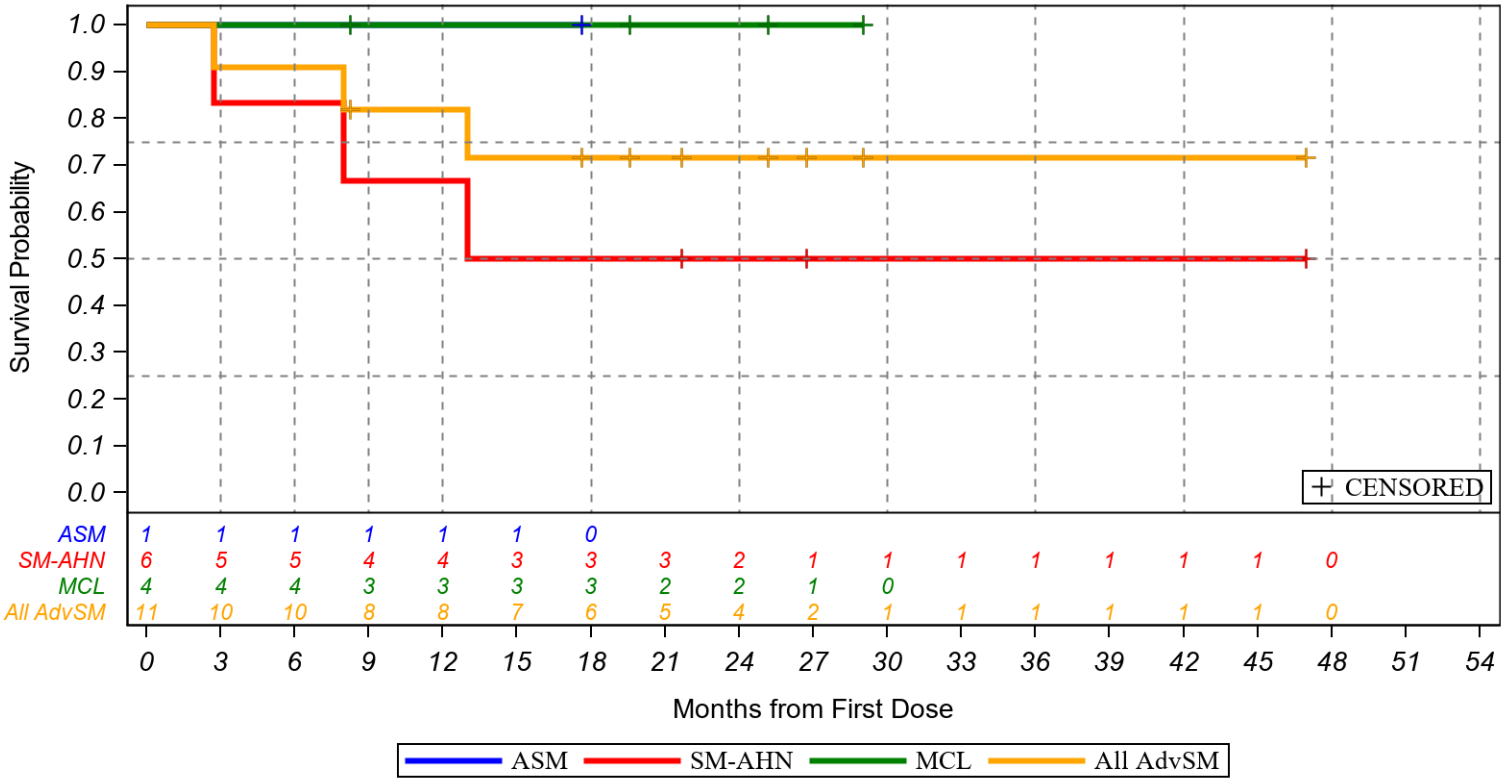

Figure 99.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: 300 mg & Prior antineoplastic therapy = Yes

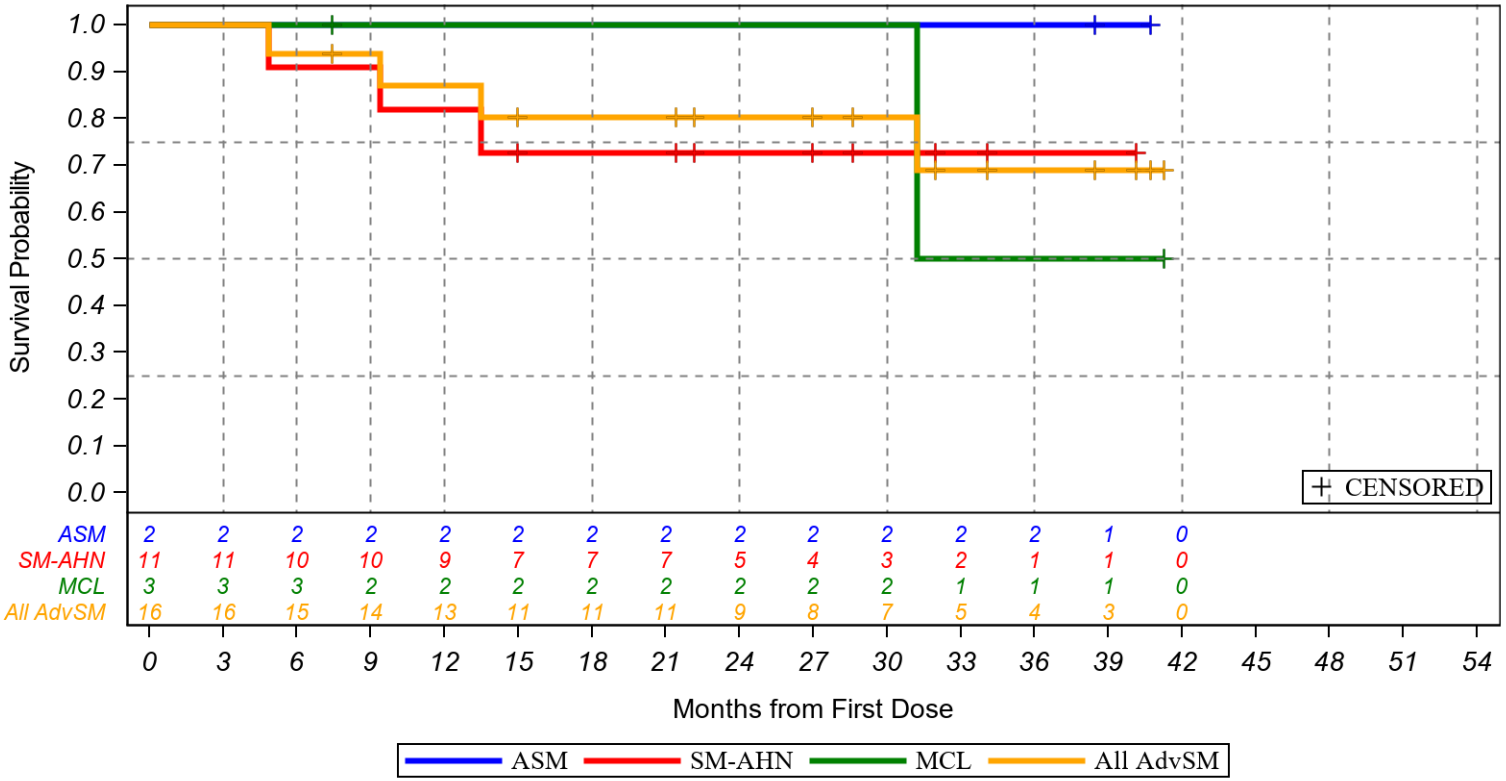

Figure 99.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: 200 mg and 300 mg & Prior antineoplastic therapy = Yes

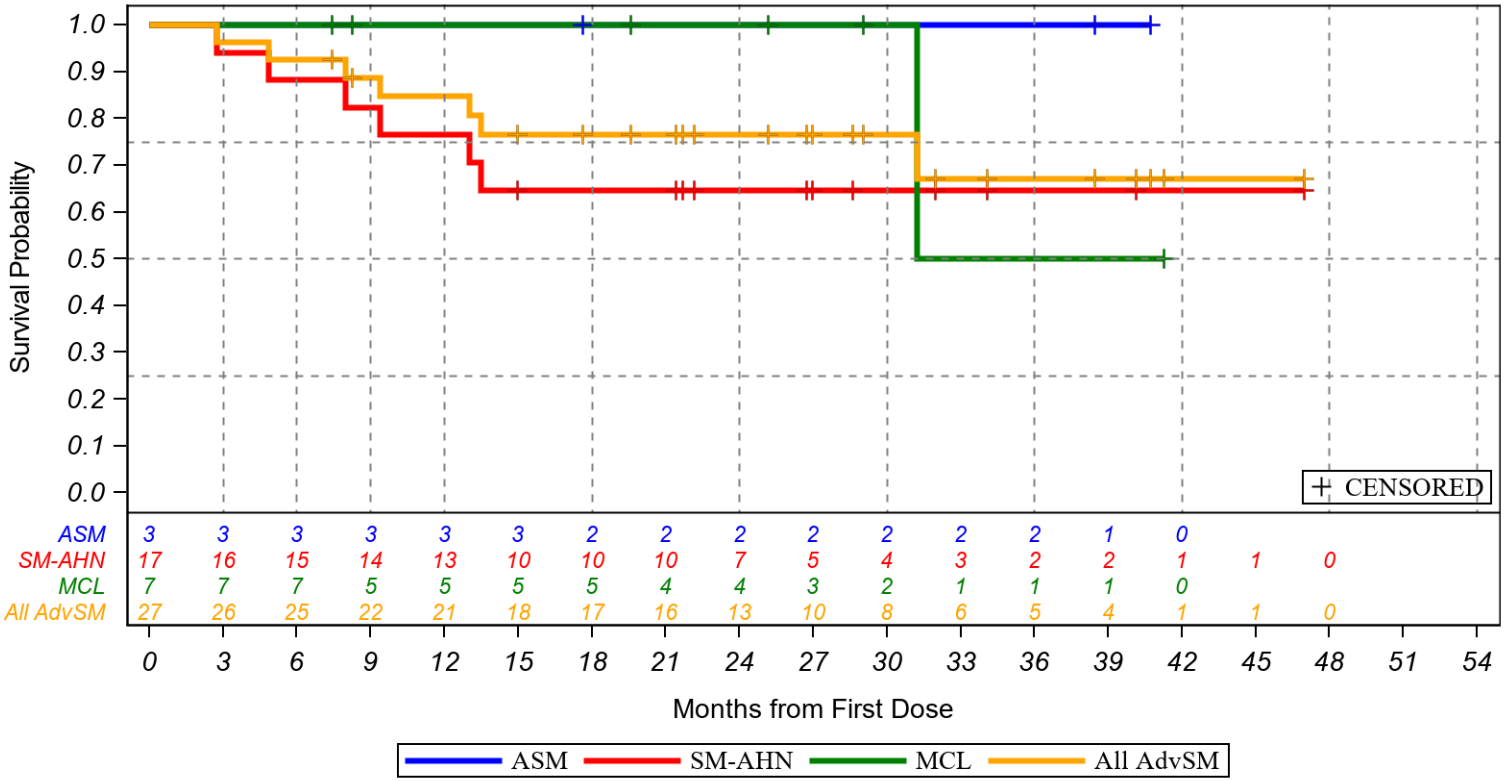

Figure 99.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: 400 mg & Prior antineoplastic therapy = Yes

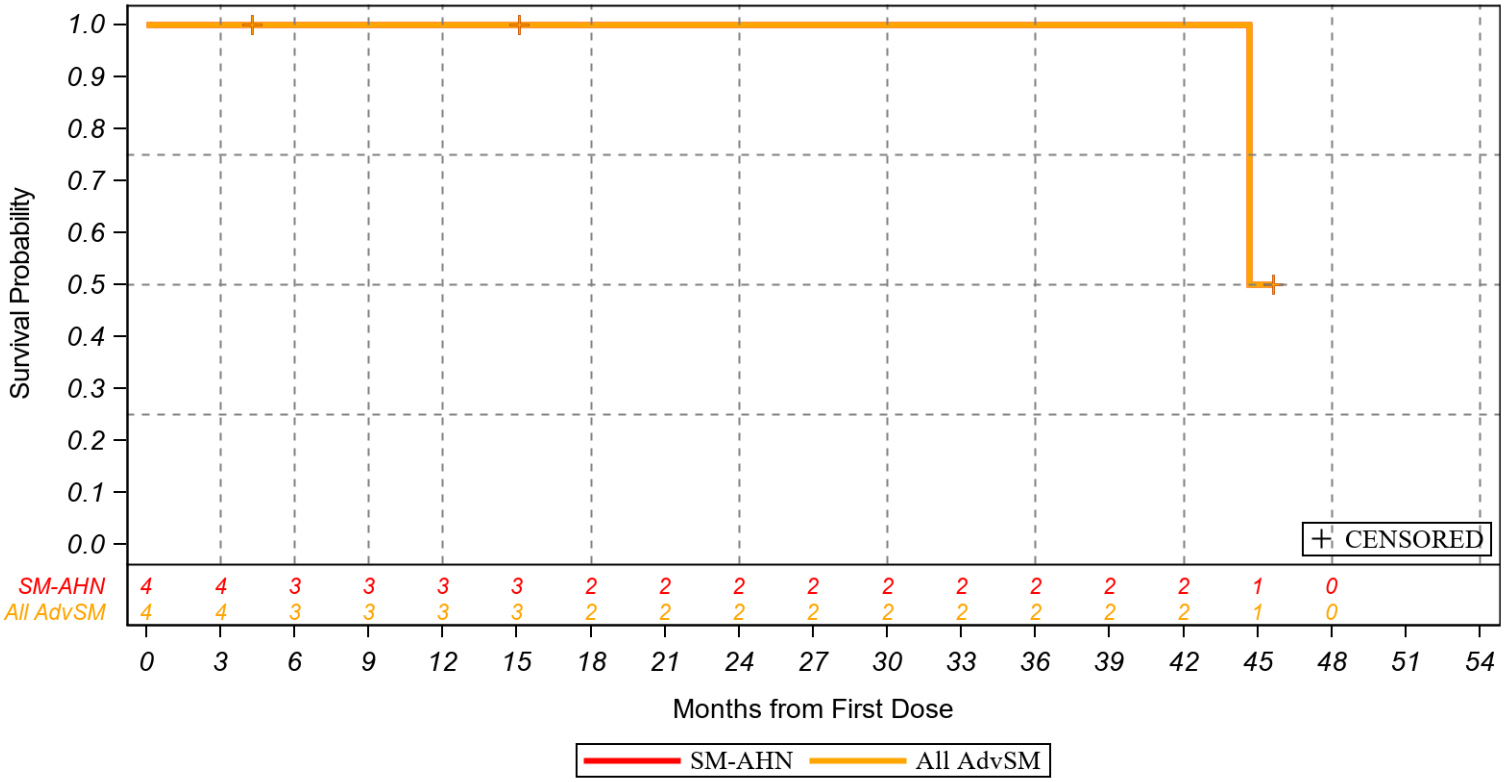

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Figure 99.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: Overall & Prior antineoplastic therapy = No

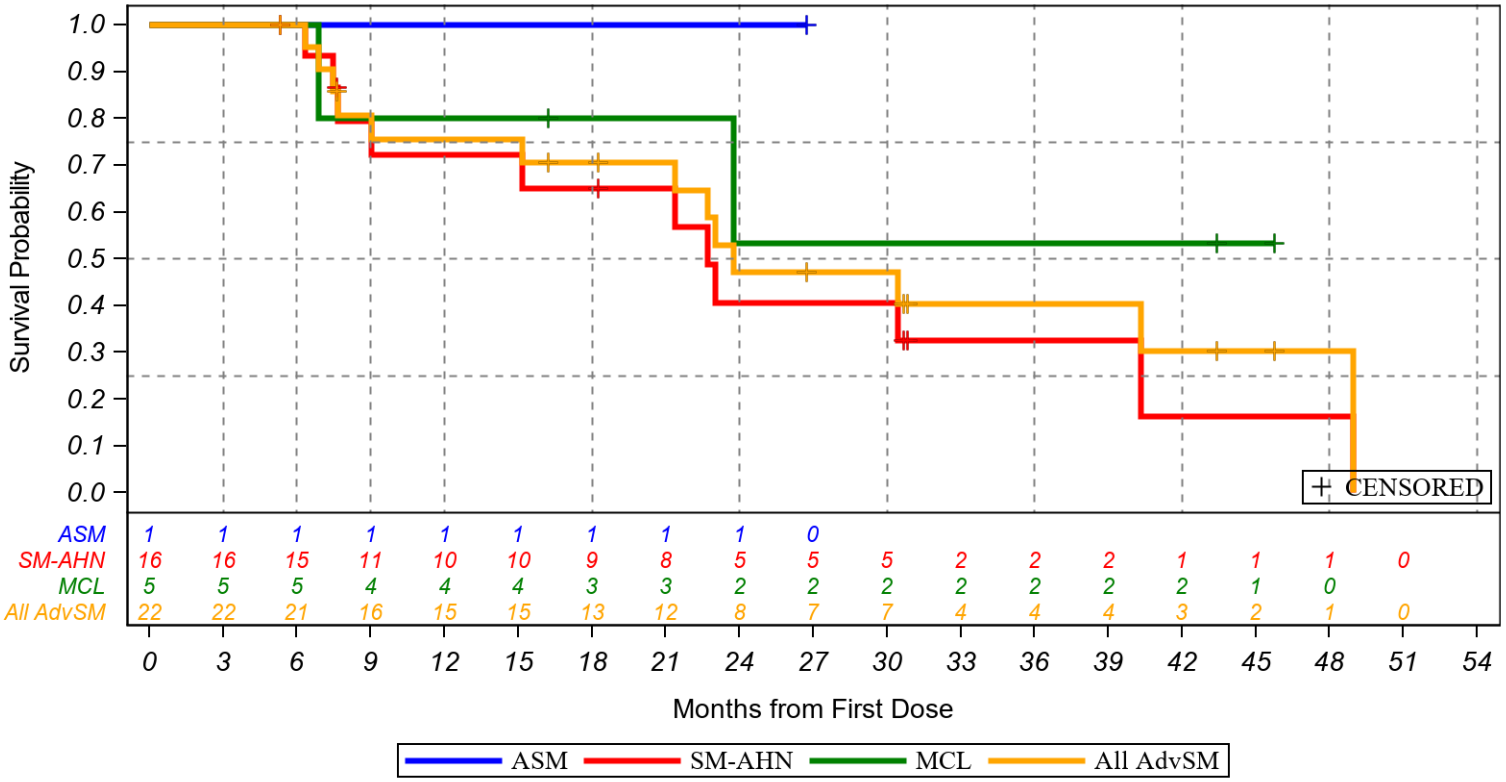

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Figure 99.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: < 200 mg & Prior antineoplastic therapy = No

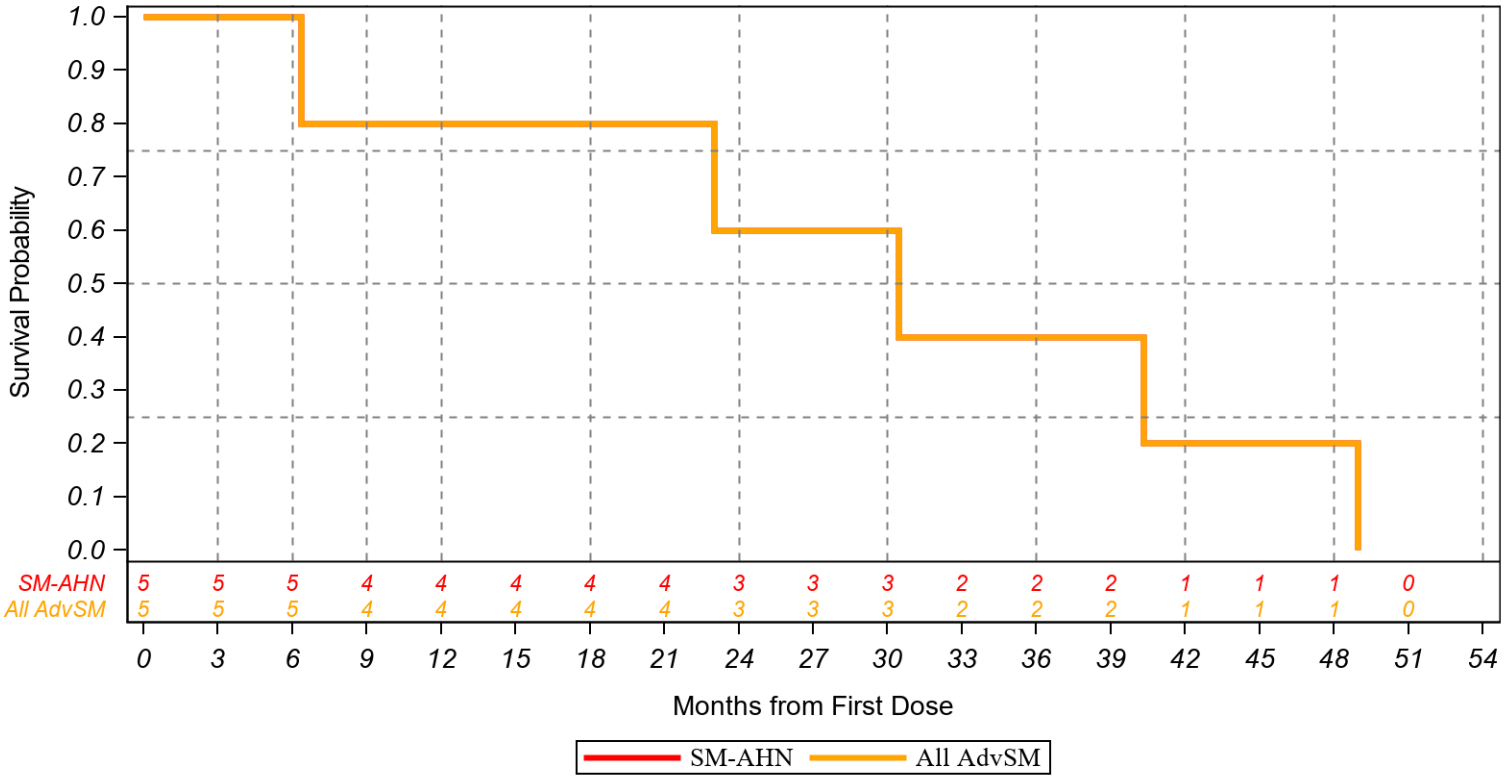

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Figure 99.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: < 300 mg & Prior antineoplastic therapy = No

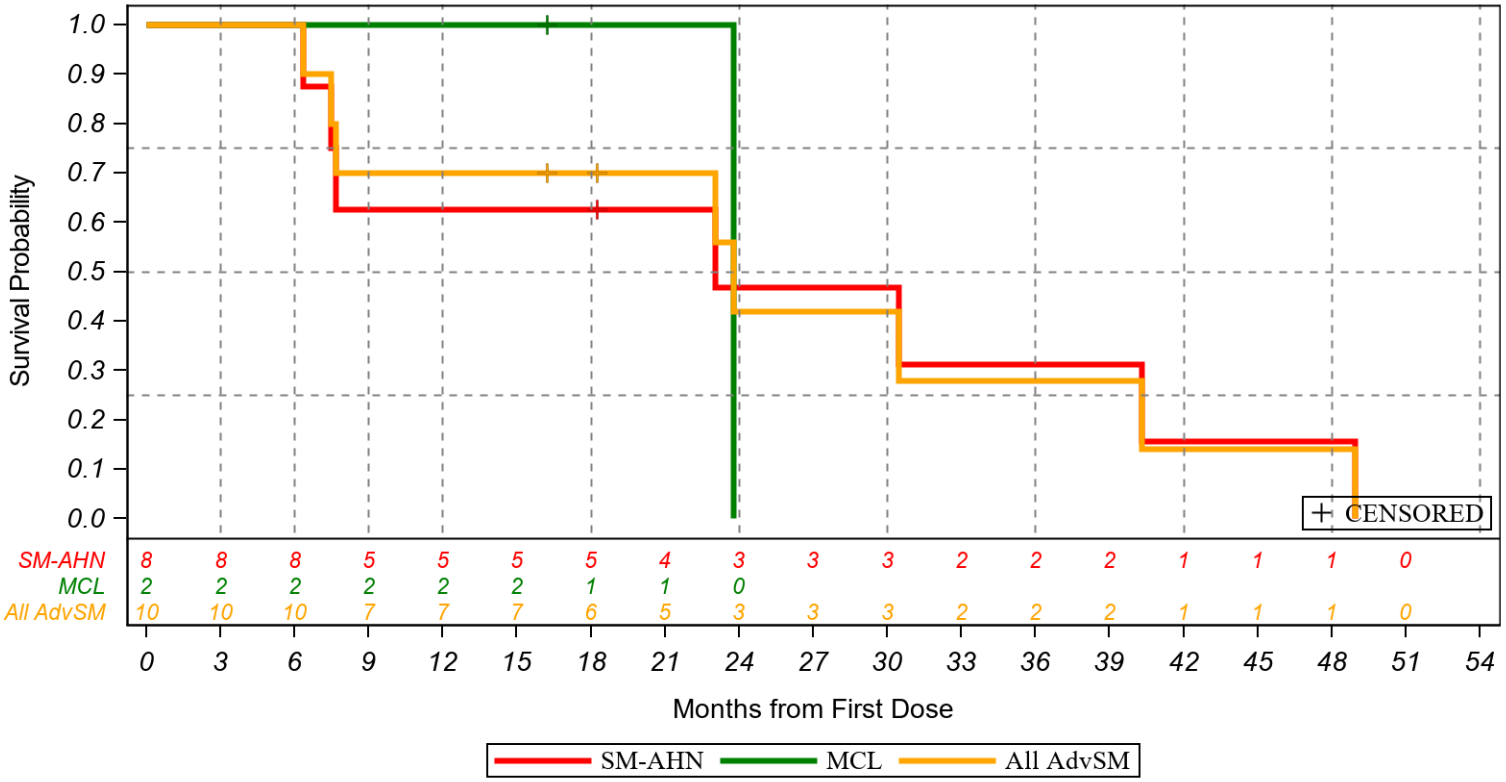

Figure 99.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: 200 mg & Prior antineoplastic therapy = No

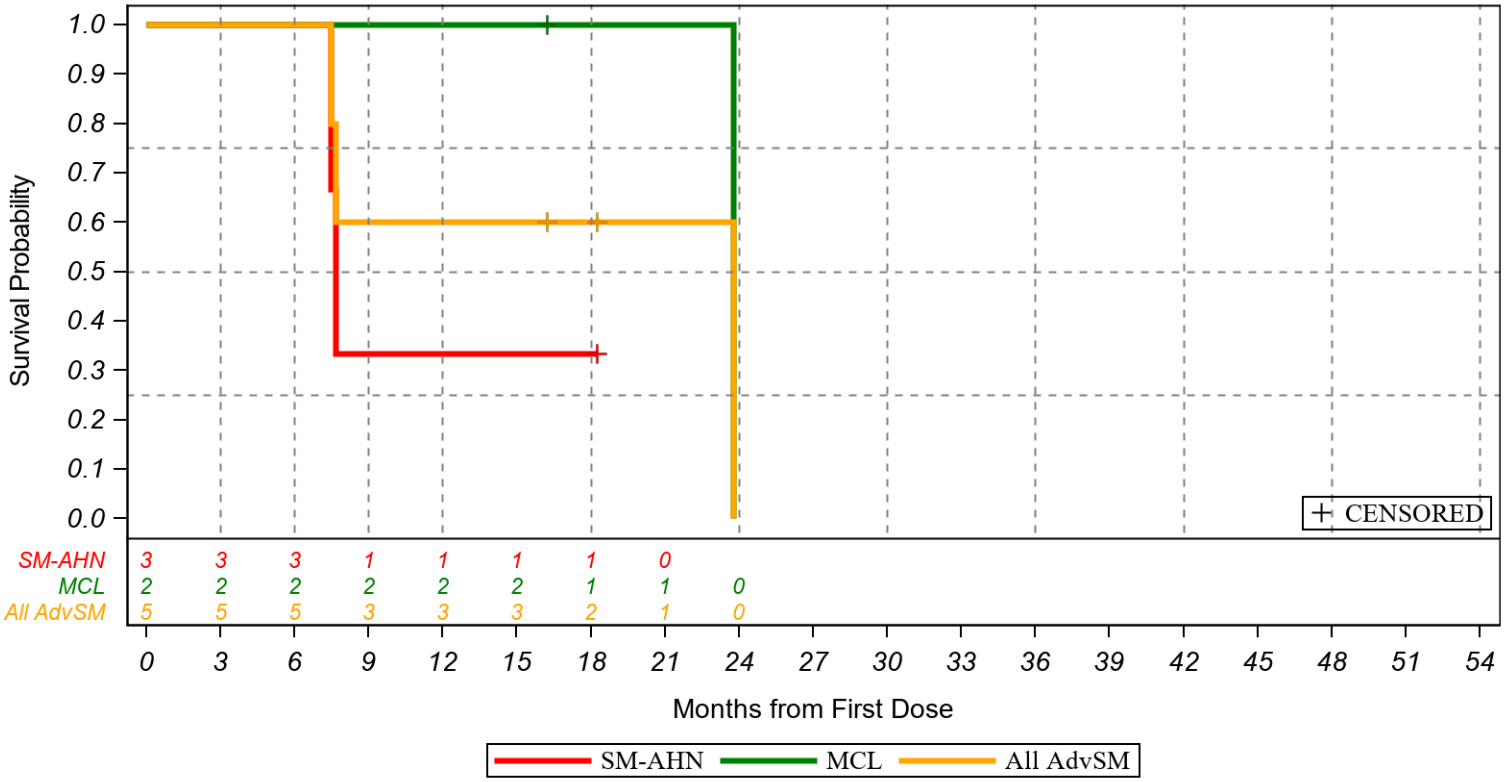

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Figure 99.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: 300 mg & Prior antineoplastic therapy = No

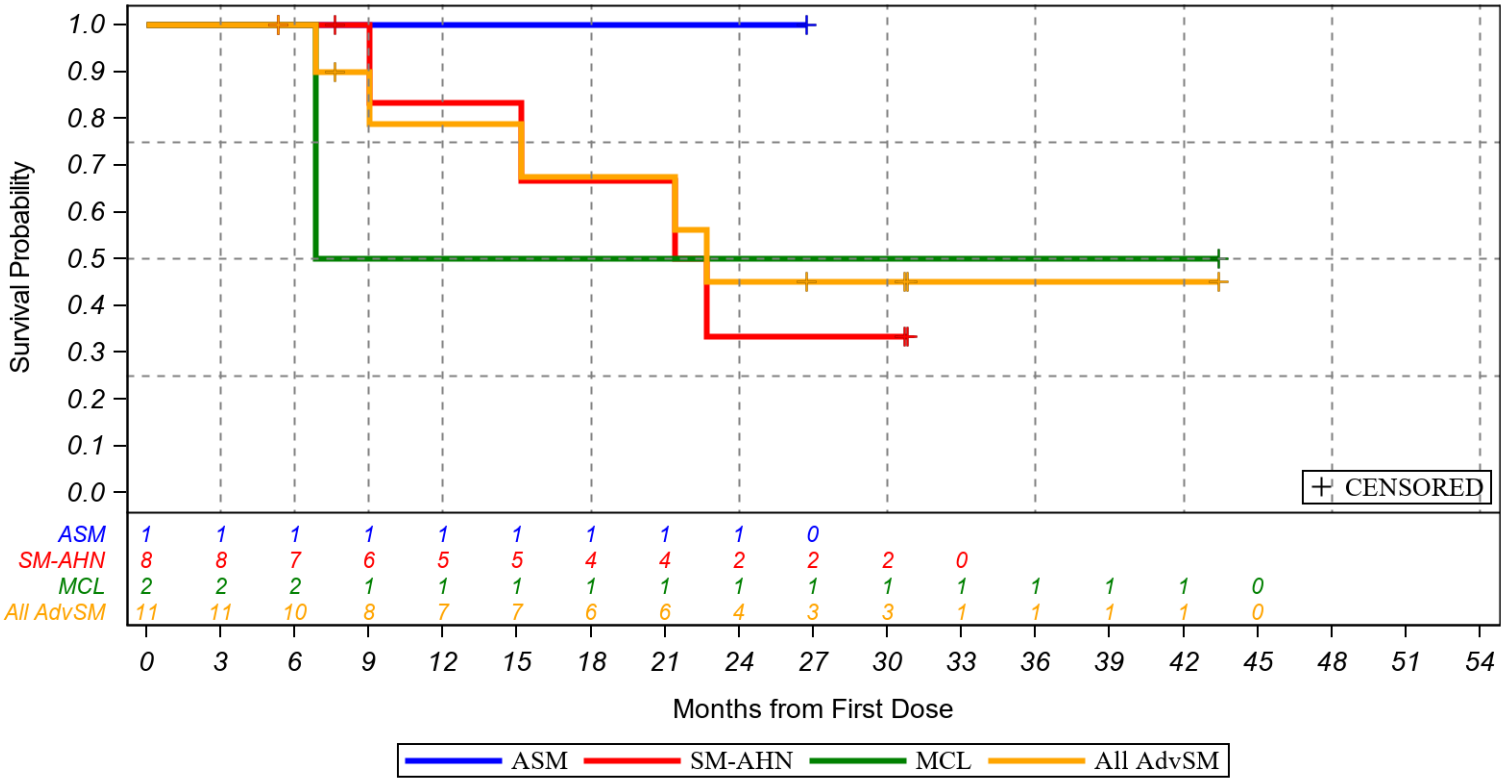

Figure 99.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: 200 mg and 300 mg & Prior antineoplastic therapy = No

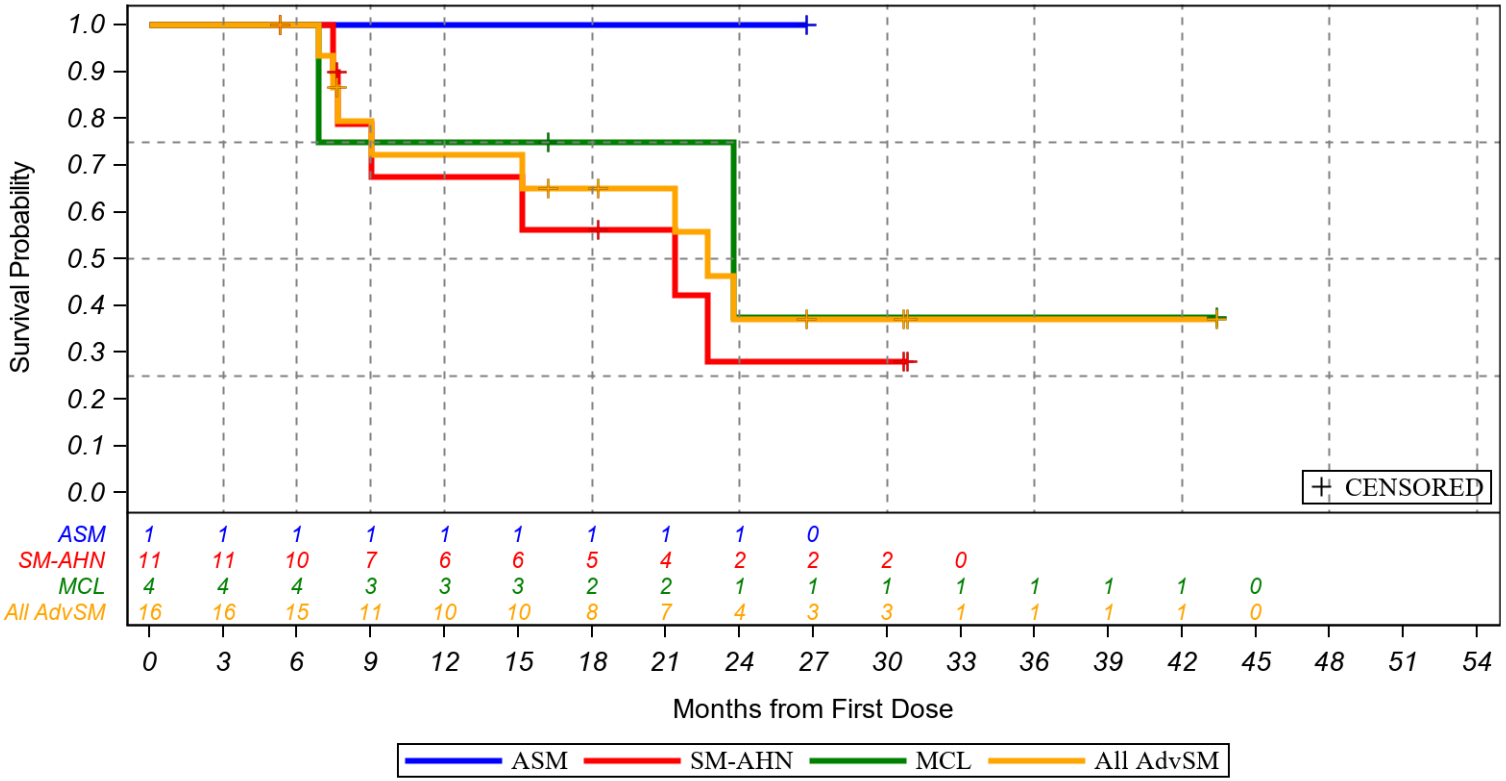

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Figure 99.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101
Starting Dose: 400 mg & Prior antineoplastic therapy = No

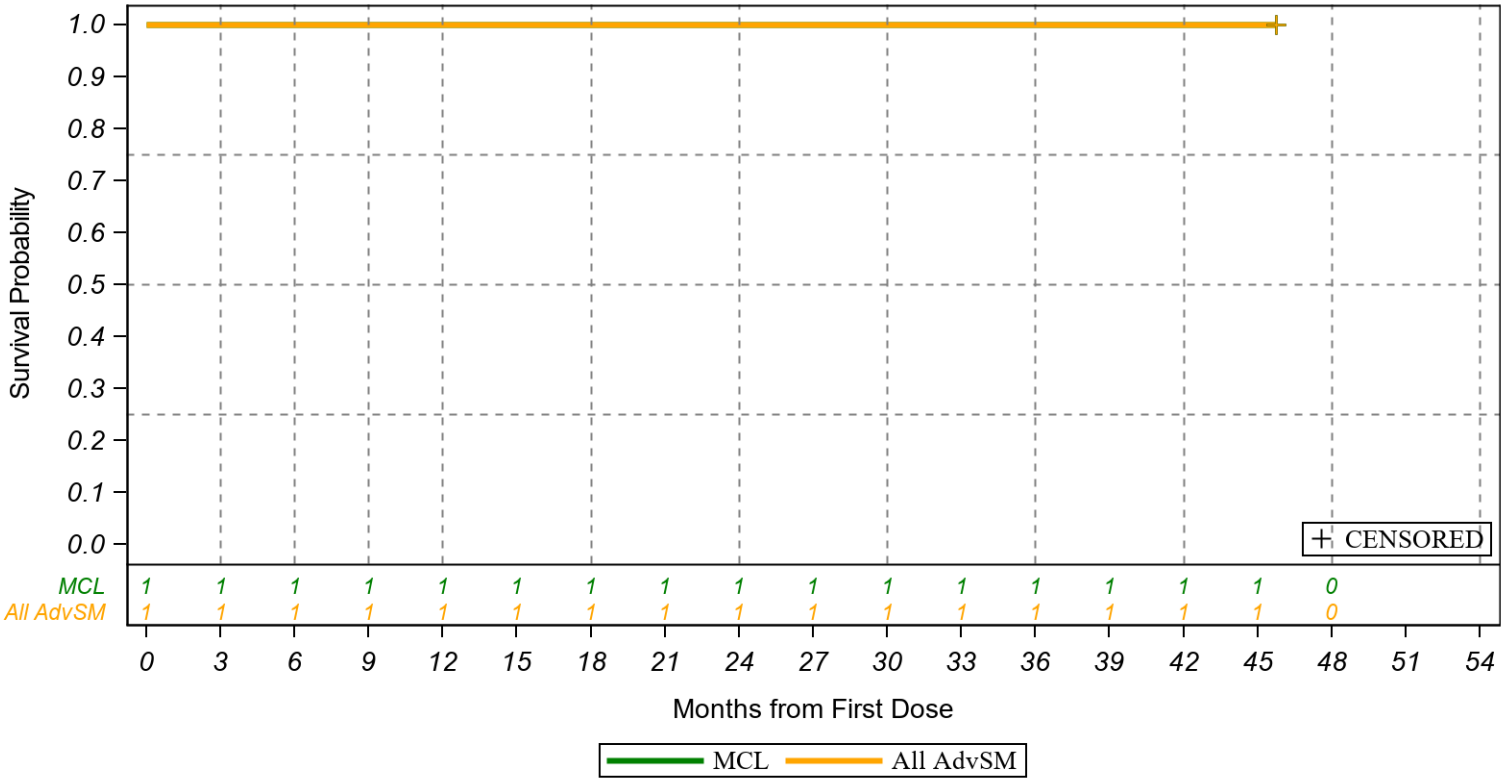

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Figure 99.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Starting Dose: Overall & Prior antineoplastic therapy = Yes

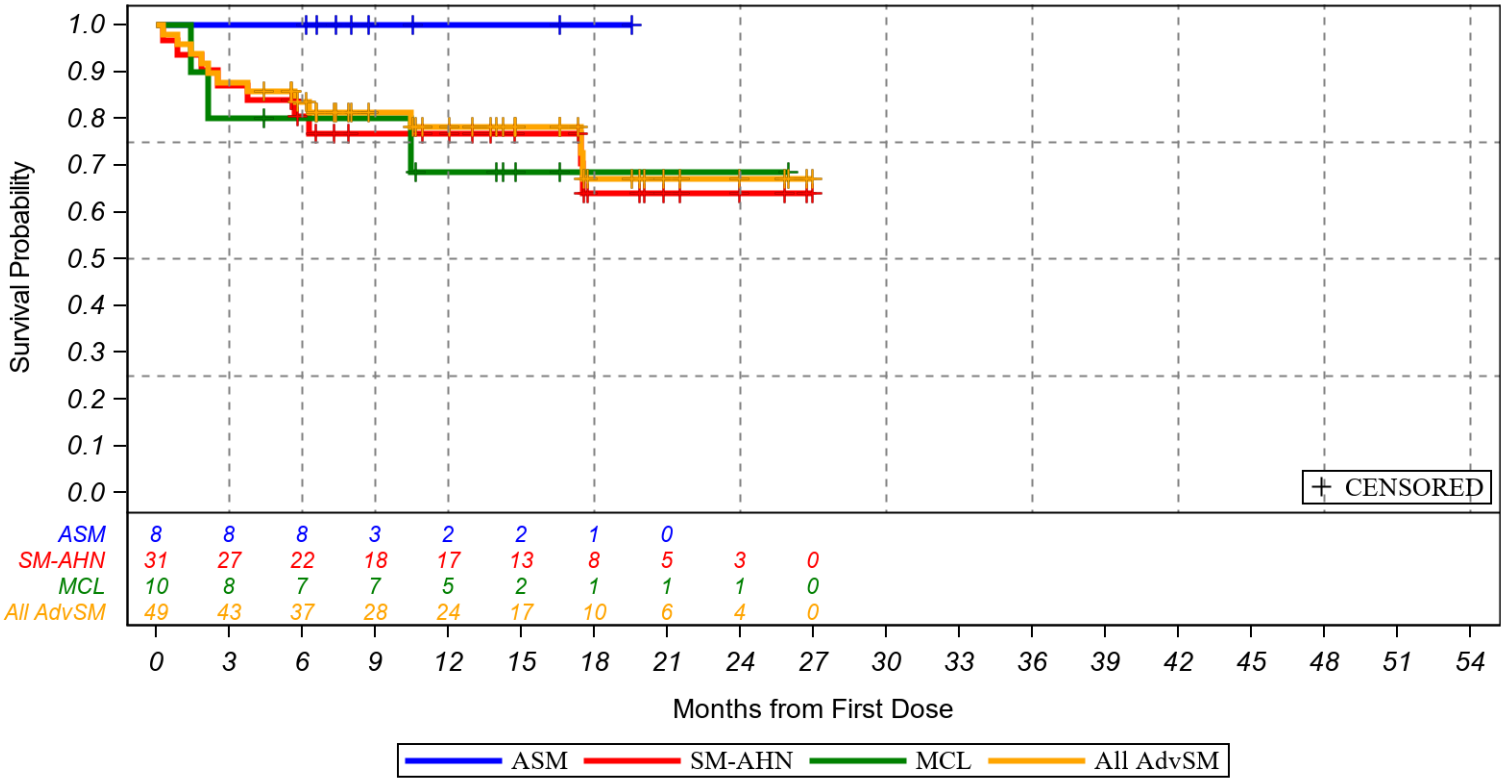

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Figure 99.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Starting Dose: 200 mg & Prior antineoplastic therapy = Yes

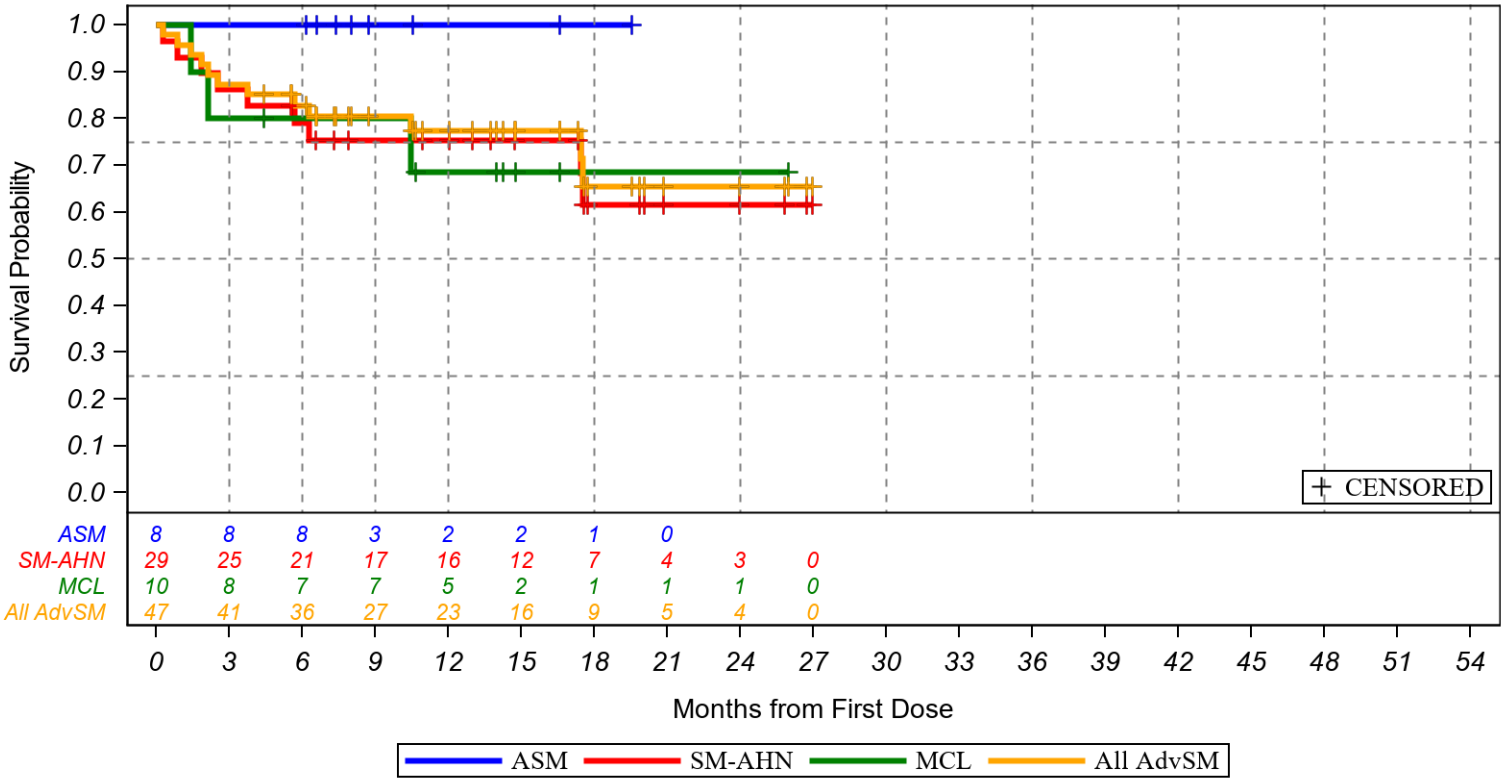

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Figure 99.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Starting Dose: Overall & Prior antineoplastic therapy = No

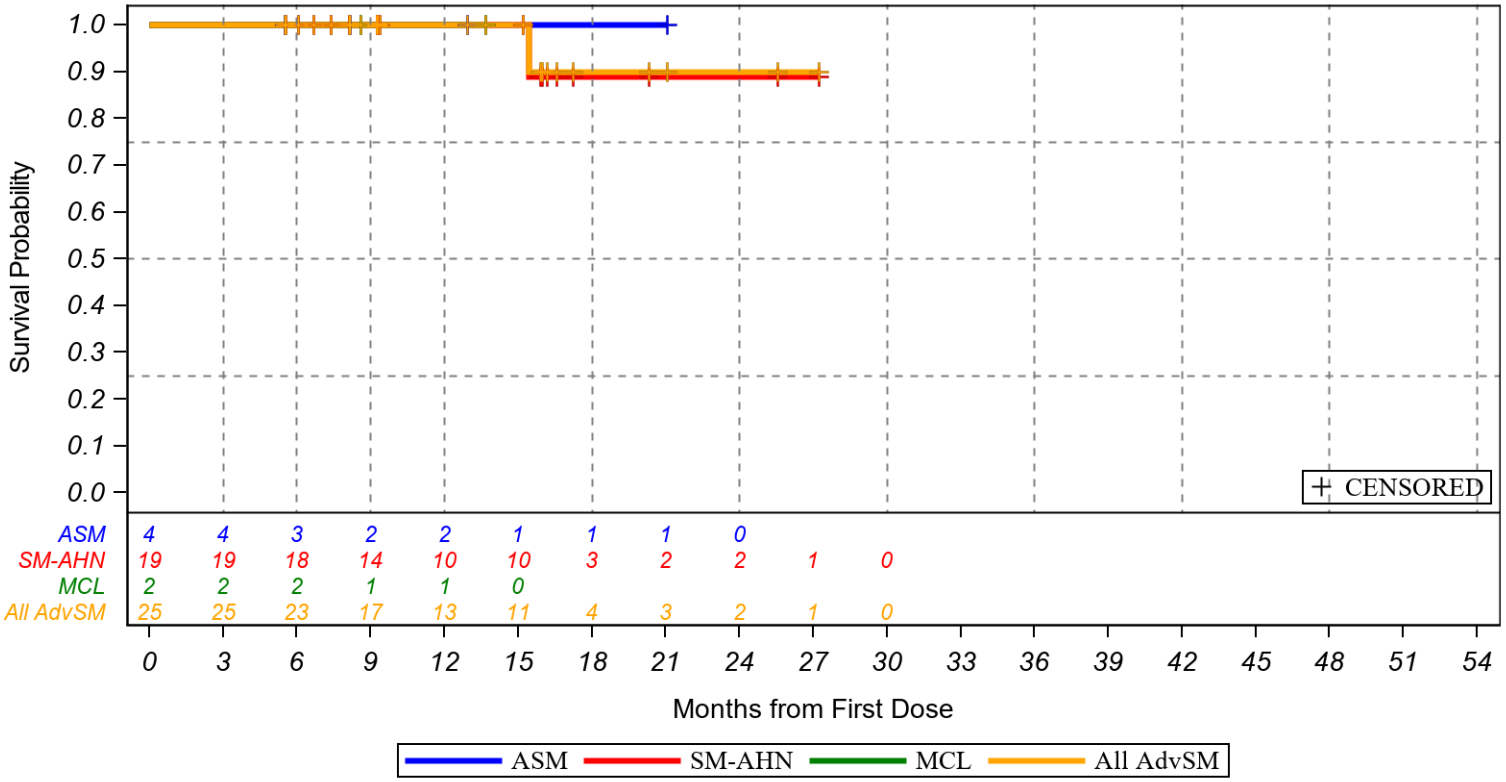

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Figure 99.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2202
Starting Dose: 200 mg & Prior antineoplastic therapy = No

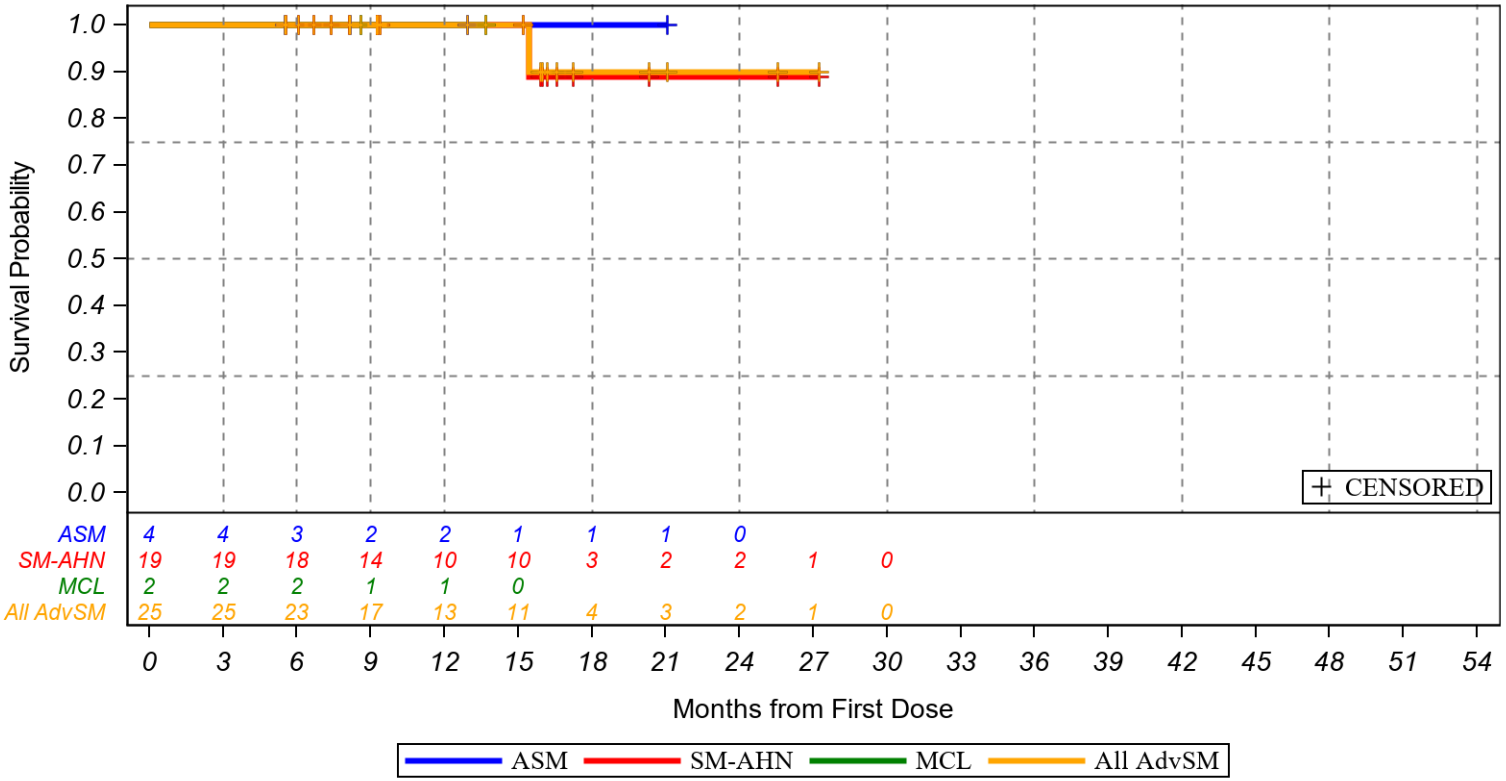

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Figure 99.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall & Prior antineoplastic therapy = Yes

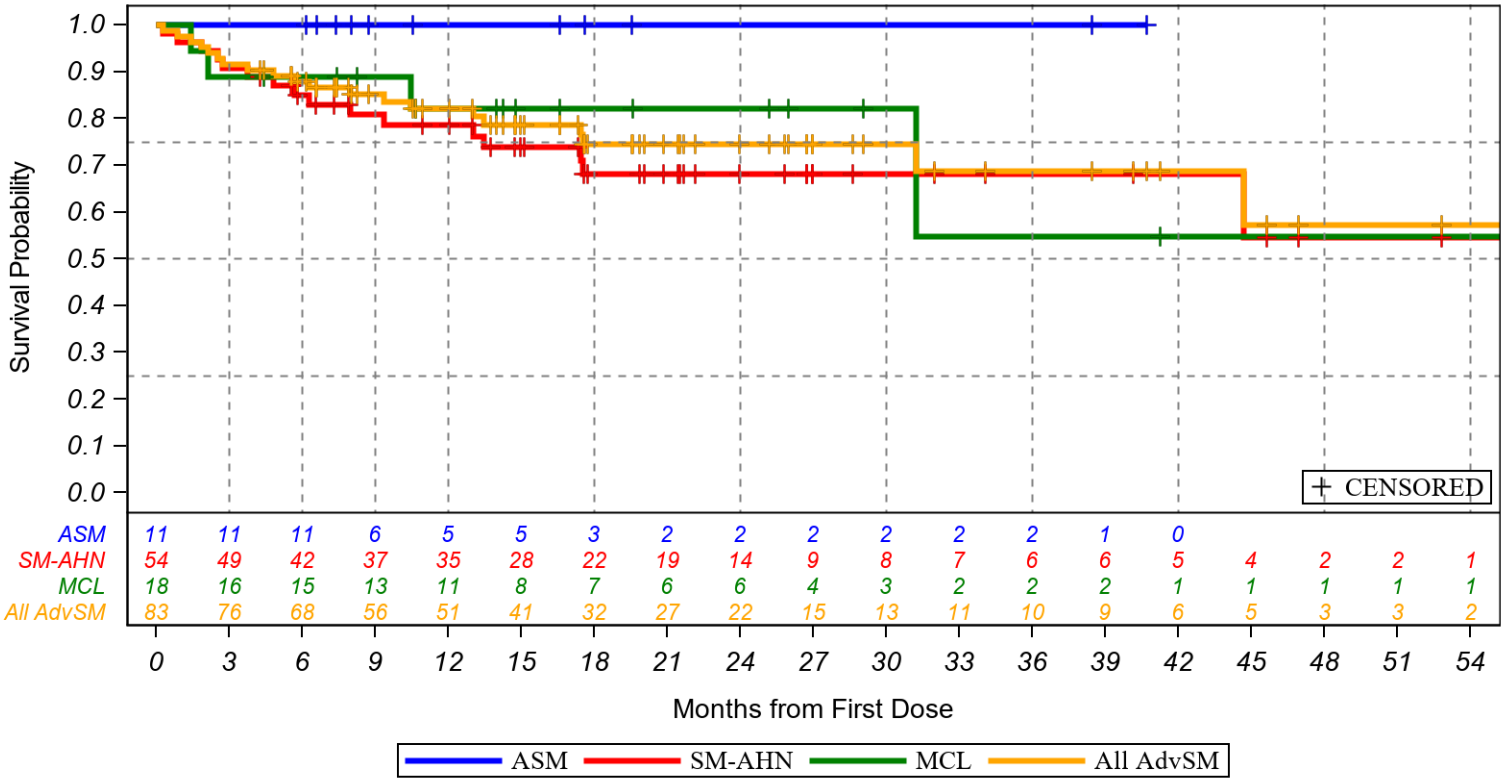

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Figure 99.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg & Prior antineoplastic therapy = Yes

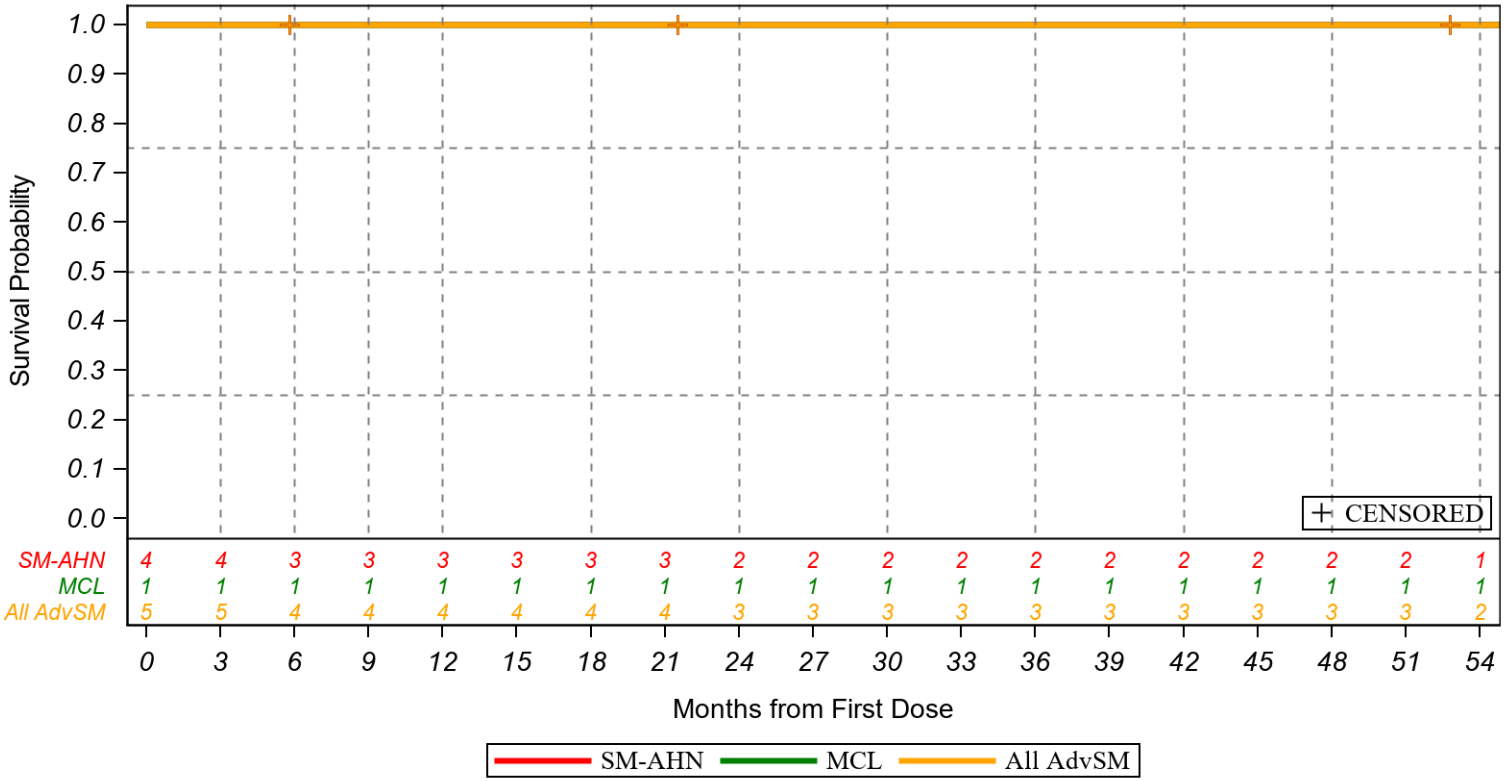

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Figure 99.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg & Prior antineoplastic therapy = Yes

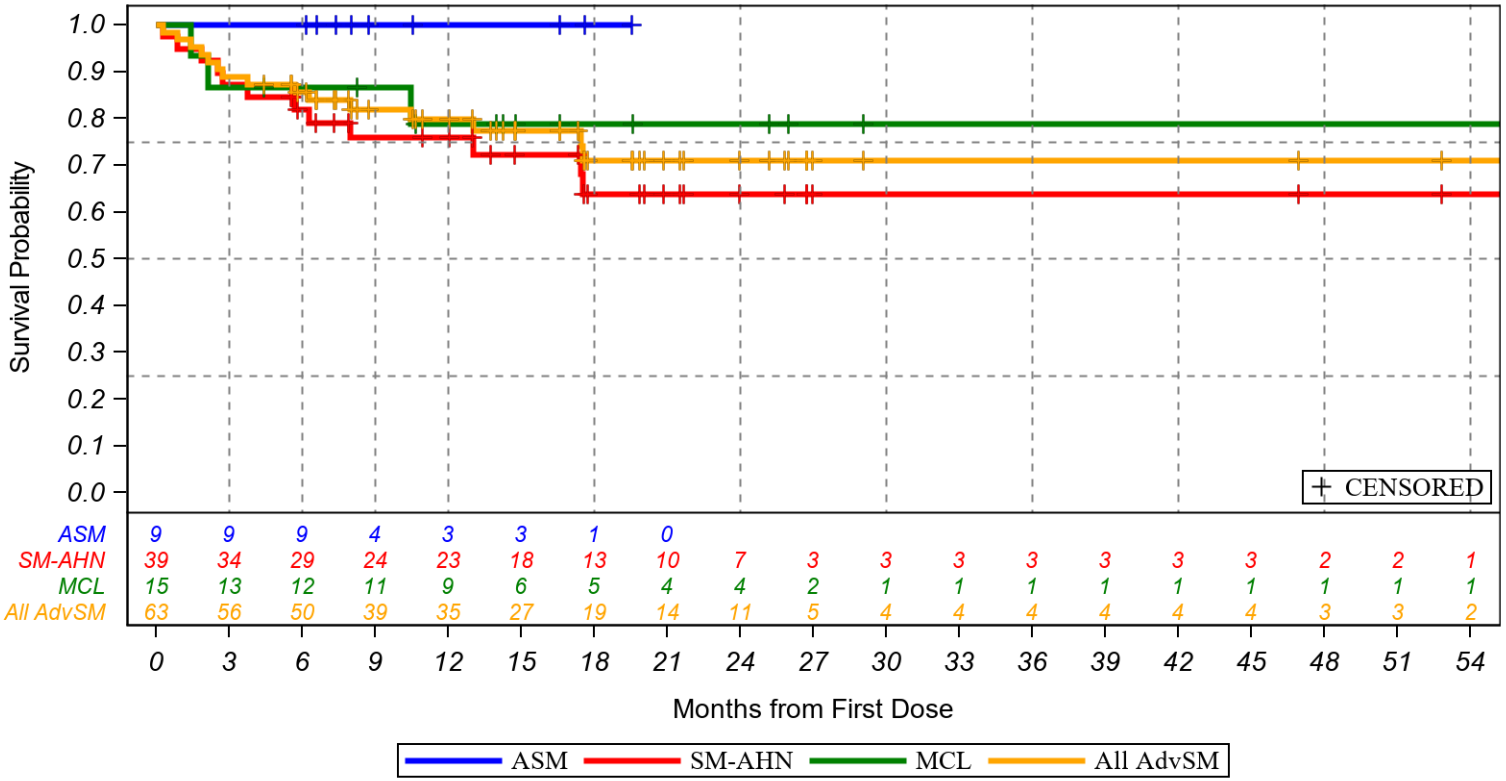

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Figure 99.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg & Prior antineoplastic therapy = Yes

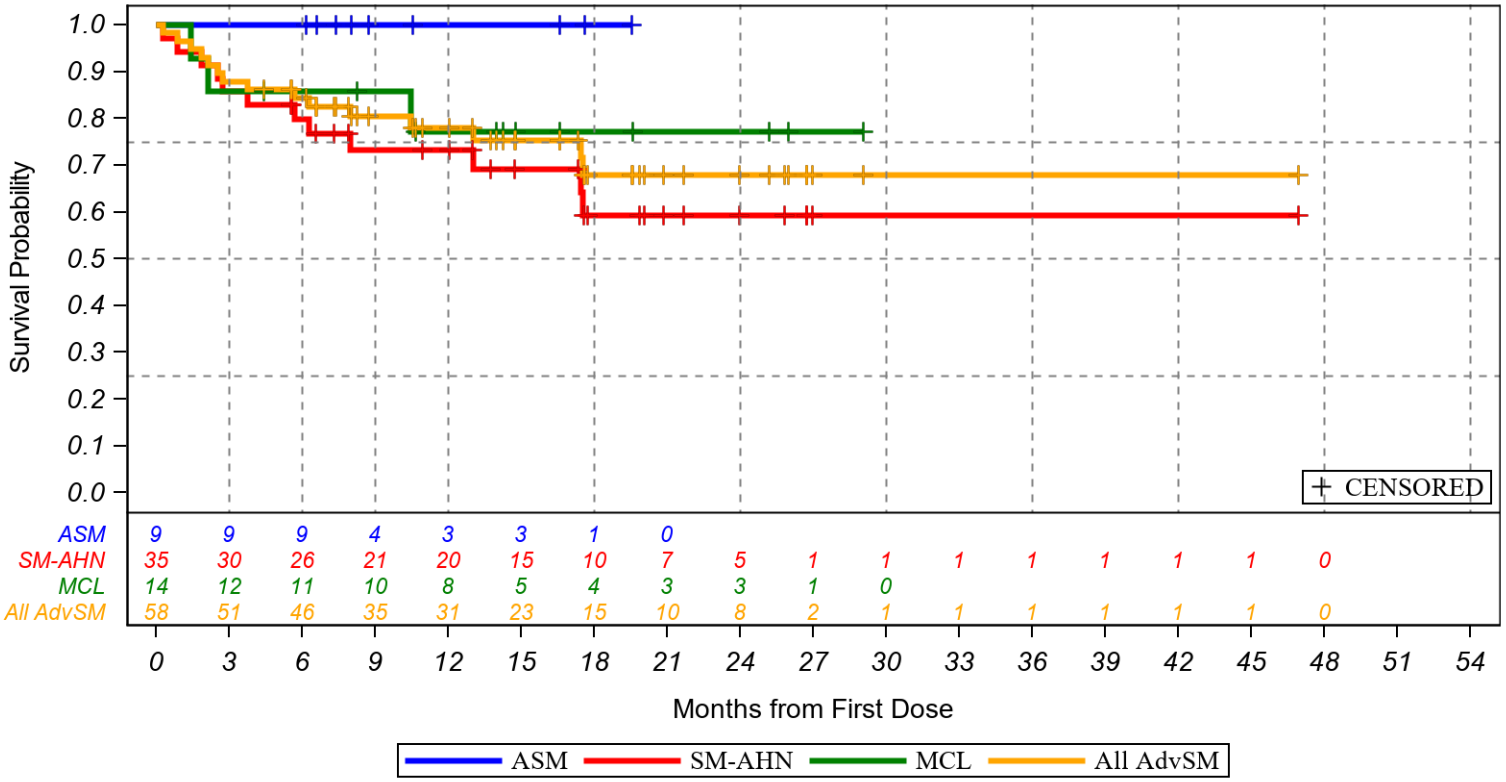

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Figure 99.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg & Prior antineoplastic therapy = Yes

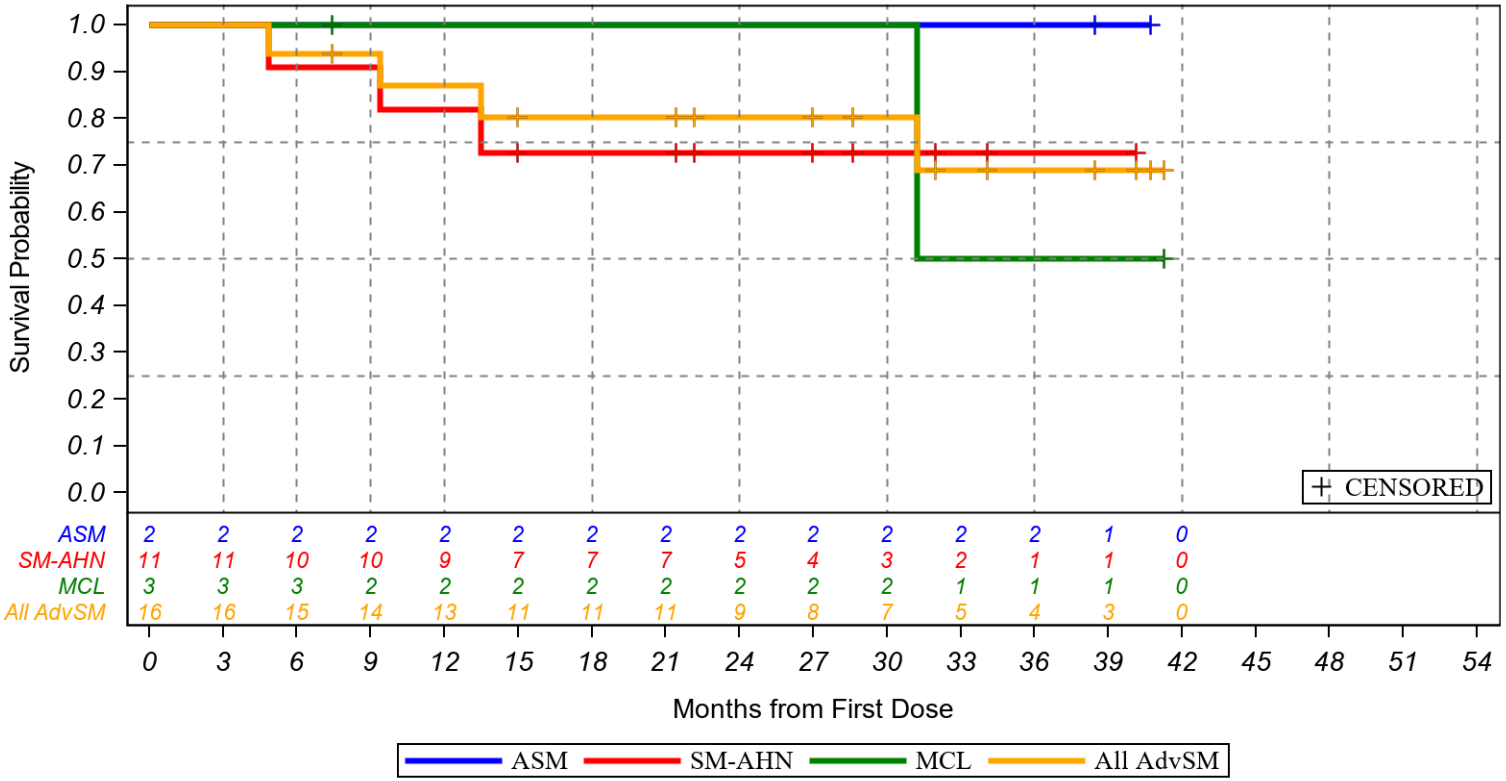

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Figure 99.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg & Prior antineoplastic therapy = Yes

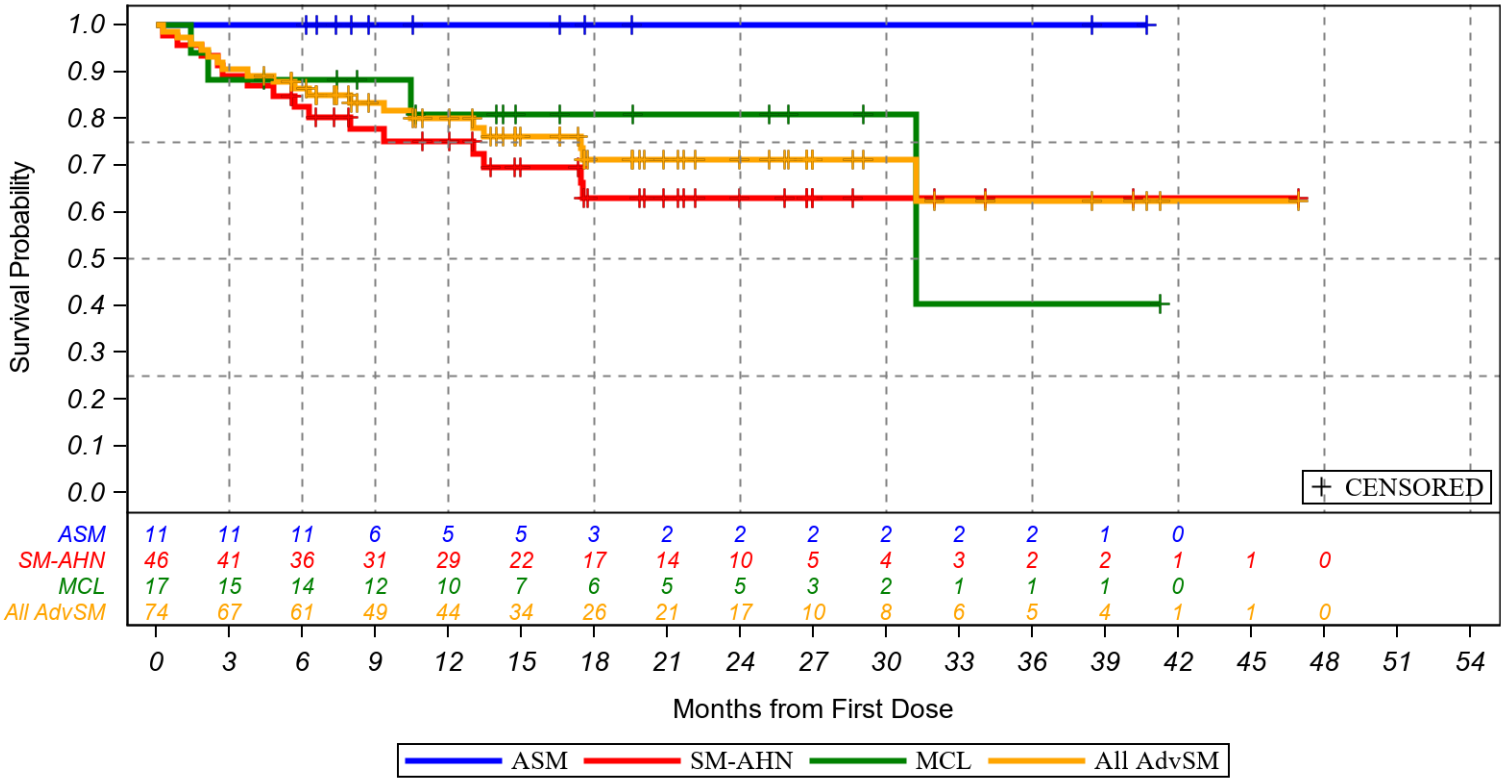

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Figure 99.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg & Prior antineoplastic therapy = Yes

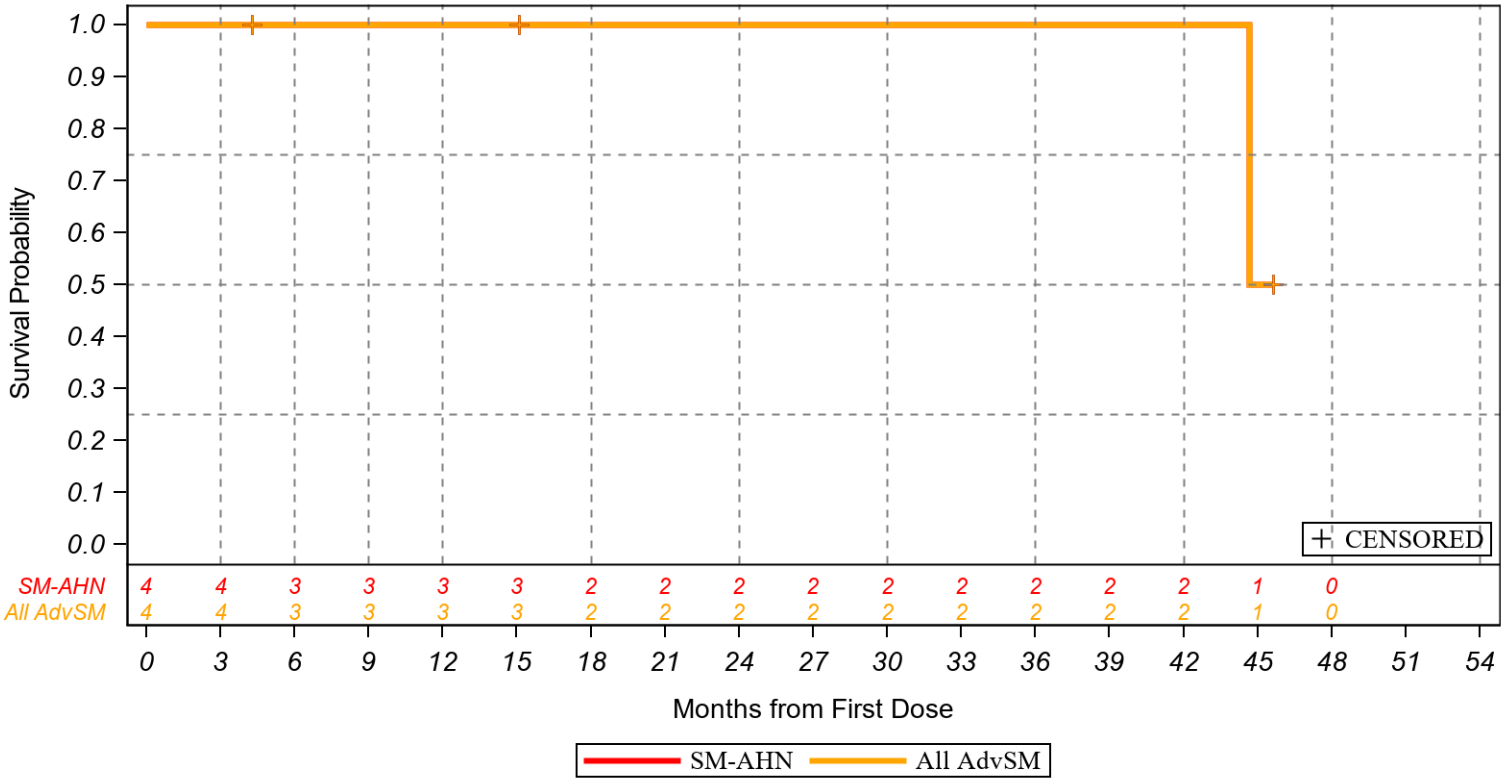

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Figure 99.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall & Prior antineoplastic therapy = No

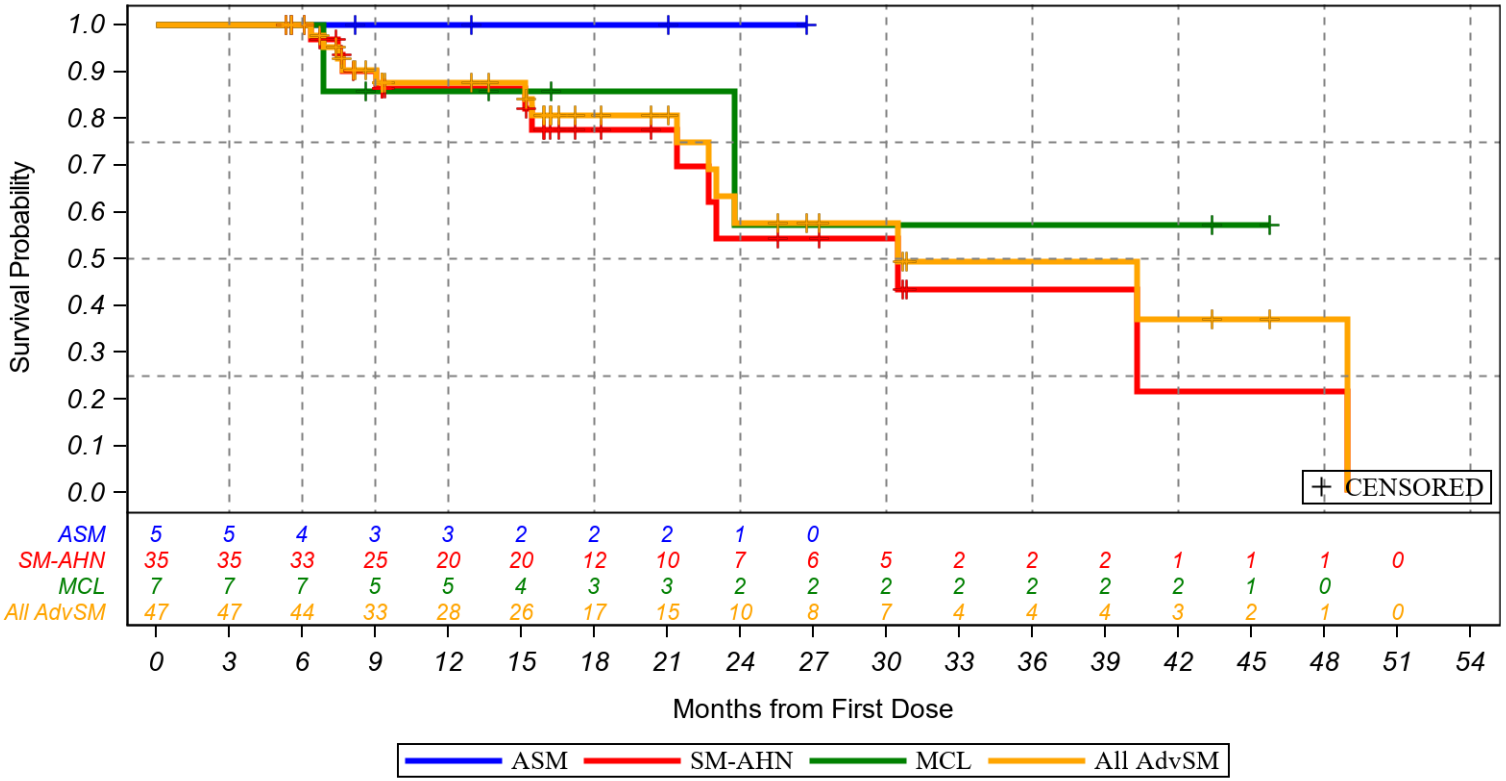

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Figure 99.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg & Prior antineoplastic therapy = No

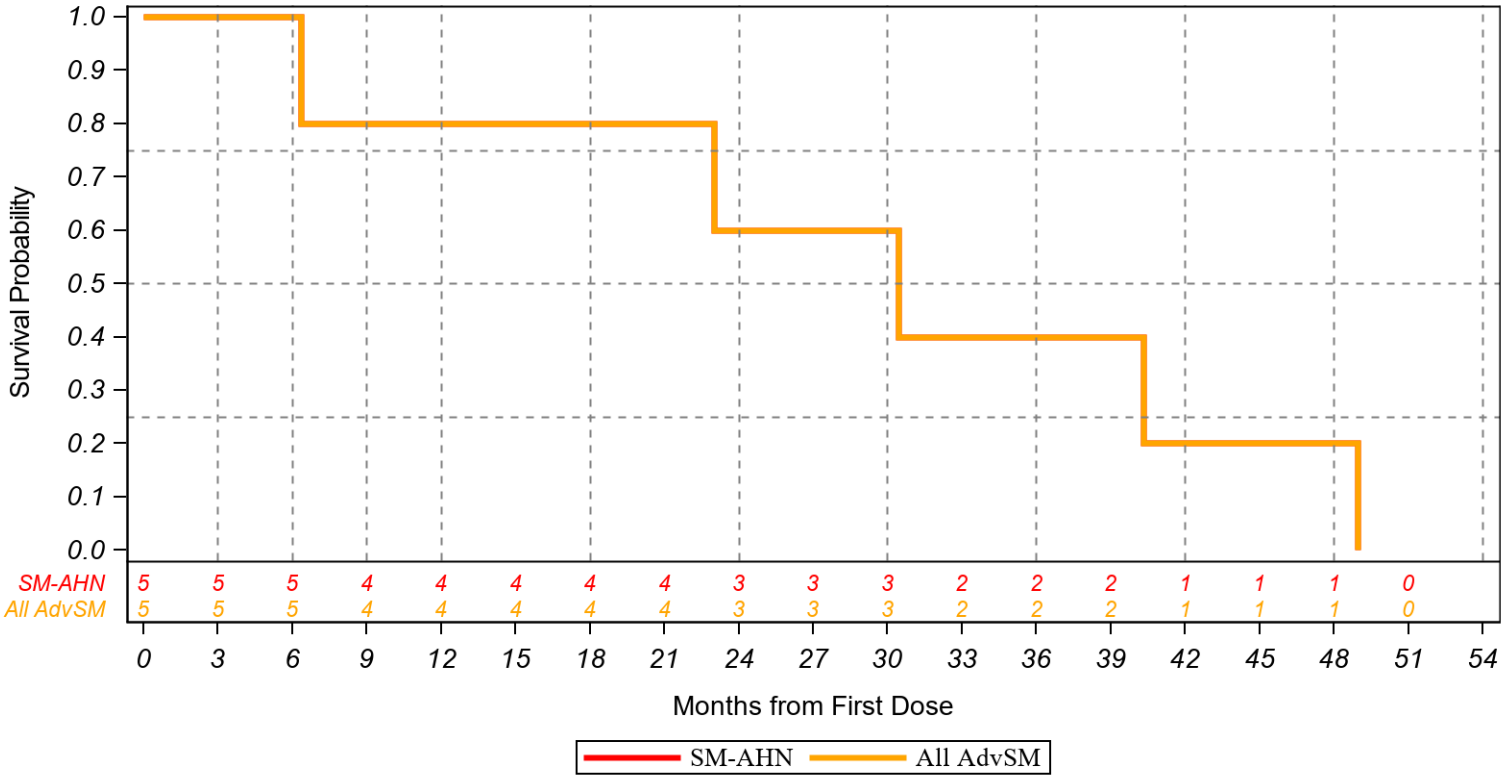

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Figure 99.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg & Prior antineoplastic therapy = No

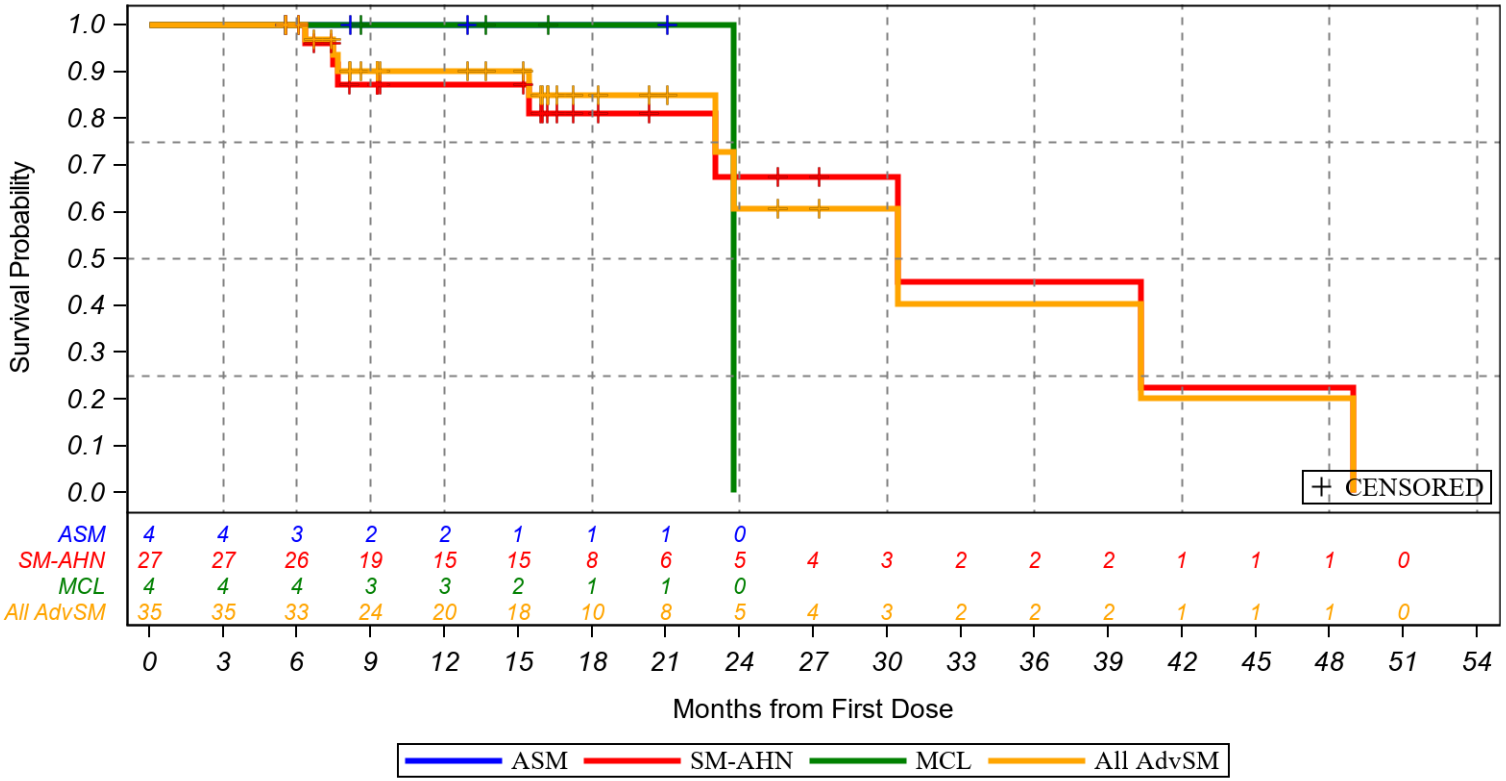

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Figure 99.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg & Prior antineoplastic therapy = No

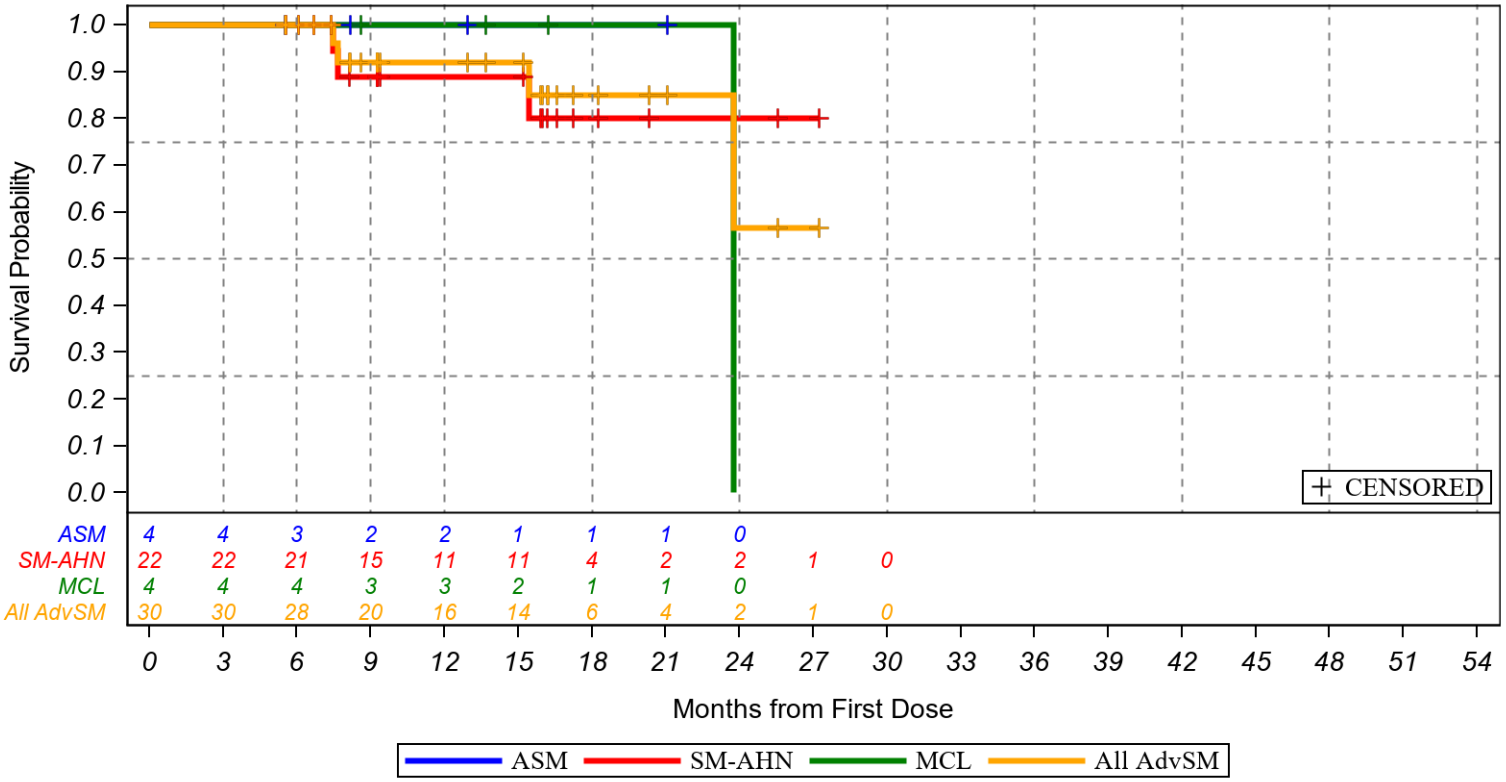

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Figure 99.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg & Prior antineoplastic therapy = No

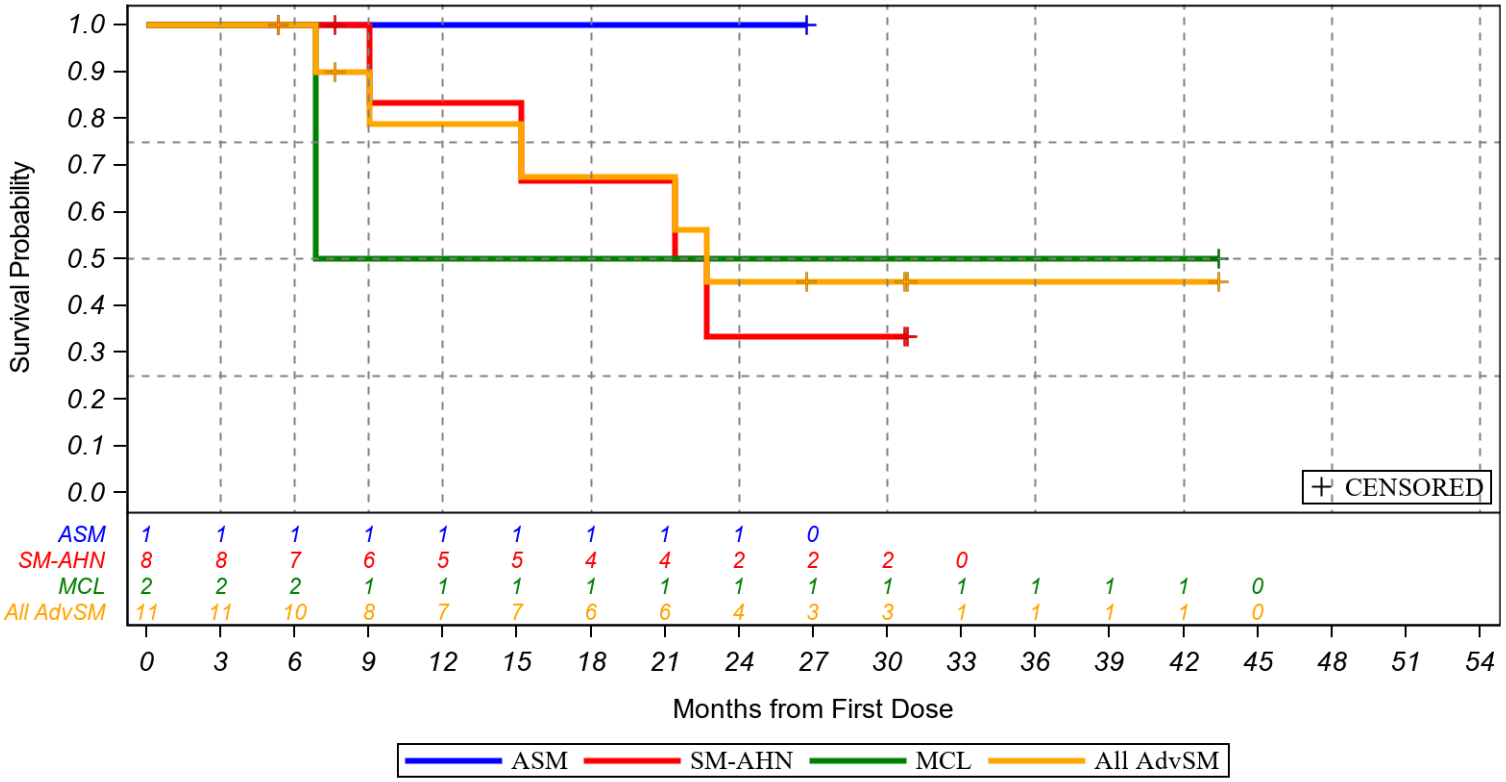

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Figure 99.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg & Prior antineoplastic therapy = No

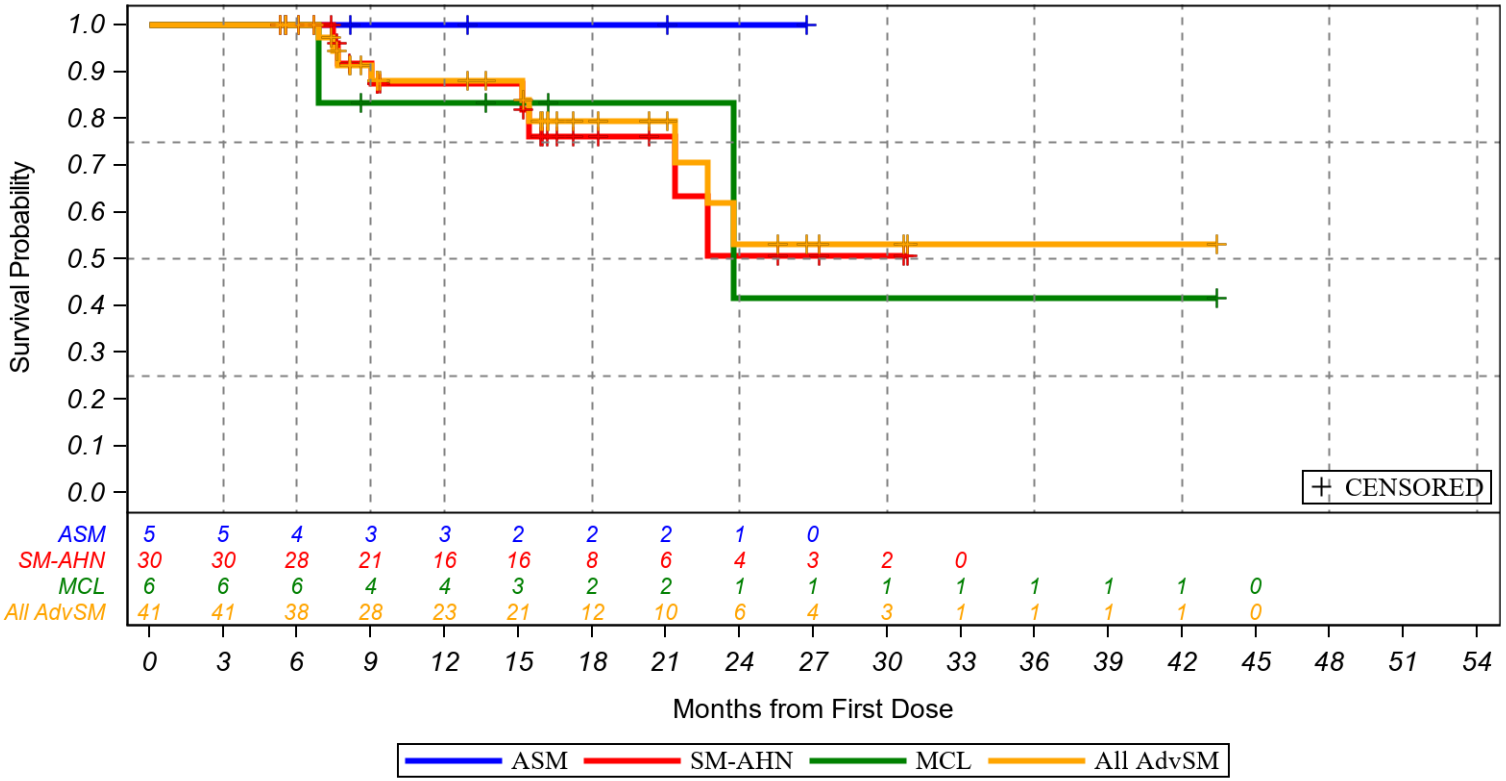

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Figure 99.2.3.1
Kaplan-Meier Curves of Adjudicated Progression Free Survival by Modified IWG Criteria by Prior Antineoplastic Therapy
RAC-RE Population
Study: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg & Prior antineoplastic therapy = No

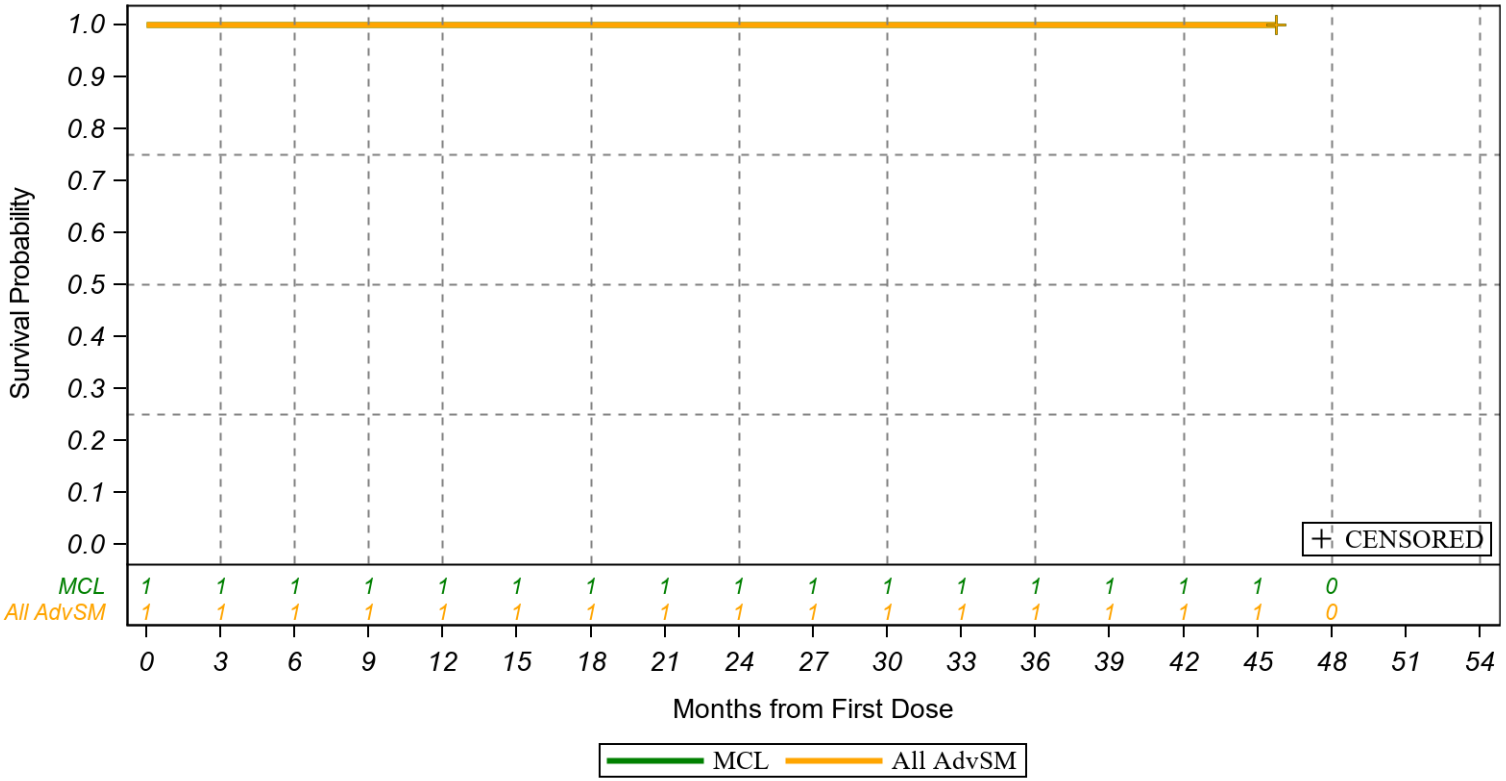

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Figure 35.2.3.2
Kaplan-Meier Curves of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101
Starting Dose: Overall

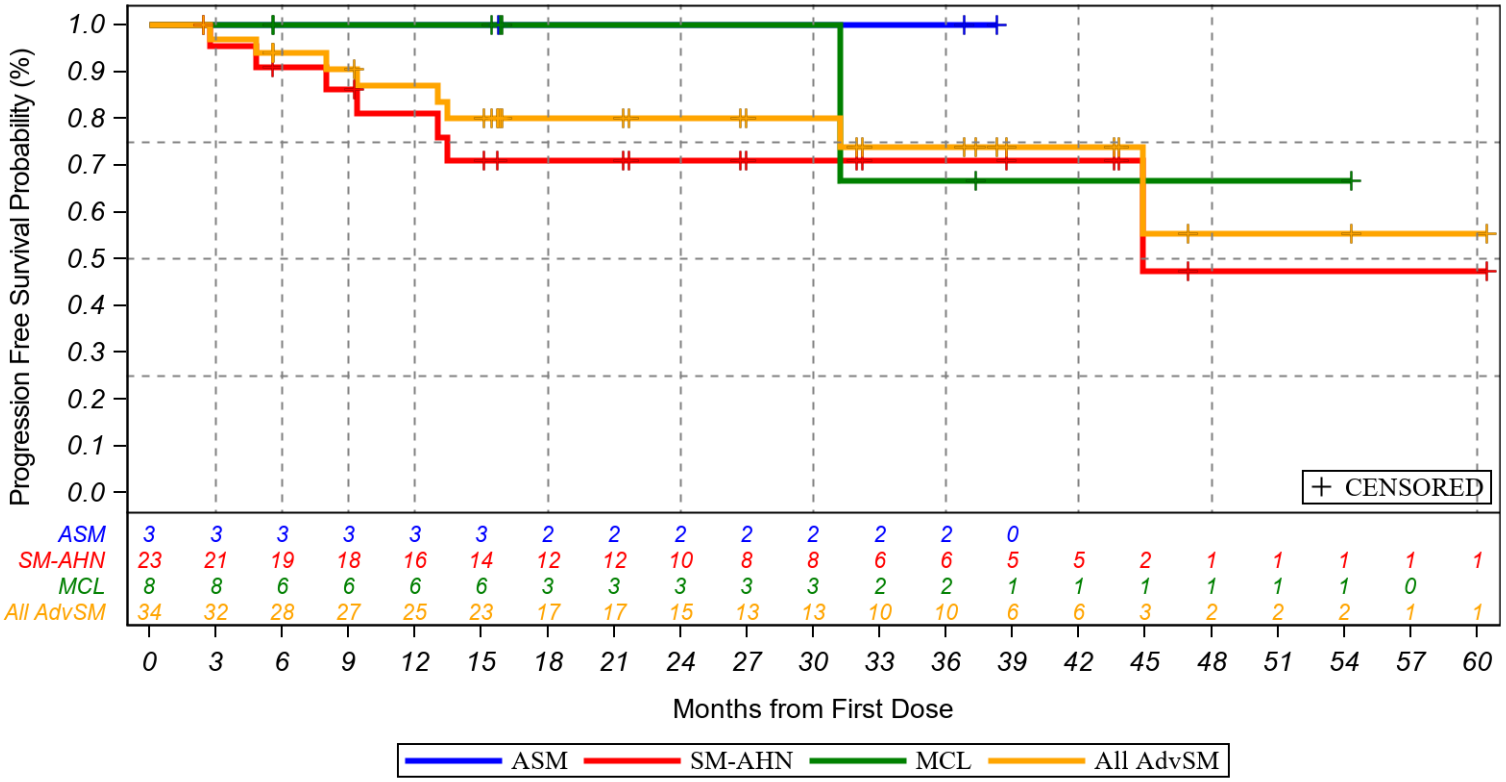


Figure 35.2.3.2
Kaplan-Meier Curves of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101
Starting Dose: < 200 mg

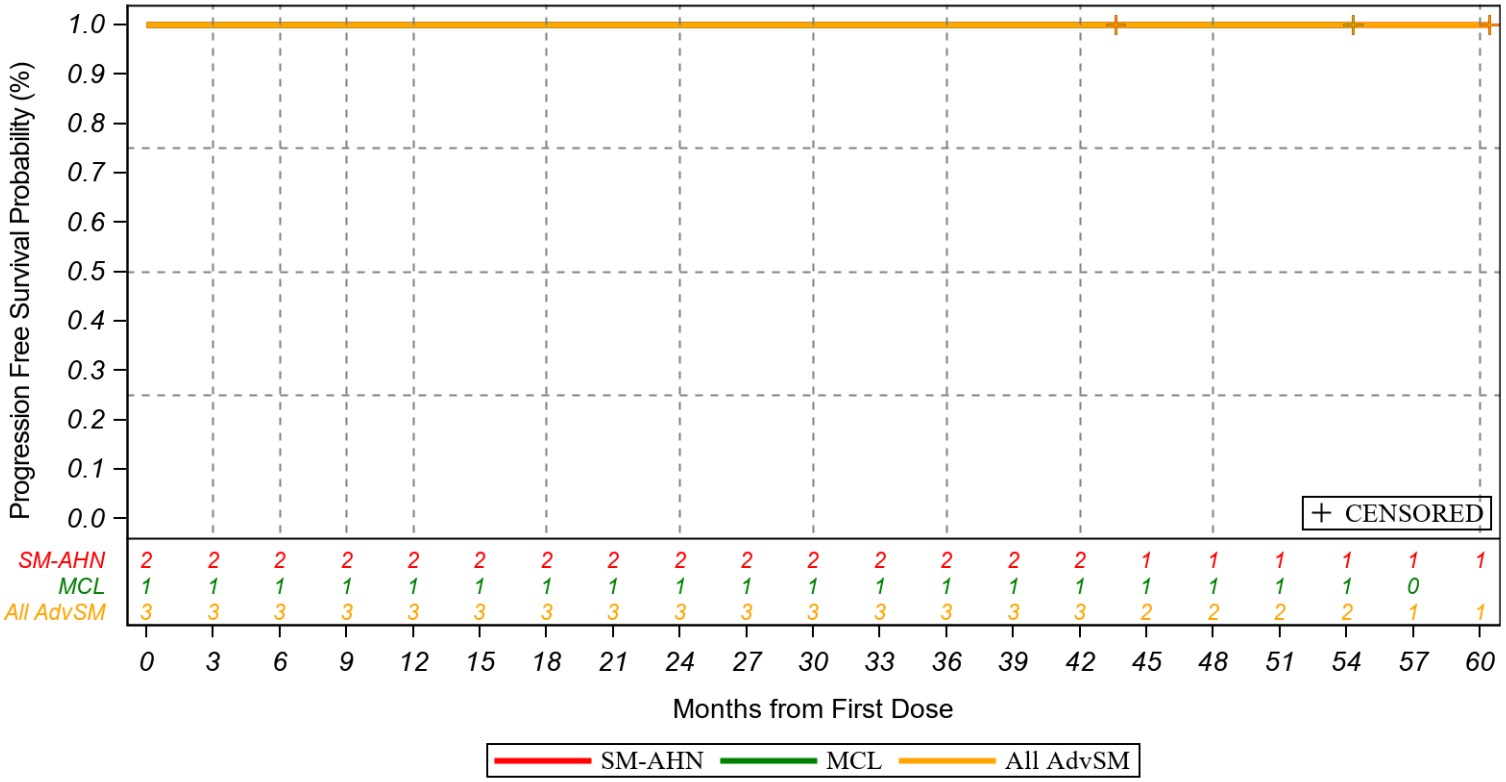


Figure 35.2.3.2
Kaplan-Meier Curves of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101
Starting Dose: < 300 mg

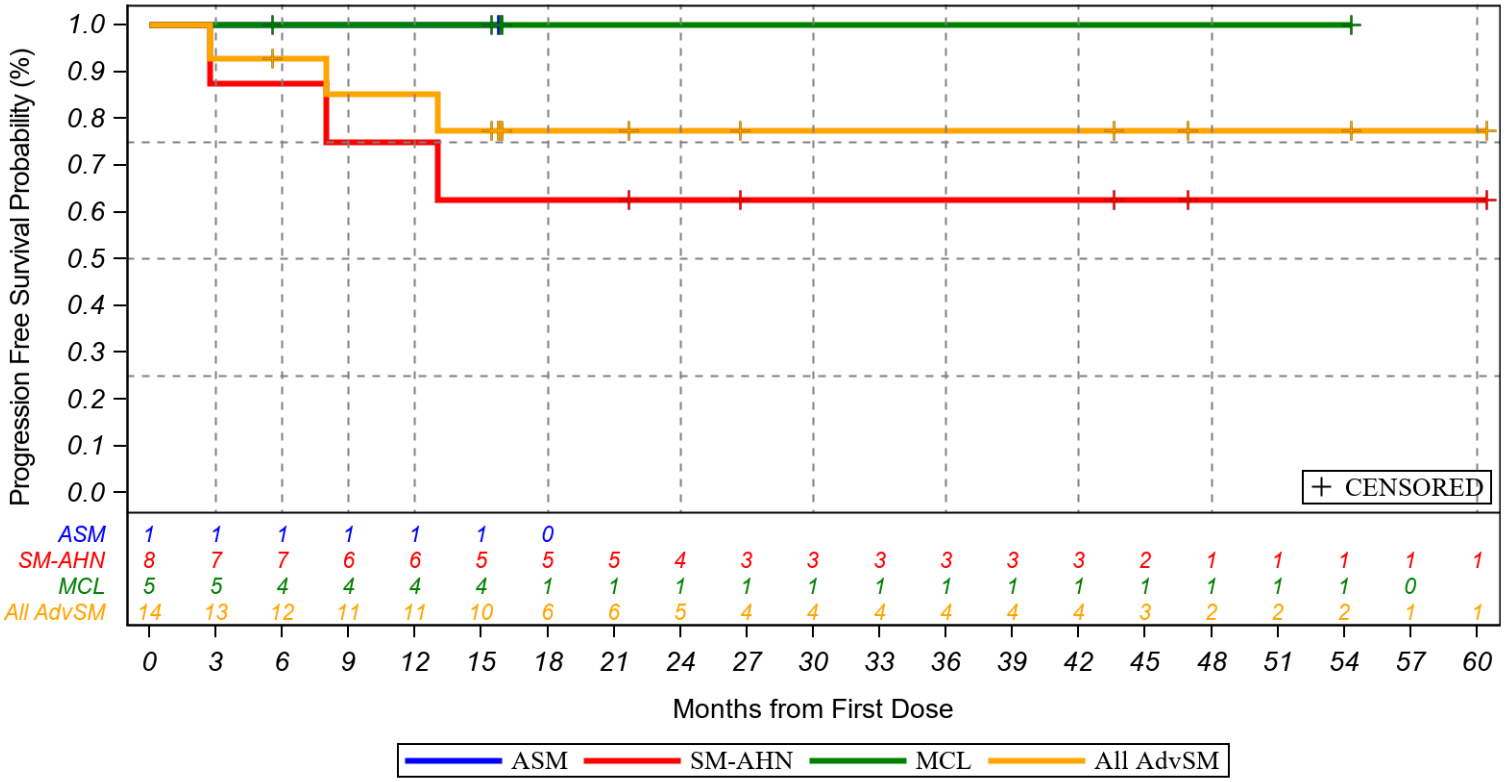


Figure 35.2.3.2
Kaplan-Meier Curves of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101
Starting Dose: 200 mg

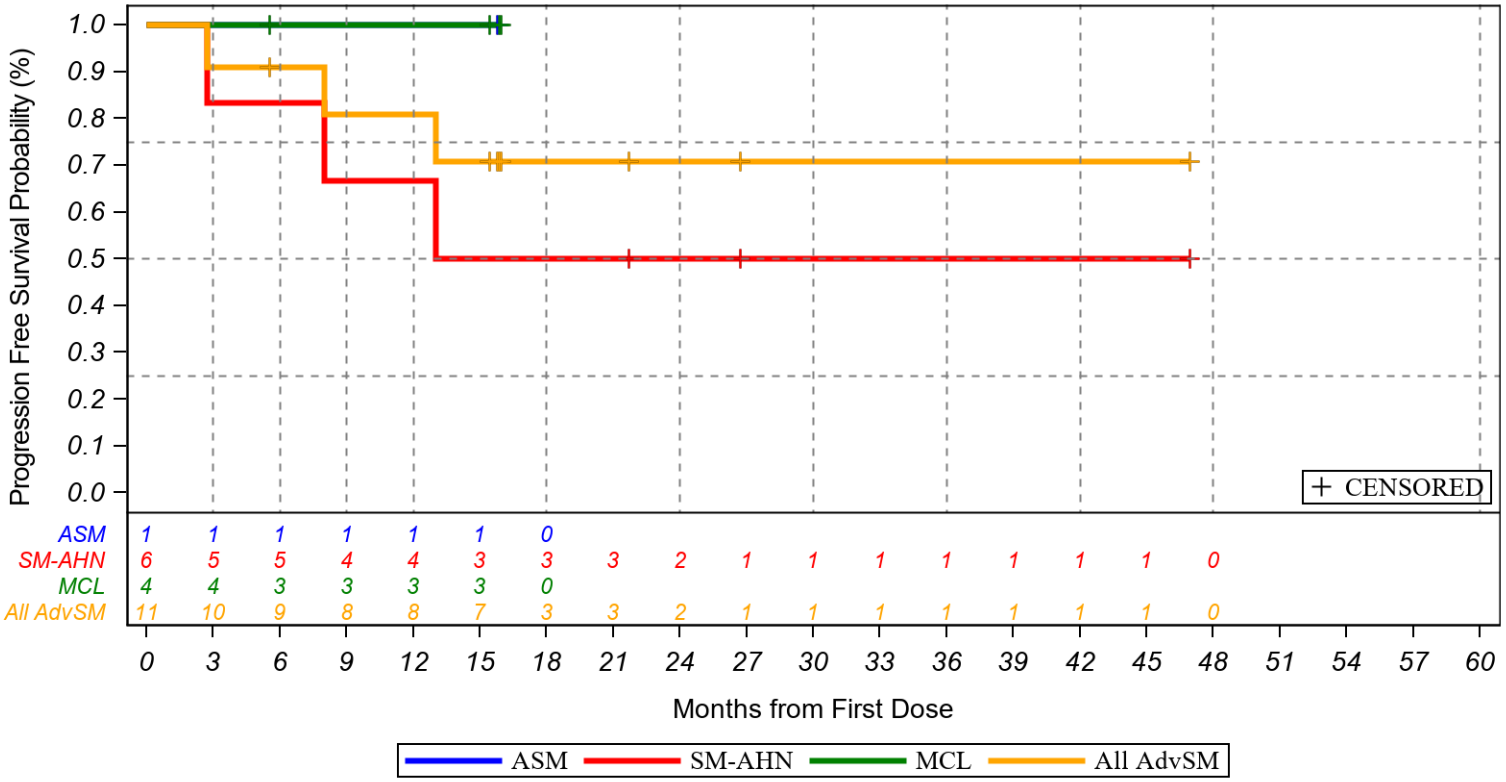


Figure 35.2.3.2
Kaplan-Meier Curves of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101
Starting Dose: 300 mg

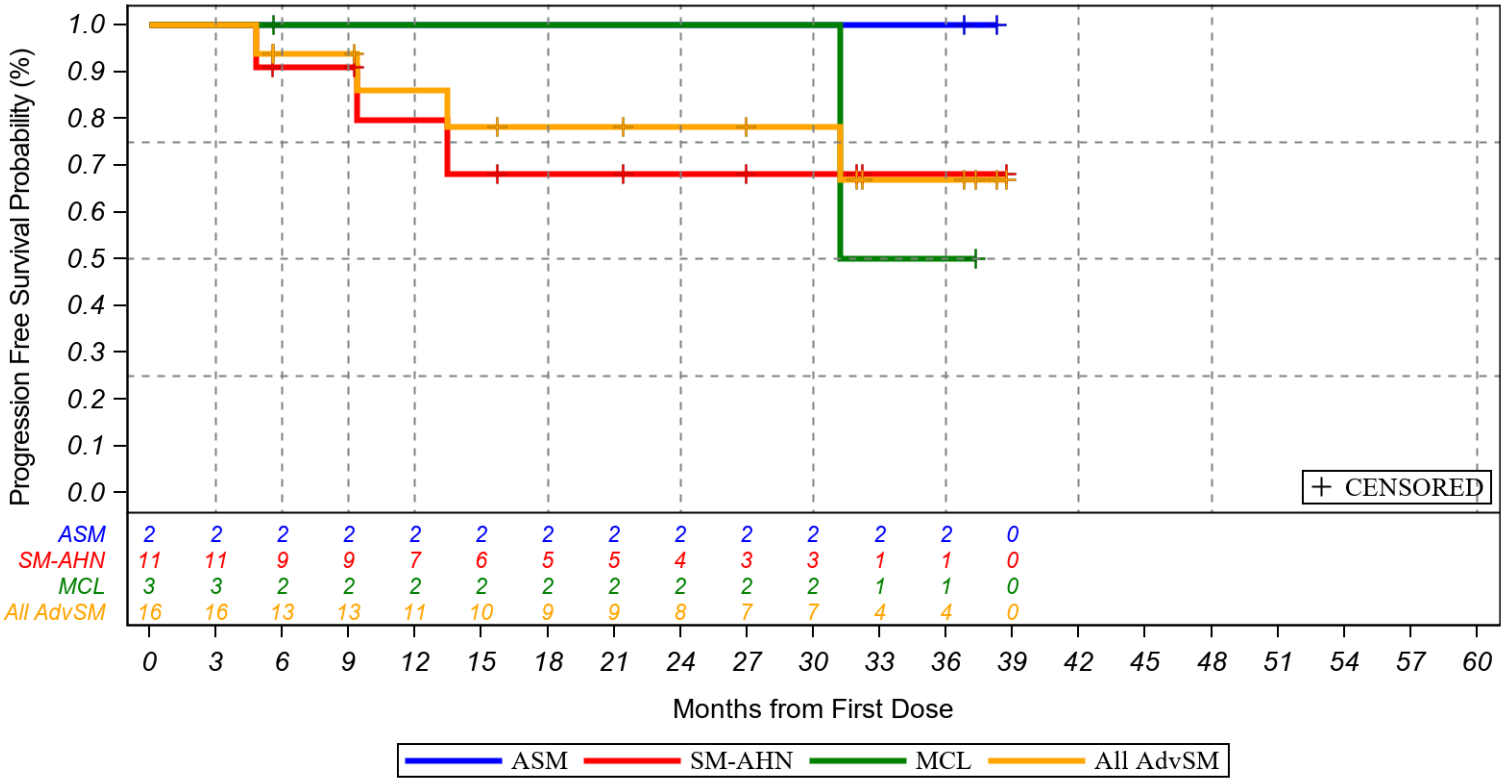


Figure 35.2.3.2
Kaplan-Meier Curves of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101
Starting Dose: 200 mg and 300 mg

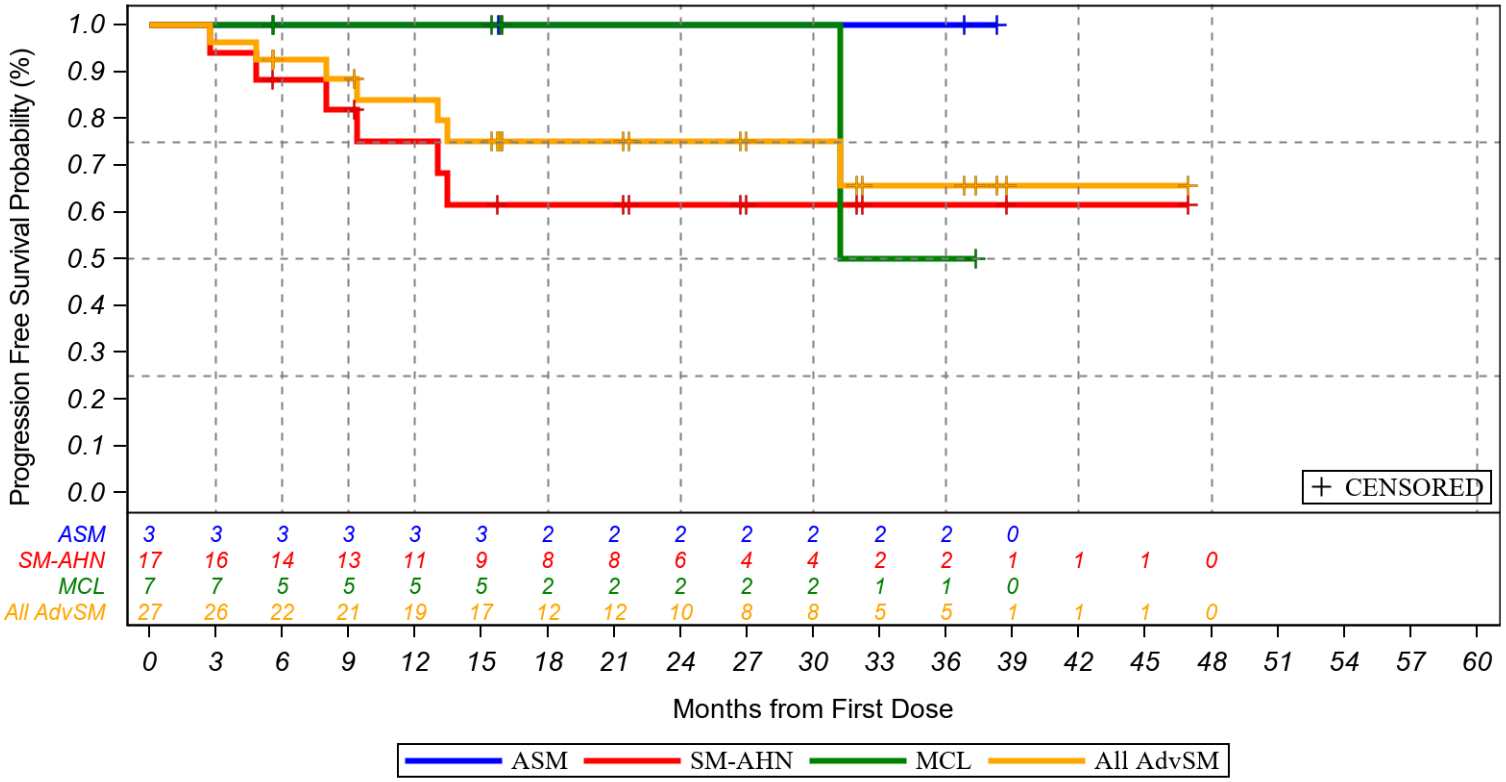


Figure 35.2.3.2
Kaplan-Meier Curves of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101
Starting Dose: 400 mg

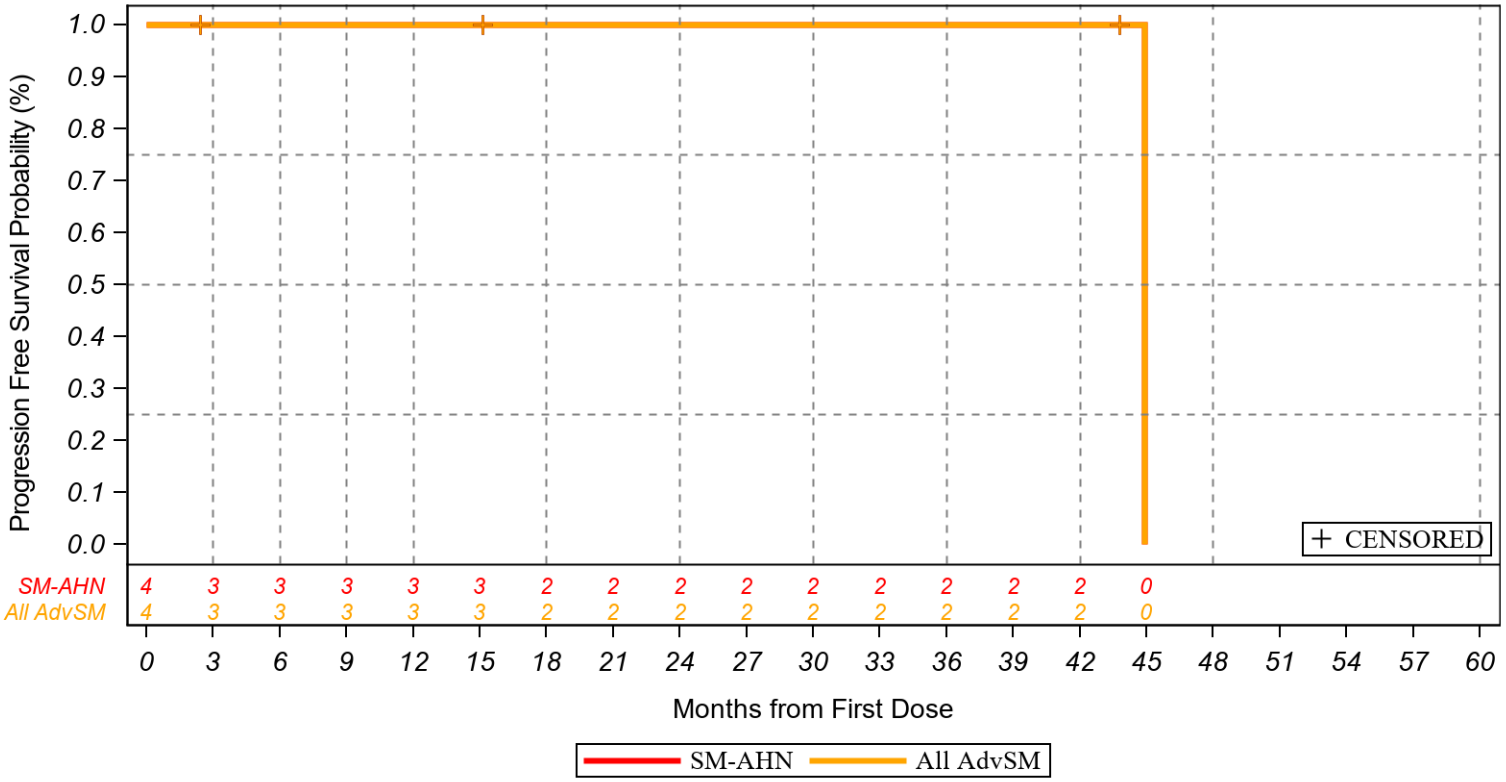


Figure 35.2.3.2
Kaplan-Meier Curves of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2202
Starting Dose: Overall

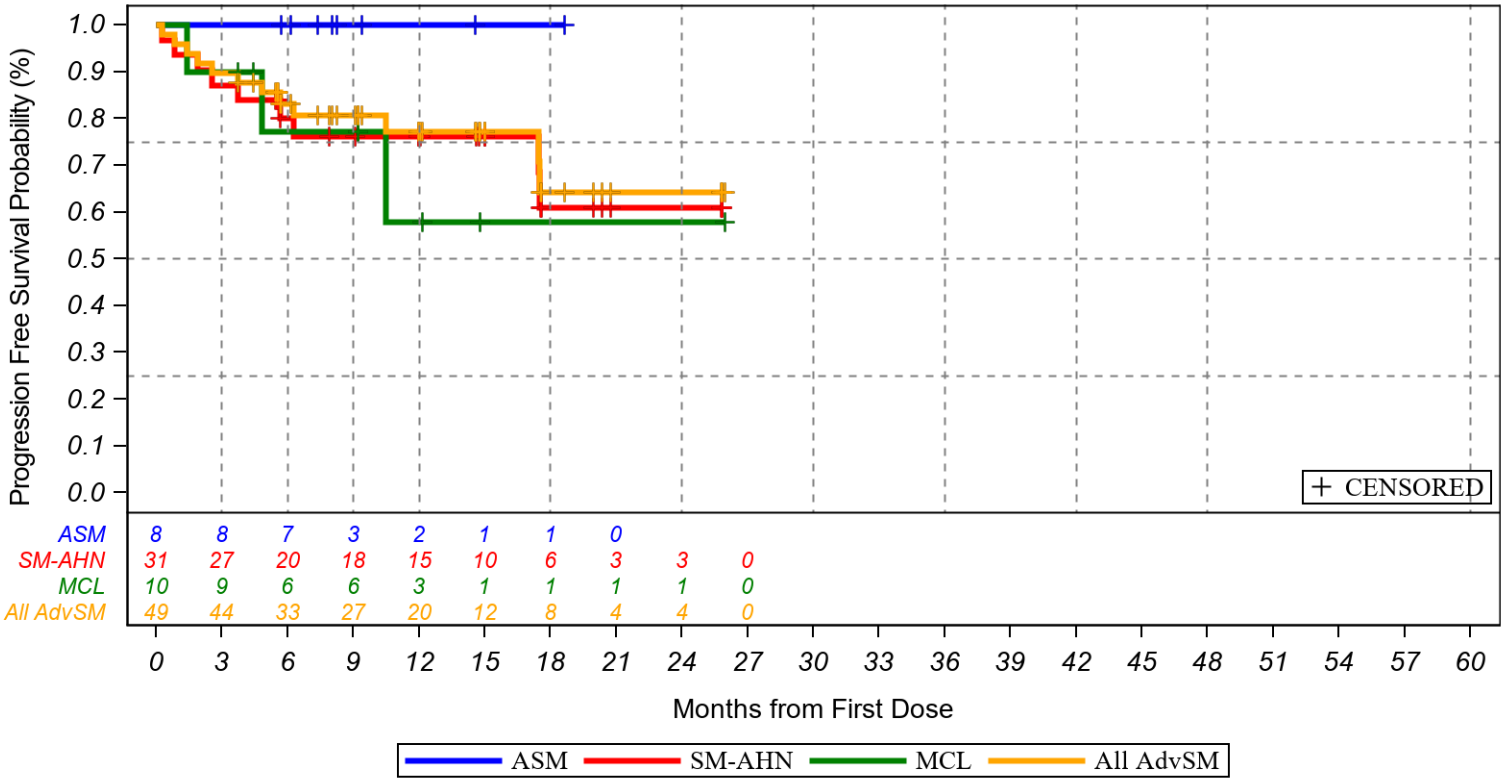
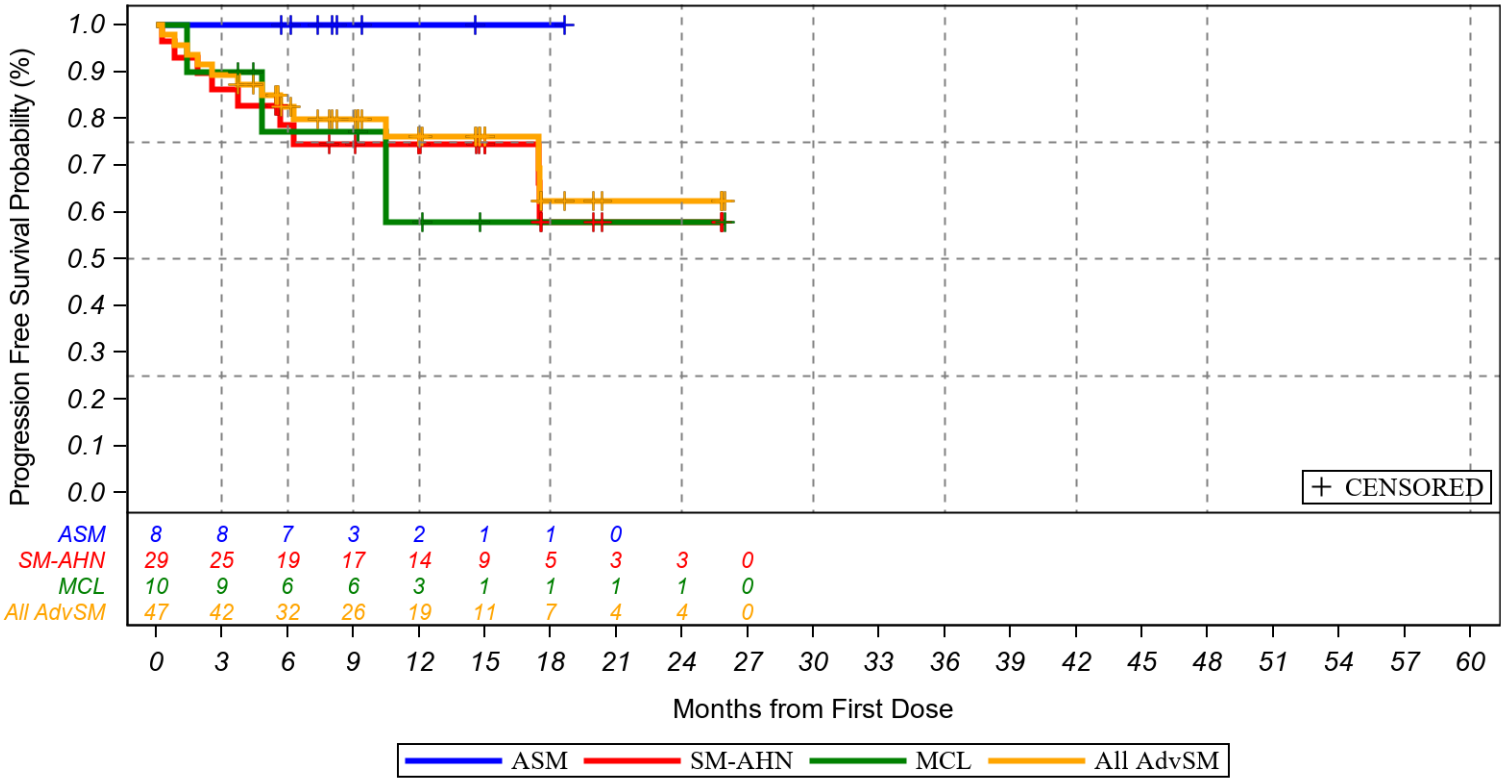


Figure 35.2.3.2
Kaplan-Meier Curves of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2202
Starting Dose: 200 mg



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Avapritinib Systemic Mastocytosis Integrated Summary of Efficacy
BLU-285 SM Germany HTA Analysis
Cutoff date: 20apr2021

Figure 35.2.3.2
Kaplan-Meier Curves of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall

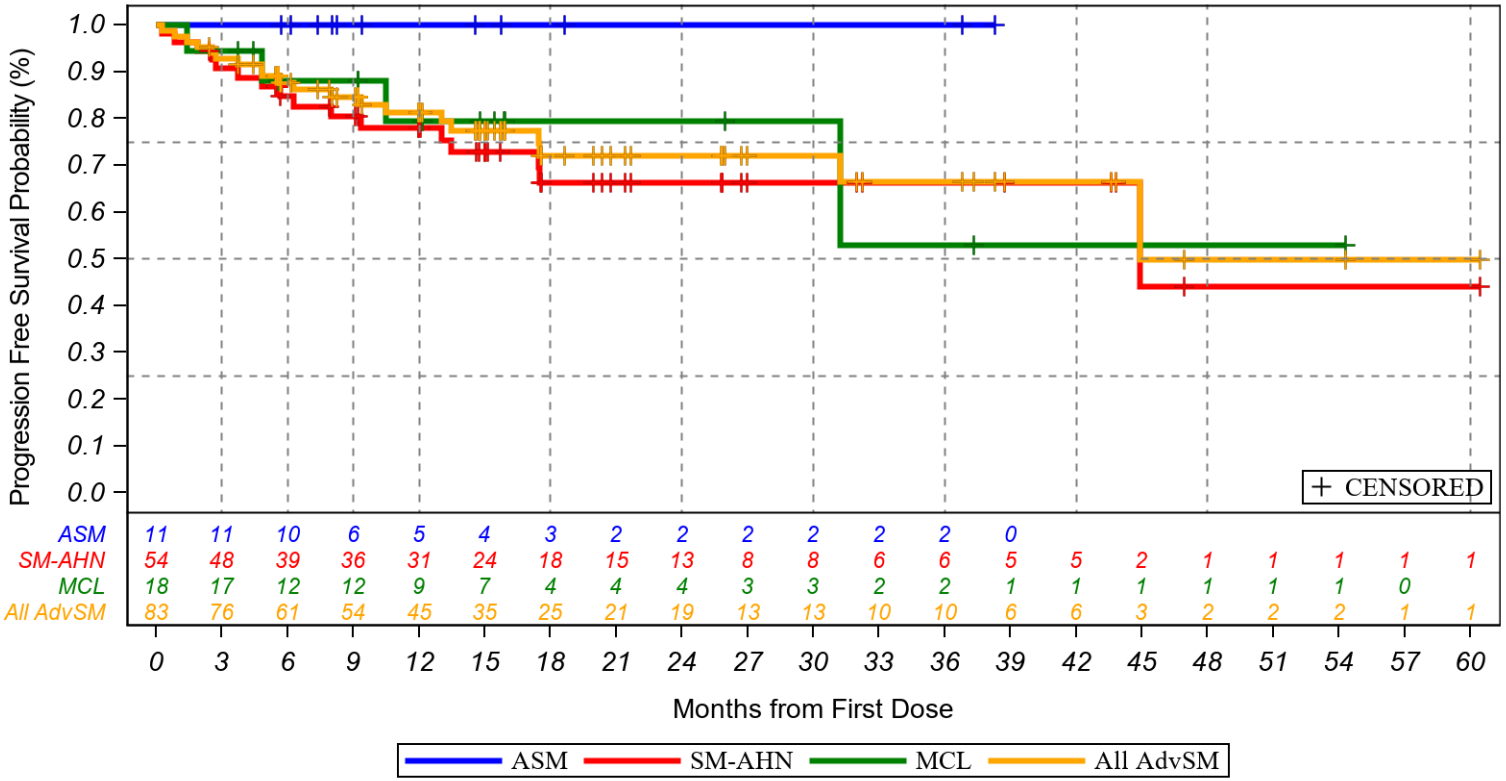

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Figure 35.2.3.2
Kaplan-Meier Curves of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg

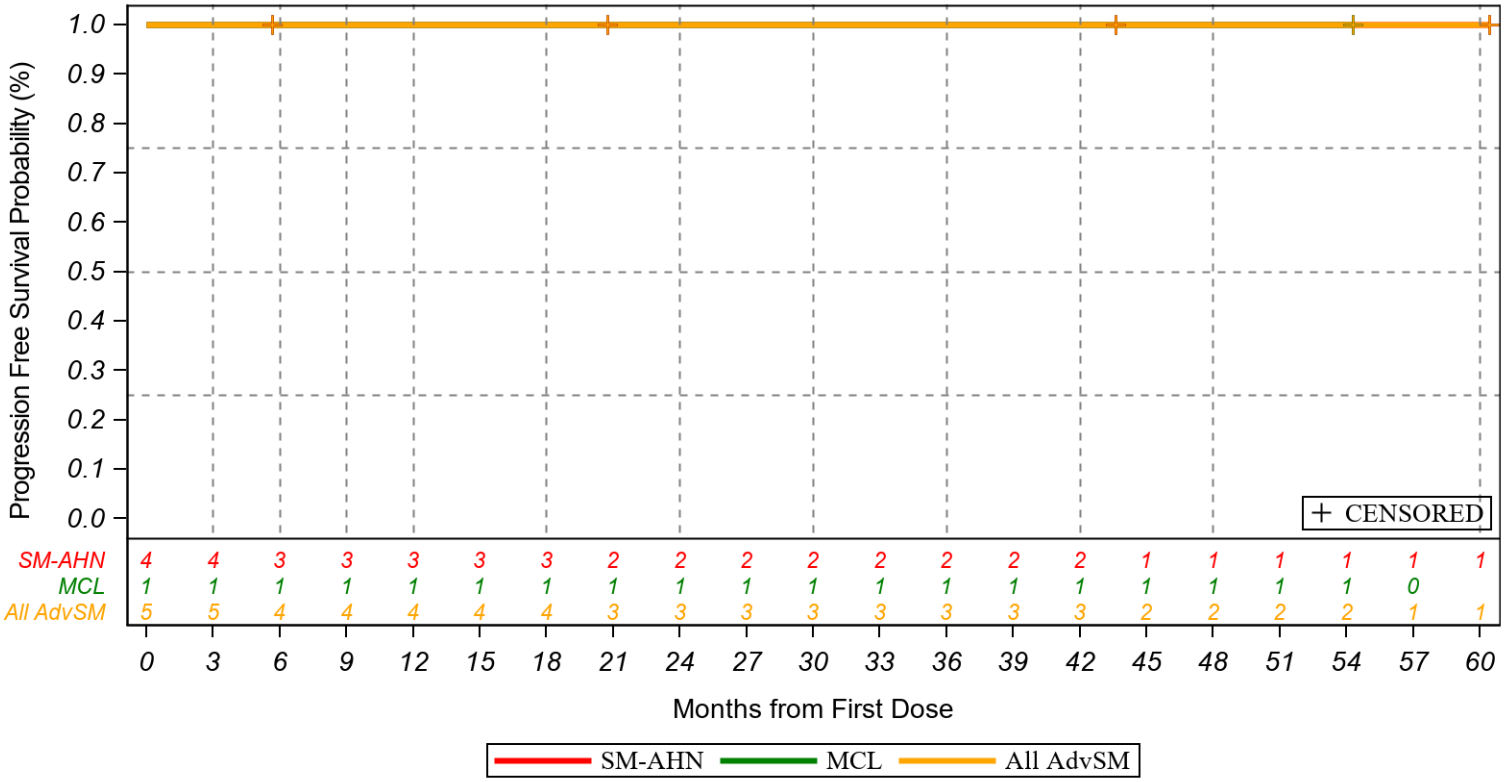


Figure 35.2.3.2
Kaplan-Meier Curves of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg

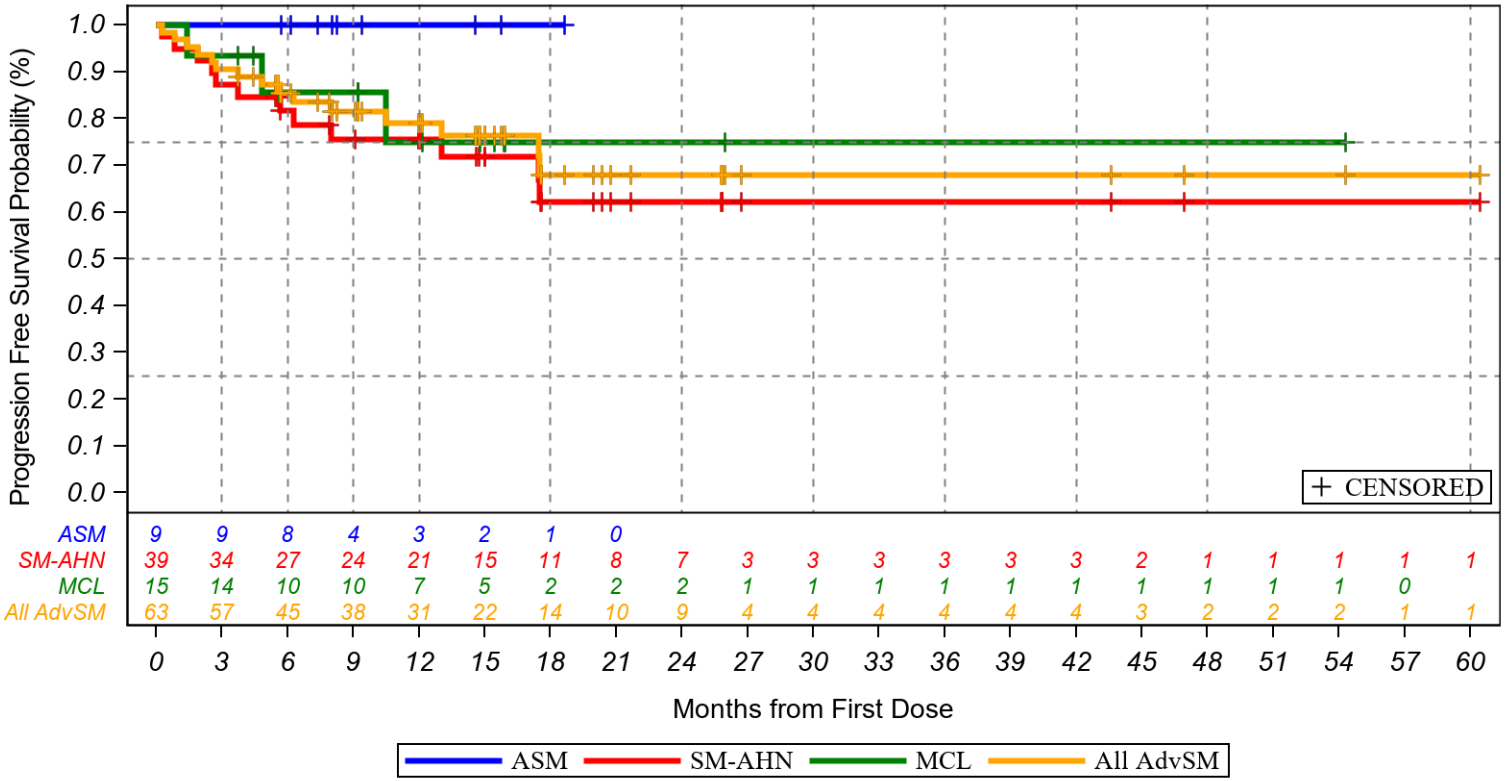


Figure 35.2.3.2
Kaplan-Meier Curves of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg

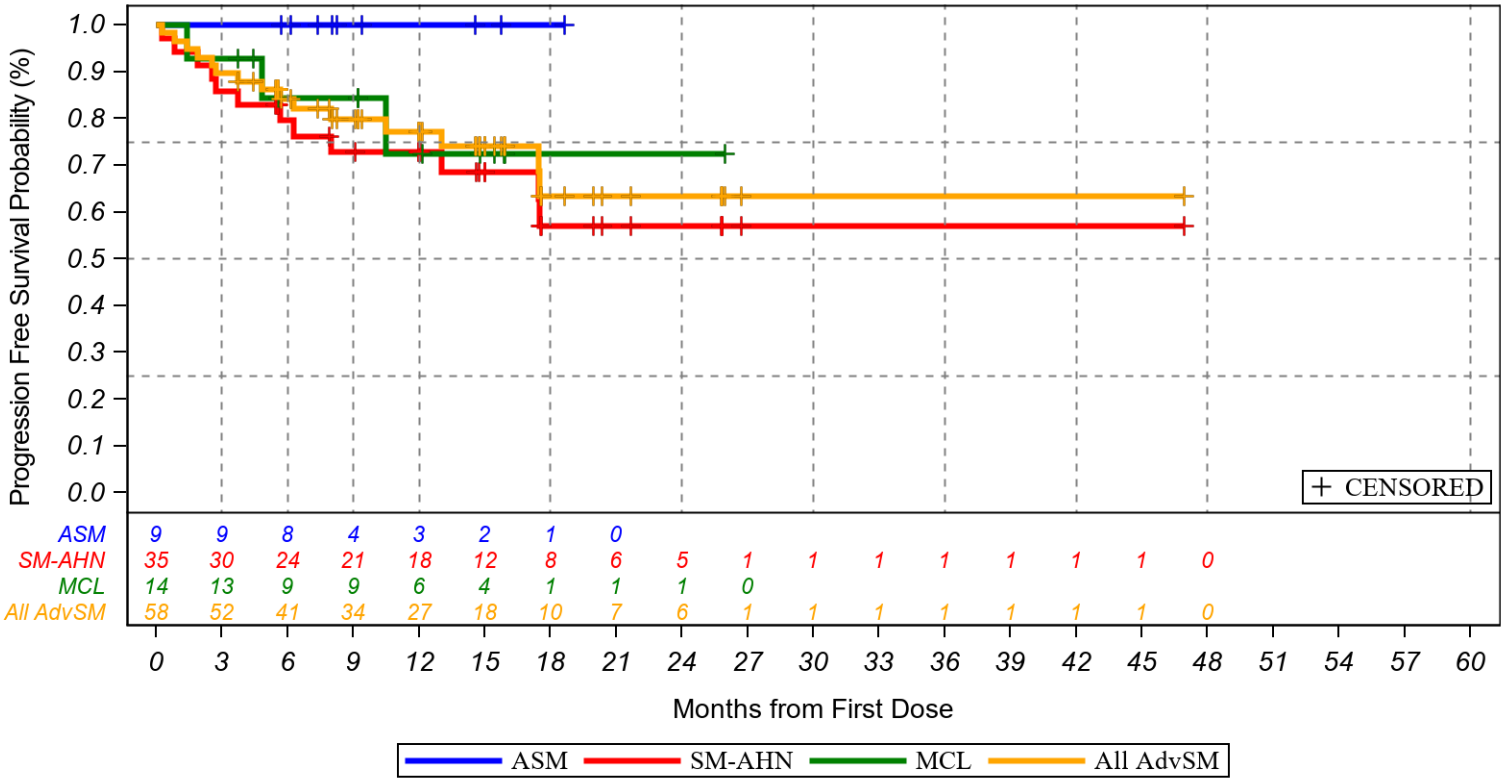
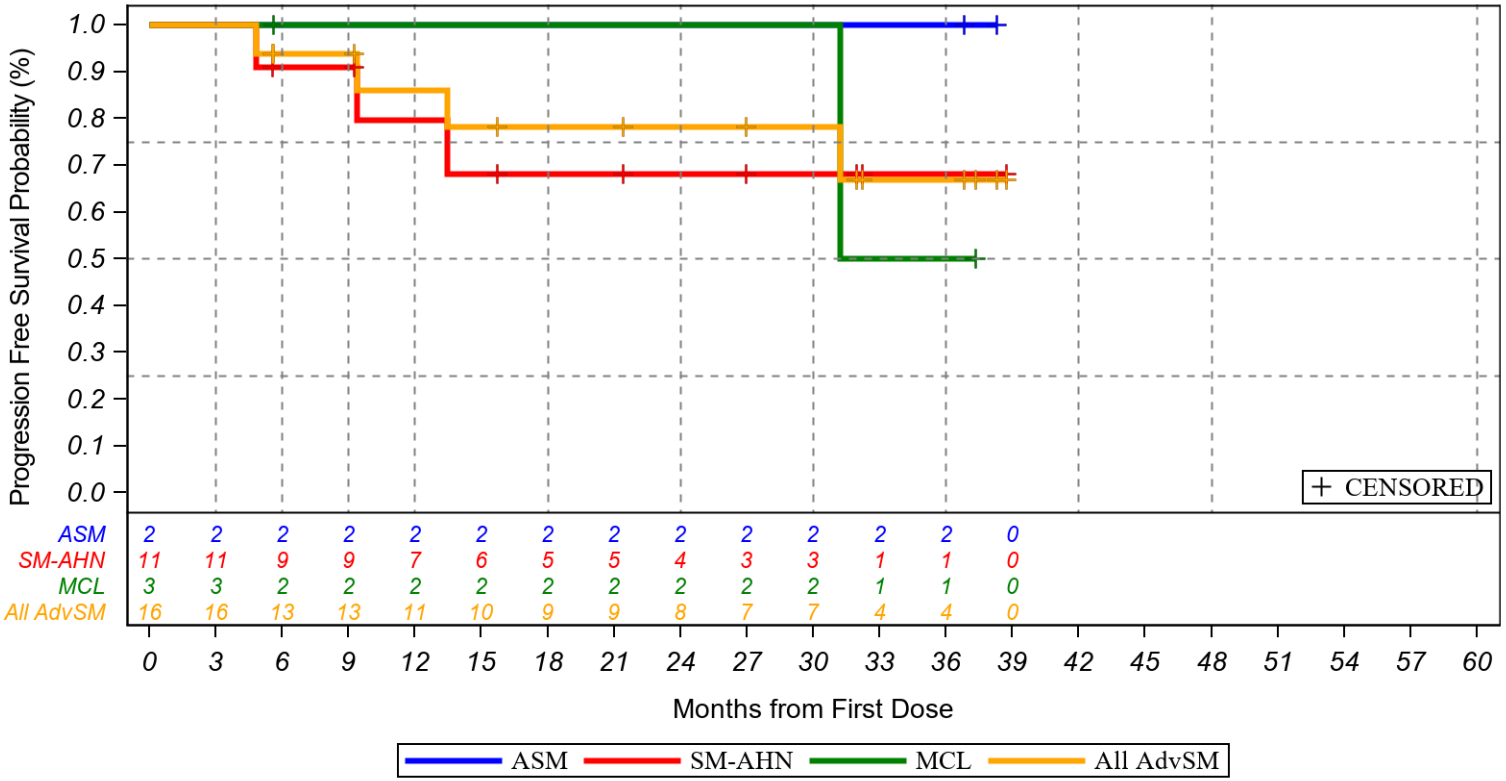


Figure 35.2.3.2
Kaplan-Meier Curves of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg



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Avapritinib Systemic Mastocytosis Integrated Summary of Efficacy
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Figure 35.2.3.2
Kaplan-Meier Curves of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg

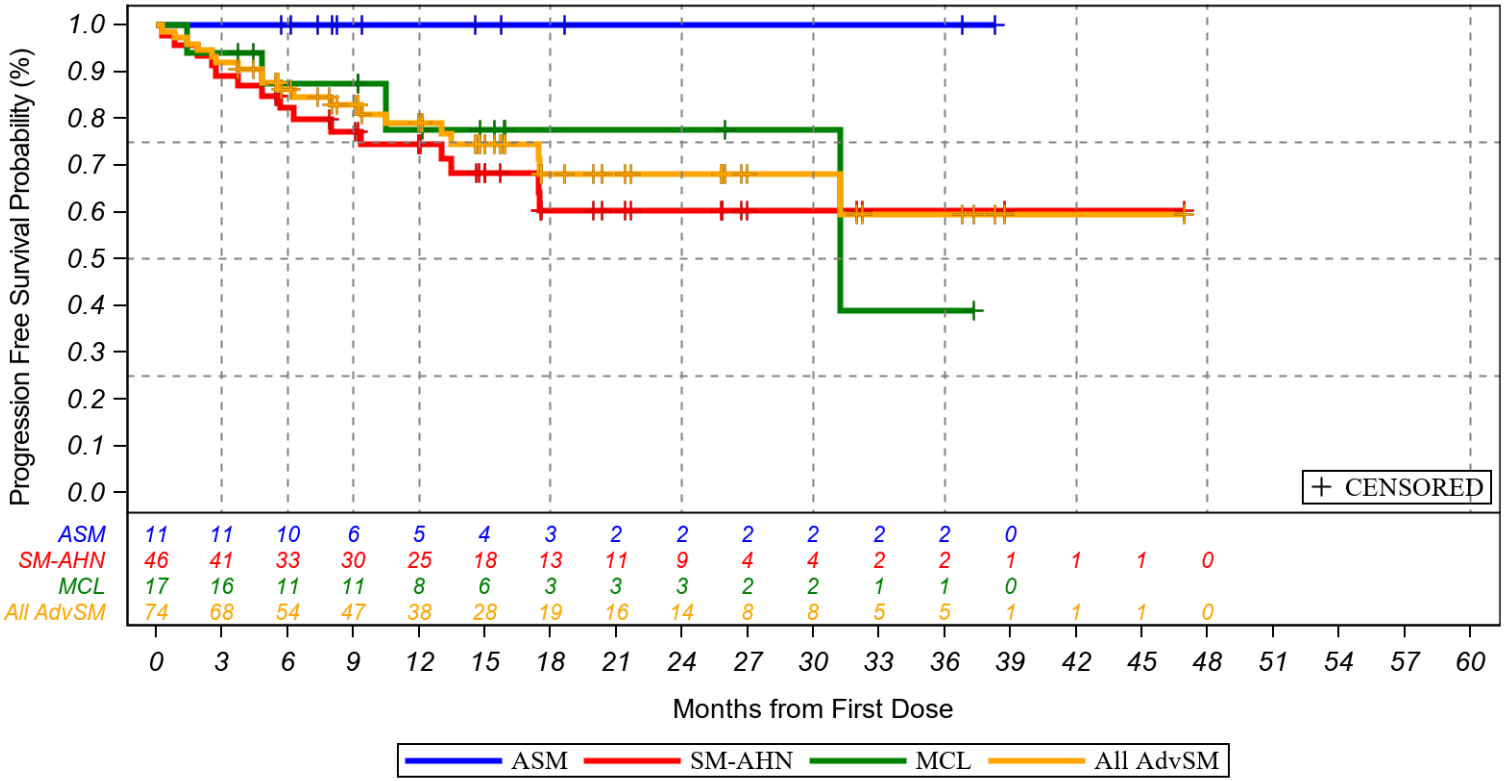

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Figure 35.2.3.2
Kaplan-Meier Curves of Investigator Assessed Progression Free Survival
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg

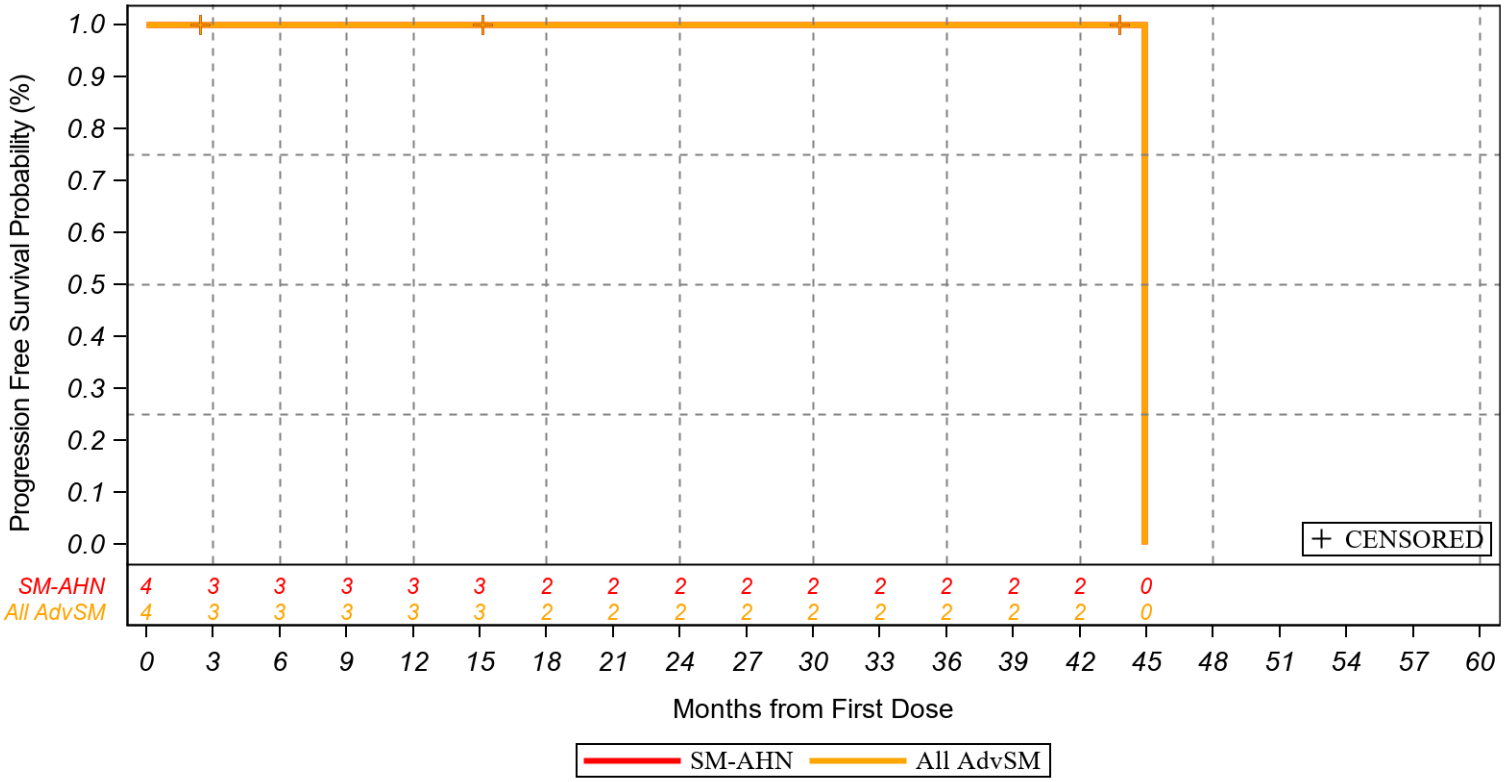

Figure 35.2.3.4
Kaplan-Meier Curves of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101
Starting Dose: Overall

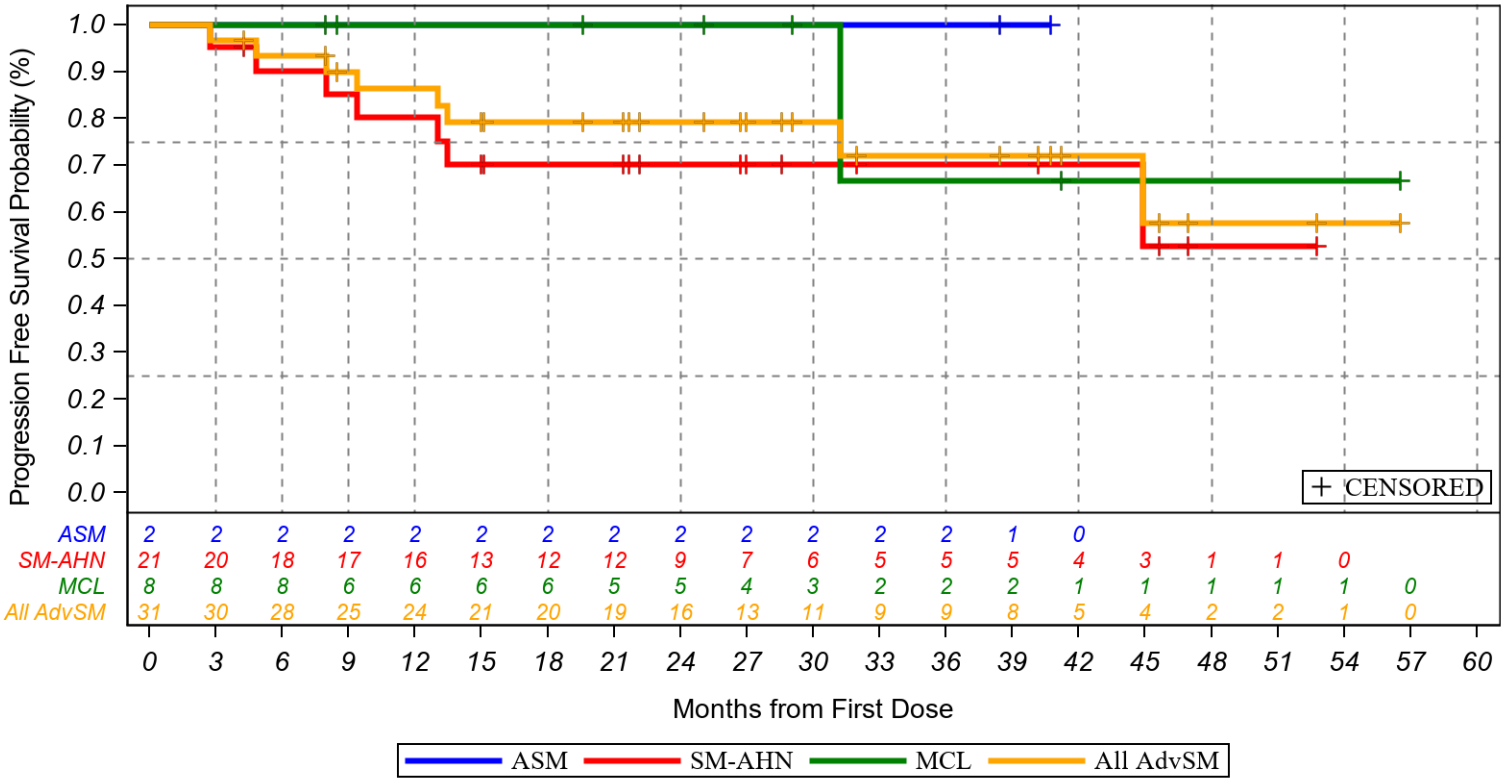

Figure 35.2.3.4
Kaplan-Meier Curves of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101
Starting Dose: < 200 mg

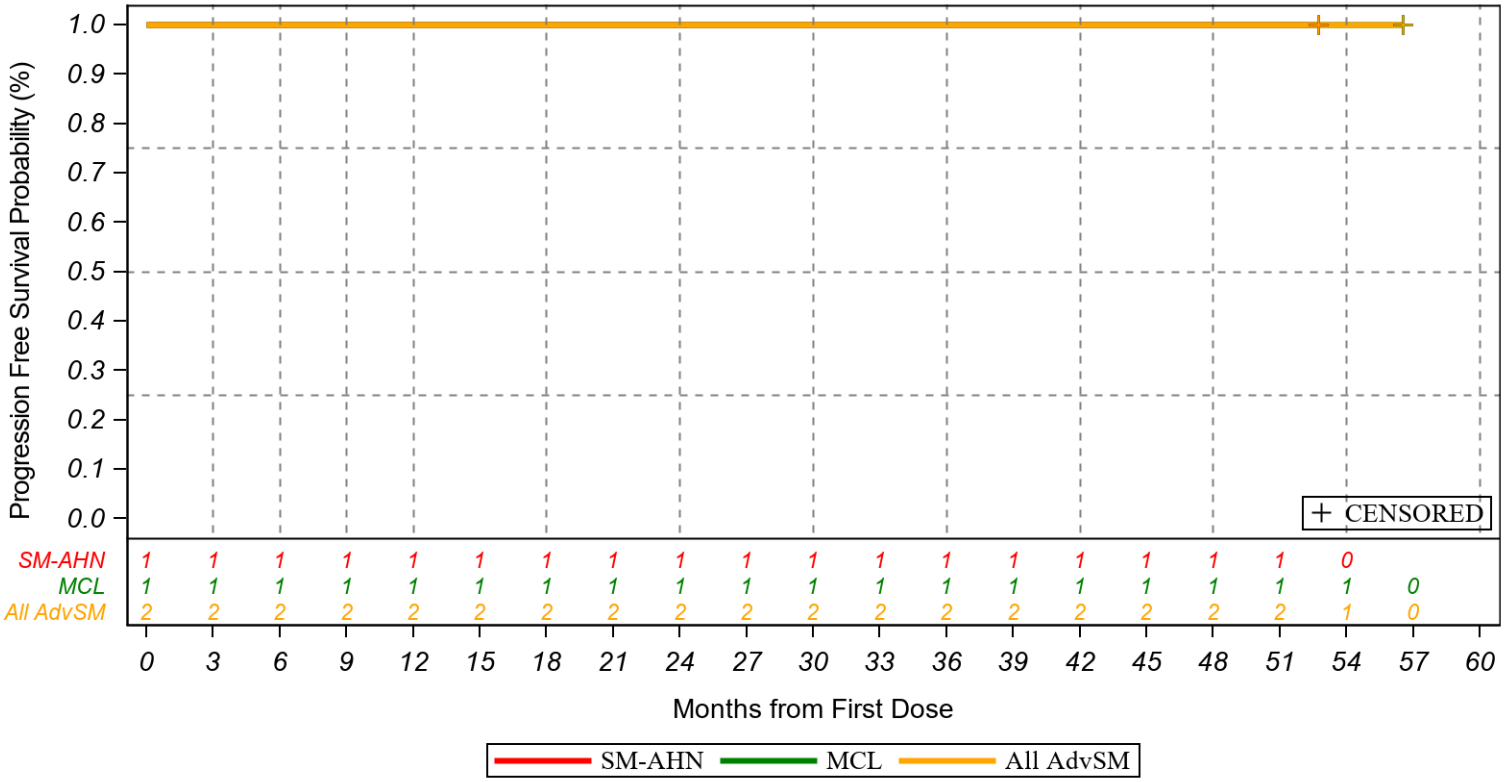

Figure 35.2.3.4
Kaplan-Meier Curves of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101
Starting Dose: < 300 mg

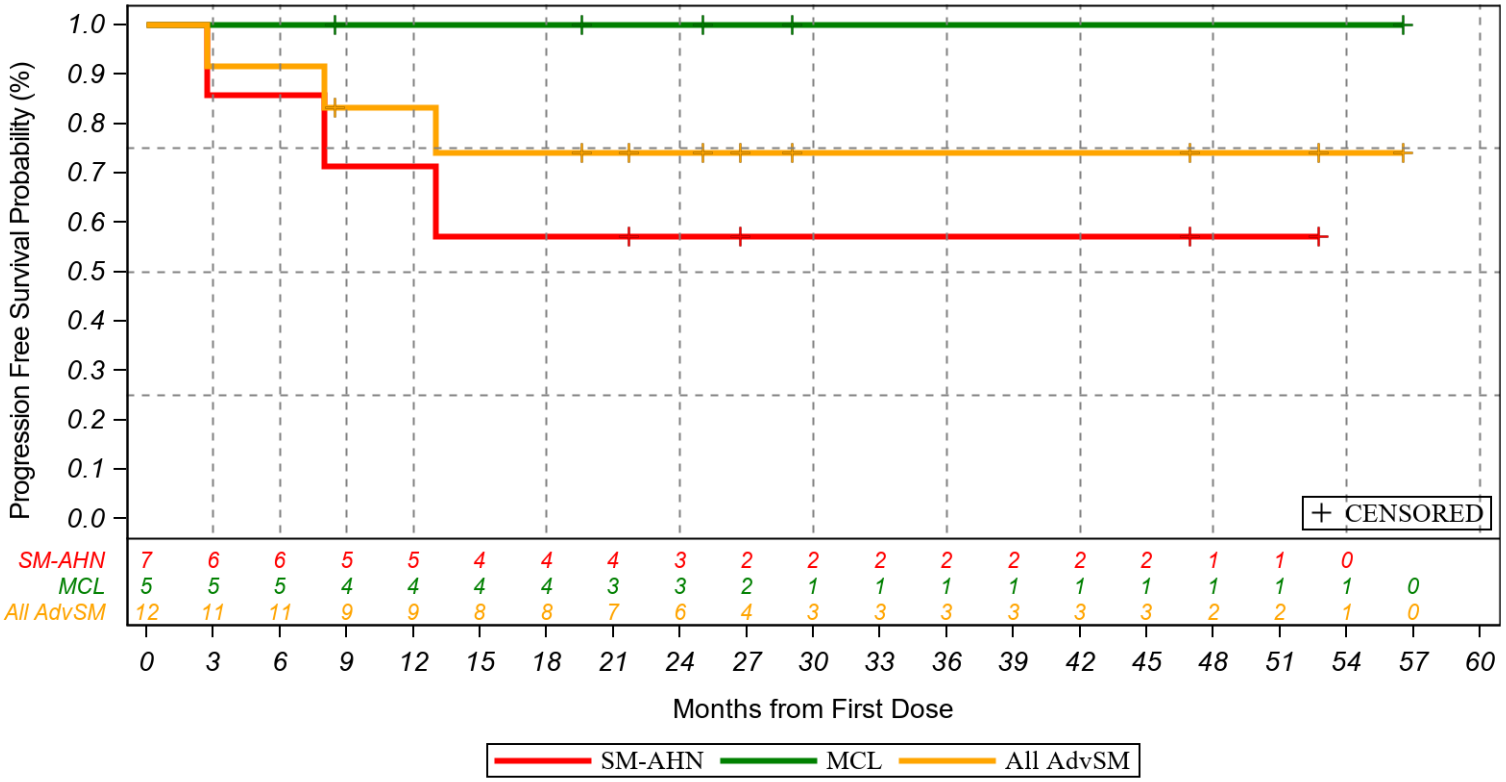

Figure 35.2.3.4
Kaplan-Meier Curves of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101
Starting Dose: 200 mg

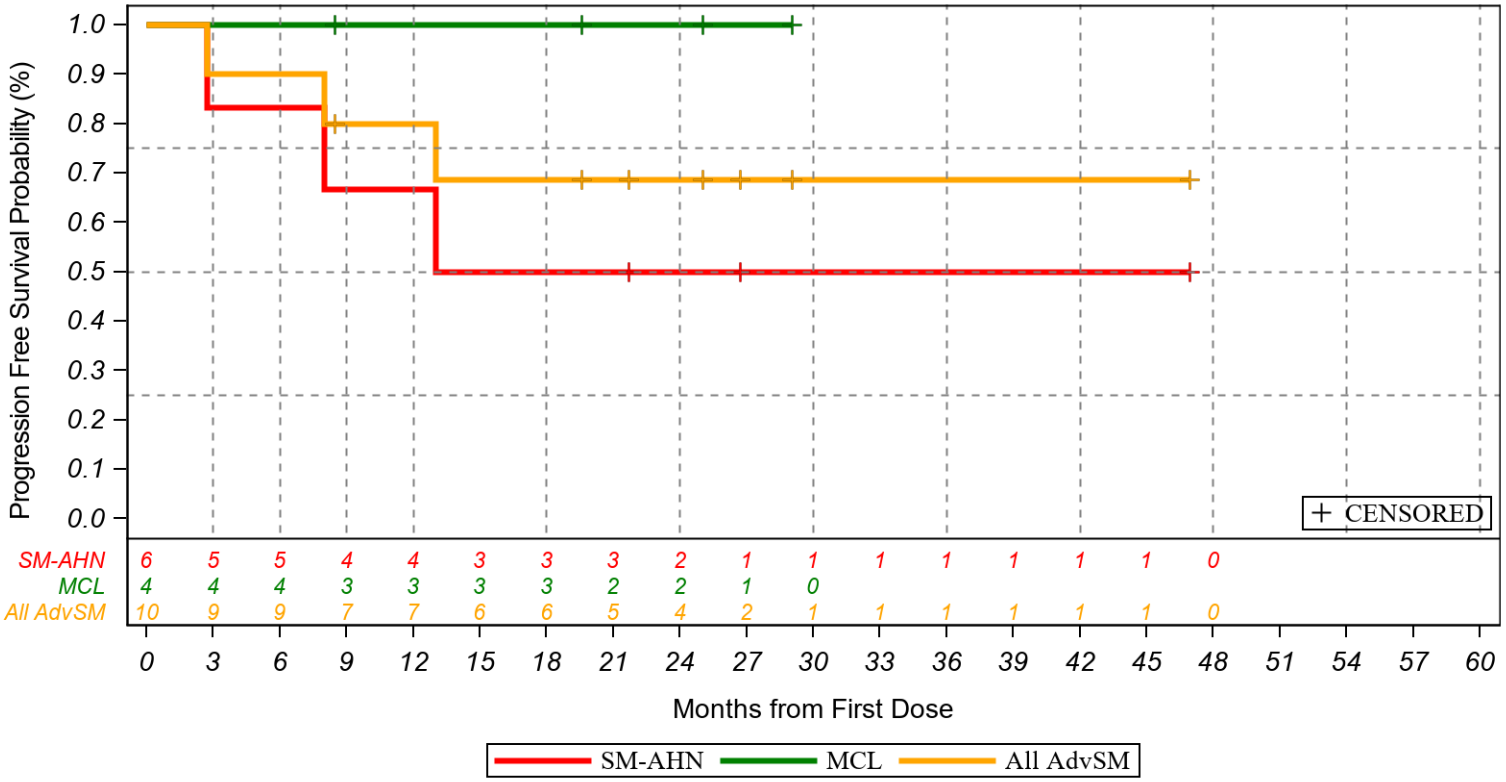

Figure 35.2.3.4
Kaplan-Meier Curves of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101
Starting Dose: 300 mg

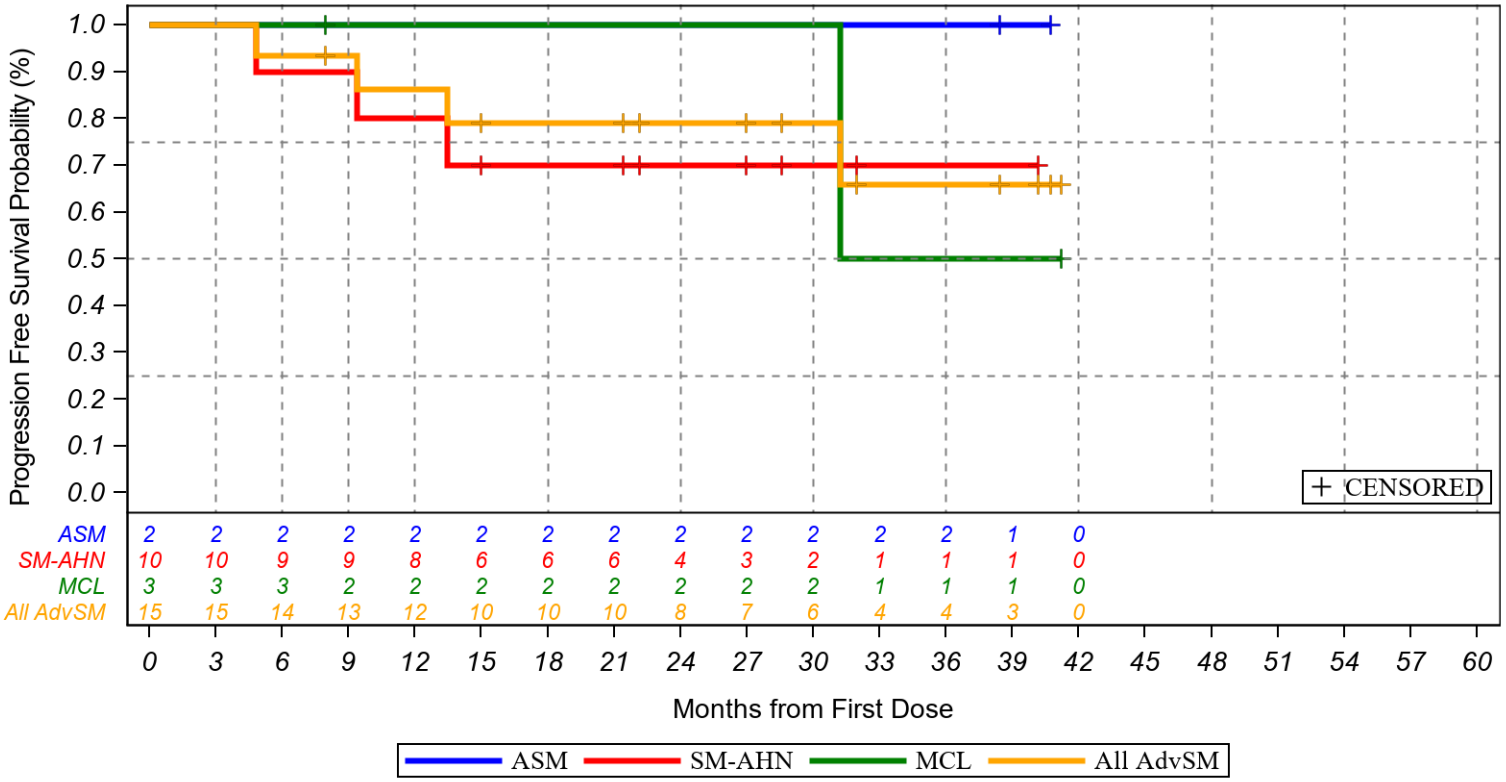

Figure 35.2.3.4
Kaplan-Meier Curves of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101
Starting Dose: 200 mg and 300 mg

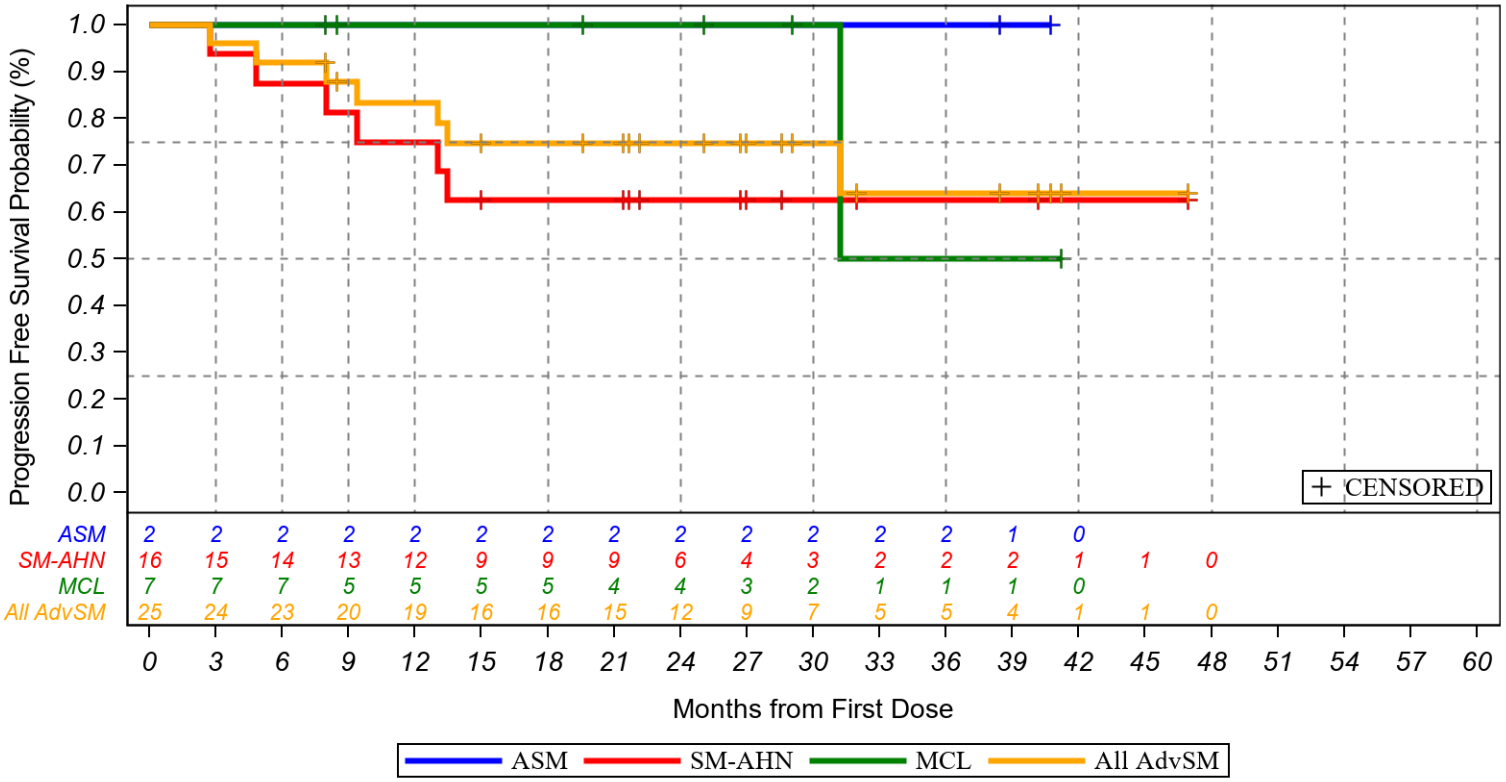

Figure 35.2.3.4
Kaplan-Meier Curves of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2101
Starting Dose: 400 mg

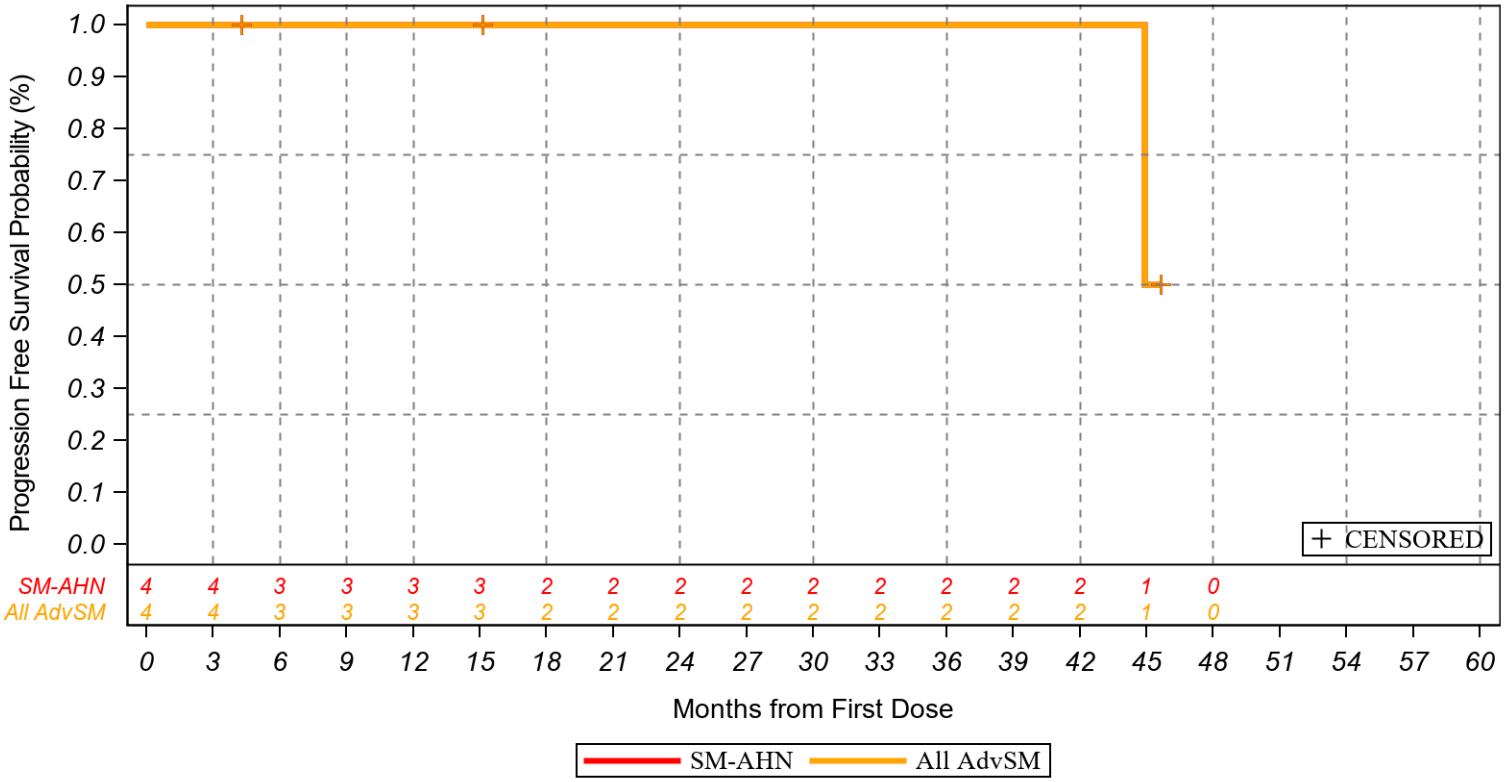

Figure 35.2.3.4
Kaplan-Meier Curves of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2202
Starting Dose: Overall

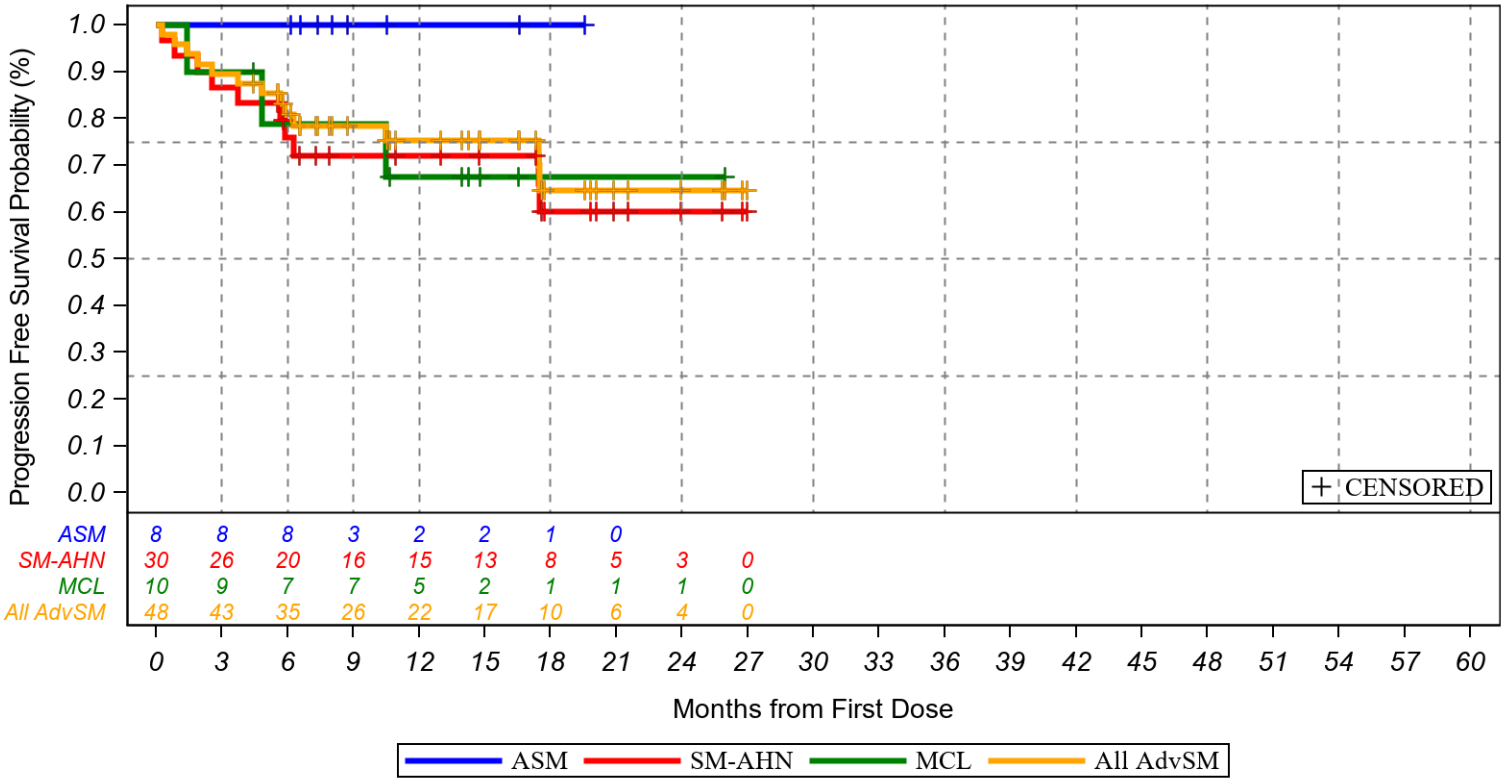

Figure 35.2.3.4
Kaplan-Meier Curves of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Study BLU-285-2202
Starting Dose: 200 mg

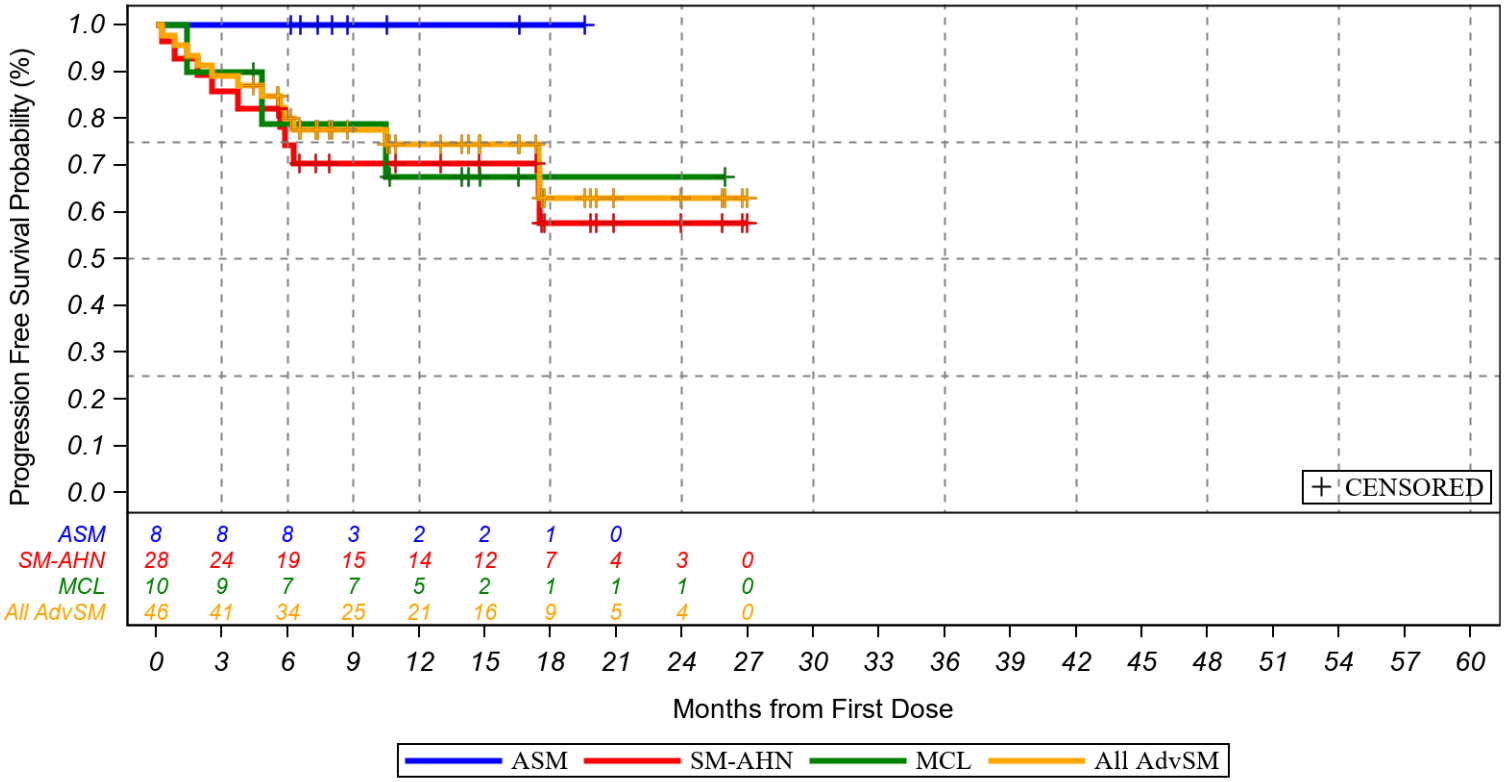

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Figure 35.2.3.4
Kaplan-Meier Curves of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: Overall

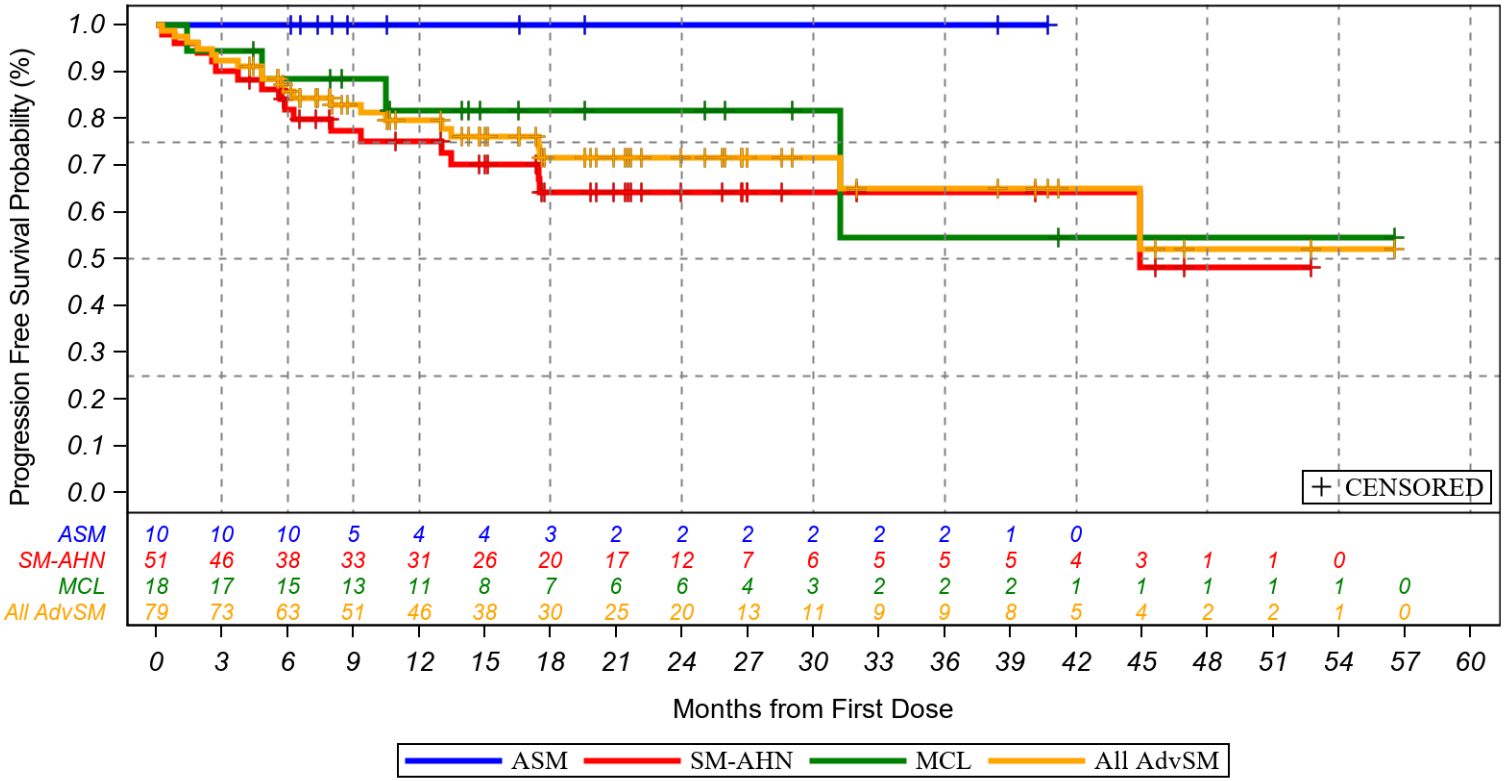

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Figure 35.2.3.4
Kaplan-Meier Curves of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 200 mg

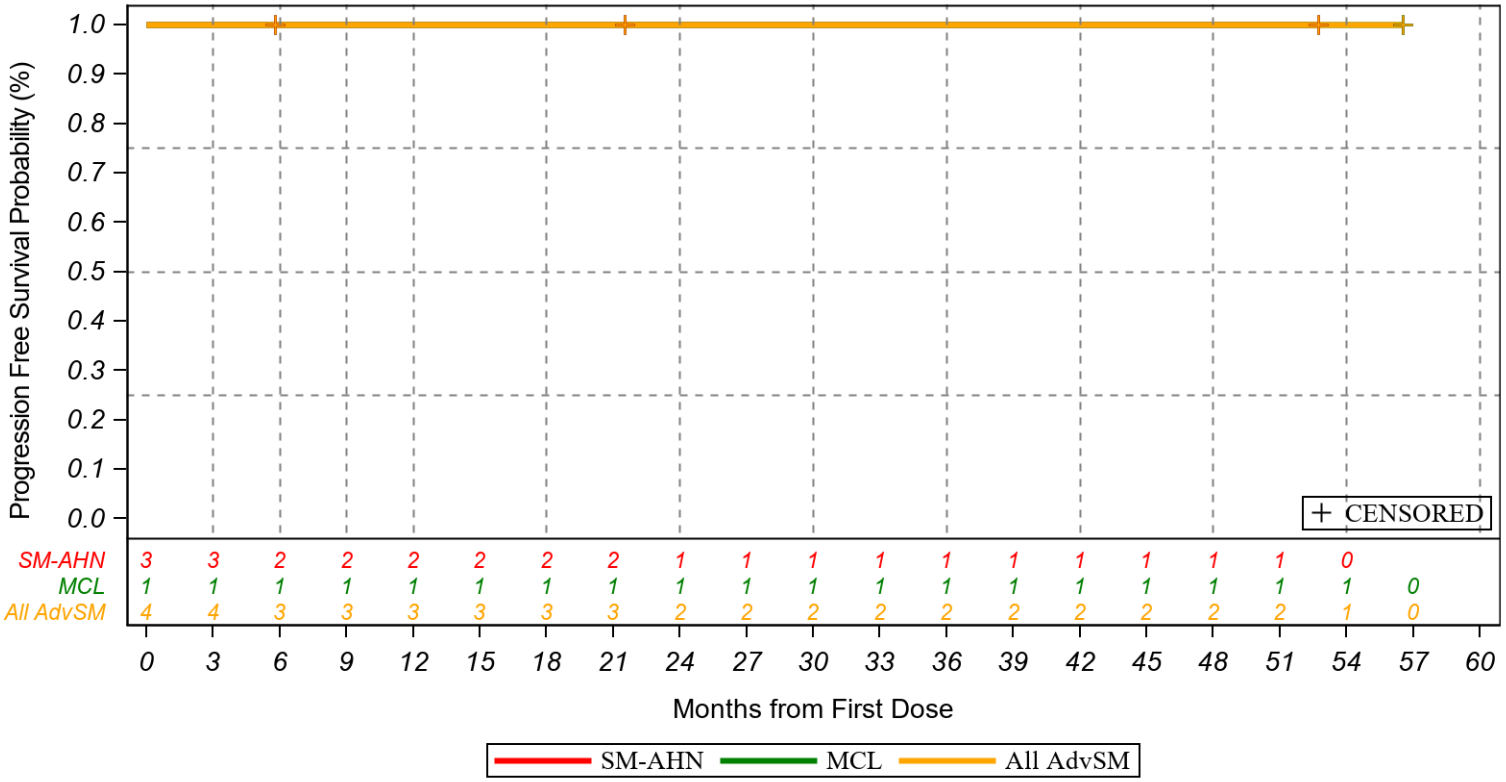

Figure 35.2.3.4
Kaplan-Meier Curves of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: < 300 mg

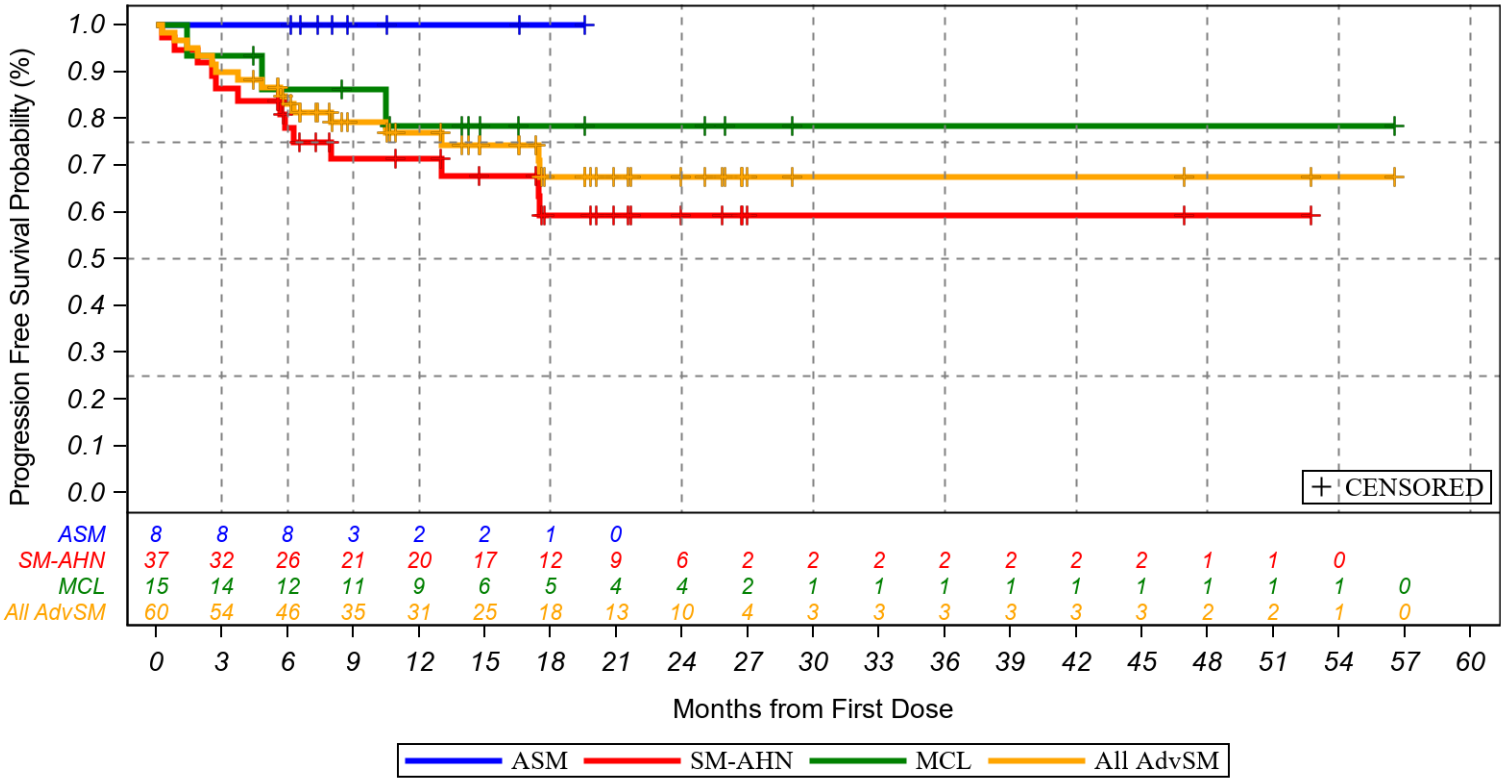

Figure 35.2.3.4
Kaplan-Meier Curves of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg

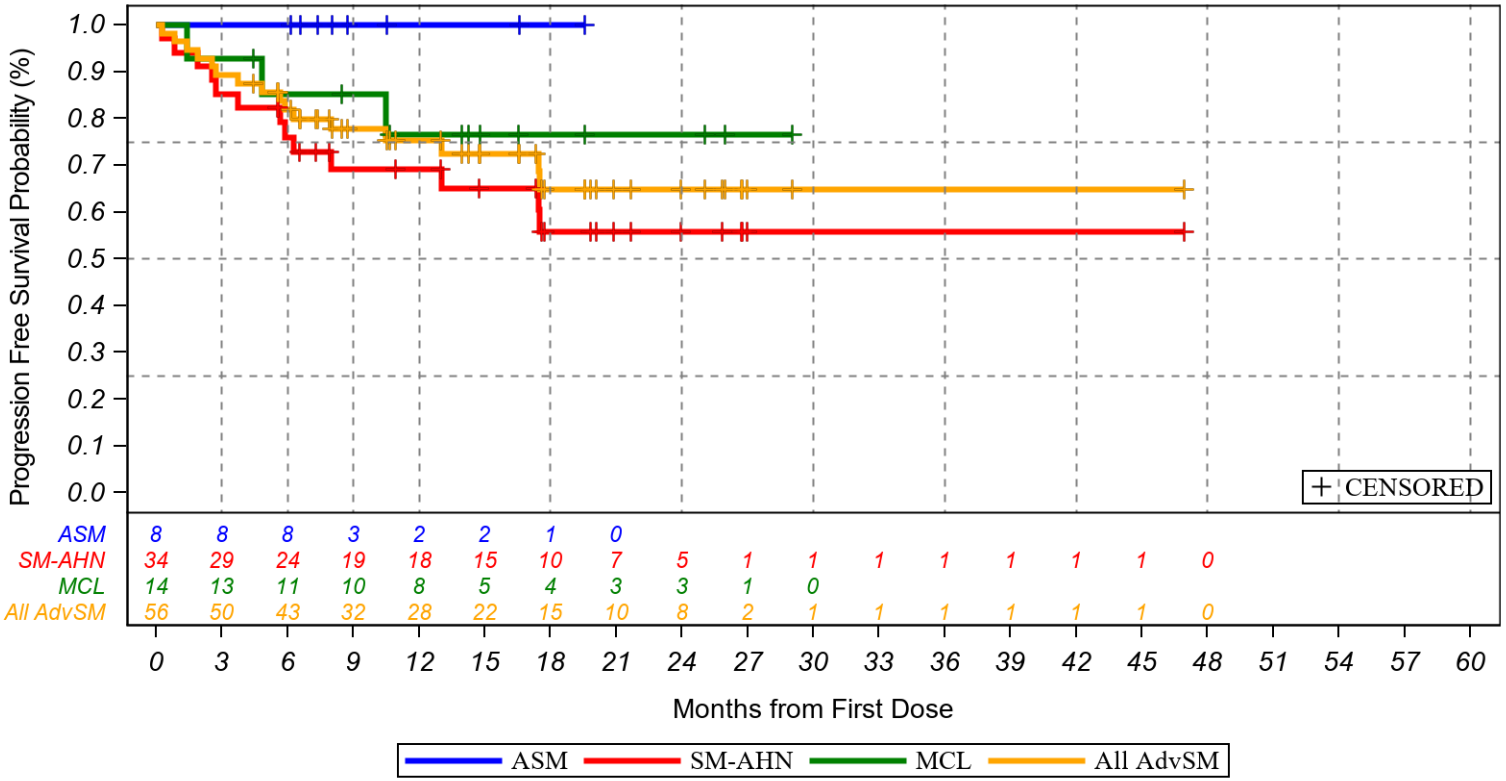

Figure 35.2.3.4
Kaplan-Meier Curves of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 300 mg

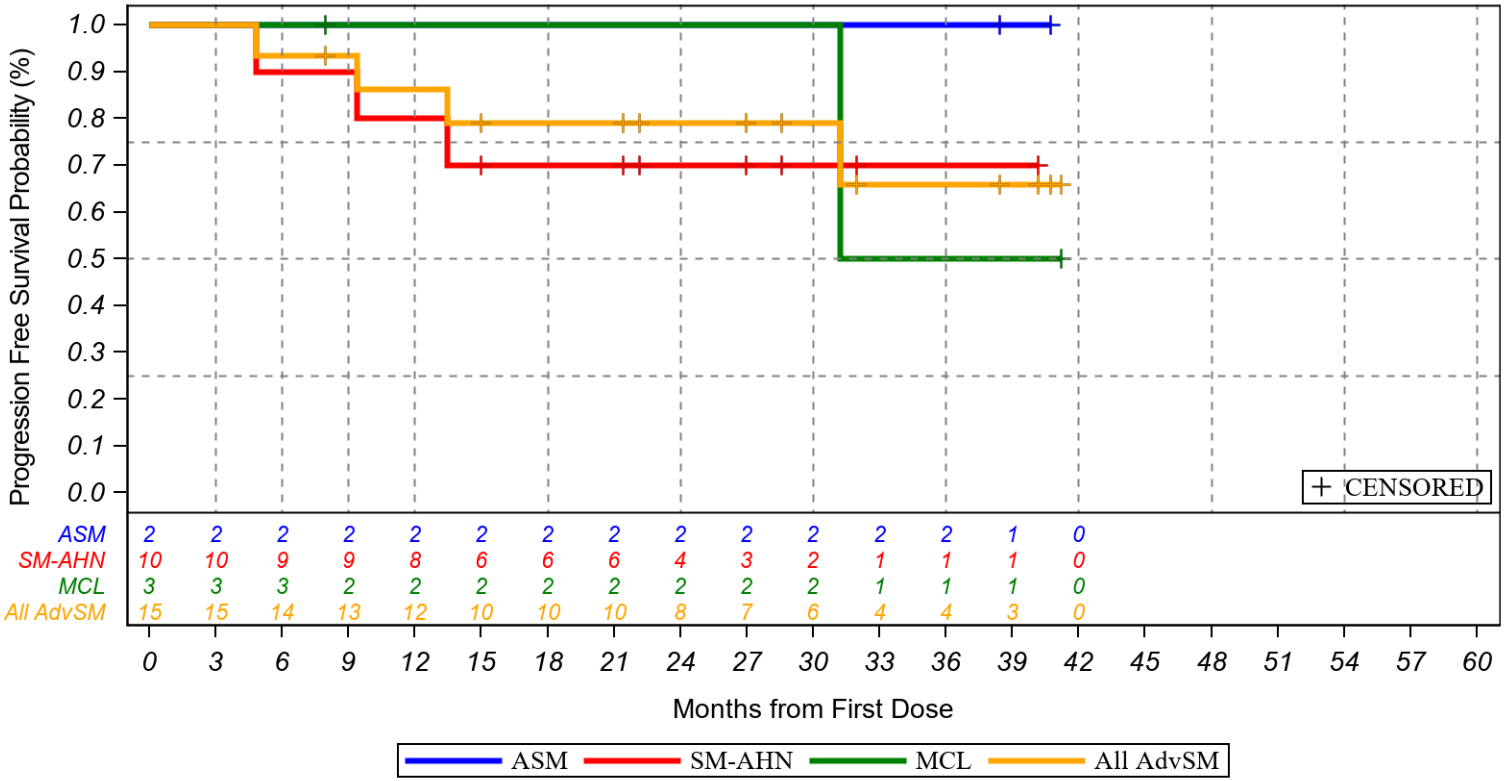

Figure 35.2.3.4
Kaplan-Meier Curves of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 200 mg and 300 mg

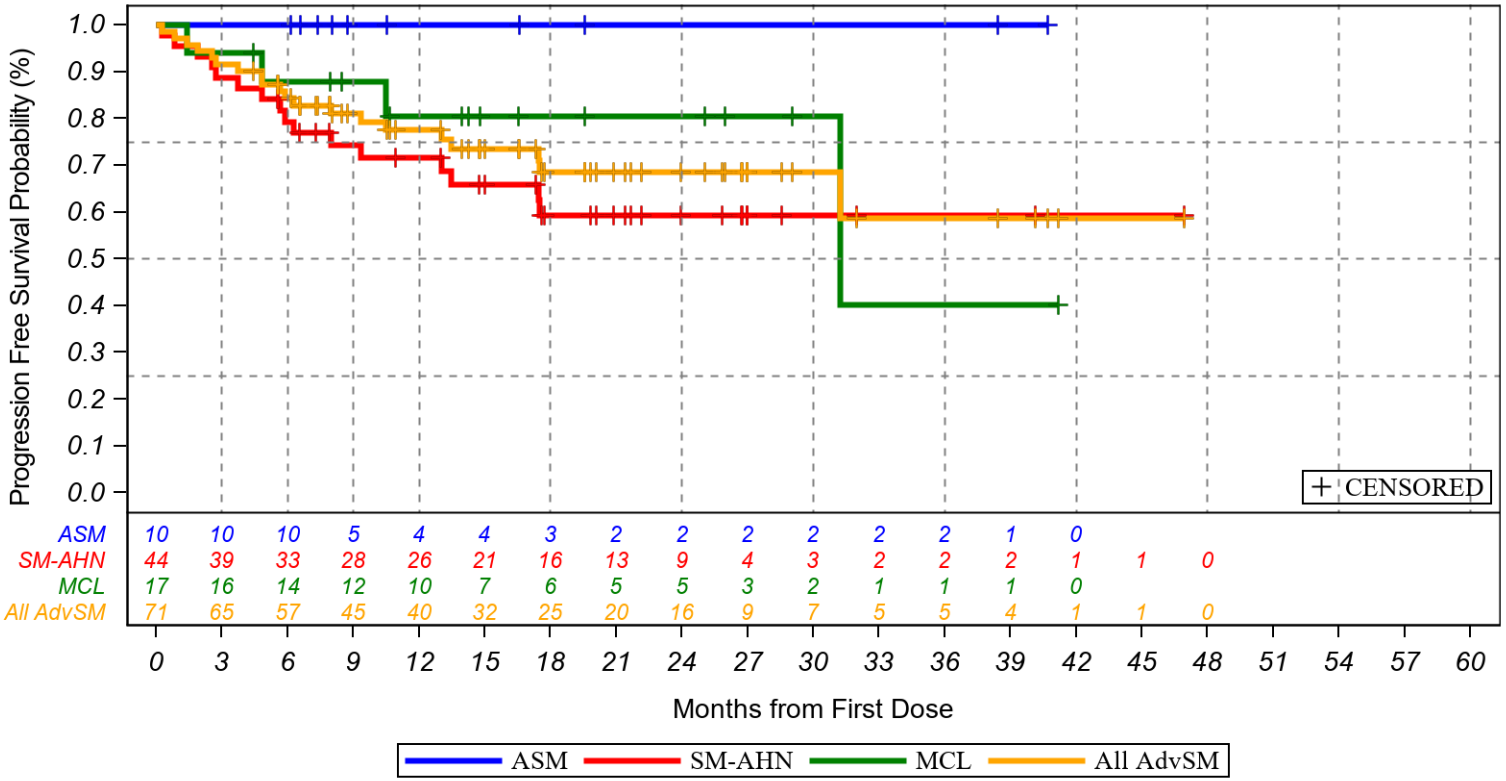

Figure 35.2.3.4
Kaplan-Meier Curves of Algorithm Progression Free Survival by IWG Criteria
RAC-RE Population with at least one prior antineoplastic therapy
Studies: BLU-285-2101 and BLU-285-2202
Starting Dose: 400 mg