Dossier zur Nutzenbewertung gemäß § 35a SGB V

Brentuximab Vedotin (ADCETRIS®)

Takeda GmbH

Anhang 4-G zu Modul 4 F

In Kombination mit Cyclophosphamid, Doxorubicin und Prednison (CHP)bei erwachsenen Patienten mit bislang unbehandeltem systemischem anaplastischem großzelligem Lymphom (sALCL)

Medizinischer Nutzen und medizinischer Zusatznutzen, Patientengruppen mit therapeutisch bedeutsamem Zusatznutzen

Stand: 26.05.2020

Table 35.1.2.7.1B
Summary of EQ-5D-3L VAS Score Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Baseline						
n	152	150				
Mean (std dev)	61.1 (24.88)	63.0 (24.02)	-1.93			
Median	65.0	70.0				
Min, Max	2, 100	0, 100				
95% CI for Mean	(57.07, 65.05)	(59.11, 66.86)	(-7.47, 3.61)			
P-value			0.4940			
Hedges's g			-0.08 (-0.30, 0.15)			
Cycle 2 Day 1						
n	154	138		147	136	
Mean (std dev)	70.4 (20.34)	71.4 (20.20)	-1.02	8.5 (20.01)	8.1 (21.34)	0.38
Median	70.0	75.0		5.0	5.0	
Min, Max	5, 100	4, 100		-35, 87	-80, 90	
95% CI for Mean	(67.13, 73.60)	(67.98, 74.78)	(-5.70, 3.66)	(5.24, 11.77)	(4.51, 11.74)	(-4.46, 5.22)
P-value			0.6680			0.8778
Hedges's g			-0.05 (-0.28, 0.18)			0.02 (-0.21, 0.25)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.

Note: Hedges's g measures the effect size of the difference between means using results from mixed model.

Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.

Data snapshot: 20SEP2018.

Table 35.1.2.7.1B
Summary of EQ-5D-3L VAS Score Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 3 Day 1						
n	152	135		144	134	
Mean (std dev)	72.0 (20.24)	74.2 (18.04)	-2.21	10.5 (22.63)	10.2 (21.21)	0.26
Median	75.0	79.0		10.0	5.0	
Min, Max	6, 100	9, 100		-55, 87	-50, 95	
95% CI for Mean	(68.71, 75.20)	(71.09, 77.23)	(-6.69, 2.27)	(6.75, 14.21)	(6.60, 13.85)	(-4.93, 5.44)
P-value			0.3323			0.9229
Hedges's g			-0.11 (-0.35, 0.12)			0.01 (-0.22, 0.25)
Cycle 4 Day 1						
n	149	131		142	129	
Mean (std dev)	72.2 (18.86)	72.6 (21.21)	-0.37	10.6 (24.02)	6.8 (24.28)	3.79
Median	76.0	80.0		9.5	5.0	
Min, Max	6, 100	6, 100		-80, 87	-69, 94	
95% CI for Mean	(69.14, 75.25)	(68.90, 76.23)	(-5.08, 4.34)	(6.60, 14.57)	(2.56, 11.02)	(-1.99, 9.58)
P-value			0.8772			0.1976
Hedges's g			-0.02 (-0.25, 0.22)			0.16 (-0.08, 0.40)

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Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.1B
Summary of EQ-5D-3L VAS Score Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 5 Day 1						
n	145	124		138	122	
Mean (std dev)	70.7 (21.02)	75.5 (17.73)	-4.80	9.2 (23.39)	9.4 (23.04)	-0.19
Median	76.0	78.5		10.0	5.0	
Min, Max	6, 100	7, 100		-75, 87	-65, 93	
95% CI for Mean	(67.26, 74.16)	(72.36, 78.66)	(-9.51, -0.08)	(5.24, 13.11)	(5.24, 13.50)	(-5.88, 5.49)
P-value			0.0461			0.9462
Hedges's g			-0.24 (-0.49, -0.00)			-0.01 (-0.25, 0.24)
Cycle 6 Day 1						
n	145	116		138	114	
Mean (std dev)	71.8 (19.23)	74.4 (20.03)	-2.63	9.8 (25.56)	7.5 (24.46)	2.33
Median	75.0	80.0		5.0	5.0	
Min, Max	6, 100	4, 100		-55, 91	-86, 95	
95% CI for Mean	(68.62, 74.93)	(70.72, 78.09)	(-7.44, 2.17)	(5.49, 14.09)	(2.92, 11.99)	(-3.91, 8.58)
P-value			0.2817			0.4627
Hedges's g			-0.13 (-0.38, 0.11)			0.09 (-0.16, 0.34)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.1B
Summary of EQ-5D-3L VAS Score Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 7 Day 1						
n	34	33		31	32	
Mean (std dev)	67.0 (18.45)	71.2 (20.14)	-4.21	9.5 (21.59)	3.4 (18.83)	6.08
Median	70.0	70.0		9.0	0.5	
Min, Max	30, 100	32, 100		-50, 77	-40, 45	
95% CI for Mean	(60.53, 73.41)	(64.04, 78.32)	(-13.63, 5.21)	(1.60, 17.44)	(-3.35, 10.22)	(-4.12, 16.27)
P-value			0.3753			0.2378
Hedges's g			-0.22 (-0.70, 0.26)			0.30 (-0.20, 0.79)
Cycle 8 Day 1						
n	31	33		28	32	
Mean (std dev)	68.8 (17.02)	71.3 (20.44)	-2.46	11.8 (23.46)	4.8 (18.89)	7.01
Median	70.0	75.0		10.5	4.5	
Min, Max	30, 100	30, 99		-50, 77	-42, 35	
95% CI for Mean	(62.60, 75.08)	(64.06, 78.55)	(-11.89, 6.97)	(2.72, 20.92)	(-2.00, 11.62)	(-3.94, 17.96)
P-value			0.6033			0.2053
Hedges's g			-0.13 (-0.62, 0.36)			0.33 (-0.18, 0.84)

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Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.1B
Summary of EQ-5D-3L VAS Score Over Time
ITT Analysis Set - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
End of Treatment						
n	141	126		135	125	
Mean (std dev)	74.3 (20.05)	76.2 (21.30)	-1.86	12.2 (27.71)	11.9 (26.03)	0.30
Median	80.0	80.0		10.0	5.0	
Min, Max	6, 100	2, 100		-89, 87	-88, 95	
95% CI for Mean	(70.99, 77.67)	(72.44, 79.95)	(-6.84, 3.13)	(7.48, 16.91)	(7.29, 16.50)	(-6.28, 6.88)
P-value			0.4638			0.9293
Hedges's g			-0.09 (-0.33, 0.15)			0.01 (-0.23, 0.25)
Long-Term Follow-Up 9 Month						
n	109	90		103	89	
Mean (std dev)	81.1 (16.05)	78.9 (19.41)	2.20	17.2 (25.48)	13.9 (27.77)	3.29
Median	85.0	85.0		10.0	10.0	
Min, Max	8, 100	5, 100		-76, 91	-85, 95	
95% CI for Mean	(78.04, 84.13)	(74.81, 82.94)	(-2.75, 7.16)	(12.22, 22.18)	(8.06, 19.76)	(-4.29, 10.88)
P-value			0.3815			0.3927
Hedges's g			0.12 (-0.15, 0.40)			0.12 (-0.16, 0.41)

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Note: Hedges's g measures the effect size of the difference between means using results from mixed model.

Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.

Data snapshot: 20SEP2018.

Table 35.1.2.7.1B
Summary of EQ-5D-3L VAS Score Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 12 Month						
n	110	84		104	83	
Mean (std dev)	81.7 (17.46)	78.5 (19.90)	3.16	18.6 (26.32)	13.6 (26.13)	4.99
Median	87.5	80.0		15.0	10.0	
Min, Max	8, 100	5, 100		-75, 96	-85, 95	
95% CI for Mean	(78.40, 85.00)	(74.22, 82.85)	(-2.14, 8.47)	(13.50, 23.73)	(7.92, 19.33)	(-2.63, 12.61)
P-value			0.2407			0.1980
Hedges's g			0.17 (-0.11, 0.45)			0.19 (-0.10, 0.48)
Long-Term Follow-Up 15 Month						
n	101	85		96	84	
Mean (std dev)	81.1 (17.19)	81.0 (17.99)	0.08	17.1 (26.66)	14.8 (23.46)	2.26
Median	85.0	88.0		12.5	10.0	
Min, Max	9, 100	5, 100		-75, 95	-43, 95	
95% CI for Mean	(77.74, 84.52)	(77.17, 84.93)	(-5.02, 5.18)	(11.67, 22.47)	(9.72, 19.90)	(-5.17, 9.70)
P-value			0.9748			0.5488
Hedges's g			0.00 (-0.28, 0.29)			0.09 (-0.20, 0.38)

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Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.1B
Summary of EQ-5D-3L VAS Score Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 18 Month						
n	101	83		96	82	
Mean (std dev)	82.6 (14.96)	80.6 (19.65)	2.01	19.1 (25.38)	13.8 (27.61)	5.30
Median	88.0	87.0		15.0	10.0	
Min, Max	20, 100	5, 100		-41, 96	-87, 95	
95% CI for Mean	(79.61, 85.52)	(76.26, 84.84)	(-3.03, 7.05)	(13.91, 24.19)	(7.69, 19.82)	(-2.55, 13.14)
P-value			0.4321			0.1844
Hedges's g			0.12 (-0.17, 0.41)			0.20 (-0.10, 0.49)
Long-Term Follow-Up 21 Month						
n	89	78		83	77	
Mean (std dev)	82.2 (18.56)	78.9 (20.84)	3.34	16.9 (27.64)	13.0 (27.06)	3.91
Median	90.0	85.0		10.0	10.0	
Min, Max	0, 100	7, 100		-80, 96	-80, 95	
95% CI for Mean	(78.29, 86.11)	(74.16, 83.56)	(-2.68, 9.36)	(10.89, 22.96)	(6.87, 19.15)	(-4.64, 12.47)
P-value			0.2744			0.3672
Hedges's g			0.17 (-0.14, 0.47)			0.14 (-0.17, 0.45)

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Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.1B
Summary of EQ-5D-3L VAS Score Over Time
ITT Analysis Set - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 24 Month						
n	89	73		84	72	
Mean (std dev)	81.6 (16.59)	78.9 (23.53)	2.73	19.2 (26.43)	14.8 (27.70)	4.37
Median	87.0	88.0		10.0	10.0	
Min, Max	20, 100	0, 100		-41, 96	-70, 95	
95% CI for Mean	(78.11, 85.10)	(73.39, 84.37)	(-3.51, 8.97)	(13.45, 24.93)	(8.31, 21.33)	(-4.20, 12.94)
P-value			0.3889			0.3154
Hedges's g			0.14 (-0.17, 0.45)			0.16 (-0.15, 0.48)
Long-Term Follow-Up 30 Month						
n	64	56		61	55	
Mean (std dev)	81.0 (20.06)	81.6 (17.38)	-0.55	19.4 (29.64)	15.1 (22.20)	4.34
Median	87.5	85.0		20.0	10.0	
Min, Max	8, 100	6, 100		-71, 92	-15, 95	
95% CI for Mean	(75.99, 86.01)	(76.90, 86.21)	(-7.39, 6.28)	(11.83, 27.02)	(9.09, 21.09)	(-5.38, 14.05)
P-value			0.8728			0.3787
Hedges's g			-0.03 (-0.39, 0.33)			0.16 (-0.20, 0.53)

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Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.1B
Summary of EQ-5D-3L VAS Score Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 36 Month						
n	51	44		48	44	
Mean (std dev)	82.4 (18.54)	85.3 (12.76)	-2.89	23.3 (30.38)	20.0 (22.25)	3.33
Median	90.0	88.5		17.5	20.0	
Min, Max	30, 100	50, 100		-30, 96	-15, 95	
95% CI for Mean	(77.22, 87.65)	(81.44, 89.20)	(-9.48, 3.70)	(14.51, 32.15)	(13.23, 26.77)	(-7.78, 14.45)
P-value			0.3867			0.5528
Hedges's g			-0.18 (-0.58, 0.23)			0.12 (-0.29, 0.53)
Overall (EOT)						
n				149	145	
Mean (std dev)				8.5 (15.22)	9.0 (15.27)	-0.46
95% CI for Mean						(-3.95, 3.03)
P-value						0.7942
Hedges's g						-0.03 (-0.26, 0.20)
Overall (70% compliance)						
n				149	145	
Mean (std dev)				12.6 (14.66)	11.6 (14.83)	0.93
95% CI for Mean						(-2.44, 4.30)
P-value						0.5888
Hedges's g						0.06 (-0.17, 0.29)

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Data snapshot: 20SEP2018.

Protocol No.: SGN35-014 -- Data cut: 15AUG2018 (Data snapshot: 20SEP2018)

Table 35.1.2.7.1B
Summary of EQ-5D-3L VAS Score Over Time
ITT Analysis Set   - Subset of Patients with sALCL

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
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Data snapshot: 20SEP2018.

Table 35.1.2.7.2B
Summary of EORTC-QLQ-C30 Global Health Status/QoL Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Baseline						
n	156	149				
Mean (std dev)	54.86 (26.990)	55.03 (25.791)	-0.17			
Median	58.33	50.00				
Min, Max	0.0, 100.0	0.0, 100.0				
95% CI for Mean	(50.59, 59.13)	(50.86, 59.21)	(-6.13, 5.78)			
P-value			0.9546			
Hedges's g			-0.01 (-0.23, 0.22)			
Cycle 2 Day 1						
n	155	143		151	139	
Mean (std dev)	66.24 (20.051)	65.33 (22.371)	0.91	10.54 (24.584)	10.49 (25.067)	0.05
Median	66.67	66.67		8.33	8.33	
Min, Max	16.7, 100.0	8.3, 100.0		-41.7, 91.7	-50.0, 100.0	
95% CI for Mean	(63.05, 69.42)	(61.63, 69.02)	(-3.93, 5.75)	(6.59, 14.49)	(6.29, 14.70)	(-5.69, 5.79)
P-value			0.7114			0.9865
Hedges's g			0.04 (-0.18, 0.27)			0.00 (-0.23, 0.23)

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Note: Hedges's g measures the effect size of the difference between means using results from mixed model.

Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.

Data snapshot: 20SEP2018.

Table 35.1.2.7.2B
Summary of EORTC-QLQ-C30 Global Health Status/QoL Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 3 Day 1						
n	153	136		149	134	
Mean (std dev)	68.85 (19.421)	68.50 (21.196)	0.34	12.98 (25.783)	12.38 (28.590)	0.60
Median	66.67	66.67		8.33	8.33	
Min, Max	16.7, 100.0	0.0, 100.0		-50.0, 91.7	-91.7, 100.0	
95% CI for Mean	(65.74, 71.95)	(64.91, 72.10)	(-4.36, 5.04)	(8.80, 17.15)	(7.49, 17.26)	(-5.76, 6.96)
P-value			0.8868			0.8529
Hedges's g			0.02 (-0.21, 0.25)			0.02 (-0.21, 0.26)
Cycle 4 Day 1						
n	150	131		146	129	
Mean (std dev)	68.28 (19.590)	69.02 (19.863)	-0.74	12.33 (26.393)	12.27 (27.045)	0.05
Median	66.67	66.67		8.33	8.33	
Min, Max	16.7, 100.0	0.0, 100.0		-75.0, 83.3	-66.7, 83.3	
95% CI for Mean	(65.12, 71.44)	(65.59, 72.45)	(-5.38, 3.90)	(8.01, 16.65)	(7.56, 16.99)	(-6.30, 6.41)
P-value			0.7530			0.9864
Hedges's g			-0.04 (-0.27, 0.20)			0.00 (-0.23, 0.24)

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Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.2B
Summary of EORTC-QLQ-C30 Global Health Status/QoL Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 5 Day 1						
n	143	123		140	121	
Mean (std dev)	66.84 (20.400)	71.07 (19.712)	-4.23	11.07 (26.209)	14.12 (28.216)	-3.05
Median	66.67	75.00		8.33	16.67	
Min, Max	0.0, 100.0	16.7, 100.0		-100.0, 83.3	-66.7, 100.0	
95% CI for Mean	(63.47, 70.21)	(67.55, 74.59)	(-9.09, 0.63)	(6.69, 15.45)	(9.04, 19.20)	(-9.68, 3.59)
P-value			0.0880			0.3669
Hedges's g			-0.21 (-0.45, 0.03)			-0.11 (-0.36, 0.13)
Cycle 6 Day 1						
n	145	117		141	115	
Mean (std dev)	63.45 (21.250)	70.16 (20.536)	-6.71	7.51 (29.686)	12.97 (29.374)	-5.47
Median	66.67	75.00		8.33	8.33	
Min, Max	0.0, 100.0	0.0, 100.0		-83.3, 83.3	-50.0, 100.0	
95% CI for Mean	(59.96, 66.94)	(66.40, 73.92)	(-11.83, -1.59)	(2.56, 12.45)	(7.54, 18.40)	(-12.78, 1.85)
P-value			0.0105			0.1422
Hedges's g			-0.32 (-0.56, -0.07)			-0.18 (-0.43, 0.06)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.2B
Summary of EORTC-QLQ-C30 Global Health Status/QoL Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 7 Day 1						
n	35	33		34	33	
Mean (std dev)	61.43 (18.312)	66.41 (19.927)	-4.99	12.99 (23.853)	10.86 (28.829)	2.13
Median	66.67	66.67		8.33	16.67	
Min, Max	16.7, 83.3	25.0, 100.0		-41.7, 66.7	-50.0, 66.7	
95% CI for Mean	(55.14, 67.72)	(59.35, 73.48)	(-14.24, 4.27)	(4.67, 21.31)	(0.64, 21.08)	(-10.76, 15.03)
P-value			0.2862			0.7423
Hedges's g			-0.26 (-0.74, 0.22)			0.08 (-0.40, 0.56)
Cycle 8 Day 1						
n	30	33		29	33	
Mean (std dev)	60.28 (18.912)	64.90 (22.024)	-4.62	12.93 (25.058)	9.34 (33.577)	3.59
Median	66.67	66.67		16.67	8.33	
Min, Max	16.7, 91.7	16.7, 100.0		-58.3, 58.3	-83.3, 66.7	
95% CI for Mean	(53.22, 67.34)	(57.09, 72.71)	(-15.01, 5.77)	(3.40, 22.46)	(-2.56, 21.25)	(-11.64, 18.81)
P-value			0.3774			0.6391
Hedges's g			-0.22 (-0.72, 0.27)			0.12 (-0.38, 0.62)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.2B
Summary of EORTC-QLQ-C30 Global Health Status/QoL Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
End of Treatment						
n	137	108		135	107	
Mean (std dev)	70.19 (20.027)	72.30 (19.529)	-2.10	15.43 (30.107)	15.65 (30.018)	-0.22
Median	75.00	66.67		8.33	16.67	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 83.3	-75.0, 100.0	
95% CI for Mean	(66.81, 73.58)	(68.57, 76.02)	(-7.13, 2.92)	(10.31, 20.56)	(9.90, 21.41)	(-7.89, 7.44)
P-value			0.4098			0.9545
Hedges's g			-0.11 (-0.36, 0.15)			-0.01 (-0.26, 0.25)
Long-Term Follow-Up 9 Month						
n	107	88		104	87	
Mean (std dev)	77.02 (16.182)	76.14 (19.985)	0.89	20.91 (28.230)	20.79 (31.125)	0.13
Median	83.33	83.33		16.67	16.67	
Min, Max	33.3, 100.0	0.0, 100.0		-50.0, 100.0	-50.0, 100.0	
95% CI for Mean	(73.92, 80.13)	(71.90, 80.37)	(-4.22, 6.00)	(15.42, 26.40)	(14.15, 27.42)	(-8.35, 8.61)
P-value			0.7319			0.9763
Hedges's g			0.05 (-0.23, 0.33)			0.00 (-0.28, 0.29)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.

Note: Hedges's g measures the effect size of the difference between means using results from mixed model.

Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.

Data snapshot: 20SEP2018.

Table 35.1.2.7.2B
Summary of EORTC-QLQ-C30 Global Health Status/QoL Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 12 Month						
n	111	81		108	80	
Mean (std dev)	77.25 (17.223)	75.41 (18.676)	1.84	20.14 (27.132)	20.10 (29.161)	0.03
Median	83.33	83.33		16.67	16.67	
Min, Max	16.7, 100.0	0.0, 100.0		-41.7, 100.0	-50.0, 100.0	
95% CI for Mean	(74.01, 80.49)	(71.28, 79.54)	(-3.30, 6.99)	(14.96, 25.31)	(13.61, 26.59)	(-8.12, 8.19)
P-value			0.4812			0.9933
Hedges's g			0.10 (-0.18, 0.39)			0.00 (-0.29, 0.29)
Long-Term Follow-Up 15 Month						
n	103	82		101	81	
Mean (std dev)	76.78 (18.730)	78.15 (17.889)	-1.37	19.72 (28.449)	23.46 (28.324)	-3.74
Median	83.33	83.33		16.67	16.67	
Min, Max	8.3, 100.0	33.3, 100.0		-58.3, 83.3	-33.3, 100.0	
95% CI for Mean	(73.12, 80.44)	(74.22, 82.08)	(-6.73, 3.99)	(14.10, 25.34)	(17.19, 29.72)	(-12.09, 4.62)
P-value			0.6147			0.3787
Hedges's g			-0.07 (-0.36, 0.22)			-0.13 (-0.42, 0.16)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.2B
Summary of EORTC-QLQ-C30 Global Health Status/QoL Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 18 Month						
n	98	83		96	82	
Mean (std dev)	78.49 (16.749)	77.71 (19.088)	0.78	23.35 (26.864)	22.76 (28.510)	0.59
Median	83.33	83.33		20.83	16.67	
Min, Max	16.7, 100.0	16.7, 100.0		-41.7, 83.3	-33.3, 100.0	
95% CI for Mean	(75.13, 81.84)	(73.54, 81.88)	(-4.48, 6.03)	(17.91, 28.79)	(16.50, 29.03)	(-7.61, 8.79)
P-value			0.7713			0.8879
Hedges's g			0.04 (-0.25, 0.34)			0.02 (-0.27, 0.32)
Long-Term Follow-Up 21 Month						
n	88	76		85	75	
Mean (std dev)	77.56 (18.713)	74.78 (22.277)	2.78	19.41 (27.769)	20.33 (30.364)	-0.92
Median	83.33	83.33		16.67	16.67	
Min, Max	8.3, 100.0	0.0, 100.0		-50.0, 83.3	-50.0, 100.0	
95% CI for Mean	(73.59, 81.52)	(69.69, 79.87)	(-3.54, 9.10)	(13.42, 25.40)	(13.35, 27.32)	(-10.00, 8.16)
P-value			0.3871			0.8414
Hedges's g			0.14 (-0.17, 0.44)			-0.03 (-0.34, 0.28)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.2B
Summary of EORTC-QLQ-C30 Global Health Status/QoL Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 24 Month						
n	88	72		85	71	
Mean (std dev)	77.08 (20.147)	77.78 (16.371)	-0.69	22.35 (28.324)	25.82 (29.552)	-3.47
Median	83.33	83.33		16.67	25.00	
Min, Max	8.3, 100.0	33.3, 100.0		-50.0, 91.7	-50.0, 100.0	
95% CI for Mean	(72.81, 81.35)	(73.93, 81.62)	(-6.52, 5.13)	(16.24, 28.46)	(18.83, 32.82)	(-12.64, 5.71)
P-value			0.8140			0.4563
Hedges's g			-0.04 (-0.35, 0.27)			-0.12 (-0.43, 0.20)
Overall (EOT)						
n				153	144	
Mean (std dev)				10.6 (16.03)	11.6 (16.15)	-0.94
95% CI for Mean						(-4.61, 2.72)
P-value						0.6143
Hedges's g						-0.06 (-0.29, 0.17)
Overall (70% compliance)						
n				153	144	
Mean (std dev)				14.8 (14.94)	15.4 (15.20)	-0.63
95% CI for Mean						(-4.06, 2.80)
P-value						0.7180
Hedges's g						-0.04 (-0.27, 0.19)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.2B
Summary of EORTC-QLQ-C30 Global Health Status/QoL Over Time
ITT Analysis Set   - Subset of Patients with sALCL

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.3B
Summary of EORTC-QLQ-C30 Physical Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

| | Actual Value | | | Change from Baseline | | |
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Baseline						
n	156	151				
Mean (std dev)	72.71 (27.880)	74.59 (26.716)	-1.88			
Median	81.67	80.00				
Min, Max	0.0, 100.0	0.0, 100.0				
95% CI for Mean	(68.30, 77.12)	(70.30, 78.89)	(-8.01, 4.26)			
P-value			0.5475			
Hedges's g			-0.07 (-0.29, 0.16)			
Cycle 2 Day 1						
n	154	140		150	139	
Mean (std dev)	78.06 (22.962)	79.76 (21.701)	-1.70	4.52 (19.637)	3.07 (20.482)	1.45
Median	83.33	86.67		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-66.7, 86.7	-86.7, 86.7	
95% CI for Mean	(74.41, 81.72)	(76.14, 83.39)	(-6.84, 3.44)	(1.35, 7.69)	(-0.37, 6.50)	(-3.19, 6.10)
P-value			0.5159			0.5387
Hedges's g			-0.08 (-0.30, 0.15)			0.07 (-0.16, 0.30)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.3B
Summary of EORTC-QLQ-C30 Physical Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 3 Day 1						
n	154	134		150	134	
Mean (std dev)	79.11 (22.634)	81.94 (20.743)	-2.83	6.00 (20.311)	4.25 (24.720)	1.75
Median	86.67	86.67		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-40.0, 86.7	-100.0, 86.7	
95% CI for Mean	(75.51, 82.72)	(78.40, 85.48)	(-7.89, 2.24)	(2.72, 9.28)	(0.03, 8.48)	(-3.52, 7.01)
P-value			0.2726			0.5143
Hedges's g			-0.13 (-0.36, 0.10)			0.08 (-0.16, 0.31)
Cycle 4 Day 1						
n	150	131		146	130	
Mean (std dev)	80.12 (21.804)	83.92 (17.647)	-3.80	7.00 (21.970)	5.92 (22.547)	1.07
Median	86.67	86.67		0.00	0.00	
Min, Max	0.0, 100.0	13.3, 100.0		-53.3, 80.0	-66.7, 80.0	
95% CI for Mean	(76.60, 83.64)	(80.87, 86.97)	(-8.50, 0.91)	(3.40, 10.59)	(2.01, 9.84)	(-4.21, 6.36)
P-value			0.1131			0.6890
Hedges's g			-0.19 (-0.42, 0.05)			0.05 (-0.19, 0.28)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.3B
Summary of EORTC-QLQ-C30 Physical Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 5 Day 1						
n	144	122		140	121	
Mean (std dev)	79.49 (22.315)	85.70 (14.716)	-6.21	6.29 (23.008)	7.15 (22.597)	-0.87
Median	86.67	87.78		0.00	0.00	
Min, Max	0.0, 100.0	33.3, 100.0		-60.0, 86.7	-46.7, 86.7	
95% CI for Mean	(75.81, 83.17)	(83.06, 88.34)	(-10.86, -1.56)	(2.44, 10.13)	(3.09, 11.22)	(-6.45, 4.71)
P-value			0.0091			0.7596
Hedges's g			-0.32 (-0.57, -0.08)			-0.04 (-0.28, 0.21)
Cycle 6 Day 1						
n	145	116		141	115	
Mean (std dev)	79.02 (21.244)	84.18 (16.993)	-5.16	4.93 (23.506)	6.10 (24.709)	-1.17
Median	86.67	86.67		0.00	0.00	
Min, Max	20.0, 100.0	33.3, 100.0		-53.3, 73.3	-60.0, 86.7	
95% CI for Mean	(75.54, 82.51)	(81.06, 87.31)	(-9.93, -0.38)	(1.02, 8.84)	(1.54, 10.67)	(-7.12, 4.78)
P-value			0.0344			0.6984
Hedges's g			-0.26 (-0.51, -0.02)			-0.05 (-0.29, 0.20)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.3B
Summary of EORTC-QLQ-C30 Physical Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 7 Day 1						
n	35	33		34	33	
Mean (std dev)	75.81 (19.069)	85.86 (14.978)	-10.05	9.61 (25.009)	2.22 (19.697)	7.39
Median	80.00	86.67		6.67	0.00	
Min, Max	33.3, 100.0	40.0, 100.0		-40.0, 66.7	-26.7, 53.3	
95% CI for Mean	(69.26, 82.36)	(80.55, 91.17)	(-18.39, -1.71)	(0.88, 18.33)	(-4.76, 9.21)	(-3.62, 18.39)
P-value			0.0189			0.1848
Hedges's g			-0.58 (-1.06, -0.09)			0.32 (-0.16, 0.81)
Cycle 8 Day 1						
n	30	33		29	33	
Mean (std dev)	76.67 (17.221)	84.04 (18.023)	-7.37	11.72 (23.815)	0.40 (24.149)	11.32
Median	80.00	86.67		6.67	0.00	
Min, Max	33.3, 100.0	26.7, 100.0		-26.7, 66.7	-73.3, 53.3	
95% CI for Mean	(70.24, 83.10)	(77.65, 90.43)	(-16.27, 1.53)	(2.67, 20.78)	(-8.16, 8.97)	(-0.90, 23.54)
P-value			0.1028			0.0687
Hedges's g			-0.41 (-0.91, 0.09)			0.47 (-0.04, 0.97)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.

Note: Hedges's g measures the effect size of the difference between means using results from mixed model.

Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.

Data snapshot: 20SEP2018.

Table 35.1.2.7.3B
Summary of EORTC-QLQ-C30 Physical Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
End of Treatment						
n	138	109		136	108	
Mean (std dev)	83.51 (18.357)	84.95 (16.861)	-1.44	9.08 (25.985)	6.51 (22.374)	2.57
Median	86.67	86.67		0.00	0.00	
Min, Max	20.0, 100.0	26.7, 100.0		-55.0, 86.7	-53.3, 86.7	
95% CI for Mean	(80.42, 86.60)	(81.75, 88.16)	(-5.91, 3.03)	(4.67, 13.49)	(2.24, 10.78)	(-3.64, 8.78)
P-value			0.5265			0.4159
Hedges's g			-0.08 (-0.33, 0.17)			0.10 (-0.15, 0.36)
Long-Term Follow-Up 9 Month						
n	108	88		105	87	
Mean (std dev)	86.30 (16.950)	88.47 (17.583)	-2.17	11.43 (25.832)	9.98 (23.683)	1.45
Median	93.33	96.67		6.67	0.00	
Min, Max	33.3, 100.0	13.3, 100.0		-46.7, 86.7	-60.0, 86.7	
95% CI for Mean	(83.06, 89.53)	(84.74, 92.19)	(-7.05, 2.71)	(6.43, 16.43)	(4.93, 15.03)	(-5.67, 8.56)
P-value			0.3818			0.6886
Hedges's g			-0.13 (-0.41, 0.16)			0.06 (-0.23, 0.34)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.3B
Summary of EORTC-QLQ-C30 Physical Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 12 Month						
n	111	81		108	80	
Mean (std dev)	86.83 (18.845)	88.72 (16.655)	-1.89	12.52 (25.666)	10.17 (24.649)	2.35
Median	93.33	93.33		6.67	0.00	
Min, Max	20.0, 100.0	26.7, 100.0		-53.3, 80.0	-66.7, 73.3	
95% CI for Mean	(83.29, 90.38)	(85.04, 92.41)	(-7.07, 3.28)	(7.62, 17.41)	(4.68, 15.65)	(-5.00, 9.69)
P-value			0.4717			0.5289
Hedges's g			-0.10 (-0.39, 0.18)			0.09 (-0.20, 0.38)
Long-Term Follow-Up 15 Month						
n	103	83		101	82	
Mean (std dev)	87.96 (17.491)	89.44 (16.833)	-1.48	13.93 (26.078)	10.98 (25.990)	2.95
Median	93.33	93.33		6.67	0.00	
Min, Max	20.0, 100.0	20.0, 100.0		-53.3, 86.7	-80.0, 80.0	
95% CI for Mean	(84.54, 91.38)	(85.77, 93.12)	(-6.49, 3.52)	(8.78, 19.08)	(5.27, 16.69)	(-4.69, 10.58)
P-value			0.5595			0.4477
Hedges's g			-0.09 (-0.38, 0.20)			0.11 (-0.18, 0.40)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.

Note: Hedges's g measures the effect size of the difference between means using results from mixed model.

Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.

Data snapshot: 20SEP2018.

Table 35.1.2.7.3B
Summary of EORTC-QLQ-C30 Physical Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 18 Month						
n	99	83		97	82	
Mean (std dev)	88.86 (16.462)	89.02 (17.328)	-0.16	15.02 (27.157)	10.63 (25.575)	4.39
Median	93.33	100.00		6.67	3.33	
Min, Max	26.7, 100.0	20.0, 100.0		-60.0, 86.7	-46.7, 86.7	
95% CI for Mean	(85.57, 92.14)	(85.23, 92.80)	(-5.11, 4.79)	(9.54, 20.49)	(5.01, 16.25)	(-3.44, 12.22)
P-value			0.9490			0.2703
Hedges's g			-0.01 (-0.30, 0.28)			0.17 (-0.13, 0.46)
Long-Term Follow-Up 21 Month						
n	88	76		85	75	
Mean (std dev)	89.70 (17.331)	89.65 (16.632)	0.05	12.94 (23.797)	10.80 (24.586)	2.14
Median	100.00	100.00		6.67	6.67	
Min, Max	20.0, 100.0	13.3, 100.0		-38.3, 80.0	-80.0, 80.0	
95% CI for Mean	(86.02, 93.37)	(85.85, 93.45)	(-5.21, 5.31)	(7.81, 18.07)	(5.14, 16.46)	(-5.42, 9.70)
P-value			0.9857			0.5768
Hedges's g			0.00 (-0.30, 0.31)			0.09 (-0.22, 0.40)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Protocol No.: SGN35-014 -- Data cut: 15AUG2018 (Data snapshot: 20SEP2018)

Table 35.1.2.7.3B
Summary of EORTC-QLQ-C30 Physical Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 24 Month						
n	88	71		85	70	
Mean (std dev)	89.77 (19.310)	90.96 (14.651)	-1.19	17.57 (26.223)	13.83 (23.841)	3.74
Median	100.00	100.00		6.67	6.67	
Min, Max	13.3, 100.0	40.0, 100.0		-33.3, 86.7	-33.3, 86.7	
95% CI for Mean	(85.68, 93.86)	(87.49, 94.43)	(-6.67, 4.29)	(11.91, 23.22)	(8.15, 19.52)	(-4.29, 11.76)
P-value			0.6686			0.3594
Hedges's g			-0.07 (-0.38, 0.24)			0.15 (-0.17, 0.46)
Overall (EOT)						
n				152	146	
Mean (std dev)				4.9 (15.96)	4.1 (16.07)	0.79
95% CI for Mean						(-2.86, 4.43)
P-value						0.6719
Hedges's g						0.05 (-0.18, 0.28)
Overall (70% compliance)						
n				152	146	
Mean (std dev)				7.3 (15.36)	6.7 (15.56)	0.64
95% CI for Mean						(-2.88, 4.15)
P-value						0.7228
Hedges's g						0.04 (-0.19, 0.27)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.3B
Summary of EORTC-QLQ-C30 Physical Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.

Note: Hedges's g measures the effect size of the difference between means using results from mixed model.

Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.

Data snapshot: 20SEP2018.

Table 35.1.2.7.4B
Summary of EORTC-QLQ-C30 Role Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Baseline						
n	156	150				
Mean (std dev)	61.97 (38.743)	63.67 (34.814)	-1.70			
Median	66.67	66.67				
Min, Max	0.0, 100.0	0.0, 100.0				
95% CI for Mean	(55.84, 68.09)	(58.05, 69.28)	(-10.00, 6.60)			
P-value			0.6869			
Hedges's g			-0.05 (-0.27, 0.18)			
Cycle 2 Day 1						
n	154	141		150	139	
Mean (std dev)	69.81 (30.475)	72.58 (29.421)	-2.77	6.33 (32.864)	7.07 (32.227)	-0.74
Median	66.67	83.33		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 100.0	-83.3, 100.0	
95% CI for Mean	(64.95, 74.66)	(67.68, 77.48)	(-9.65, 4.10)	(1.03, 11.64)	(1.67, 12.48)	(-8.29, 6.80)
P-value			0.4283			0.8469
Hedges's g			-0.09 (-0.32, 0.14)			-0.02 (-0.25, 0.21)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were
obtained using mixed effects models.
Data snapshot: 20SEP2018.

Protocol No.: SGN35-014 -- Data cut: 15AUG2018 (Data snapshot: 20SEP2018)

Table 35.1.2.7.4B
Summary of EORTC-QLQ-C30 Role Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 3 Day 1						
n	154	137		150	136	
Mean (std dev)	71.65 (28.528)	77.49 (26.629)	-5.85	9.00 (34.142)	11.27 (34.479)	-2.27
Median	66.67	83.33		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-66.7, 100.0	-83.3, 100.0	
95% CI for Mean	(67.10, 76.19)	(72.99, 81.99)	(-12.24, 0.54)	(3.49, 14.51)	(5.43, 17.12)	(-10.27, 5.72)
P-value			0.0727			0.5759
Hedges's g			-0.21 (-0.44, 0.02)			-0.07 (-0.30, 0.17)
Cycle 4 Day 1						
n	150	131		146	129	
Mean (std dev)	72.67 (29.302)	79.52 (22.886)	-6.85	9.36 (35.932)	12.27 (34.329)	-2.91
Median	66.67	83.33		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 100.0	-66.7, 100.0	
95% CI for Mean	(67.94, 77.39)	(75.56, 83.47)	(-13.09, -0.61)	(3.48, 15.24)	(6.29, 18.25)	(-11.28, 5.46)
P-value			0.0315			0.4939
Hedges's g			-0.26 (-0.49, -0.02)			-0.08 (-0.32, 0.15)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.4B
Summary of EORTC-QLQ-C30 Role Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 5 Day 1						
n	144	122		140	120	
Mean (std dev)	72.57 (29.399)	81.15 (21.741)	-8.58	9.05 (37.899)	12.08 (33.679)	-3.04
Median	66.67	83.33		0.00	0.00	
Min, Max	0.0, 100.0	16.7, 100.0		-100.0, 100.0	-66.7, 100.0	
95% CI for Mean	(67.73, 77.41)	(77.25, 85.04)	(-14.92, -2.24)	(2.71, 15.38)	(6.00, 18.17)	(-11.86, 5.79)
P-value			0.0082			0.4986
Hedges's g			-0.33 (-0.57, -0.08)			-0.08 (-0.33, 0.16)
Cycle 6 Day 1						
n	145	115		141	114	
Mean (std dev)	71.15 (29.217)	78.55 (25.627)	-7.40	6.97 (38.738)	9.94 (36.415)	-2.97
Median	66.67	83.33		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 100.0	-100.0, 100.0	
95% CI for Mean	(66.35, 75.95)	(73.82, 83.28)	(-14.21, -0.59)	(0.52, 13.42)	(3.18, 16.70)	(-12.32, 6.39)
P-value			0.0332			0.5328
Hedges's g			-0.27 (-0.51, -0.02)			-0.08 (-0.33, 0.17)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.4B
Summary of EORTC-QLQ-C30 Role Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 7 Day 1						
n	35	33		34	33	
Mean (std dev)	66.67 (29.978)	77.27 (26.945)	-10.61	17.65 (39.556)	2.53 (37.063)	15.12
Median	66.67	83.33		16.67	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-66.7, 100.0	-100.0, 66.7	
95% CI for Mean	(56.37, 76.96)	(67.72, 86.83)	(-24.44, 3.22)	(3.85, 31.45)	(-10.62, 15.67)	(-3.59, 33.84)
P-value			0.1305			0.1114
Hedges's g			-0.37 (-0.85, 0.11)			0.39 (-0.09, 0.87)
Cycle 8 Day 1						
n	30	33		29	33	
Mean (std dev)	66.67 (33.333)	73.23 (23.176)	-6.57	17.82 (41.769)	-1.52 (39.167)	19.33
Median	66.67	66.67		16.67	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-83.3, 100.0	-100.0, 66.7	
95% CI for Mean	(54.22, 79.11)	(65.01, 81.45)	(-20.92, 7.79)	(1.93, 33.70)	(-15.40, 12.37)	(-1.24, 39.90)
P-value			0.3641			0.0650
Hedges's g			-0.23 (-0.72, 0.27)			0.47 (-0.03, 0.98)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.4B
Summary of EORTC-QLQ-C30 Role Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
End of Treatment						
n	138	109		136	107	
Mean (std dev)	75.85 (27.247)	83.64 (21.752)	-7.79	11.64 (39.300)	15.58 (35.338)	-3.93
Median	83.33	100.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-83.3, 100.0	-66.7, 100.0	
95% CI for Mean	(71.26, 80.43)	(79.51, 87.77)	(-14.10, -1.49)	(4.98, 18.31)	(8.80, 22.35)	(-13.51, 5.64)
P-value			0.0156			0.4190
Hedges's g			-0.31 (-0.56, -0.06)			-0.10 (-0.36, 0.15)
Long-Term Follow-Up 9 Month						
n	108	86		105	85	
Mean (std dev)	82.56 (22.943)	85.47 (22.694)	-2.90	17.46 (36.279)	17.84 (37.953)	-0.38
Median	100.00	100.00		0.00	0.00	
Min, Max	0.0, 100.0	16.7, 100.0		-50.0, 100.0	-66.7, 100.0	
95% CI for Mean	(78.19, 86.94)	(80.60, 90.33)	(-9.41, 3.61)	(10.44, 24.48)	(9.66, 26.03)	(-11.04, 10.28)
P-value			0.3801			0.9436
Hedges's g			-0.13 (-0.41, 0.16)			-0.01 (-0.30, 0.28)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.

Note: Hedges's g measures the effect size of the difference between means using results from mixed model.

Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.

Data snapshot: 20SEP2018.

Table 35.1.2.7.4B
Summary of EORTC-QLQ-C30 Role Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 12 Month						
n	111	81		108	80	
Mean (std dev)	84.53 (23.753)	83.95 (24.216)	0.58	18.83 (36.677)	16.67 (36.745)	2.16
Median	100.00	100.00		8.33	0.00	
Min, Max	16.7, 100.0	0.0, 100.0		-83.3, 100.0	-66.7, 100.0	
95% CI for Mean	(80.07, 89.00)	(78.60, 89.31)	(-6.32, 7.49)	(11.83, 25.82)	(8.49, 24.84)	(-8.52, 12.84)
P-value			0.8677			0.6903
Hedges's g			0.02 (-0.26, 0.31)			0.06 (-0.23, 0.35)
Long-Term Follow-Up 15 Month						
n	102	82		100	81	
Mean (std dev)	84.97 (23.040)	87.40 (21.843)	-2.43	22.17 (40.275)	20.78 (34.210)	1.38
Median	100.00	100.00		16.67	0.00	
Min, Max	0.0, 100.0	16.7, 100.0		-100.0, 100.0	-33.3, 100.0	
95% CI for Mean	(80.44, 89.49)	(82.60, 92.20)	(-9.02, 4.16)	(14.18, 30.16)	(13.22, 28.35)	(-9.73, 12.50)
P-value			0.4676			0.8061
Hedges's g			-0.11 (-0.40, 0.18)			0.04 (-0.26, 0.33)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.4B
Summary of EORTC-QLQ-C30 Role Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 18 Month						
n	99	83		97	81	
Mean (std dev)	86.70 (24.395)	86.55 (21.693)	0.15	24.23 (41.179)	18.93 (35.233)	5.30
Median	100.00	100.00		16.67	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 100.0	-66.7, 100.0	
95% CI for Mean	(81.83, 91.57)	(81.81, 91.28)	(-6.66, 6.97)	(15.93, 32.53)	(11.14, 26.72)	(-6.17, 16.76)
P-value			0.9644			0.3631
Hedges's g			0.01 (-0.29, 0.30)			0.14 (-0.16, 0.43)
Long-Term Follow-Up 21 Month						
n	88	76		85	74	
Mean (std dev)	87.50 (20.876)	89.04 (20.467)	-1.54	23.53 (38.687)	22.30 (34.487)	1.23
Median	100.00	100.00		0.00	8.33	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 100.0	-50.0, 100.0	
95% CI for Mean	(83.08, 91.92)	(84.36, 93.71)	(-7.93, 4.86)	(15.18, 31.87)	(14.31, 30.29)	(-10.32, 12.79)
P-value			0.6362			0.8335
Hedges's g			-0.07 (-0.38, 0.23)			0.03 (-0.28, 0.34)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.4B
Summary of EORTC-QLQ-C30 Role Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 24 Month						
n	88	72		85	70	
Mean (std dev)	87.31 (23.839)	90.51 (19.745)	-3.20	27.45 (41.204)	26.19 (36.841)	1.26
Median	100.00	100.00		16.67	16.67	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 100.0	-50.0, 100.0	
95% CI for Mean	(82.26, 92.36)	(85.87, 95.15)	(-10.13, 3.74)	(18.56, 36.34)	(17.41, 34.97)	(-11.27, 13.79)
P-value			0.3636			0.8427
Hedges's g			-0.14 (-0.46, 0.17)			0.03 (-0.28, 0.35)
Overall (EOT)						
n				152	145	
Mean (std dev)				6.9 (21.54)	10.6 (21.72)	-3.66
95% CI for Mean						(-8.59, 1.27)
P-value						0.1454
Hedges's g						-0.17 (-0.40, 0.06)
Overall (70% compliance)						
n				152	145	
Mean (std dev)				12.1 (19.47)	15.6 (19.86)	-3.50
95% CI for Mean						(-7.98, 0.98)
P-value						0.1256
Hedges's g						-0.18 (-0.41, 0.05)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.4B
Summary of EORTC-QLQ-C30 Role Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.

Note: Hedges's g measures the effect size of the difference between means using results from mixed model.

Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.

Data snapshot: 20SEP2018.

Table 35.1.2.7.5B
Summary of EORTC-QLQ-C30 Emotional Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

| | Actual Value | | | Change from Baseline | | |
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Baseline						
n	156	150				
Mean (std dev)	69.46 (24.766)	74.13 (23.813)	-4.67			
Median	75.00	75.00				
Min, Max	0.0, 100.0	0.0, 100.0				
95% CI for Mean	(65.55, 73.38)	(70.29, 77.97)	(-10.14, 0.80)			
P-value			0.0941			
Hedges's g			-0.19 (-0.42, 0.03)			
Cycle 2 Day 1						
n	155	143		151	140	
Mean (std dev)	79.52 (20.501)	83.08 (21.456)	-3.56	9.20 (21.877)	9.13 (20.007)	0.07
Median	83.33	91.67		8.33	8.33	
Min, Max	0.0, 100.0	0.0, 100.0		-75.0, 91.7	-58.3, 83.3	
95% CI for Mean	(76.26, 82.77)	(79.53, 86.63)	(-8.35, 1.22)	(5.68, 12.72)	(5.78, 12.47)	(-4.78, 4.92)
P-value			0.1436			0.9770
Hedges's g			-0.17 (-0.40, 0.06)			0.00 (-0.23, 0.23)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.5B
Summary of EORTC-QLQ-C30 Emotional Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 3 Day 1						
n	154	136		150	135	
Mean (std dev)	83.01 (18.274)	85.60 (17.317)	-2.59	12.81 (20.859)	11.15 (21.925)	1.66
Median	87.50	91.67		8.33	8.33	
Min, Max	8.3, 100.0	16.7, 100.0		-41.7, 91.7	-41.7, 91.7	
95% CI for Mean	(80.10, 85.92)	(82.66, 88.54)	(-6.72, 1.54)	(9.45, 16.18)	(7.42, 14.88)	(-3.33, 6.65)
P-value			0.2178			0.5125
Hedges's g			-0.14 (-0.38, 0.09)			0.08 (-0.16, 0.31)
Cycle 4 Day 1						
n	150	131		146	130	
Mean (std dev)	81.17 (19.392)	85.54 (19.511)	-4.37	11.51 (23.346)	10.66 (20.185)	0.85
Median	83.33	91.67		8.33	8.33	
Min, Max	0.0, 100.0	16.7, 100.0		-50.0, 91.7	-58.3, 75.0	
95% CI for Mean	(78.04, 84.30)	(82.17, 88.91)	(-8.95, 0.21)	(7.69, 15.33)	(7.16, 14.17)	(-4.35, 6.05)
P-value			0.0612			0.7485
Hedges's g			-0.22 (-0.46, 0.01)			0.04 (-0.20, 0.27)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.5B
Summary of EORTC-QLQ-C30 Emotional Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 5 Day 1						
n	143	123		140	122	
Mean (std dev)	80.54 (21.187)	84.08 (20.385)	-3.54	10.63 (23.888)	9.61 (21.691)	1.03
Median	83.33	91.67		8.33	8.33	
Min, Max	0.0, 100.0	16.7, 100.0		-66.7, 91.7	-50.0, 75.0	
95% CI for Mean	(77.03, 84.04)	(80.44, 87.72)	(-8.58, 1.50)	(6.64, 14.63)	(5.72, 13.50)	(-4.56, 6.61)
P-value			0.1677			0.7176
Hedges's g			-0.17 (-0.41, 0.07)			0.04 (-0.20, 0.29)
Cycle 6 Day 1						
n	145	117		141	116	
Mean (std dev)	82.59 (19.142)	84.95 (21.876)	-2.36	13.40 (23.044)	11.23 (22.598)	2.17
Median	91.67	100.00		8.33	8.33	
Min, Max	25.0, 100.0	0.0, 100.0		-50.0, 100.0	-83.3, 75.0	
95% CI for Mean	(79.44, 85.73)	(80.94, 88.95)	(-7.36, 2.63)	(9.56, 17.23)	(7.07, 15.39)	(-3.47, 7.80)
P-value			0.3526			0.4502
Hedges's g			-0.12 (-0.36, 0.13)			0.09 (-0.15, 0.34)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.5B
Summary of EORTC-QLQ-C30 Emotional Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 7 Day 1						
n	35	33		34	33	
Mean (std dev)	74.05 (24.569)	84.60 (19.887)	-10.55	5.15 (25.294)	8.08 (18.574)	-2.93
Median	75.00	91.67		8.33	8.33	
Min, Max	8.3, 100.0	25.0, 100.0		-50.0, 58.3	-41.7, 41.7	
95% CI for Mean	(65.61, 82.49)	(77.54, 91.65)	(-21.41, 0.31)	(-3.68, 13.97)	(1.49, 14.67)	(-13.79, 7.92)
P-value			0.0568			0.5912
Hedges's g			-0.47 (-0.95, 0.02)			-0.13 (-0.61, 0.35)
Cycle 8 Day 1						
n	30	33		29	33	
Mean (std dev)	79.17 (22.291)	83.50 (24.255)	-4.34	10.06 (22.314)	6.99 (24.426)	3.07
Median	87.50	100.00		8.33	8.33	
Min, Max	16.7, 100.0	0.0, 100.0		-66.7, 58.3	-66.7, 41.7	
95% CI for Mean	(70.84, 87.49)	(74.90, 92.10)	(-16.11, 7.44)	(1.57, 18.55)	(-1.67, 15.65)	(-8.88, 15.02)
P-value			0.4644			0.6090
Hedges's g			-0.18 (-0.68, 0.31)			0.13 (-0.37, 0.63)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.5B
Summary of EORTC-QLQ-C30 Emotional Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
End of Treatment						
n	137	108		135	107	
Mean (std dev)	82.95 (21.945)	85.26 (21.665)	-2.31	13.60 (23.172)	10.15 (22.085)	3.45
Median	91.67	91.67		8.33	8.33	
Min, Max	8.3, 100.0	0.0, 100.0		-50.0, 91.7	-66.7, 75.0	
95% CI for Mean	(79.24, 86.66)	(81.13, 89.40)	(-7.85, 3.22)	(9.66, 17.55)	(5.92, 14.38)	(-2.34, 9.24)
P-value			0.4107			0.2414
Hedges's g			-0.11 (-0.36, 0.15)			0.15 (-0.10, 0.41)
Long-Term Follow-Up 9 Month						
n	107	88		104	87	
Mean (std dev)	84.50 (19.542)	88.83 (17.548)	-4.32	14.64 (27.546)	14.21 (23.288)	0.43
Median	91.67	100.00		16.67	8.33	
Min, Max	0.0, 100.0	8.3, 100.0		-83.3, 91.7	-41.7, 100.0	
95% CI for Mean	(80.76, 88.25)	(85.11, 92.54)	(-9.62, 0.97)	(9.28, 19.99)	(9.24, 19.17)	(-6.94, 7.79)
P-value			0.1091			0.9087
Hedges's g			-0.23 (-0.51, 0.05)			0.02 (-0.27, 0.30)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.5B
Summary of EORTC-QLQ-C30 Emotional Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

| | Actual Value | | | Change from Baseline | | |
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 12 Month						
n	111	81		108	80	
Mean (std dev)	86.64 (17.670)	86.83 (18.440)	-0.19	16.26 (22.795)	12.57 (19.306)	3.69
Median	91.67	100.00		16.67	8.33	
Min, Max	16.7, 100.0	8.3, 100.0		-50.0, 91.7	-41.7, 66.7	
95% CI for Mean	(83.31, 89.96)	(82.75, 90.91)	(-5.38, 4.99)	(11.91, 20.60)	(8.27, 16.87)	(-2.54, 9.91)
P-value			0.9411			0.2441
Hedges's g			-0.01 (-0.30, 0.28)			0.17 (-0.12, 0.46)
Long-Term Follow-Up 15 Month						
n	103	82		101	81	
Mean (std dev)	84.47 (18.817)	89.94 (17.010)	-5.47	13.92 (23.920)	15.19 (23.245)	-1.28
Median	91.67	100.00		8.33	16.67	
Min, Max	0.0, 100.0	0.0, 100.0		-58.3, 91.7	-58.3, 100.0	
95% CI for Mean	(80.79, 88.14)	(86.20, 93.68)	(-10.74, -0.21)	(9.19, 18.64)	(10.05, 20.33)	(-8.23, 5.68)
P-value			0.0418			0.7177
Hedges's g			-0.30 (-0.59, -0.01)			-0.05 (-0.35, 0.24)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.5B
Summary of EORTC-QLQ-C30 Emotional Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 18 Month						
n	98	83		96	82	
Mean (std dev)	86.14 (19.624)	90.16 (16.775)	-4.02	15.68 (27.716)	16.12 (22.382)	-0.44
Median	100.00	100.00		16.67	8.33	
Min, Max	0.0, 100.0	8.3, 100.0		-91.7, 91.7	-41.7, 100.0	
95% CI for Mean	(82.21, 90.07)	(86.50, 93.82)	(-9.43, 1.39)	(10.07, 21.30)	(11.21, 21.04)	(-7.98, 7.10)
P-value			0.1441			0.9081
Hedges's g			-0.22 (-0.51, 0.08)			-0.02 (-0.31, 0.28)
Long-Term Follow-Up 21 Month						
n	88	76		85	75	
Mean (std dev)	84.66 (19.488)	89.58 (17.802)	-4.92	14.28 (23.481)	15.30 (21.509)	-1.02
Median	91.67	100.00		16.67	8.33	
Min, Max	8.3, 100.0	0.0, 100.0		-58.3, 91.7	-33.3, 100.0	
95% CI for Mean	(80.53, 88.79)	(85.52, 93.65)	(-10.71, 0.87)	(9.22, 19.35)	(10.35, 20.24)	(-8.08, 6.05)
P-value			0.0950			0.7769
Hedges's g			-0.26 (-0.57, 0.05)			-0.04 (-0.36, 0.27)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.5B
Summary of EORTC-QLQ-C30 Emotional Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 24 Month						
n	88	72		85	71	
Mean (std dev)	85.89 (21.156)	89.24 (20.241)	-3.35	17.71 (30.104)	16.51 (26.676)	1.20
Median	100.00	100.00		16.67	13.89	
Min, Max	0.0, 100.0	0.0, 100.0		-91.7, 91.7	-58.3, 100.0	
95% CI for Mean	(81.41, 90.37)	(84.48, 93.99)	(-9.86, 3.17)	(11.22, 24.21)	(10.20, 22.82)	(-7.88, 10.29)
P-value			0.3118			0.7941
Hedges's g			-0.16 (-0.47, 0.15)			0.04 (-0.27, 0.36)
Overall (EOT)						
n				153	145	
Mean (std dev)				9.7 (14.24)	11.1 (14.37)	-1.44
95% CI for Mean						(-4.70, 1.82)
P-value						0.3871
Hedges's g						-0.10 (-0.33, 0.13)
Overall (70% compliance)						
n				153	145	
Mean (std dev)				11.6 (13.08)	13.6 (13.36)	-2.02
95% CI for Mean						(-5.03, 0.99)
P-value						0.1887
Hedges's g						-0.15 (-0.38, 0.08)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.5B
Summary of EORTC-QLQ-C30 Emotional Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.6B
Summary of EORTC-QLQ-C30 Cognitive Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Baseline						
n	156	150				
Mean (std dev)	82.37 (23.283)	85.00 (20.594)	-2.63			
Median	91.67	91.67				
Min, Max	0.0, 100.0	0.0, 100.0				
95% CI for Mean	(78.69, 86.05)	(81.68, 88.32)	(-7.58, 2.32)			
P-value			0.2971			
Hedges's g			-0.12 (-0.34, 0.11)			
Cycle 2 Day 1						
n	155	143		151	140	
Mean (std dev)	86.45 (20.961)	87.41 (20.576)	-0.96	3.86 (21.555)	2.74 (18.171)	1.13
Median	100.00	100.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-83.3, 66.7	-66.7, 50.0	
95% CI for Mean	(83.13, 89.78)	(84.01, 90.81)	(-5.70, 3.78)	(0.40, 7.33)	(-0.30, 5.77)	(-3.49, 5.74)
P-value			0.6903			0.6320
Hedges's g			-0.05 (-0.27, 0.18)			0.06 (-0.17, 0.29)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.6B
Summary of EORTC-QLQ-C30 Cognitive Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 3 Day 1						
n	154	136		150	135	
Mean (std dev)	85.71 (19.933)	88.48 (19.406)	-2.77	3.78 (21.253)	4.20 (20.636)	-0.42
Median	100.00	100.00		0.00	0.00	
Min, Max	0.0, 100.0	16.7, 100.0		-66.7, 83.3	-66.7, 83.3	
95% CI for Mean	(82.54, 88.89)	(85.19, 91.77)	(-7.33, 1.79)	(0.35, 7.21)	(0.68, 7.71)	(-5.32, 4.48)
P-value			0.2335			0.8661
Hedges's g			-0.14 (-0.37, 0.09)			-0.02 (-0.25, 0.21)
Cycle 4 Day 1						
n	150	131		146	130	
Mean (std dev)	85.67 (19.504)	89.31 (17.180)	-3.65	3.65 (23.201)	4.62 (20.754)	-0.96
Median	100.00	100.00		0.00	0.00	
Min, Max	0.0, 100.0	33.3, 100.0		-100.0, 83.3	-66.7, 83.3	
95% CI for Mean	(82.52, 88.81)	(86.34, 92.28)	(-7.99, 0.70)	(-0.14, 7.45)	(1.01, 8.22)	(-6.20, 4.28)
P-value			0.0997			0.7181
Hedges's g			-0.20 (-0.43, 0.04)			-0.04 (-0.28, 0.19)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.6B
Summary of EORTC-QLQ-C30 Cognitive Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 5 Day 1						
n	143	123		140	122	
Mean (std dev)	85.78 (19.376)	89.02 (19.185)	-3.24	3.93 (21.215)	3.69 (22.114)	0.24
Median	100.00	100.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-66.7, 66.7	-66.7, 83.3	
95% CI for Mean	(82.58, 88.98)	(85.60, 92.45)	(-7.91, 1.43)	(0.38, 7.47)	(-0.28, 7.65)	(-5.04, 5.52)
P-value			0.1727			0.9287
Hedges's g			-0.17 (-0.41, 0.07)			0.01 (-0.23, 0.25)
Cycle 6 Day 1						
n	145	116		141	115	
Mean (std dev)	84.37 (20.621)	89.80 (19.258)	-5.43	2.48 (22.087)	4.49 (20.980)	-2.01
Median	100.00	100.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-66.7, 66.7	-83.3, 83.3	
95% CI for Mean	(80.98, 87.75)	(86.26, 93.34)	(-10.34, -0.52)	(-1.20, 6.16)	(0.62, 8.37)	(-7.35, 3.33)
P-value			0.0304			0.4595
Hedges's g			-0.27 (-0.52, -0.03)			-0.09 (-0.34, 0.15)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.6B
Summary of EORTC-QLQ-C30 Cognitive Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 7 Day 1						
n	35	33		34	33	
Mean (std dev)	82.86 (19.590)	87.37 (20.846)	-4.52	5.88 (23.883)	-0.51 (23.005)	6.39
Median	83.33	100.00		0.00	0.00	
Min, Max	33.3, 100.0	0.0, 100.0		-66.7, 66.7	-50.0, 66.7	
95% CI for Mean	(76.13, 89.59)	(79.98, 94.77)	(-14.31, 5.27)	(-2.45, 14.22)	(-8.66, 7.65)	(-5.06, 17.83)
P-value			0.3603			0.2692
Hedges's g			-0.22 (-0.70, 0.26)			0.27 (-0.21, 0.75)
Cycle 8 Day 1						
n	30	33		29	33	
Mean (std dev)	83.33 (20.529)	89.39 (20.757)	-6.06	7.47 (24.635)	1.52 (19.259)	5.96
Median	91.67	100.00		0.00	0.00	
Min, Max	33.3, 100.0	0.0, 100.0		-66.7, 66.7	-50.0, 50.0	
95% CI for Mean	(75.67, 91.00)	(82.03, 96.75)	(-16.48, 4.36)	(-1.90, 16.84)	(-5.31, 8.34)	(-5.21, 17.12)
P-value			0.2492			0.2903
Hedges's g			-0.29 (-0.79, 0.21)			0.27 (-0.23, 0.77)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.6B
Summary of EORTC-QLQ-C30 Cognitive Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
End of Treatment						
n	137	108		135	107	
Mean (std dev)	85.89 (20.501)	89.51 (18.313)	-3.62	4.07 (22.533)	4.36 (19.336)	-0.29
Median	100.00	100.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-50.0, 83.3	-66.7, 66.7	
95% CI for Mean	(82.42, 89.35)	(86.01, 93.00)	(-8.58, 1.34)	(0.24, 7.91)	(0.66, 8.07)	(-5.69, 5.11)
P-value			0.1520			0.9166
Hedges's g			-0.18 (-0.44, 0.07)			-0.01 (-0.27, 0.24)
Long-Term Follow-Up 9 Month						
n	107	88		104	87	
Mean (std dev)	86.45 (17.455)	87.69 (19.654)	-1.24	2.72 (22.289)	3.26 (22.280)	-0.53
Median	100.00	100.00		0.00	0.00	
Min, Max	16.7, 100.0	0.0, 100.0		-66.7, 66.7	-83.3, 66.7	
95% CI for Mean	(83.10, 89.79)	(83.53, 91.85)	(-6.49, 4.00)	(-1.61, 7.06)	(-1.49, 8.01)	(-6.92, 5.85)
P-value			0.6413			0.8696
Hedges's g			-0.07 (-0.35, 0.22)			-0.02 (-0.31, 0.26)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Protocol No.: SGN35-014 -- Data cut: 15AUG2018 (Data snapshot: 20SEP2018)

Table 35.1.2.7.6B
Summary of EORTC-QLQ-C30 Cognitive Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 12 Month						
n	111	81		108	80	
Mean (std dev)	87.09 (19.935)	88.27 (19.444)	-1.18	4.17 (19.750)	4.58 (24.301)	-0.42
Median	100.00	100.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-50.0, 50.0	-50.0, 100.0	
95% CI for Mean	(83.34, 90.84)	(83.97, 92.57)	(-6.87, 4.50)	(0.40, 7.93)	(-0.82, 9.99)	(-6.76, 5.93)
P-value			0.6817			0.8970
Hedges's g			-0.06 (-0.35, 0.23)			-0.02 (-0.31, 0.27)
Long-Term Follow-Up 15 Month						
n	103	82		101	81	
Mean (std dev)	86.89 (20.164)	90.24 (15.033)	-3.35	4.29 (19.952)	4.94 (21.960)	-0.65
Median	100.00	100.00		0.00	0.00	
Min, Max	0.0, 100.0	33.3, 100.0		-66.7, 66.7	-50.0, 83.3	
95% CI for Mean	(82.95, 90.83)	(86.94, 93.55)	(-8.63, 1.93)	(0.35, 8.23)	(0.08, 9.79)	(-6.79, 5.49)
P-value			0.2119			0.8354
Hedges's g			-0.18 (-0.48, 0.11)			-0.03 (-0.32, 0.26)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.6B
Summary of EORTC-QLQ-C30 Cognitive Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

| | Actual Value | | | Change from Baseline | | |
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 18 Month						
n	98	83		96	82	
Mean (std dev)	87.41 (19.888)	89.16 (17.737)	-1.74	5.21 (20.421)	4.88 (20.199)	0.33
Median	100.00	100.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-50.0, 50.0	-50.0, 83.3	
95% CI for Mean	(83.43, 91.40)	(85.28, 93.03)	(-7.31, 3.83)	(1.07, 9.35)	(0.44, 9.32)	(-5.70, 6.36)
P-value			0.5382			0.9140
Hedges's g			-0.09 (-0.38, 0.20)			0.02 (-0.28, 0.31)
Long-Term Follow-Up 21 Month						
n	88	76		85	75	
Mean (std dev)	87.50 (18.783)	91.45 (16.886)	-3.95	4.12 (20.878)	7.78 (24.405)	-3.66
Median	100.00	100.00		0.00	0.00	
Min, Max	16.7, 100.0	0.0, 100.0		-50.0, 66.7	-50.0, 83.3	
95% CI for Mean	(83.52, 91.48)	(87.59, 95.31)	(-9.49, 1.60)	(-0.39, 8.62)	(2.16, 13.39)	(-10.73, 3.41)
P-value			0.1617			0.3082
Hedges's g			-0.22 (-0.53, 0.09)			-0.16 (-0.47, 0.15)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Protocol No.: SGN35-014 -- Data cut: 15AUG2018 (Data snapshot: 20SEP2018)

Table 35.1.2.7.6B
Summary of EORTC-QLQ-C30 Cognitive Functioning Over Time
ITT Analysis Set - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 24 Month						
n	88	72		85	71	
Mean (std dev)	86.36 (21.374)	90.51 (17.430)	-4.15	4.31 (24.688)	7.04 (20.828)	-2.73
Median	100.00	100.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-83.3, 66.7	-33.3, 66.7	
95% CI for Mean	(81.83, 90.89)	(86.41, 94.61)	(-10.33, 2.04)	(-1.01, 9.64)	(2.11, 11.97)	(-10.04, 4.58)
P-value			0.1873			0.4620
Hedges's g			-0.21 (-0.52, 0.10)			-0.12 (-0.43, 0.20)
Overall (EOT)						
n				153	145	
Mean (std dev)				2.3 (14.37)	4.3 (14.49)	-2.06
95% CI for Mean						(-5.34, 1.23)
P-value						0.2196
Hedges's g						-0.14 (-0.37, 0.09)
Overall (70% compliance)						
n				153	145	
Mean (std dev)				2.7 (13.25)	5.5 (13.50)	-2.78
95% CI for Mean						(-5.82, 0.27)
P-value						0.0738
Hedges's g						-0.21 (-0.43, 0.02)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.6B
Summary of EORTC-QLQ-C30 Cognitive Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.7B
Summary of EORTC-QLQ-C30 Social Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Baseline						
n	156	150				
Mean (std dev)	64.85 (34.887)	69.11 (29.562)	-4.26			
Median	66.67	66.67				
Min, Max	0.0, 100.0	0.0, 100.0				
95% CI for Mean	(59.33, 70.37)	(64.34, 73.88)	(-11.55, 3.03)			
P-value			0.2509			
Hedges's g			-0.13 (-0.36, 0.09)			
Cycle 2 Day 1						
n	154	143		150	140	
Mean (std dev)	70.78 (27.831)	76.11 (25.296)	-5.33	5.00 (31.180)	6.79 (30.575)	-1.79
Median	66.67	83.33		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 100.0	-83.3, 100.0	
95% CI for Mean	(66.35, 75.21)	(71.93, 80.29)	(-11.42, 0.76)	(-0.03, 10.03)	(1.68, 11.89)	(-8.93, 5.36)
P-value			0.0861			0.6231
Hedges's g			-0.20 (-0.43, 0.03)			-0.06 (-0.29, 0.17)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.

Note: Hedges's g measures the effect size of the difference between means using results from mixed model.

Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.

Data snapshot: 20SEP2018.

Table 35.1.2.7.7B
Summary of EORTC-QLQ-C30 Social Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 3 Day 1						
n	154	136		150	135	
Mean (std dev)	74.35 (27.754)	79.41 (22.520)	-5.06	8.33 (29.459)	10.00 (28.882)	-1.67
Median	83.33	83.33		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-83.3, 83.3	-66.7, 100.0	
95% CI for Mean	(69.93, 78.77)	(75.59, 83.23)	(-10.95, 0.83)	(3.58, 13.09)	(5.08, 14.92)	(-8.48, 5.15)
P-value			0.0919			0.6307
Hedges's g			-0.20 (-0.43, 0.03)			-0.06 (-0.29, 0.18)
Cycle 4 Day 1						
n	149	131		145	130	
Mean (std dev)	74.27 (29.222)	80.53 (22.183)	-6.26	9.31 (34.296)	10.00 (30.542)	-0.69
Median	83.33	83.33		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-83.3, 100.0	-83.3, 100.0	
95% CI for Mean	(69.54, 79.00)	(76.70, 84.37)	(-12.43, -0.09)	(3.68, 14.94)	(4.70, 15.30)	(-8.44, 7.06)
P-value			0.0467			0.8610
Hedges's g			-0.24 (-0.47, -0.00)			-0.02 (-0.26, 0.22)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.7B
Summary of EORTC-QLQ-C30 Social Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 5 Day 1						
n	142	122		139	121	
Mean (std dev)	73.94 (29.001)	78.83 (24.435)	-4.88	8.39 (33.296)	7.99 (29.510)	0.40
Median	83.33	83.33		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-83.3, 100.0	-66.7, 100.0	
95% CI for Mean	(69.13, 78.75)	(74.45, 83.20)	(-11.44, 1.68)	(2.81, 13.98)	(2.68, 13.30)	(-7.33, 8.14)
P-value			0.1441			0.9181
Hedges's g			-0.18 (-0.42, 0.06)			0.01 (-0.23, 0.26)
Cycle 6 Day 1						
n	144	116		140	115	
Mean (std dev)	72.57 (28.865)	79.31 (26.614)	-6.74	6.55 (37.332)	9.28 (31.929)	-2.73
Median	66.67	83.33		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-83.3, 100.0	-100.0, 100.0	
95% CI for Mean	(67.81, 77.32)	(74.42, 84.21)	(-13.59, 0.11)	(0.31, 12.79)	(3.38, 15.17)	(-11.40, 5.95)
P-value			0.0538			0.5363
Hedges's g			-0.24 (-0.49, 0.00)			-0.08 (-0.32, 0.17)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.7B
Summary of EORTC-QLQ-C30 Social Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 7 Day 1						
n	35	33		34	33	
Mean (std dev)	67.14 (27.262)	79.29 (19.996)	-12.15	10.78 (39.967)	6.57 (28.547)	4.22
Median	66.67	83.33		0.00	0.00	
Min, Max	0.0, 100.0	33.3, 100.0		-66.7, 100.0	-66.7, 66.7	
95% CI for Mean	(57.78, 76.51)	(72.20, 86.38)	(-23.78, -0.52)	(-3.16, 24.73)	(-3.56, 16.69)	(-12.77, 21.21)
P-value			0.0409			0.6217
Hedges's g			-0.50 (-0.98, -0.02)			0.12 (-0.36, 0.60)
Cycle 8 Day 1						
n	30	33		29	33	
Mean (std dev)	65.56 (30.303)	74.75 (23.980)	-9.19	13.22 (41.399)	2.02 (32.210)	11.20
Median	66.67	66.67		16.67	0.00	
Min, Max	0.0, 100.0	33.3, 100.0		-83.3, 100.0	-66.7, 66.7	
95% CI for Mean	(54.24, 76.87)	(66.24, 83.25)	(-22.90, 4.51)	(-2.53, 28.97)	(-9.40, 13.44)	(-7.53, 29.93)
P-value			0.1849			0.2364
Hedges's g			-0.33 (-0.83, 0.16)			0.30 (-0.20, 0.80)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.7B
Summary of EORTC-QLQ-C30 Social Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

| | Actual Value | | | Change from Baseline | | |
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
End of Treatment						
n	136	108		134	107	
Mean (std dev)	77.94 (26.903)	79.63 (25.305)	-1.69	12.69 (38.626)	8.88 (28.623)	3.81
Median	83.33	83.33		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-83.3, 100.0	-66.7, 83.3	
95% CI for Mean	(73.38, 82.50)	(74.80, 84.46)	(-8.34, 4.97)	(6.09, 19.29)	(3.39, 14.36)	(-5.02, 12.63)
P-value			0.6176			0.3961
Hedges's g			-0.06 (-0.32, 0.19)			0.11 (-0.14, 0.36)
Long-Term Follow-Up 9 Month						
n	107	88		104	87	
Mean (std dev)	84.58 (22.513)	84.85 (22.409)	-0.27	19.23 (35.585)	15.52 (29.727)	3.71
Median	100.00	100.00		16.67	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-66.7, 100.0	-66.7, 83.3	
95% CI for Mean	(80.26, 88.89)	(80.10, 89.60)	(-6.65, 6.11)	(12.31, 26.15)	(9.18, 21.85)	(-5.76, 13.19)
P-value			0.9338			0.4403
Hedges's g			-0.01 (-0.29, 0.27)			0.11 (-0.17, 0.40)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.7B
Summary of EORTC-QLQ-C30 Social Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 12 Month						
n	111	81		108	80	
Mean (std dev)	87.09 (22.994)	84.57 (23.685)	2.52	21.60 (34.726)	15.83 (33.638)	5.77
Median	100.00	100.00		16.67	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-66.7, 100.0	-66.7, 100.0	
95% CI for Mean	(82.76, 91.41)	(79.33, 89.80)	(-4.19, 9.23)	(14.98, 28.23)	(8.35, 23.32)	(-4.20, 15.74)
P-value			0.4600			0.2550
Hedges's g			0.11 (-0.18, 0.39)			0.17 (-0.12, 0.46)
Long-Term Follow-Up 15 Month						
n	103	82		101	81	
Mean (std dev)	87.54 (22.106)	91.06 (19.101)	-3.52	22.94 (35.422)	22.02 (31.161)	0.92
Median	100.00	100.00		16.67	16.67	
Min, Max	0.0, 100.0	0.0, 100.0		-66.7, 100.0	-33.3, 100.0	
95% CI for Mean	(83.22, 91.86)	(86.86, 95.25)	(-9.60, 2.57)	(15.94, 29.93)	(15.13, 28.91)	(-8.97, 10.81)
P-value			0.2555			0.8544
Hedges's g			-0.17 (-0.46, 0.12)			0.03 (-0.27, 0.32)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.7B
Summary of EORTC-QLQ-C30 Social Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 18 Month						
n	98	83		96	82	
Mean (std dev)	88.10 (20.587)	89.76 (18.558)	-1.66	25.87 (36.823)	21.14 (31.323)	4.73
Median	100.00	100.00		25.00	16.67	
Min, Max	16.7, 100.0	0.0, 100.0		-83.3, 100.0	-50.0, 100.0	
95% CI for Mean	(83.97, 92.22)	(85.71, 93.81)	(-7.46, 4.13)	(18.41, 33.33)	(14.26, 28.02)	(-5.48, 14.94)
P-value			0.5717			0.3618
Hedges's g			-0.08 (-0.38, 0.21)			0.14 (-0.16, 0.43)
Long-Term Follow-Up 21 Month						
n	88	76		85	75	
Mean (std dev)	88.07 (20.983)	90.35 (20.415)	-2.28	24.31 (34.747)	20.22 (31.870)	4.09
Median	100.00	100.00		16.67	16.67	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 100.0	-66.7, 100.0	
95% CI for Mean	(83.62, 92.51)	(85.69, 95.02)	(-8.69, 4.13)	(16.82, 31.81)	(12.89, 27.55)	(-6.37, 14.55)
P-value			0.4828			0.4410
Hedges's g			-0.11 (-0.42, 0.20)			0.12 (-0.19, 0.43)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.7B
Summary of EORTC-QLQ-C30 Social Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 24 Month						
n	88	72		85	71	
Mean (std dev)	87.88 (22.984)	90.74 (19.358)	-2.86	24.90 (38.199)	23.71 (33.293)	1.19
Median	100.00	100.00		16.67	16.67	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 100.0	-66.7, 100.0	
95% CI for Mean	(83.01, 92.75)	(86.19, 95.29)	(-9.59, 3.86)	(16.66, 33.14)	(15.83, 31.59)	(-10.26, 12.64)
P-value			0.4020			0.8372
Hedges's g			-0.13 (-0.44, 0.18)			0.03 (-0.28, 0.35)
Overall (EOT)						
n				153	145	
Mean (std dev)				5.9 (20.82)	9.6 (20.98)	-3.71
95% CI for Mean						(-8.47, 1.04)
P-value						0.1260
Hedges's g						-0.18 (-0.40, 0.05)
Overall (70% compliance)						
n				153	145	
Mean (std dev)				11.8 (18.43)	15.1 (18.79)	-3.38
95% CI for Mean						(-7.61, 0.86)
P-value						0.1183
Hedges's g						-0.18 (-0.41, 0.05)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.7B
Summary of EORTC-QLQ-C30 Social Functioning Over Time
ITT Analysis Set   - Subset of Patients with sALCL

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.

Note: Hedges's g measures the effect size of the difference between means using results from mixed model.

Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.

Data snapshot: 20SEP2018.

Table 35.1.2.7.8B
Summary of EORTC-QLQ-C30 Fatigue Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Baseline						
n	156	151				
Mean (std dev)	41.52 (30.790)	41.87 (29.044)	-0.34			
Median	33.33	33.33				
Min, Max	0.0, 100.0	0.0, 100.0				
95% CI for Mean	(36.65, 46.39)	(37.20, 46.54)	(-7.07, 6.38)			
P-value			0.9197			
Hedges's g			-0.01 (-0.24, 0.21)			
Cycle 2 Day 1						
n	155	141		151	140	
Mean (std dev)	33.66 (23.487)	33.18 (24.451)	0.48	-7.03 (25.497)	-6.98 (24.732)	-0.04
Median	33.33	33.33		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 77.8	-77.8, 77.8	
95% CI for Mean	(29.93, 37.38)	(29.10, 37.25)	(-5.01, 5.97)	(-11.13, -2.93)	(-11.12, -2.85)	(-5.85, 5.76)
P-value			0.8633			0.9883
Hedges's g			0.02 (-0.21, 0.25)			-0.00 (-0.23, 0.23)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.8B
Summary of EORTC-QLQ-C30 Fatigue Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 3 Day 1						
n	154	137		150	137	
Mean (std dev)	31.46 (23.895)	30.62 (24.700)	0.84	-9.78 (28.898)	-9.69 (27.647)	-0.09
Median	33.33	33.33		-11.11	-11.11	
Min, Max	0.0, 88.9	0.0, 100.0		-100.0, 55.6	-88.9, 77.8	
95% CI for Mean	(27.65, 35.26)	(26.44, 34.79)	(-4.77, 6.45)	(-14.44, -5.12)	(-14.36, -5.02)	(-6.67, 6.50)
P-value			0.7682			0.9795
Hedges's g			0.03 (-0.20, 0.26)			-0.00 (-0.23, 0.23)
Cycle 4 Day 1						
n	150	132		146	131	
Mean (std dev)	31.63 (23.762)	28.83 (22.424)	2.80	-9.06 (28.200)	-10.64 (27.787)	1.59
Median	33.33	33.33		-5.56	-11.11	
Min, Max	0.0, 100.0	0.0, 100.0		-88.9, 66.7	-77.8, 77.8	
95% CI for Mean	(27.80, 35.46)	(24.97, 32.69)	(-2.64, 8.24)	(-13.67, -4.44)	(-15.45, -5.84)	(-5.05, 8.22)
P-value			0.3117			0.6378
Hedges's g			0.12 (-0.11, 0.35)			0.06 (-0.18, 0.29)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.

Note: Hedges's g measures the effect size of the difference between means using results from mixed model.

Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.

Data snapshot: 20SEP2018.

Table 35.1.2.7.8B
Summary of EORTC-QLQ-C30 Fatigue Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 5 Day 1						
n	144	123		140	122	
Mean (std dev)	32.56 (24.606)	26.96 (21.990)	5.60	-8.89 (30.105)	-11.52 (28.013)	2.63
Median	33.33	22.22		0.00	-11.11	
Min, Max	0.0, 100.0	0.0, 88.9		-100.0, 100.0	-100.0, 55.6	
95% CI for Mean	(28.51, 36.61)	(23.04, 30.89)	(-0.07, 11.26)	(-13.92, -3.86)	(-16.54, -6.50)	(-4.48, 9.74)
P-value			0.0528			0.4666
Hedges's g			0.24 (-0.00, 0.48)			0.09 (-0.15, 0.33)
Cycle 6 Day 1						
n	145	117		141	116	
Mean (std dev)	34.33 (26.154)	27.92 (22.725)	6.41	-6.62 (31.678)	-10.34 (31.315)	3.73
Median	33.33	22.22		0.00	-11.11	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 77.8	-77.8, 66.7	
95% CI for Mean	(30.04, 38.62)	(23.76, 32.08)	(0.37, 12.45)	(-11.89, -1.35)	(-16.10, -4.59)	(-4.05, 11.51)
P-value			0.0376			0.3465
Hedges's g			0.26 (0.01, 0.50)			0.12 (-0.13, 0.36)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Protocol No.: SGN35-014 -- Data cut: 15AUG2018 (Data snapshot: 20SEP2018)

Table 35.1.2.7.8B
Summary of EORTC-QLQ-C30 Fatigue Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 7 Day 1						
n	35	33		34	33	
Mean (std dev)	40.32 (26.553)	28.28 (19.855)	12.03	-13.07 (31.602)	-6.73 (29.258)	-6.34
Median	33.33	33.33		-11.11	0.00	
Min, Max	0.0, 100.0	0.0, 66.7		-66.7, 66.7	-77.8, 44.4	
95% CI for Mean	(31.20, 49.44)	(21.24, 35.32)	(0.63, 23.44)	(-24.10, -2.05)	(-17.11, 3.64)	(-21.21, 8.53)
P-value			0.0390			0.3978
Hedges's g			0.51 (0.02, 0.99)			-0.21 (-0.69, 0.27)
Cycle 8 Day 1						
n	30	33		29	33	
Mean (std dev)	38.52 (26.380)	29.63 (24.003)	8.89	-15.33 (33.520)	-5.39 (37.384)	-9.94
Median	33.33	33.33		-11.11	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-77.8, 77.8	-66.7, 100.0	
95% CI for Mean	(28.67, 48.37)	(21.12, 38.14)	(-3.80, 21.58)	(-28.08, -2.58)	(-18.64, 7.87)	(-28.08, 8.20)
P-value			0.1664			0.2775
Hedges's g			0.35 (-0.15, 0.85)			-0.28 (-0.78, 0.23)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.8B
Summary of EORTC-QLQ-C30 Fatigue Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
End of Treatment						
n	138	109		136	108	
Mean (std dev)	28.62 (23.967)	23.55 (21.208)	5.08	-11.97 (31.244)	-14.30 (30.648)	2.33
Median	33.33	22.22		-11.11	-11.11	
Min, Max	0.0, 100.0	0.0, 88.9		-100.0, 66.7	-100.0, 55.6	
95% CI for Mean	(24.59, 32.66)	(19.52, 27.57)	(-0.68, 10.83)	(-17.27, -6.67)	(-20.15, -8.45)	(-5.53, 10.20)
P-value			0.0835			0.5599
Hedges's g			0.22 (-0.03, 0.47)			0.08 (-0.18, 0.33)
Long-Term Follow-Up 9 Month						
n	108	88		105	87	
Mean (std dev)	23.56 (22.568)	21.34 (22.679)	2.22	-16.93 (31.992)	-17.75 (30.380)	0.82
Median	22.22	11.11		-11.11	-11.11	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 77.8	-88.9, 44.4	
95% CI for Mean	(19.25, 27.86)	(16.53, 26.14)	(-4.18, 8.63)	(-23.12, -10.74)	(-24.23, -11.28)	(-8.12, 9.76)
P-value			0.4949			0.8565
Hedges's g			0.10 (-0.18, 0.38)			0.03 (-0.26, 0.31)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.8B
Summary of EORTC-QLQ-C30 Fatigue Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 12 Month						
n	111	81		108	80	
Mean (std dev)	21.87 (22.995)	19.75 (23.373)	2.12	-18.16 (32.613)	-19.86 (28.871)	1.70
Median	11.11	11.11		-16.67	-11.11	
Min, Max	0.0, 100.0	0.0, 88.9		-100.0, 55.6	-100.0, 55.6	
95% CI for Mean	(17.55, 26.20)	(14.58, 24.92)	(-4.56, 8.79)	(-24.38, -11.94)	(-26.29, -13.44)	(-7.34, 10.75)
P-value			0.5320			0.7108
Hedges's g			0.09 (-0.20, 0.38)			0.05 (-0.23, 0.34)
Long-Term Follow-Up 15 Month						
n	102	83		100	82	
Mean (std dev)	20.92 (23.416)	17.34 (20.281)	3.58	-20.11 (33.115)	-22.56 (29.089)	2.45
Median	11.11	11.11		-22.22	-22.22	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 77.8	-100.0, 44.4	
95% CI for Mean	(16.32, 25.51)	(12.91, 21.76)	(-2.86, 10.01)	(-26.68, -13.54)	(-28.95, -16.17)	(-6.77, 11.67)
P-value			0.2740			0.6008
Hedges's g			0.16 (-0.13, 0.45)			0.08 (-0.21, 0.37)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.8B
Summary of EORTC-QLQ-C30 Fatigue Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 18 Month						
n	99	83		97	82	
Mean (std dev)	20.65 (22.852)	19.41 (21.870)	1.24	-20.73 (32.568)	-20.19 (29.994)	-0.54
Median	11.11	11.11		-22.22	-11.11	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 66.7	-100.0, 44.4	
95% CI for Mean	(16.09, 25.21)	(14.64, 24.19)	(-5.34, 7.82)	(-27.30, -14.17)	(-26.78, -13.60)	(-9.84, 8.76)
P-value			0.7105			0.9083
Hedges's g			0.06 (-0.24, 0.35)			-0.02 (-0.31, 0.28)
Long-Term Follow-Up 21 Month						
n	88	76		85	75	
Mean (std dev)	20.20 (24.211)	16.81 (18.636)	3.39	-19.08 (28.515)	-23.26 (30.191)	4.17
Median	11.11	11.11		-11.11	-11.11	
Min, Max	0.0, 100.0	0.0, 77.8		-100.0, 44.4	-100.0, 22.2	
95% CI for Mean	(15.07, 25.33)	(12.55, 21.07)	(-3.35, 10.13)	(-25.24, -12.93)	(-30.21, -16.31)	(-5.00, 13.35)
P-value			0.3225			0.3701
Hedges's g			0.15 (-0.15, 0.46)			0.14 (-0.17, 0.45)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.8B
Summary of EORTC-QLQ-C30 Fatigue Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 24 Month						
n	88	71		85	70	
Mean (std dev)	17.17 (21.103)	18.15 (20.422)	-0.98	-25.75 (33.911)	-24.29 (32.119)	-1.47
Median	11.11	11.11		-22.22	-22.22	
Min, Max	0.0, 100.0	0.0, 88.9		-100.0, 55.6	-100.0, 55.6	
95% CI for Mean	(12.70, 21.64)	(13.32, 22.99)	(-7.54, 5.57)	(-33.07, -18.44)	(-31.94, -16.63)	(-12.03, 9.09)
P-value			0.7678			0.7842
Hedges's g			-0.05 (-0.36, 0.27)			-0.04 (-0.36, 0.27)
Overall (EOT)						
n				153	146	
Mean (std dev)				-7.9 (18.26)	-10.0 (18.40)	2.13
95% CI for Mean						(-2.03, 6.29)
P-value						0.3153
Hedges's g						0.12 (-0.11, 0.34)
Overall (70% compliance)						
n				153	146	
Mean (std dev)				-12.4 (16.85)	-14.8 (17.16)	2.43
95% CI for Mean						(-1.43, 6.29)
P-value						0.2172
Hedges's g						0.14 (-0.08, 0.37)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.8B
Summary of EORTC-QLQ-C30 Fatigue Over Time
ITT Analysis Set   - Subset of Patients with sALCL

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.

Note: Hedges's g measures the effect size of the difference between means using results from mixed model.

Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.

Data snapshot: 20SEP2018.

Table 35.1.2.7.9B
Summary of EORTC-QLQ-C30 Pain Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Baseline						
n	156	151				
Mean (std dev)	39.42 (32.851)	37.86 (33.274)	1.56			
Median	33.33	33.33				
Min, Max	0.0, 100.0	0.0, 100.0				
95% CI for Mean	(34.23, 44.62)	(32.51, 43.21)	(-5.86, 8.99)			
P-value			0.6788			
Hedges's g			0.05 (-0.18, 0.27)			
Cycle 2 Day 1						
n	155	143		151	141	
Mean (std dev)	22.58 (26.843)	17.37 (23.643)	5.21	-15.89 (30.450)	-20.33 (32.799)	4.44
Median	16.67	0.00		-16.67	-16.67	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 83.3	-100.0, 66.7	
95% CI for Mean	(18.32, 26.84)	(13.46, 21.27)	(-0.57, 11.00)	(-20.79, -11.00)	(-25.79, -14.87)	(-2.85, 11.72)
P-value			0.0772			0.2316
Hedges's g			0.21 (-0.02, 0.43)			0.14 (-0.09, 0.37)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.9B
Summary of EORTC-QLQ-C30 Pain Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 3 Day 1						
n	154	137		150	137	
Mean (std dev)	19.26 (24.113)	14.48 (21.938)	4.79	-19.89 (32.581)	-22.75 (35.000)	2.86
Median	16.67	0.00		-16.67	-16.67	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 50.0	-100.0, 100.0	
95% CI for Mean	(15.43, 23.10)	(10.77, 18.18)	(-0.56, 10.13)	(-25.15, -14.63)	(-28.66, -16.84)	(-4.99, 10.71)
P-value			0.0789			0.4739
Hedges's g			0.21 (-0.02, 0.44)			0.08 (-0.15, 0.32)
Cycle 4 Day 1						
n	150	132		146	131	
Mean (std dev)	20.22 (25.660)	11.24 (17.893)	8.98	-19.41 (34.631)	-25.19 (30.757)	5.78
Median	16.67	0.00		-16.67	-16.67	
Min, Max	0.0, 100.0	0.0, 66.7		-100.0, 100.0	-100.0, 33.3	
95% CI for Mean	(16.08, 24.36)	(8.16, 14.32)	(3.73, 14.24)	(-25.07, -13.74)	(-30.51, -19.87)	(-2.00, 13.57)
P-value			0.0009			0.1446
Hedges's g			0.40 (0.16, 0.64)			0.18 (-0.06, 0.41)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.9B
Summary of EORTC-QLQ-C30 Pain Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 5 Day 1						
n	144	123		140	122	
Mean (std dev)	19.10 (25.697)	12.06 (18.270)	7.04	-20.83 (35.377)	-24.86 (33.281)	4.03
Median	0.00	0.00		-16.67	-16.67	
Min, Max	0.0, 100.0	0.0, 66.7		-100.0, 66.7	-100.0, 50.0	
95% CI for Mean	(14.86, 23.33)	(8.80, 15.32)	(1.58, 12.50)	(-26.74, -14.92)	(-30.83, -18.90)	(-4.36, 12.42)
P-value			0.0117			0.3453
Hedges's g			0.31 (0.07, 0.55)			0.12 (-0.13, 0.36)
Cycle 6 Day 1						
n	145	116		141	115	
Mean (std dev)	20.57 (26.861)	15.66 (22.553)	4.91	-18.44 (37.199)	-20.29 (36.460)	1.85
Median	16.67	0.00		-16.67	-16.67	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 83.3	-100.0, 66.7	
95% CI for Mean	(16.17, 24.98)	(11.51, 19.81)	(-1.23, 11.06)	(-24.63, -12.25)	(-27.03, -13.55)	(-7.27, 10.97)
P-value			0.1164			0.6900
Hedges's g			0.20 (-0.05, 0.44)			0.05 (-0.20, 0.30)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.9B
Summary of EORTC-QLQ-C30 Pain Over Time
ITT Analysis Set   - Subset of Patients with sALCL

| | Actual Value | | | Change from Baseline | | |
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 7 Day 1						
n	35	33		34	33	
Mean (std dev)	26.67 (26.568)	17.68 (28.547)	8.99	-19.12 (40.852)	-16.16 (39.853)	-2.96
Median	16.67	0.00		-16.67	-16.67	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 83.3	-100.0, 100.0	
95% CI for Mean	(17.54, 35.79)	(7.55, 27.80)	(-4.35, 22.33)	(-33.37, -4.86)	(-30.29, -2.03)	(-22.65, 16.74)
P-value			0.1832			0.7654
Hedges's g			0.32 (-0.16, 0.80)			-0.07 (-0.55, 0.41)
Cycle 8 Day 1						
n	30	33		29	33	
Mean (std dev)	22.22 (20.216)	14.14 (20.464)	8.08	-25.86 (37.157)	-19.70 (38.064)	-6.17
Median	16.67	0.00		-33.33	-16.67	
Min, Max	0.0, 66.7	0.0, 100.0		-100.0, 66.7	-83.3, 100.0	
95% CI for Mean	(14.67, 29.77)	(6.89, 21.40)	(-2.18, 18.34)	(-40.00, -11.73)	(-33.19, -6.20)	(-25.33, 13.00)
P-value			0.1206			0.5224
Hedges's g			0.39 (-0.11, 0.89)			-0.16 (-0.66, 0.34)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.9B
Summary of EORTC-QLQ-C30 Pain Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
End of Treatment						
n	138	109		136	108	
Mean (std dev)	18.60 (24.914)	11.01 (19.006)	7.59	-20.47 (36.905)	-25.46 (33.291)	5.00
Median	0.00	0.00		-16.67	-16.67	
Min, Max	0.0, 100.0	0.0, 83.3		-100.0, 66.7	-100.0, 66.7	
95% CI for Mean	(14.41, 22.79)	(7.40, 14.62)	(1.91, 13.27)	(-26.72, -14.21)	(-31.81, -19.11)	(-3.98, 13.97)
P-value			0.0090			0.2739
Hedges's g			0.34 (0.08, 0.59)			0.14 (-0.11, 0.39)
Long-Term Follow-Up 9 Month						
n	108	88		105	87	
Mean (std dev)	14.97 (21.368)	11.55 (20.114)	3.42	-23.97 (35.651)	-24.90 (32.536)	0.94
Median	0.00	0.00		-16.67	-16.67	
Min, Max	0.0, 83.3	0.0, 100.0		-100.0, 50.0	-100.0, 50.0	
95% CI for Mean	(10.89, 19.05)	(7.29, 15.81)	(-2.48, 9.31)	(-30.87, -17.07)	(-31.84, -17.97)	(-8.87, 10.74)
P-value			0.2545			0.8508
Hedges's g			0.16 (-0.12, 0.45)			0.03 (-0.26, 0.31)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Protocol No.: SGN35-014 -- Data cut: 15AUG2018 (Data snapshot: 20SEP2018)

Table 35.1.2.7.9B
Summary of EORTC-QLQ-C30 Pain Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 12 Month						
n	111	81		108	80	
Mean (std dev)	15.17 (22.423)	11.73 (20.318)	3.44	-24.23 (33.519)	-26.46 (36.812)	2.23
Median	0.00	0.00		-16.67	-16.67	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 50.0	-100.0, 33.3	
95% CI for Mean	(10.95, 19.38)	(7.24, 16.22)	(-2.78, 9.65)	(-30.62, -17.83)	(-34.65, -18.27)	(-7.94, 12.40)
P-value			0.2768			0.6659
Hedges's g			0.16 (-0.13, 0.45)			0.06 (-0.23, 0.35)
Long-Term Follow-Up 15 Month						
n	103	83		101	82	
Mean (std dev)	15.70 (23.434)	11.04 (21.975)	4.65	-24.75 (32.881)	-26.22 (35.528)	1.47
Median	0.00	0.00		-16.67	-16.67	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 50.0	-100.0, 50.0	
95% CI for Mean	(11.12, 20.28)	(6.25, 15.84)	(-1.98, 11.29)	(-31.24, -18.26)	(-34.03, -18.41)	(-8.53, 11.47)
P-value			0.1682			0.7725
Hedges's g			0.20 (-0.09, 0.49)			0.04 (-0.25, 0.33)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.

Note: Hedges's g measures the effect size of the difference between means using results from mixed model.

Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.

Data snapshot: 20SEP2018.

Protocol No.: SGN35-014 -- Data cut: 15AUG2018 (Data snapshot: 20SEP2018)

Table 35.1.2.7.9B
Summary of EORTC-QLQ-C30 Pain Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 18 Month						
n	99	83		97	82	
Mean (std dev)	13.64 (22.758)	10.04 (19.468)	3.60	-26.63 (34.415)	-26.63 (33.728)	-0.01
Median	0.00	0.00		-33.33	-16.67	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 83.3	-100.0, 50.0	
95% CI for Mean	(9.10, 18.18)	(5.79, 14.29)	(-2.67, 9.86)	(-33.57, -19.70)	(-34.04, -19.22)	(-10.10, 10.09)
P-value			0.2586			0.9990
Hedges's g			0.17 (-0.12, 0.46)			-0.00 (-0.29, 0.29)
Long-Term Follow-Up 21 Month						
n	88	76		85	75	
Mean (std dev)	12.50 (19.777)	10.31 (20.542)	2.19	-26.86 (32.336)	-26.22 (36.676)	-0.64
Median	0.00	0.00		-16.67	-16.67	
Min, Max	0.0, 83.3	0.0, 100.0		-100.0, 33.3	-100.0, 66.7	
95% CI for Mean	(8.31, 16.69)	(5.61, 15.00)	(-4.03, 8.42)	(-33.84, -19.89)	(-34.66, -17.78)	(-11.42, 10.13)
P-value			0.4877			0.9067
Hedges's g			0.11 (-0.20, 0.42)			-0.02 (-0.33, 0.29)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.9B
Summary of EORTC-QLQ-C30 Pain Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 24 Month						
n	88	72		85	71	
Mean (std dev)	12.69 (22.029)	11.81 (24.134)	0.88	-29.41 (34.565)	-28.64 (35.207)	-0.77
Median	0.00	0.00		-33.33	-16.67	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 66.7	-100.0, 50.0	
95% CI for Mean	(8.02, 17.36)	(6.13, 17.48)	(-6.33, 8.10)	(-36.87, -21.96)	(-36.97, -20.31)	(-11.84, 10.30)
P-value			0.8092			0.8904
Hedges's g			0.04 (-0.27, 0.35)			-0.02 (-0.34, 0.29)
Overall (EOT)						
n				153	146	
Mean (std dev)				-17.8 (18.28)	-22.0 (18.44)	4.21
95% CI for Mean						(0.04, 8.37)
P-value						0.0480
Hedges's g						0.23 (0.00, 0.46)
Overall (70% compliance)						
n				153	146	
Mean (std dev)				-20.2 (17.19)	-23.4 (17.54)	3.27
95% CI for Mean						(-0.67, 7.21)
P-value						0.1042
Hedges's g						0.19 (-0.04, 0.41)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.9B
Summary of EORTC-QLQ-C30 Pain Over Time
ITT Analysis Set   - Subset of Patients with sALCL

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.

Note: Hedges's g measures the effect size of the difference between means using results from mixed model.

Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.

Data snapshot: 20SEP2018.

Table 35.1.2.7.10B
Summary of EORTC-QLQ-C30 Nausea and Vomiting Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Baseline						
n	156	151				
Mean (std dev)	9.40 (20.841)	7.95 (18.342)	1.45			
Median	0.00	0.00				
Min, Max	0.0, 100.0	0.0, 100.0				
95% CI for Mean	(6.11, 12.70)	(5.00, 10.90)	(-2.96, 5.87)			
P-value			0.5172			
Hedges's g			0.07 (-0.15, 0.30)			
Cycle 2 Day 1						
n	155	142		151	141	
Mean (std dev)	7.63 (14.863)	4.34 (9.861)	3.29	-2.21 (21.229)	-2.25 (15.839)	0.04
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 83.3	0.0, 50.0		-100.0, 66.7	-66.7, 33.3	
95% CI for Mean	(5.28, 9.99)	(2.71, 5.98)	(0.38, 6.20)	(-5.62, 1.21)	(-4.88, 0.39)	(-4.30, 4.38)
P-value			0.0267			0.9861
Hedges's g			0.26 (0.03, 0.49)			0.00 (-0.23, 0.23)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.

Note: Hedges's g measures the effect size of the difference between means using results from mixed model.

Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.

Data snapshot: 20SEP2018.

Table 35.1.2.7.10B
Summary of EORTC-QLQ-C30 Nausea and Vomiting Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 3 Day 1						
n	154	137		150	137	
Mean (std dev)	7.58 (14.524)	5.84 (10.807)	1.74	-2.44 (21.879)	-0.24 (15.654)	-2.20
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 83.3	0.0, 50.0		-100.0, 50.0	-50.0, 33.3	
95% CI for Mean	(5.26, 9.89)	(4.01, 7.67)	(-1.25, 4.72)	(-5.97, 1.09)	(-2.89, 2.40)	(-6.66, 2.26)
P-value			0.2530			0.3319
Hedges's g			0.13 (-0.10, 0.36)			-0.11 (-0.35, 0.12)
Cycle 4 Day 1						
n	150	132		146	131	
Mean (std dev)	9.00 (15.880)	6.57 (14.082)	2.43	-1.14 (23.215)	0.51 (18.015)	-1.65
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 83.3		-100.0, 83.3	-50.0, 83.3	
95% CI for Mean	(6.44, 11.56)	(4.14, 8.99)	(-1.10, 5.97)	(-4.94, 2.66)	(-2.60, 3.62)	(-6.61, 3.31)
P-value			0.1768			0.5126
Hedges's g			0.16 (-0.07, 0.40)			-0.08 (-0.31, 0.16)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.10B
Summary of EORTC-QLQ-C30 Nausea and Vomiting Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 5 Day 1						
n	144	123		140	122	
Mean (std dev)	8.22 (13.368)	5.96 (11.318)	2.26	-2.14 (23.042)	-0.41 (17.469)	-1.73
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 50.0	0.0, 50.0		-100.0, 50.0	-50.0, 50.0	
95% CI for Mean	(6.02, 10.42)	(3.94, 7.98)	(-0.76, 5.27)	(-5.99, 1.71)	(-3.54, 2.72)	(-6.77, 3.30)
P-value			0.1418			0.4983
Hedges's g			0.18 (-0.06, 0.42)			-0.08 (-0.33, 0.16)
Cycle 6 Day 1						
n	145	117		141	116	
Mean (std dev)	7.93 (13.620)	5.13 (12.078)	2.80	-2.84 (24.231)	-1.44 (18.852)	-1.40
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 83.3	0.0, 83.3		-100.0, 83.3	-50.0, 83.3	
95% CI for Mean	(5.70, 10.17)	(2.92, 7.34)	(-0.37, 5.97)	(-6.87, 1.20)	(-4.90, 2.03)	(-6.82, 4.02)
P-value			0.0829			0.6116
Hedges's g			0.22 (-0.03, 0.46)			-0.06 (-0.31, 0.18)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.10B
Summary of EORTC-QLQ-C30 Nausea and Vomiting Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 7 Day 1						
n	35	33		34	33	
Mean (std dev)	12.38 (19.107)	4.55 (10.436)	7.84	-5.88 (30.672)	-1.01 (17.648)	-4.87
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 83.3	0.0, 33.3		-100.0, 33.3	-50.0, 33.3	
95% CI for Mean	(5.82, 18.94)	(0.85, 8.25)	(0.32, 15.35)	(-16.58, 4.82)	(-7.27, 5.25)	(-17.13, 7.39)
P-value			0.0413			0.4302
Hedges's g			0.50 (0.02, 0.98)			-0.19 (-0.67, 0.29)
Cycle 8 Day 1						
n	30	33		29	33	
Mean (std dev)	15.00 (19.253)	7.58 (17.225)	7.42	-5.17 (28.208)	2.02 (23.108)	-7.19
Median	8.33	0.00		0.00	0.00	
Min, Max	0.0, 66.7	0.0, 83.3		-100.0, 33.3	-50.0, 83.3	
95% CI for Mean	(7.81, 22.19)	(1.47, 13.68)	(-1.77, 16.61)	(-15.90, 5.56)	(-6.17, 10.21)	(-20.23, 5.85)
P-value			0.1114			0.2743
Hedges's g			0.40 (-0.10, 0.90)			-0.28 (-0.78, 0.22)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.10B
Summary of EORTC-QLQ-C30 Nausea and Vomiting Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
End of Treatment						
n	138	109		136	108	
Mean (std dev)	4.71 (12.247)	3.21 (7.684)	1.50	-5.51 (24.767)	-2.31 (15.021)	-3.20
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 33.3		-100.0, 100.0	-50.0, 33.3	
95% CI for Mean	(2.65, 6.77)	(1.75, 4.67)	(-1.15, 4.15)	(-9.71, -1.31)	(-5.18, 0.55)	(-8.54, 2.14)
P-value			0.2655			0.2388
Hedges's g			0.14 (-0.11, 0.39)			-0.15 (-0.40, 0.10)
Long-Term Follow-Up 9 Month						
n	108	88		105	87	
Mean (std dev)	2.31 (8.664)	1.89 (8.162)	0.42	-6.51 (22.586)	-3.45 (15.696)	-3.06
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 66.7	0.0, 50.0		-100.0, 66.7	-50.0, 50.0	
95% CI for Mean	(0.66, 3.97)	(0.16, 3.62)	(-1.97, 2.81)	(-10.88, -2.14)	(-6.79, -0.10)	(-8.71, 2.59)
P-value			0.7289			0.2870
Hedges's g			0.05 (-0.23, 0.33)			-0.15 (-0.44, 0.13)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were
obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.10B
Summary of EORTC-QLQ-C30 Nausea and Vomiting Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 12 Month						
n	111	81		108	80	
Mean (std dev)	2.55 (7.520)	2.26 (6.321)	0.29	-7.10 (21.278)	-3.54 (15.393)	-3.56
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 33.3	0.0, 33.3		-100.0, 33.3	-50.0, 33.3	
95% CI for Mean	(1.14, 3.97)	(0.87, 3.66)	(-1.74, 2.32)	(-11.16, -3.04)	(-6.97, -0.12)	(-9.09, 1.97)
P-value			0.7790			0.2060
Hedges's g			0.04 (-0.25, 0.33)			-0.19 (-0.48, 0.10)
Long-Term Follow-Up 15 Month						
n	102	83		100	82	
Mean (std dev)	1.31 (4.503)	1.00 (3.990)	0.30	-8.83 (20.848)	-4.67 (14.410)	-4.16
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 16.7	0.0, 16.7		-100.0, 16.7	-66.7, 16.7	
95% CI for Mean	(0.42, 2.19)	(0.13, 1.88)	(-0.95, 1.55)	(-12.97, -4.70)	(-7.84, -1.51)	(-9.52, 1.20)
P-value			0.6324			0.1276
Hedges's g			0.07 (-0.22, 0.36)			-0.23 (-0.52, 0.07)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Protocol No.: SGN35-014 -- Data cut: 15AUG2018 (Data snapshot: 20SEP2018)

Table 35.1.2.7.10B
Summary of EORTC-QLQ-C30 Nausea and Vomiting Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 18 Month						
n	99	83		97	82	
Mean (std dev)	2.53 (8.704)	1.20 (5.063)	1.32	-8.08 (22.709)	-4.07 (14.944)	-4.01
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 66.7	0.0, 33.3		-100.0, 66.7	-66.7, 33.3	
95% CI for Mean	(0.79, 4.26)	(0.10, 2.31)	(-0.82, 3.46)	(-12.65, -3.50)	(-7.35, -0.78)	(-9.80, 1.77)
P-value			0.2242			0.1730
Hedges's g			0.18 (-0.11, 0.47)			-0.20 (-0.50, 0.09)
Long-Term Follow-Up 21 Month						
n	88	76		85	75	
Mean (std dev)	3.79 (10.335)	1.97 (7.682)	1.81	-7.45 (21.286)	-3.78 (16.342)	-3.67
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 50.0	0.0, 50.0		-100.0, 50.0	-66.7, 50.0	
95% CI for Mean	(1.60, 5.98)	(0.22, 3.73)	(-1.03, 4.66)	(-12.04, -2.86)	(-7.54, -0.02)	(-9.66, 2.31)
P-value			0.2099			0.2273
Hedges's g			0.20 (-0.11, 0.50)			-0.19 (-0.50, 0.12)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.10B
Summary of EORTC-QLQ-C30 Nausea and Vomiting Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 24 Month						
n	88	71		85	70	
Mean (std dev)	1.70 (6.210)	0.23 (1.978)	1.47	-8.43 (20.833)	-5.95 (15.024)	-2.48
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 33.3	0.0, 16.7		-100.0, 33.3	-66.7, 16.7	
95% CI for Mean	(0.39, 3.02)	(-0.23, 0.70)	(-0.05, 2.98)	(-12.92, -3.94)	(-9.53, -2.37)	(-8.36, 3.40)
P-value			0.0571			0.4062
Hedges's g			0.30 (-0.01, 0.62)			-0.13 (-0.45, 0.18)
Overall (EOT)						
n				153	146	
Mean (std dev)				-0.2 (8.88)	-3.0 (8.96)	2.77
95% CI for Mean						(0.74, 4.79)
P-value						0.0076
Hedges's g						0.31 (0.08, 0.54)
Overall (70% compliance)						
n				153	146	
Mean (std dev)				-2.5 (6.38)	-4.6 (6.58)	2.05
95% CI for Mean						(0.57, 3.52)
P-value						0.0065
Hedges's g						0.31 (0.09, 0.54)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.10B
Summary of EORTC-QLQ-C30 Nausea and Vomiting Over Time
ITT Analysis Set   - Subset of Patients with sALCL

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.

Note: Hedges's g measures the effect size of the difference between means using results from mixed model.

Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.

Data snapshot: 20SEP2018.

Table 35.1.2.7.11B
Summary of EORTC-QLQ-C30 Dyspnoea Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Baseline						
n	155	151				
Mean (std dev)	19.14 (27.641)	18.32 (26.300)	0.82			
Median	0.00	0.00				
Min, Max	0.0, 100.0	0.0, 100.0				
95% CI for Mean	(14.75, 23.53)	(14.09, 22.55)	(-5.25, 6.89)			
P-value			0.7913			
Hedges's g			0.03 (-0.19, 0.25)			
Cycle 2 Day 1						
n	154	142		149	141	
Mean (std dev)	13.20 (21.019)	11.74 (20.704)	1.47	-5.15 (29.440)	-6.15 (27.488)	1.00
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 66.7	-100.0, 66.7	
95% CI for Mean	(9.86, 16.55)	(8.30, 15.17)	(-3.31, 6.24)	(-9.91, -0.38)	(-10.72, -1.57)	(-5.59, 7.59)
P-value			0.5463			0.7652
Hedges's g			0.07 (-0.16, 0.30)			0.04 (-0.20, 0.27)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.

Note: Hedges's g measures the effect size of the difference between means using results from mixed model.

Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.

Data snapshot: 20SEP2018.

Table 35.1.2.7.11B
Summary of EORTC-QLQ-C30 Dyspnoea Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 3 Day 1						
n	154	136		149	136	
Mean (std dev)	13.64 (23.373)	12.25 (21.007)	1.38	-5.59 (29.358)	-4.90 (27.376)	-0.69
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 66.7	-100.0, 66.7	
95% CI for Mean	(9.92, 17.36)	(8.69, 15.82)	(-3.78, 6.55)	(-10.35, -0.84)	(-9.54, -0.26)	(-7.33, 5.95)
P-value			0.5989			0.8378
Hedges's g			0.06 (-0.17, 0.29)			-0.02 (-0.26, 0.21)
Cycle 4 Day 1						
n	150	132		145	131	
Mean (std dev)	16.00 (22.756)	12.88 (18.715)	3.12	-2.99 (30.408)	-3.31 (28.899)	0.32
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 66.7		-100.0, 100.0	-100.0, 66.7	
95% CI for Mean	(12.33, 19.67)	(9.66, 16.10)	(-1.80, 8.05)	(-7.98, 2.00)	(-8.30, 1.69)	(-6.73, 7.37)
P-value			0.2132			0.9290
Hedges's g			0.15 (-0.09, 0.38)			0.01 (-0.23, 0.25)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.

Note: Hedges's g measures the effect size of the difference between means using results from mixed model.

Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.

Data snapshot: 20SEP2018.

Table 35.1.2.7.11B
Summary of EORTC-QLQ-C30 Dyspnoea Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 5 Day 1						
n	143	123		138	122	
Mean (std dev)	15.85 (24.332)	12.47 (19.743)	3.38	-3.62 (31.115)	-2.73 (27.968)	-0.89
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 100.0	-100.0, 66.7	
95% CI for Mean	(11.83, 19.87)	(8.94, 15.99)	(-2.02, 8.79)	(-8.86, 1.61)	(-7.75, 2.28)	(-8.15, 6.37)
P-value			0.2188			0.8093
Hedges's g			0.15 (-0.09, 0.39)			-0.03 (-0.27, 0.21)
Cycle 6 Day 1						
n	145	116		140	115	
Mean (std dev)	17.70 (23.588)	12.07 (21.263)	5.63	-0.95 (30.436)	-4.06 (29.666)	3.11
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 66.7	-100.0, 66.7	
95% CI for Mean	(13.83, 21.57)	(8.16, 15.98)	(0.09, 11.17)	(-6.04, 4.13)	(-9.54, 1.42)	(-4.35, 10.56)
P-value			0.0463			0.4130
Hedges's g			0.25 (0.00, 0.49)			0.10 (-0.14, 0.35)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.11B
Summary of EORTC-QLQ-C30 Dyspnoea Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 7 Day 1						
n	35	33		34	33	
Mean (std dev)	19.05 (21.822)	15.15 (20.566)	3.90	-4.90 (32.960)	-1.01 (24.274)	-3.89
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 66.7	0.0, 66.7		-66.7, 66.7	-33.3, 66.7	
95% CI for Mean	(11.55, 26.54)	(7.86, 22.44)	(-6.39, 14.18)	(-16.40, 6.60)	(-9.62, 7.60)	(-18.05, 10.27)
P-value			0.4520			0.5849
Hedges's g			0.18 (-0.30, 0.66)			-0.13 (-0.61, 0.35)
Cycle 8 Day 1						
n	30	33		29	33	
Mean (std dev)	17.78 (19.045)	17.17 (22.238)	0.61	-5.75 (32.206)	1.01 (25.665)	-6.76
Median	16.67	0.00		0.00	0.00	
Min, Max	0.0, 66.7	0.0, 66.7		-66.7, 66.7	-33.3, 66.7	
95% CI for Mean	(10.67, 24.89)	(9.29, 25.06)	(-9.88, 11.09)	(-18.00, 6.50)	(-8.09, 10.11)	(-21.47, 7.96)
P-value			0.9083			0.3620
Hedges's g			0.03 (-0.47, 0.52)			-0.23 (-0.73, 0.27)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.11B
Summary of EORTC-QLQ-C30 Dyspnoea Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
End of Treatment						
n	138	109		136	108	
Mean (std dev)	13.53 (22.293)	13.46 (21.334)	0.07	-6.13 (31.999)	-0.93 (28.262)	-5.20
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 66.7	-100.0, 100.0	
95% CI for Mean	(9.77, 17.28)	(9.41, 17.51)	(-5.45, 5.59)	(-11.55, -0.70)	(-6.32, 4.47)	(-12.92, 2.52)
P-value			0.9798			0.1856
Hedges's g			0.00 (-0.25, 0.25)			-0.17 (-0.42, 0.08)
Long-Term Follow-Up 9 Month						
n	108	88		105	87	
Mean (std dev)	8.33 (18.859)	8.71 (17.135)	-0.38	-12.38 (33.094)	-5.36 (24.837)	-7.02
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 66.7		-100.0, 100.0	-100.0, 66.7	
95% CI for Mean	(4.74, 11.93)	(5.08, 12.34)	(-5.51, 4.75)	(-18.79, -5.98)	(-10.66, -0.07)	(-15.49, 1.46)
P-value			0.8843			0.1042
Hedges's g			-0.02 (-0.30, 0.26)			-0.24 (-0.52, 0.05)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.11B
Summary of EORTC-QLQ-C30 Dyspnoea Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 12 Month						
n	111	81		108	80	
Mean (std dev)	7.51 (18.359)	7.00 (17.253)	0.51	-9.88 (30.659)	-6.25 (27.607)	-3.63
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 100.0	-100.0, 66.7	
95% CI for Mean	(4.05, 10.96)	(3.18, 10.81)	(-4.65, 5.67)	(-15.72, -4.03)	(-12.39, -0.11)	(-12.18, 4.93)
P-value			0.8452			0.4041
Hedges's g			0.03 (-0.26, 0.31)			-0.12 (-0.41, 0.17)
Long-Term Follow-Up 15 Month						
n	102	83		100	82	
Mean (std dev)	8.17 (19.017)	8.03 (16.121)	0.14	-9.00 (31.375)	-5.69 (25.555)	-3.31
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 66.7		-100.0, 100.0	-100.0, 66.7	
95% CI for Mean	(4.43, 11.91)	(4.51, 11.55)	(-5.05, 5.32)	(-15.23, -2.77)	(-11.31, -0.08)	(-11.81, 5.19)
P-value			0.9582			0.4432
Hedges's g			0.01 (-0.28, 0.30)			-0.11 (-0.41, 0.18)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.11B
Summary of EORTC-QLQ-C30 Dyspnoea Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 18 Month						
n	99	83		97	82	
Mean (std dev)	6.40 (16.272)	8.43 (18.656)	-2.04	-11.68 (30.062)	-5.28 (26.948)	-6.40
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 66.7	0.0, 100.0		-100.0, 66.7	-66.7, 66.7	
95% CI for Mean	(3.15, 9.64)	(4.36, 12.51)	(-7.15, 3.07)	(-17.74, -5.62)	(-11.21, 0.64)	(-14.89, 2.09)
P-value			0.4326			0.1387
Hedges's g			-0.12 (-0.41, 0.18)			-0.22 (-0.52, 0.07)
Long-Term Follow-Up 21 Month						
n	88	76		85	75	
Mean (std dev)	9.09 (20.043)	10.53 (19.021)	-1.44	-7.84 (29.388)	-2.67 (23.094)	-5.18
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 66.7		-100.0, 100.0	-66.7, 66.7	
95% CI for Mean	(4.84, 13.34)	(6.18, 14.87)	(-7.49, 4.62)	(-14.18, -1.50)	(-7.98, 2.65)	(-13.51, 3.15)
P-value			0.6402			0.2216
Hedges's g			-0.07 (-0.38, 0.23)			-0.19 (-0.50, 0.12)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.11B
Summary of EORTC-QLQ-C30 Dyspnoea Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 24 Month						
n	88	71		85	70	
Mean (std dev)	6.82 (15.295)	9.86 (18.165)	-3.04	-13.33 (33.014)	-5.24 (28.734)	-8.10
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 66.7	0.0, 66.7		-100.0, 66.7	-100.0, 66.7	
95% CI for Mean	(3.58, 10.06)	(5.56, 14.16)	(-8.28, 2.20)	(-20.45, -6.21)	(-12.09, 1.61)	(-18.03, 1.84)
P-value			0.2536			0.1095
Hedges's g			-0.18 (-0.50, 0.13)			-0.26 (-0.58, 0.06)
Overall (EOT)						
n				151	146	
Mean (std dev)				-3.0 (16.73)	-4.1 (16.91)	1.11
95% CI for Mean						(-2.72, 4.94)
P-value						0.5702
Hedges's g						0.07 (-0.16, 0.29)
Overall (70% compliance)						
n				151	146	
Mean (std dev)				-5.0 (14.30)	-5.8 (14.67)	0.85
95% CI for Mean						(-2.45, 4.15)
P-value						0.6141
Hedges's g						0.06 (-0.17, 0.29)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.11B
Summary of EORTC-QLQ-C30 Dyspnoea Over Time
ITT Analysis Set   - Subset of Patients with sALCL

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.

Note: Hedges's g measures the effect size of the difference between means using results from mixed model.

Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.

Data snapshot: 20SEP2018.

Table 35.1.2.7.12B
Summary of EORTC-QLQ-C30 Insomnia Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Baseline						
n	156	151				
Mean (std dev)	42.52 (34.615)	39.07 (33.280)	3.45			
Median	33.33	33.33				
Min, Max	0.0, 100.0	0.0, 100.0				
95% CI for Mean	(37.05, 48.00)	(33.72, 44.42)	(-4.18, 11.08)			
P-value			0.3745			
Hedges's g			0.10 (-0.12, 0.33)			
Cycle 2 Day 1						
n	154	141		150	140	
Mean (std dev)	28.79 (28.537)	27.19 (30.499)	1.60	-13.78 (36.266)	-11.43 (35.712)	-2.35
Median	33.33	33.33		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 100.0	-100.0, 100.0	
95% CI for Mean	(24.24, 33.33)	(22.11, 32.26)	(-5.16, 8.37)	(-19.63, -7.93)	(-17.40, -5.46)	(-10.68, 5.98)
P-value			0.6417			0.5791
Hedges's g			0.05 (-0.17, 0.28)			-0.07 (-0.30, 0.17)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.12B
Summary of EORTC-QLQ-C30 Insomnia Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 3 Day 1						
n	154	136		150	136	
Mean (std dev)	22.29 (27.231)	22.06 (30.149)	0.24	-20.67 (33.594)	-15.20 (37.596)	-5.47
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 66.7	-100.0, 100.0	
95% CI for Mean	(17.96, 26.63)	(16.95, 27.17)	(-6.40, 6.87)	(-26.09, -15.25)	(-21.57, -8.82)	(-13.76, 2.82)
P-value			0.9443			0.1948
Hedges's g			0.01 (-0.22, 0.24)			-0.15 (-0.39, 0.08)
Cycle 4 Day 1						
n	149	131		145	130	
Mean (std dev)	24.61 (28.840)	21.37 (26.496)	3.23	-18.39 (37.046)	-14.87 (35.719)	-3.52
Median	33.33	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 66.7	-100.0, 100.0	
95% CI for Mean	(19.94, 29.28)	(16.79, 25.95)	(-3.31, 9.78)	(-24.47, -12.31)	(-21.07, -8.67)	(-12.18, 5.14)
P-value			0.3316			0.4245
Hedges's g			0.12 (-0.12, 0.35)			-0.10 (-0.33, 0.14)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.12B
Summary of EORTC-QLQ-C30 Insomnia Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 5 Day 1						
n	144	123		140	122	
Mean (std dev)	24.77 (29.696)	20.05 (28.226)	4.71	-18.57 (38.199)	-14.75 (34.297)	-3.82
Median	0.00	0.00		-33.33	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 100.0	-100.0, 100.0	
95% CI for Mean	(19.88, 29.66)	(15.02, 25.09)	(-2.30, 11.73)	(-24.95, -12.19)	(-20.90, -8.61)	(-12.70, 5.07)
P-value			0.1871			0.3984
Hedges's g			0.16 (-0.08, 0.40)			-0.10 (-0.35, 0.14)
Cycle 6 Day 1						
n	145	116		141	115	
Mean (std dev)	25.06 (29.536)	19.54 (26.764)	5.52	-17.26 (38.339)	-15.07 (37.527)	-2.19
Median	33.33	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 100.0	-100.0, 100.0	
95% CI for Mean	(20.21, 29.91)	(14.62, 24.46)	(-1.43, 12.47)	(-23.64, -10.87)	(-22.00, -8.14)	(-11.58, 7.21)
P-value			0.1193			0.6474
Hedges's g			0.19 (-0.05, 0.44)			-0.06 (-0.30, 0.19)

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Note: Hedges's g measures the effect size of the difference between means using results from mixed model.

Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.

Data snapshot: 20SEP2018.

Table 35.1.2.7.12B
Summary of EORTC-QLQ-C30 Insomnia Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 7 Day 1						
n	35	33		34	33	
Mean (std dev)	20.00 (24.522)	15.15 (20.566)	4.85	-28.43 (35.894)	-21.21 (34.175)	-7.22
Median	0.00	0.00		-33.33	-33.33	
Min, Max	0.0, 100.0	0.0, 66.7		-100.0, 33.3	-100.0, 33.3	
95% CI for Mean	(11.58, 28.42)	(7.86, 22.44)	(-6.14, 15.84)	(-40.96, -15.91)	(-33.33, -9.09)	(-24.33, 9.89)
P-value			0.3817			0.4025
Hedges's g			0.21 (-0.27, 0.69)			-0.20 (-0.68, 0.28)
Cycle 8 Day 1						
n	30	33		29	33	
Mean (std dev)	21.11 (26.957)	22.22 (28.464)	-1.11	-32.18 (39.322)	-14.14 (39.992)	-18.04
Median	0.00	0.00		-33.33	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 33.3	-100.0, 100.0	
95% CI for Mean	(11.05, 31.18)	(12.13, 32.32)	(-15.11, 12.89)	(-47.14, -17.23)	(-28.32, 0.04)	(-38.25, 2.16)
P-value			0.8744			0.0791
Hedges's g			-0.04 (-0.53, 0.45)			-0.45 (-0.95, 0.06)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.12B
Summary of EORTC-QLQ-C30 Insomnia Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
End of Treatment						
n	138	109		136	108	
Mean (std dev)	18.36 (24.851)	15.90 (26.292)	2.46	-25.00 (36.907)	-18.21 (38.504)	-6.79
Median	0.00	0.00		-33.33	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 66.7	-100.0, 100.0	
95% CI for Mean	(14.17, 22.54)	(10.91, 20.89)	(-3.98, 8.89)	(-31.26, -18.74)	(-25.55, -10.87)	(-16.34, 2.76)
P-value			0.4531			0.1627
Hedges's g			0.10 (-0.16, 0.35)			-0.18 (-0.43, 0.07)
Long-Term Follow-Up 9 Month						
n	108	88		105	87	
Mean (std dev)	17.90 (26.348)	13.64 (21.818)	4.26	-26.03 (38.669)	-22.61 (36.121)	-3.43
Median	0.00	0.00		-33.33	-33.33	
Min, Max	0.0, 100.0	0.0, 66.7		-100.0, 100.0	-100.0, 66.7	
95% CI for Mean	(12.88, 22.93)	(9.01, 18.26)	(-2.65, 11.18)	(-33.52, -18.55)	(-30.30, -14.91)	(-14.16, 7.31)
P-value			0.2254			0.5297
Hedges's g			0.17 (-0.11, 0.46)			-0.09 (-0.38, 0.19)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.12B
Summary of EORTC-QLQ-C30 Insomnia Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 12 Month						
n	111	81		108	80	
Mean (std dev)	18.02 (26.887)	15.64 (23.026)	2.38	-25.31 (36.705)	-22.08 (36.724)	-3.23
Median	0.00	0.00		-33.33	-33.33	
Min, Max	0.0, 100.0	0.0, 66.7		-100.0, 66.7	-100.0, 66.7	
95% CI for Mean	(12.96, 23.08)	(10.55, 20.73)	(-4.92, 9.68)	(-32.31, -18.31)	(-30.26, -13.91)	(-13.91, 7.46)
P-value			0.5210			0.5522
Hedges's g			0.09 (-0.19, 0.38)			-0.09 (-0.38, 0.20)
Long-Term Follow-Up 15 Month						
n	102	83		100	82	
Mean (std dev)	18.95 (25.481)	11.65 (19.080)	7.31	-25.00 (37.418)	-26.42 (37.309)	1.42
Median	0.00	0.00		-33.33	-33.33	
Min, Max	0.0, 100.0	0.0, 66.7		-100.0, 66.7	-100.0, 33.3	
95% CI for Mean	(13.95, 23.96)	(7.48, 15.81)	(0.65, 13.97)	(-32.42, -17.58)	(-34.62, -18.23)	(-9.56, 12.41)
P-value			0.0317			0.7986
Hedges's g			0.32 (0.03, 0.61)			0.04 (-0.25, 0.33)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.12B
Summary of EORTC-QLQ-C30 Insomnia Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 18 Month						
n	99	83		97	82	
Mean (std dev)	15.82 (24.441)	10.04 (17.056)	5.78	-28.52 (38.185)	-26.83 (33.308)	-1.69
Median	0.00	0.00		-33.33	-33.33	
Min, Max	0.0, 100.0	0.0, 66.7		-100.0, 66.7	-100.0, 33.3	
95% CI for Mean	(10.95, 20.70)	(6.32, 13.76)	(-0.50, 12.07)	(-36.22, -20.83)	(-34.15, -19.51)	(-12.36, 8.98)
P-value			0.0709			0.7545
Hedges's g			0.27 (-0.02, 0.56)			-0.05 (-0.34, 0.25)
Long-Term Follow-Up 21 Month						
n	88	76		85	75	
Mean (std dev)	14.39 (24.130)	16.67 (25.240)	-2.27	-30.98 (34.036)	-22.67 (37.232)	-8.31
Median	0.00	0.00		-33.33	-33.33	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 33.3	-100.0, 100.0	
95% CI for Mean	(9.28, 19.51)	(10.90, 22.43)	(-9.90, 5.35)	(-38.32, -23.64)	(-31.23, -14.10)	(-19.44, 2.82)
P-value			0.5568			0.1421
Hedges's g			-0.09 (-0.40, 0.22)			-0.23 (-0.54, 0.08)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.12B
Summary of EORTC-QLQ-C30 Insomnia Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 24 Month						
n	88	71		85	70	
Mean (std dev)	13.26 (23.456)	11.74 (21.893)	1.52	-30.59 (35.341)	-29.52 (36.578)	-1.06
Median	0.00	0.00		-33.33	-33.33	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 66.7	-100.0, 66.7	
95% CI for Mean	(8.29, 18.23)	(6.56, 16.92)	(-5.65, 8.70)	(-38.21, -22.97)	(-38.25, -20.80)	(-12.51, 10.38)
P-value			0.6761			0.8545
Hedges's g			0.07 (-0.25, 0.38)			-0.03 (-0.35, 0.29)
Overall (EOT)						
n				152	146	
Mean (std dev)				-17.4 (21.83)	-16.6 (22.04)	0.84
95% CI for Mean						(-5.83, 4.16)
P-value						0.7425
Hedges's g						-0.04 (-0.27, 0.19)
Overall (70% compliance)						
n				152	146	
Mean (std dev)				-20.3 (18.95)	-20.8 (19.42)	0.59
95% CI for Mean						(-3.78, 4.95)
P-value						0.7921
Hedges's g						0.03 (-0.20, 0.26)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.12B
Summary of EORTC-QLQ-C30 Insomnia Over Time
ITT Analysis Set   - Subset of Patients with sALCL

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.

Note: Hedges's g measures the effect size of the difference between means using results from mixed model.

Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.

Data snapshot: 20SEP2018.

Protocol No.: SGN35-014 -- Data cut: 15AUG2018 (Data snapshot: 20SEP2018)

Table 35.1.2.7.13B
Summary of EORTC-QLQ-C30 Appetite Loss Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Baseline						
n	156	151				
Mean (std dev)	28.21 (32.385)	24.72 (31.379)	3.48			
Median	33.33	0.00				
Min, Max	0.0, 100.0	0.0, 100.0				
95% CI for Mean	(23.08, 33.33)	(19.68, 29.77)	(-3.68, 10.65)			
P-value			0.3398			
Hedges's g			0.11 (-0.12, 0.33)			
Cycle 2 Day 1						
n	155	141		151	140	
Mean (std dev)	17.20 (26.956)	16.78 (26.011)	0.42	-9.93 (33.288)	-7.14 (32.920)	-2.79
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 100.0	-100.0, 100.0	
95% CI for Mean	(12.93, 21.48)	(12.45, 21.12)	(-5.65, 6.49)	(-15.29, -4.58)	(-12.64, -1.64)	(-10.44, 4.86)
P-value			0.8920			0.4731
Hedges's g			0.02 (-0.21, 0.24)			-0.08 (-0.31, 0.15)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.13B
Summary of EORTC-QLQ-C30 Appetite Loss Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 3 Day 1						
n	154	137		150	137	
Mean (std dev)	13.42 (23.031)	10.71 (21.365)	2.71	-14.22 (35.468)	-11.44 (34.876)	-2.79
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 66.7	-100.0, 100.0	
95% CI for Mean	(9.75, 17.09)	(7.10, 14.32)	(-2.43, 7.86)	(-19.94, -8.50)	(-17.33, -5.54)	(-10.97, 5.40)
P-value			0.3001			0.5033
Hedges's g			0.12 (-0.11, 0.35)			-0.08 (-0.31, 0.15)
Cycle 4 Day 1						
n	150	132		146	131	
Mean (std dev)	16.00 (24.031)	10.10 (20.568)	5.90	-12.10 (35.207)	-12.21 (36.092)	0.11
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 66.7	-100.0, 100.0	
95% CI for Mean	(12.12, 19.88)	(6.56, 13.64)	(0.62, 11.18)	(-17.86, -6.34)	(-18.45, -5.98)	(-8.33, 8.55)
P-value			0.0287			0.9789
Hedges's g			0.26 (0.03, 0.50)			0.00 (-0.23, 0.24)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.13B
Summary of EORTC-QLQ-C30 Appetite Loss Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 5 Day 1						
n	144	123		140	122	
Mean (std dev)	17.59 (26.428)	10.30 (20.077)	7.29	-10.48 (37.313)	-11.48 (34.222)	1.00
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 100.0	-100.0, 100.0	
95% CI for Mean	(13.24, 21.95)	(6.71, 13.88)	(1.56, 13.03)	(-16.71, -4.24)	(-17.61, -5.34)	(-7.76, 9.76)
P-value			0.0128			0.8224
Hedges's g			0.31 (0.06, 0.55)			0.03 (-0.22, 0.27)
Cycle 6 Day 1						
n	145	115		141	114	
Mean (std dev)	17.47 (26.955)	10.14 (20.790)	7.33	-10.87 (36.187)	-12.28 (36.099)	1.41
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 66.7	-100.0, 100.0	
95% CI for Mean	(13.05, 21.90)	(6.30, 13.99)	(1.32, 13.33)	(-16.90, -4.85)	(-18.98, -5.58)	(-7.56, 10.37)
P-value			0.0170			0.7577
Hedges's g			0.30 (0.05, 0.55)			0.04 (-0.21, 0.29)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.13B
Summary of EORTC-QLQ-C30 Appetite Loss Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 7 Day 1						
n	35	33		34	33	
Mean (std dev)	19.05 (28.337)	13.13 (27.562)	5.92	-19.61 (39.456)	-1.01 (37.717)	-18.60
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 66.7	-100.0, 100.0	
95% CI for Mean	(9.31, 28.78)	(3.36, 22.90)	(-7.63, 19.46)	(-33.37, -5.84)	(-14.38, 12.36)	(-37.44, 0.24)
P-value			0.3864			0.0530
Hedges's g			0.21 (-0.27, 0.69)			-0.48 (-0.96, 0.01)
Cycle 8 Day 1						
n	30	33		29	33	
Mean (std dev)	21.11 (28.343)	17.17 (27.790)	3.94	-19.54 (35.093)	3.03 (39.409)	-22.57
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 33.3	-100.0, 100.0	
95% CI for Mean	(10.53, 31.69)	(7.32, 27.03)	(-10.21, 18.09)	(-32.89, -6.19)	(-10.94, 17.00)	(-41.64, -3.50)
P-value			0.5798			0.0212
Hedges's g			0.14 (-0.36, 0.63)			-0.60 (-1.10, -0.09)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.13B
Summary of EORTC-QLQ-C30 Appetite Loss Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
End of Treatment						
n	138	109		136	108	
Mean (std dev)	11.84 (21.986)	9.79 (19.406)	2.05	-15.20 (32.928)	-10.80 (34.355)	-4.39
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 66.7		-100.0, 66.7	-100.0, 66.7	
95% CI for Mean	(8.13, 15.54)	(6.10, 13.47)	(-3.22, 7.32)	(-20.78, -9.61)	(-17.36, -4.25)	(-12.92, 4.13)
P-value			0.4445			0.3109
Hedges's g			0.10 (-0.15, 0.35)			-0.13 (-0.38, 0.12)
Long-Term Follow-Up 9 Month						
n	108	88		105	87	
Mean (std dev)	8.64 (19.533)	8.33 (19.078)	0.31	-16.19 (31.390)	-12.26 (36.343)	-3.93
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 66.7	-100.0, 100.0	
95% CI for Mean	(4.92, 12.37)	(4.29, 12.38)	(-5.17, 5.78)	(-22.27, -10.12)	(-20.01, -4.51)	(-13.57, 5.71)
P-value			0.9116			0.4225
Hedges's g			0.02 (-0.27, 0.30)			-0.12 (-0.40, 0.17)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.

Note: Hedges's g measures the effect size of the difference between means using results from mixed model.

Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.

Data snapshot: 20SEP2018.

Table 35.1.2.7.13B
Summary of EORTC-QLQ-C30 Appetite Loss Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 12 Month						
n	111	81		108	80	
Mean (std dev)	7.51 (17.224)	9.47 (21.880)	-1.96	-19.14 (32.610)	-11.67 (35.221)	-7.47
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 66.7	0.0, 100.0		-100.0, 66.7	-100.0, 100.0	
95% CI for Mean	(4.27, 10.75)	(4.63, 14.30)	(-7.53, 3.61)	(-25.36, -12.92)	(-19.50, -3.83)	(-17.29, 2.35)
P-value			0.4890			0.1352
Hedges's g			-0.10 (-0.39, 0.19)			-0.22 (-0.51, 0.07)
Long-Term Follow-Up 15 Month						
n	102	83		100	82	
Mean (std dev)	4.90 (12.757)	6.43 (16.010)	-1.52	-20.33 (32.097)	-15.45 (34.425)	-4.89
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 66.7	0.0, 66.7		-100.0, 66.7	-100.0, 66.7	
95% CI for Mean	(2.40, 7.41)	(2.93, 9.92)	(-5.70, 2.65)	(-26.70, -13.96)	(-23.01, -7.88)	(-14.64, 4.86)
P-value			0.4721			0.3240
Hedges's g			-0.11 (-0.40, 0.18)			-0.15 (-0.44, 0.15)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.13B
Summary of EORTC-QLQ-C30 Appetite Loss Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 18 Month						
n	99	83		97	82	
Mean (std dev)	6.73 (14.270)	4.82 (16.571)	1.91	-21.31 (34.422)	-17.07 (34.043)	-4.23
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 66.7	0.0, 100.0		-100.0, 33.3	-100.0, 100.0	
95% CI for Mean	(3.89, 9.58)	(1.20, 8.44)	(-2.60, 6.43)	(-28.24, -14.37)	(-24.55, -9.59)	(-14.37, 5.91)
P-value			0.4034			0.4112
Hedges's g			0.12 (-0.17, 0.42)			-0.12 (-0.42, 0.17)
Long-Term Follow-Up 21 Month						
n	88	76		85	75	
Mean (std dev)	8.71 (19.241)	4.82 (14.094)	3.89	-16.08 (28.458)	-17.78 (31.160)	1.70
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 66.7		-100.0, 66.7	-100.0, 33.3	
95% CI for Mean	(4.64, 12.79)	(1.60, 8.05)	(-1.39, 9.16)	(-22.22, -9.94)	(-24.95, -10.61)	(-7.61, 11.01)
P-value			0.1474			0.7189
Hedges's g			0.23 (-0.08, 0.53)			0.06 (-0.25, 0.37)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.13B
Summary of EORTC-QLQ-C30 Appetite Loss Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 24 Month						
n	88	71		85	70	
Mean (std dev)	6.82 (17.623)	3.76 (12.018)	3.06	-20.78 (31.697)	-20.00 (32.798)	-0.78
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 66.7		-100.0, 33.3	-100.0, 33.3	
95% CI for Mean	(3.08, 10.55)	(0.91, 6.60)	(-1.78, 7.91)	(-27.62, -13.95)	(-27.82, -12.18)	(-11.05, 9.48)
P-value			0.2138			0.8802
Hedges's g			0.20 (-0.12, 0.51)			-0.02 (-0.34, 0.29)
Overall (EOT)						
n				153	146	
Mean (std dev)				-9.0 (19.06)	-12.0 (19.23)	3.03
95% CI for Mean						(-1.33, 7.38)
P-value						0.1729
Hedges's g						0.16 (-0.07, 0.38)
Overall (70% compliance)						
n				153	146	
Mean (std dev)				-11.9 (16.06)	-14.8 (16.40)	2.87
95% CI for Mean						(-0.82, 6.56)
P-value						0.1278
Hedges's g						0.18 (-0.05, 0.40)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.13B
Summary of EORTC-QLQ-C30 Appetite Loss Over Time
ITT Analysis Set   - Subset of Patients with sALCL

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.14B
Summary of EORTC-QLQ-C30 Constipation Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Baseline						
n	156	149				
Mean (std dev)	22.22 (31.755)	19.46 (27.427)	2.76			
Median	0.00	0.00				
Min, Max	0.0, 100.0	0.0, 100.0				
95% CI for Mean	(17.20, 27.24)	(15.02, 23.90)	(-3.94, 9.46)			
P-value			0.4183			
Hedges's g			0.09 (-0.13, 0.32)			
Cycle 2 Day 1						
n	154	142		150	139	
Mean (std dev)	15.80 (26.458)	16.67 (25.957)	-0.87	-5.56 (33.538)	-2.16 (34.335)	-3.40
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 100.0	-100.0, 100.0	
95% CI for Mean	(11.59, 20.01)	(12.36, 20.97)	(-6.87, 5.14)	(-10.97, -0.14)	(-7.92, 3.60)	(-11.26, 4.46)
P-value			0.7767			0.3957
Hedges's g			-0.03 (-0.26, 0.20)			-0.10 (-0.33, 0.13)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.

Note: Hedges's g measures the effect size of the difference between means using results from mixed model.

Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.

Data snapshot: 20SEP2018.

Table 35.1.2.7.14B
Summary of EORTC-QLQ-C30 Constipation Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 3 Day 1						
n	153	136		149	134	
Mean (std dev)	13.51 (24.613)	13.48 (21.613)	0.03	-8.95 (33.699)	-4.48 (33.655)	-4.47
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 100.0	-100.0, 100.0	
95% CI for Mean	(9.58, 17.44)	(9.82, 17.15)	(-5.37, 5.42)	(-14.40, -3.49)	(-10.23, 1.27)	(-12.36, 3.42)
P-value			0.9921			0.2658
Hedges's g			0.00 (-0.23, 0.23)			-0.13 (-0.37, 0.10)
Cycle 4 Day 1						
n	150	132		146	130	
Mean (std dev)	13.78 (22.908)	12.12 (22.661)	1.66	-8.22 (30.716)	-5.13 (32.539)	-3.09
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 33.3	-100.0, 100.0	
95% CI for Mean	(10.08, 17.47)	(8.22, 16.02)	(-3.70, 7.01)	(-13.24, -3.19)	(-10.77, 0.52)	(-10.59, 4.41)
P-value			0.5430			0.4178
Hedges's g			0.07 (-0.16, 0.31)			-0.10 (-0.33, 0.14)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.14B
Summary of EORTC-QLQ-C30 Constipation Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 5 Day 1						
n	144	122		140	120	
Mean (std dev)	12.50 (21.183)	12.02 (19.669)	0.48	-9.29 (32.253)	-5.28 (31.459)	-4.01
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 100.0	-100.0, 100.0	
95% CI for Mean	(9.01, 15.99)	(8.50, 15.55)	(-4.49, 5.45)	(-14.68, -3.90)	(-10.96, 0.41)	(-11.82, 3.80)
P-value			0.8498			0.3133
Hedges's g			0.02 (-0.22, 0.26)			-0.13 (-0.37, 0.12)
Cycle 6 Day 1						
n	145	115		141	113	
Mean (std dev)	11.72 (20.983)	9.57 (16.965)	2.16	-8.98 (32.337)	-7.67 (27.821)	-1.31
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 66.7		-100.0, 66.7	-100.0, 66.7	
95% CI for Mean	(8.28, 15.17)	(6.43, 12.70)	(-2.59, 6.91)	(-14.37, -3.60)	(-12.86, -2.48)	(-8.88, 6.25)
P-value			0.3715			0.7325
Hedges's g			0.11 (-0.13, 0.36)			-0.04 (-0.29, 0.20)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.14B
Summary of EORTC-QLQ-C30 Constipation Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 7 Day 1						
n	35	33		34	33	
Mean (std dev)	13.33 (24.522)	9.09 (17.225)	4.24	-20.59 (41.043)	-5.05 (27.790)	-15.54
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 66.7		-100.0, 66.7	-100.0, 33.3	
95% CI for Mean	(4.91, 21.76)	(2.98, 15.20)	(-6.08, 14.56)	(-34.91, -6.27)	(-14.90, 4.80)	(-32.69, 1.62)
P-value			0.4146			0.0751
Hedges's g			0.20 (-0.28, 0.67)			-0.44 (-0.92, 0.05)
Cycle 8 Day 1						
n	30	33		29	33	
Mean (std dev)	16.67 (30.006)	10.10 (17.648)	6.57	-19.54 (42.274)	-4.04 (30.909)	-15.50
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 66.7		-100.0, 66.7	-100.0, 66.7	
95% CI for Mean	(5.46, 27.87)	(3.84, 16.36)	(-5.70, 18.83)	(-35.62, -3.46)	(-15.00, 6.92)	(-34.16, 3.16)
P-value			0.2887			0.1019
Hedges's g			0.27 (-0.23, 0.76)			-0.42 (-0.92, 0.09)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.14B
Summary of EORTC-QLQ-C30 Constipation Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
End of Treatment						
n	138	109		136	107	
Mean (std dev)	10.14 (20.381)	7.03 (16.401)	3.11	-11.27 (30.690)	-9.35 (27.008)	-1.93
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 66.7		-100.0, 66.7	-100.0, 66.7	
95% CI for Mean	(6.71, 13.58)	(3.92, 10.15)	(-1.62, 7.84)	(-16.48, -6.07)	(-14.52, -4.17)	(-9.34, 5.49)
P-value			0.1961			0.6088
Hedges's g			0.17 (-0.09, 0.42)			-0.07 (-0.32, 0.19)
Long-Term Follow-Up 9 Month						
n	108	88		105	86	
Mean (std dev)	4.32 (15.178)	3.41 (13.410)	0.91	-15.24 (28.128)	-12.02 (27.493)	-3.22
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 33.3	-100.0, 33.3	
95% CI for Mean	(1.43, 7.22)	(0.57, 6.25)	(-3.17, 4.99)	(-20.68, -9.79)	(-17.91, -6.12)	(-11.21, 4.77)
P-value			0.6600			0.4272
Hedges's g			0.06 (-0.22, 0.34)			-0.12 (-0.40, 0.17)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.14B
Summary of EORTC-QLQ-C30 Constipation Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 12 Month						
n	111	81		108	79	
Mean (std dev)	6.01 (15.041)	4.53 (12.642)	1.48	-14.20 (31.640)	-13.50 (27.487)	-0.70
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 66.7	0.0, 66.7		-100.0, 66.7	-100.0, 33.3	
95% CI for Mean	(3.18, 8.84)	(1.73, 7.32)	(-2.58, 5.54)	(-20.23, -8.16)	(-19.66, -7.35)	(-9.45, 8.05)
P-value			0.4731			0.8756
Hedges's g			0.10 (-0.18, 0.39)			-0.02 (-0.31, 0.27)
Long-Term Follow-Up 15 Month						
n	103	83		101	81	
Mean (std dev)	7.44 (15.433)	2.81 (10.675)	4.63	-13.53 (29.881)	-15.23 (27.411)	1.69
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 66.7	0.0, 66.7		-100.0, 33.3	-100.0, 33.3	
95% CI for Mean	(4.43, 10.46)	(0.48, 5.14)	(0.70, 8.57)	(-19.43, -7.63)	(-21.29, -9.17)	(-6.78, 10.17)
P-value			0.0213			0.6937
Hedges's g			0.34 (0.05, 0.63)			0.06 (-0.23, 0.35)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

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Table 35.1.2.7.14B
Summary of EORTC-QLQ-C30 Constipation Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 18 Month						
n	99	83		97	81	
Mean (std dev)	6.73 (17.805)	3.61 (12.764)	3.12	-13.06 (30.260)	-14.40 (26.320)	1.34
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 66.7		-100.0, 66.7	-100.0, 33.3	
95% CI for Mean	(3.18, 10.29)	(0.83, 6.40)	(-1.49, 7.73)	(-19.16, -6.96)	(-20.22, -8.58)	(-7.13, 9.82)
P-value			0.1838			0.7546
Hedges's g			0.20 (-0.09, 0.49)			0.05 (-0.25, 0.34)
Long-Term Follow-Up 21 Month						
n	88	76		85	74	
Mean (std dev)	5.68 (13.582)	2.63 (10.559)	3.05	-15.29 (31.519)	-13.96 (25.288)	-1.33
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 66.7	0.0, 66.7		-100.0, 33.3	-100.0, 33.3	
95% CI for Mean	(2.80, 8.56)	(0.22, 5.04)	(-0.75, 6.85)	(-22.09, -8.50)	(-19.82, -8.11)	(-10.37, 7.71)
P-value			0.1145			0.7717
Hedges's g			0.25 (-0.06, 0.56)			-0.05 (-0.36, 0.27)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.14B
Summary of EORTC-QLQ-C30 Constipation Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 24 Month						
n	88	71		85	69	
Mean (std dev)	6.82 (18.334)	5.16 (15.582)	1.65	-13.33 (30.946)	-14.98 (27.734)	1.64
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 33.3	-100.0, 33.3	
95% CI for Mean	(2.93, 10.70)	(1.48, 8.85)	(-3.75, 7.06)	(-20.01, -6.66)	(-21.64, -8.31)	(-7.82, 11.10)
P-value			0.5466			0.7321
Hedges's g			0.10 (-0.22, 0.41)			0.06 (-0.26, 0.37)
Overall (EOT)						
n				153	144	
Mean (std dev)				-6.7 (16.14)	-8.6 (16.26)	1.91
95% CI for Mean						(-1.78, 5.61)
P-value						0.3101
Hedges's g						0.12 (-0.11, 0.35)
Overall (70% compliance)						
n				153	144	
Mean (std dev)				-9.1 (13.24)	-11.1 (13.56)	2.03
95% CI for Mean						(-1.03, 5.08)
P-value						0.1930
Hedges's g						0.15 (-0.08, 0.38)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.14B
Summary of EORTC-QLQ-C30 Constipation Over Time
ITT Analysis Set   - Subset of Patients with sALCL

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.

Note: Hedges's g measures the effect size of the difference between means using results from mixed model.

Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.

Data snapshot: 20SEP2018.

Table 35.1.2.7.15B
Summary of EORTC-QLQ-C30 Diarrhoea Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Baseline						
n	156	150				
Mean (std dev)	9.83 (23.100)	9.56 (22.957)	0.27			
Median	0.00	0.00				
Min, Max	0.0, 100.0	0.0, 100.0				
95% CI for Mean	(6.18, 13.48)	(5.85, 13.26)	(-4.91, 5.46)			
P-value			0.9174			
Hedges's g			0.01 (-0.21, 0.24)			
Cycle 2 Day 1						
n	155	143		151	140	
Mean (std dev)	13.33 (23.601)	9.56 (17.965)	3.78	2.65 (27.359)	0.00 (18.323)	2.65
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 100.0	-100.0, 33.3	
95% CI for Mean	(9.59, 17.08)	(6.59, 12.53)	(-1.04, 8.59)	(-1.75, 7.05)	(-3.06, 3.06)	(-2.77, 8.06)
P-value			0.1235			0.3365
Hedges's g			0.18 (-0.05, 0.41)			0.11 (-0.12, 0.34)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.15B
Summary of EORTC-QLQ-C30 Diarrhoea Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 3 Day 1						
n	154	136		150	135	
Mean (std dev)	8.87 (17.893)	6.86 (15.244)	2.01	-1.56 (27.670)	-1.48 (22.625)	-0.07
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 66.7		-100.0, 100.0	-100.0, 66.7	
95% CI for Mean	(6.03, 11.72)	(4.28, 9.45)	(-1.86, 5.88)	(-6.02, 2.91)	(-5.33, 2.37)	(-6.01, 5.86)
P-value			0.3069			0.9804
Hedges's g			0.12 (-0.11, 0.35)			-0.00 (-0.24, 0.23)
Cycle 4 Day 1						
n	150	130		146	129	
Mean (std dev)	8.44 (16.010)	7.69 (15.826)	0.75	-2.05 (29.092)	-0.52 (24.645)	-1.54
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 66.7	0.0, 66.7		-100.0, 66.7	-100.0, 66.7	
95% CI for Mean	(5.86, 11.03)	(4.95, 10.44)	(-3.00, 4.51)	(-6.81, 2.70)	(-4.81, 3.78)	(-7.98, 4.91)
P-value			0.6938			0.6389
Hedges's g			0.05 (-0.19, 0.28)			-0.06 (-0.29, 0.18)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Protocol No.: SGN35-014 -- Data cut: 15AUG2018 (Data snapshot: 20SEP2018)

Table 35.1.2.7.15B
Summary of EORTC-QLQ-C30 Diarrhoea Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 5 Day 1						
n	143	123		139	122	
Mean (std dev)	10.02 (20.569)	5.69 (13.297)	4.33	-0.96 (29.745)	-2.19 (19.981)	1.23
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 66.7		-100.0, 66.7	-100.0, 33.3	
95% CI for Mean	(6.62, 13.42)	(3.32, 8.06)	(0.07, 8.59)	(-5.95, 4.03)	(-5.77, 1.40)	(-5.04, 7.49)
P-value			0.0462			0.7002
Hedges's g			0.25 (0.00, 0.49)			0.05 (-0.20, 0.29)
Cycle 6 Day 1						
n	145	116		141	115	
Mean (std dev)	11.03 (22.241)	6.03 (14.311)	5.00	-0.47 (32.363)	-2.32 (25.256)	1.85
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 66.7		-100.0, 100.0	-100.0, 66.7	
95% CI for Mean	(7.38, 14.69)	(3.40, 8.67)	(0.31, 9.69)	(-5.86, 4.92)	(-6.98, 2.35)	(-5.43, 9.12)
P-value			0.0369			0.6175
Hedges's g			0.26 (0.02, 0.51)			0.06 (-0.18, 0.31)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.15B
Summary of EORTC-QLQ-C30 Diarrhoea Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 7 Day 1						
n	34	33		33	33	
Mean (std dev)	20.59 (28.444)	5.05 (14.722)	15.54	6.06 (39.489)	0.00 (14.434)	6.06
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 66.7		-100.0, 100.0	-33.3, 33.3	
95% CI for Mean	(10.66, 30.51)	(-0.17, 10.27)	(4.44, 26.64)	(-7.94, 20.06)	(-5.12, 5.12)	(-8.56, 20.68)
P-value			0.0068			0.4107
Hedges's g			0.68 (0.18, 1.17)			0.20 (-0.28, 0.69)
Cycle 8 Day 1						
n	30	33		29	33	
Mean (std dev)	15.56 (25.869)	6.06 (13.056)	9.49	0.00 (34.503)	1.01 (15.556)	-1.01
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 33.3		-100.0, 66.7	-33.3, 33.3	
95% CI for Mean	(5.90, 25.22)	(1.43, 10.69)	(-0.69, 19.68)	(-13.12, 13.12)	(-4.51, 6.53)	(-14.33, 12.31)
P-value			0.0671			0.8800
Hedges's g			0.46 (-0.04, 0.97)			-0.04 (-0.54, 0.46)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.

Note: Hedges's g measures the effect size of the difference between means using results from mixed model.

Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.

Data snapshot: 20SEP2018.

Table 35.1.2.7.15B
Summary of EORTC-QLQ-C30 Diarrhoea Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
End of Treatment						
n	137	106		135	105	
Mean (std dev)	7.30 (17.948)	5.97 (15.117)	1.32	-3.95 (30.215)	-1.59 (20.868)	-2.36
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 66.7		-100.0, 100.0	-100.0, 66.7	
95% CI for Mean	(4.27, 10.33)	(3.06, 8.89)	(-2.95, 5.60)	(-9.09, 1.19)	(-5.63, 2.45)	(-9.17, 4.44)
P-value			0.5422			0.4944
Hedges's g			0.08 (-0.17, 0.33)			-0.09 (-0.34, 0.17)
Long-Term Follow-Up 9 Month						
n	107	88		104	87	
Mean (std dev)	7.48 (16.064)	4.92 (13.878)	2.55	-3.85 (28.749)	-2.30 (25.816)	-1.55
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 66.7	0.0, 66.7		-100.0, 66.7	-100.0, 66.7	
95% CI for Mean	(4.40, 10.56)	(1.98, 7.86)	(-1.74, 6.84)	(-9.44, 1.74)	(-7.80, 3.20)	(-9.42, 6.32)
P-value			0.2421			0.6985
Hedges's g			0.17 (-0.11, 0.45)			-0.06 (-0.34, 0.23)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.15B
Summary of EORTC-QLQ-C30 Diarrhoea Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 12 Month						
n	111	81		108	80	
Mean (std dev)	6.31 (14.574)	3.29 (11.310)	3.01	-5.25 (28.153)	-3.33 (21.609)	-1.91
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 66.7	0.0, 66.7		-100.0, 66.7	-100.0, 33.3	
95% CI for Mean	(3.56, 9.05)	(0.79, 5.79)	(-0.82, 6.85)	(-10.62, 0.12)	(-8.14, 1.48)	(-9.36, 5.53)
P-value			0.1225			0.6126
Hedges's g			0.23 (-0.06, 0.51)			-0.07 (-0.36, 0.21)
Long-Term Follow-Up 15 Month						
n	102	82		100	81	
Mean (std dev)	4.90 (11.864)	5.69 (14.633)	-0.79	-7.00 (27.745)	-2.06 (23.773)	-4.94
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 33.3	0.0, 66.7		-100.0, 33.3	-100.0, 66.7	
95% CI for Mean	(2.57, 7.23)	(2.48, 8.91)	(-4.64, 3.06)	(-12.51, -1.49)	(-7.31, 3.20)	(-12.63, 2.74)
P-value			0.6867			0.2059
Hedges's g			-0.06 (-0.35, 0.23)			-0.19 (-0.48, 0.10)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Protocol No.: SGN35-014 -- Data cut: 15AUG2018 (Data snapshot: 20SEP2018)

Table 35.1.2.7.15B
Summary of EORTC-QLQ-C30 Diarrhoea Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 18 Month						
n	98	83		96	82	
Mean (std dev)	6.12 (14.633)	4.82 (13.903)	1.30	-6.25 (25.735)	-2.44 (20.137)	-3.81
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 66.7	0.0, 66.7		-100.0, 66.7	-100.0, 66.7	
95% CI for Mean	(3.19, 9.06)	(1.78, 7.86)	(-2.91, 5.51)	(-11.46, -1.04)	(-6.86, 1.99)	(-10.73, 3.11)
P-value			0.5421			0.2787
Hedges's g			0.09 (-0.20, 0.38)			-0.16 (-0.46, 0.13)
Long-Term Follow-Up 21 Month						
n	88	76		85	75	
Mean (std dev)	8.71 (20.526)	8.77 (21.339)	-0.06	-1.57 (31.667)	0.44 (29.252)	-2.01
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 100.0	-100.0, 100.0	
95% CI for Mean	(4.36, 13.06)	(3.90, 13.65)	(-6.52, 6.41)	(-8.40, 5.26)	(-6.29, 7.17)	(-11.58, 7.55)
P-value			0.9854			0.6781
Hedges's g			-0.00 (-0.31, 0.30)			-0.07 (-0.38, 0.25)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.15B
Summary of EORTC-QLQ-C30 Diarrhoea Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 24 Month						
n	88	72		85	71	
Mean (std dev)	8.33 (17.689)	6.02 (16.143)	2.31	-3.92 (29.282)	-2.82 (21.637)	-1.10
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 66.7	0.0, 100.0		-100.0, 66.7	-100.0, 33.3	
95% CI for Mean	(4.59, 12.08)	(2.23, 9.81)	(-3.02, 7.65)	(-10.24, 2.39)	(-7.94, 2.30)	(-9.39, 7.18)
P-value			0.3931			0.7926
Hedges's g			0.14 (-0.18, 0.45)			-0.04 (-0.36, 0.27)
Overall (EOT)						
n				153	145	
Mean (std dev)				1.1 (12.64)	-2.5 (12.73)	3.64
95% CI for Mean						(0.75, 6.53)
P-value						0.0134
Hedges's g						0.29 (0.06, 0.51)
Overall (70% compliance)						
n				153	145	
Mean (std dev)				-0.8 (10.14)	-2.9 (10.43)	2.17
95% CI for Mean						(-0.17, 4.51)
P-value						0.0695
Hedges's g						0.21 (-0.02, 0.44)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.15B
Summary of EORTC-QLQ-C30 Diarrhoea Over Time
ITT Analysis Set   - Subset of Patients with sALCL

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.

Note: Hedges's g measures the effect size of the difference between means using results from mixed model.

Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.

Data snapshot: 20SEP2018.

Table 35.1.2.7.16B
Summary of EORTC-QLQ-C30 Financial Difficulties Over Time
ITT Analysis Set   - Subset of Patients with sALCL

| | Actual Value | | | Change from Baseline | | |
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Baseline						
n	156	149				
Mean (std dev)	23.50 (32.399)	23.49 (30.879)	0.01			
Median	0.00	0.00				
Min, Max	0.0, 100.0	0.0, 100.0				
95% CI for Mean	(18.38, 28.63)	(18.49, 28.49)	(-7.12, 7.15)			
P-value			0.9968			
Hedges's g			0.00 (-0.22, 0.22)			
Cycle 2 Day 1						
n	155	141		151	137	
Mean (std dev)	20.00 (28.830)	22.22 (31.539)	-2.22	-3.97 (23.390)	-0.49 (27.112)	-3.49
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-66.7, 100.0	-100.0, 66.7	
95% CI for Mean	(15.43, 24.57)	(16.97, 27.47)	(-9.13, 4.68)	(-7.73, -0.21)	(-5.07, 4.09)	(-9.35, 2.37)
P-value			0.5270			0.2424
Hedges's g			-0.07 (-0.30, 0.15)			-0.14 (-0.37, 0.09)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.16B
Summary of EORTC-QLQ-C30 Financial Difficulties Over Time
ITT Analysis Set - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 3 Day 1						
n	154	135		150	133	
Mean (std dev)	23.16 (31.960)	20.00 (28.853)	3.16	-1.11 (29.007)	-3.26 (27.483)	2.15
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 100.0	-100.0, 100.0	
95% CI for Mean	(18.07, 28.25)	(15.09, 24.91)	(-3.93, 10.25)	(-5.79, 3.57)	(-7.97, 1.46)	(-4.49, 8.78)
P-value			0.3810			0.5247
Hedges's g			0.10 (-0.13, 0.33)			0.08 (-0.16, 0.31)
Cycle 4 Day 1						
n	150	131		146	129	
Mean (std dev)	18.89 (27.960)	20.36 (29.691)	-1.47	-5.48 (25.075)	-3.10 (25.834)	-2.38
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 66.7	-100.0, 66.7	
95% CI for Mean	(14.38, 23.40)	(15.22, 25.49)	(-8.24, 5.31)	(-9.58, -1.38)	(-7.60, 1.40)	(-8.43, 3.67)
P-value			0.6702			0.4396
Hedges's g			-0.05 (-0.29, 0.18)			-0.09 (-0.33, 0.14)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.16B
Summary of EORTC-QLQ-C30 Financial Difficulties Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 5 Day 1						
n	143	121		140	119	
Mean (std dev)	21.68 (29.140)	19.56 (29.398)	2.12	-2.14 (25.668)	-2.80 (21.073)	0.66
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 66.7	-100.0, 33.3	
95% CI for Mean	(16.86, 26.50)	(14.27, 24.85)	(-5.00, 9.24)	(-6.43, 2.15)	(-6.63, 1.02)	(-5.15, 6.47)
P-value			0.5581			0.8237
Hedges's g			0.07 (-0.17, 0.31)			0.03 (-0.22, 0.27)
Cycle 6 Day 1						
n	145	115		141	113	
Mean (std dev)	20.69 (28.618)	20.87 (29.769)	-0.18	-3.31 (27.975)	-1.47 (24.956)	-1.83
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 100.0	-100.0, 66.7	
95% CI for Mean	(15.99, 25.39)	(15.37, 26.37)	(-7.34, 6.98)	(-7.97, 1.35)	(-6.13, 3.18)	(-8.47, 4.80)
P-value			0.9606			0.5864
Hedges's g			-0.01 (-0.25, 0.24)			-0.07 (-0.32, 0.18)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.16B
Summary of EORTC-QLQ-C30 Financial Difficulties Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 7 Day 1						
n	35	33		34	33	
Mean (std dev)	24.76 (30.618)	17.17 (25.168)	7.59	-2.94 (28.859)	-2.02 (21.952)	-0.92
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 66.7	-33.3, 33.3	
95% CI for Mean	(14.24, 35.28)	(8.25, 26.10)	(-6.03, 21.21)	(-13.01, 7.13)	(-9.80, 5.76)	(-13.46, 11.62)
P-value			0.2698			0.8838
Hedges's g			0.27 (-0.21, 0.74)			-0.04 (-0.51, 0.44)
Cycle 8 Day 1						
n	30	33		29	33	
Mean (std dev)	21.11 (29.664)	16.16 (26.512)	4.95	-3.45 (25.735)	-3.03 (24.100)	-0.42
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-66.7, 66.7	-66.7, 33.3	
95% CI for Mean	(10.03, 32.19)	(6.76, 25.56)	(-9.20, 19.10)	(-13.24, 6.34)	(-11.58, 5.52)	(-13.08, 12.25)
P-value			0.4870			0.9476
Hedges's g			0.17 (-0.32, 0.67)			-0.02 (-0.52, 0.48)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.16B
Summary of EORTC-QLQ-C30 Financial Difficulties Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
End of Treatment						
n	137	108		135	106	
Mean (std dev)	20.19 (29.803)	19.14 (29.955)	1.06	-4.44 (26.951)	-5.35 (26.879)	0.90
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 100.0	-100.0, 100.0	
95% CI for Mean	(15.16, 25.23)	(13.42, 24.85)	(-6.51, 8.63)	(-9.03, 0.14)	(-10.52, -0.17)	(-5.98, 7.78)
P-value			0.7832			0.7966
Hedges's g			0.04 (-0.22, 0.29)			0.03 (-0.22, 0.29)
Long-Term Follow-Up 9 Month						
n	107	88		104	86	
Mean (std dev)	13.71 (26.284)	15.15 (27.174)	-1.44	-8.97 (29.093)	-7.75 (25.398)	-1.22
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 66.7	-100.0, 100.0	
95% CI for Mean	(8.67, 18.74)	(9.39, 20.91)	(-9.02, 6.13)	(-14.63, -3.32)	(-13.20, -2.31)	(-9.12, 6.68)
P-value			0.7073			0.7606
Hedges's g			-0.05 (-0.34, 0.23)			-0.04 (-0.33, 0.24)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.

Note: Hedges's g measures the effect size of the difference between means using results from mixed model.

Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.

Data snapshot: 20SEP2018.

Table 35.1.2.7.16B
Summary of EORTC-QLQ-C30 Financial Difficulties Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 12 Month						
n	111	80		108	78	
Mean (std dev)	13.81 (26.003)	12.08 (24.445)	1.73	-8.95 (28.680)	-11.97 (29.412)	3.02
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 100.0	-100.0, 100.0	
95% CI for Mean	(8.92, 18.70)	(6.64, 17.52)	(-5.61, 9.07)	(-14.42, -3.48)	(-18.60, -5.33)	(-5.48, 11.51)
P-value			0.6423			0.4848
Hedges's g			0.07 (-0.22, 0.36)			0.10 (-0.19, 0.40)
Long-Term Follow-Up 15 Month						
n	103	82		101	80	
Mean (std dev)	12.94 (24.358)	13.41 (27.146)	-0.47	-8.25 (28.443)	-12.50 (25.642)	4.25
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 66.7	-100.0, 33.3	
95% CI for Mean	(8.18, 17.71)	(7.45, 19.38)	(-7.95, 7.01)	(-13.87, -2.64)	(-18.21, -6.79)	(-3.80, 12.30)
P-value			0.9016			0.2988
Hedges's g			-0.02 (-0.31, 0.27)			0.16 (-0.14, 0.45)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Protocol No.: SGN35-014 -- Data cut: 15AUG2018 (Data snapshot: 20SEP2018)

Table 35.1.2.7.16B
Summary of EORTC-QLQ-C30 Financial Difficulties Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 18 Month						
n	98	83		96	81	
Mean (std dev)	12.59 (24.647)	11.65 (24.657)	0.94	-9.37 (28.492)	-13.58 (26.759)	4.21
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 100.0	-100.0, 33.3	
95% CI for Mean	(7.64, 17.53)	(6.26, 17.03)	(-6.32, 8.19)	(-15.15, -3.60)	(-19.50, -7.66)	(-4.05, 12.46)
P-value			0.7989			0.3159
Hedges's g			0.04 (-0.25, 0.33)			0.15 (-0.15, 0.45)
Long-Term Follow-Up 21 Month						
n	88	76		85	74	
Mean (std dev)	10.98 (22.444)	11.40 (23.446)	-0.42	-11.37 (31.097)	-11.26 (28.816)	-0.11
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 100.0	-100.0, 100.0	
95% CI for Mean	(6.23, 15.74)	(6.05, 16.76)	(-7.50, 6.67)	(-18.08, -4.67)	(-17.94, -4.59)	(-9.55, 9.33)
P-value			0.9073			0.9815
Hedges's g			-0.02 (-0.33, 0.29)			-0.00 (-0.32, 0.31)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.16B
Summary of EORTC-QLQ-C30 Financial Difficulties Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 24 Month						
n	87	72		84	70	
Mean (std dev)	9.58 (20.902)	12.04 (24.581)	-2.46	-11.11 (29.423)	-13.33 (27.452)	2.22
Median	0.00	0.00		0.00	0.00	
Min, Max	0.0, 100.0	0.0, 100.0		-100.0, 66.7	-100.0, 33.3	
95% CI for Mean	(5.12, 14.03)	(6.26, 17.81)	(-9.58, 4.67)	(-17.50, -4.73)	(-19.88, -6.79)	(-6.90, 11.35)
P-value			0.4965			0.6312
Hedges's g			-0.11 (-0.42, 0.20)			0.08 (-0.24, 0.39)
Overall (EOT)						
n				153	144	
Mean (std dev)				-3.2 (19.89)	-2.7 (20.04)	-0.52
95% CI for Mean						(-5.06, 4.03)
P-value						0.8238
Hedges's g						-0.03 (-0.25, 0.20)
Overall (70% compliance)						
n				153	144	
Mean (std dev)				-5.8 (17.83)	-6.5 (18.18)	0.64
95% CI for Mean						(-3.46, 4.74)
P-value						0.7586
Hedges's g						0.04 (-0.19, 0.26)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.16B
Summary of EORTC-QLQ-C30 Financial Difficulties Over Time
ITT Analysis Set   - Subset of Patients with sALCL

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.17B
Summary of FACT/GOG-NTX Neurotoxicity Subscale Scores Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Baseline						
n	155	151				
Mean (std dev)	38.78 (6.197)	39.42 (5.152)	-0.64			
Median	41.00	41.00				
Min, Max	10.0, 44.0	20.0, 44.0				
95% CI for Mean	(37.79, 39.76)	(38.59, 40.25)	(-1.93, 0.64)			
P-value			0.3260			
Hedges's g			-0.11 (-0.34, 0.11)			
Cycle 2 Day 1						
n	154	143		150	141	
Mean (std dev)	39.84 (4.709)	39.62 (5.059)	0.22	0.84 (4.318)	0.08 (4.732)	0.75
Median	41.50	41.00		0.00	0.00	
Min, Max	21.0, 44.0	11.0, 44.0		-14.0, 18.0	-14.0, 18.0	
95% CI for Mean	(39.09, 40.59)	(38.78, 40.45)	(-0.90, 1.34)	(0.14, 1.53)	(-0.70, 0.87)	(-0.29, 1.80)
P-value			0.6981			0.1578
Hedges's g			0.04 (-0.18, 0.27)			0.17 (-0.06, 0.40)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.17B
Summary of FACT/GOG-NTX Neurotoxicity Subscale Scores Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 3 Day 1						
n	154	136		149	136	
Mean (std dev)	39.12 (5.593)	39.54 (5.036)	-0.42	0.22 (4.784)	-0.31 (5.538)	0.52
Median	41.00	41.00		0.00	0.00	
Min, Max	18.0, 44.0	14.0, 44.0		-16.0, 18.0	-21.0, 19.0	
95% CI for Mean	(38.23, 40.01)	(38.69, 40.40)	(-1.66, 0.82)	(-0.56, 0.99)	(-1.24, 0.63)	(-0.68, 1.73)
P-value			0.5045			0.3936
Hedges's g			-0.08 (-0.31, 0.15)			0.10 (-0.13, 0.33)
Cycle 4 Day 1						
n	150	131		145	130	
Mean (std dev)	38.84 (5.976)	39.32 (4.585)	-0.48	-0.11 (5.064)	-0.63 (5.902)	0.52
Median	41.00	41.00		0.00	0.00	
Min, Max	15.0, 44.0	23.0, 44.0		-16.0, 22.0	-15.0, 17.0	
95% CI for Mean	(37.87, 39.80)	(38.53, 40.11)	(-1.75, 0.78)	(-0.94, 0.72)	(-1.66, 0.39)	(-0.78, 1.83)
P-value			0.4535			0.4286
Hedges's g			-0.09 (-0.32, 0.14)			0.10 (-0.14, 0.33)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.17B
Summary of FACT/GOG-NTX Neurotoxicity Subscale Scores Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 5 Day 1						
n	145	122		140	121	
Mean (std dev)	37.70 (6.592)	38.80 (5.610)	-1.09	-1.25 (6.055)	-1.09 (6.119)	-0.16
Median	40.00	40.50		-1.00	-1.00	
Min, Max	14.0, 44.0	13.0, 44.0		-29.0, 19.0	-26.0, 17.0	
95% CI for Mean	(36.62, 38.78)	(37.79, 39.80)	(-2.59, 0.40)	(-2.26, -0.24)	(-2.19, 0.01)	(-1.65, 1.33)
P-value			0.1493			0.8318
Hedges's g			-0.18 (-0.42, 0.06)			-0.03 (-0.27, 0.22)
Cycle 6 Day 1						
n	144	115		140	114	
Mean (std dev)	36.42 (7.379)	38.29 (6.275)	-1.87	-2.66 (6.712)	-1.65 (6.647)	-1.01
Median	39.00	40.00		-2.00	-1.00	
Min, Max	8.0, 44.0	11.0, 44.0		-20.0, 28.0	-29.0, 17.0	
95% CI for Mean	(35.21, 37.64)	(37.13, 39.45)	(-3.57, -0.17)	(-3.78, -1.54)	(-2.88, -0.41)	(-2.67, 0.65)
P-value			0.0314			0.2316
Hedges's g			-0.27 (-0.52, -0.02)			-0.15 (-0.40, 0.10)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.17B
Summary of FACT/GOG-NTX Neurotoxicity Subscale Scores Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Cycle 7 Day 1						
n	34	33		33	33	
Mean (std dev)	34.94 (8.773)	38.17 (6.584)	-3.23	-3.16 (7.145)	-1.92 (7.732)	-1.25
Median	39.00	39.00		-2.00	0.00	
Min, Max	13.0, 44.0	11.0, 44.0		-19.0, 11.0	-28.0, 19.0	
95% CI for Mean	(31.88, 38.00)	(35.84, 40.51)	(-7.02, 0.56)	(-5.70, -0.63)	(-4.66, 0.82)	(-4.91, 2.42)
P-value			0.0937			0.4992
Hedges's g			-0.41 (-0.89, 0.07)			-0.17 (-0.65, 0.32)
Cycle 8 Day 1						
n	30	33		29	33	
Mean (std dev)	33.37 (9.129)	36.85 (8.128)	-3.48	-4.63 (7.944)	-3.24 (8.507)	-1.39
Median	36.50	39.00		-4.00	-2.00	
Min, Max	13.0, 44.0	7.0, 44.0		-21.0, 11.0	-32.0, 19.0	
95% CI for Mean	(29.96, 36.78)	(33.97, 39.73)	(-7.83, 0.87)	(-7.66, -1.61)	(-6.26, -0.23)	(-5.59, 2.81)
P-value			0.1144			0.5099
Hedges's g			-0.40 (-0.90, 0.10)			-0.17 (-0.67, 0.33)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.

Note: Hedges's g measures the effect size of the difference between means using results from mixed model.

Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.

Data snapshot: 20SEP2018.

Table 35.1.2.7.17B
Summary of FACT/GOG-NTX Neurotoxicity Subscale Scores Over Time
ITT Analysis Set   - Subset of Patients with sALCL

| | Actual Value | | | Change from Baseline | | |
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
End of Treatment						
n	136	108		134	108	
Mean (std dev)	35.43 (8.296)	38.44 (6.737)	-3.01	-3.84 (7.745)	-1.76 (6.244)	-2.08
Median	38.00	41.00		-2.30	-1.00	
Min, Max	4.0, 44.0	12.0, 44.0		-32.0, 19.0	-26.0, 21.0	
95% CI for Mean	(34.03, 36.84)	(37.16, 39.73)	(-4.95, -1.07)	(-5.16, -2.52)	(-2.95, -0.57)	(-3.89, -0.27)
P-value			0.0025			0.0246
Hedges's g			-0.39 (-0.65, -0.14)			-0.29 (-0.55, -0.04)
Long-Term Follow-Up 9 Month						
n	100	73		96	72	
Mean (std dev)	36.50 (8.193)	39.30 (6.330)	-2.80	-2.92 (8.360)	-0.81 (6.282)	-2.11
Median	40.00	42.00		-1.50	0.00	
Min, Max	0.0, 44.0	15.0, 44.0		-36.0, 19.0	-27.0, 24.0	
95% CI for Mean	(34.87, 38.13)	(37.82, 40.78)	(-5.07, -0.53)	(-4.61, -1.22)	(-2.28, 0.67)	(-4.43, 0.21)
P-value			0.0158			0.0743
Hedges's g			-0.37 (-0.68, -0.07)			-0.28 (-0.59, 0.03)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.17B
Summary of FACT/GOG-NTX Neurotoxicity Subscale Scores Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 12 Month						
n	101	69		97	68	
Mean (std dev)	37.15 (8.204)	39.31 (6.545)	-2.16	-1.96 (7.465)	-0.48 (6.052)	-1.48
Median	40.00	42.00		-2.00	0.00	
Min, Max	2.0, 44.0	10.0, 44.0		-34.0, 23.0	-22.0, 20.0	
95% CI for Mean	(35.53, 38.77)	(37.74, 40.88)	(-4.50, 0.18)	(-3.47, -0.46)	(-1.95, 0.98)	(-3.64, 0.68)
P-value			0.0697			0.1780
Hedges's g			-0.28 (-0.59, 0.02)			-0.21 (-0.52, 0.10)
Long-Term Follow-Up 15 Month						
n	96	70		93	70	
Mean (std dev)	37.88 (8.424)	39.78 (6.212)	-1.90	-1.31 (7.116)	-0.47 (5.940)	-0.84
Median	41.00	42.00		0.00	0.00	
Min, Max	8.0, 44.0	15.0, 44.0		-22.0, 19.0	-21.0, 22.0	
95% CI for Mean	(36.17, 39.59)	(38.29, 41.26)	(-4.25, 0.45)	(-2.78, 0.15)	(-1.88, 0.95)	(-2.92, 1.23)
P-value			0.1132			0.4231
Hedges's g			-0.25 (-0.56, 0.06)			-0.13 (-0.44, 0.18)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Table 35.1.2.7.17B
Summary of FACT/GOG-NTX Neurotoxicity Subscale Scores Over Time
ITT Analysis Set   - Subset of Patients with sALCL

	Actual Value			Change from Baseline		
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Long-Term Follow-Up 18 Month						
n	90	74		87	73	
Mean (std dev)	38.07 (7.124)	39.27 (6.869)	-1.20	-1.05 (6.847)	-0.69 (6.074)	-0.36
Median	41.00	42.00		0.00	0.00	
Min, Max	17.0, 44.0	11.0, 44.0		-22.0, 21.0	-21.0, 24.0	
95% CI for Mean	(36.58, 39.56)	(37.67, 40.86)	(-3.37, 0.98)	(-2.51, 0.41)	(-2.11, 0.73)	(-2.40, 1.68)
P-value			0.2789			0.7300
Hedges's g			-0.17 (-0.48, 0.14)			-0.05 (-0.37, 0.26)
Long-Term Follow-Up 21 Month						
n	78	65		75	64	
Mean (std dev)	38.07 (8.588)	39.54 (6.710)	-1.47	-1.81 (7.659)	-0.43 (6.566)	-1.37
Median	42.00	43.00		0.00	0.00	
Min, Max	1.0, 44.0	12.0, 44.0		-35.0, 17.0	-23.0, 24.0	
95% CI for Mean	(36.13, 40.00)	(37.88, 41.20)	(-4.06, 1.11)	(-3.57, -0.05)	(-2.07, 1.21)	(-3.79, 1.04)
P-value			0.2620			0.2622
Hedges's g			-0.19 (-0.52, 0.14)			-0.19 (-0.52, 0.14)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.

Protocol No.: SGN35-014 -- Data cut: 15AUG2018 (Data snapshot: 20SEP2018)

Table 35.1.2.7.17B
Summary of FACT/GOG-NTX Neurotoxicity Subscale Scores Over Time
ITT Analysis Set   - Subset of Patients with sALCL

| | Change from Baseline | | |
	A+CHP N=162	CHOP N=154	A+CHP vs CHOP Mean Difference
Overall (EOT)			
n	152	146	
Mean (std dev)	-2.1 (4.68)	-0.9 (4.71)	-0.89
95% CI for Mean			(-1.96, 0.18)
P-value			0.1021
Hedges's g			-0.19 (-0.42, 0.04)
Overall (70% compliance)			
n	152	146	
Mean (std dev)	-2.1 (4.85)	-0.9 (4.92)	-1.20
95% CI for Mean			(-2.31, -0.09)
P-value			0.0343
Hedges's g			-0.24 (-0.47, -0.02)

Baseline is defined as the last observed measurement on or before the date of initial dose of any study drug.
Note: Hedges's g measures the effect size of the difference between means using results from mixed model.
Note: The Overall analysis uses least squares means for change from baseline, differences in LS means in change from baseline, 95% CIs and p-values. All results were obtained using mixed effects models.
Data snapshot: 20SEP2018.